Intubation with Airtraq™ laryngoscope in a morbidly obese patient

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ABSTRACT

In the present study, we report a case of successful endotracheal intubation using Airtraq™ Laryngoscope (AQL) in a morbidly obese patient. A 35-year-old woman, morbidly obese (weight, 105 kg; height, 160 cm; BMI, 41 kg/m^2), known hypertensive and diabetic, was admitted in the operating room for total abdominal hysterectomy under general anesthesia. The preoperative airway assessment anticipated both difficult bag-mask ventilation and intubation. Tracheal intubation using AQL was attempted after induction with propofol and relaxation with succinylcholine. Successful tracheal intubation was accomplished within 12 seconds of insertion of AQL into the oral cavity. The minimal hemodynamic response during this maneuver was advantageous in our patient.

Key words: *Airtraq™ optical laryngoscope, difficult intubation, morbidly obese*

INTRODUCTION

Morbidly obese patients (body mass index [BMI] > 40) (BMI = weight in kilogram/[height in centimeter]^2) present a challenge to the anesthesiologist in terms of securing the airway. Predictors of difficult laryngoscopy and intubation in these patients include fat face and cheeks, large breasts in females, limited range of motion of head, neck and jaw, small mouth and a large tongue, excessive palatal and pharyngeal tissue, short thick neck (large circumference), high Mallampati scores (III or IV) and more rapid oxygen (O_2) desaturation.[1] Associated comorbidities such as hypertension and diabetes add to the already difficult situation in terms of exaggerated hemodynamic response to laryngoscopy and intubation.

The Airtraq™ (Prodol Meditec S.A., Vizcaya, Spain) optical laryngoscope is a useful tracheal intubation device that can be used in patients with potential difficult airway, as in our case. It shortens the duration for tracheal intubation, and thus prevents reduction in arterial O_2 saturation.[2] Because of less forceful blade elevation, maneuvering is gentle with minimal hemodynamic alterations,[3] adding to the advantage in hypertensive patients.

We report a case of successful and rapid (12 seconds) endotracheal intubation in a morbidly obese patient using AQL.

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CASE REPORT

A 35-year-old woman, with 105 kg weight and 160 cm height (BMI, 41 kg/m^2), having dysfunctional uterine bleeding unresponsive to medical management, was admitted in the operating room for total abdominal hysterectomy under general anesthesia. She had well-controlled hypertension, diabetes mellitus type II, history of snoring and symptoms of gastroesophageal reflux. No history of obstructive sleep apnoea was detected. The preoperative airway assessment showed Mallampati class IV, interincisor gap of 3 cm, thyromental distance of 5.5 cm, and neck circumference of 55 cm. Head extension and cervical flexion were markedly limited. Patient was anemic with moderate pallor, resting pulse rate of 100/min, blood pressure of 150/94 mmHg, and fasting blood glucose of 116 mg/dl on the day of surgery, while other preoperative laboratory investigations were within normal limits. Informed consent was taken from the patient. Difficult airway cart was prepared, including the instruments of

cricothyrotomy and tracheostomy, as difficulty in mask ventilation and intubation was anticipated. Endotracheal tube of 7.0 mm ID was lubricated and then passed through the side channel of Airtraq™ laryngoscope. Patient was put in supine position, her head supported with a soft pillow put under the head, and premedicated with Ondansetron 8 mg, Tramadol 200 mg and Midazolam 2 mg intravenously (i.v.). After preoxygenation with 100% O_2 for 3 minutes, induction with propofol 200 mg i.v. and relaxation with succinylcholine150 mg i.v., endotracheal intubation was attempted with Airtraq™ laryngoscope. A full view of centered glottis could be obtained after elevation of the epiglottis and endotracheal tube could be passed through the vocal cords easily. Time taken from insertion of Airtraq™ into the oral cavity to successful endotracheal intubation was 12 seconds. Endotracheal intubation was confirmed by capnography and auscultation of the chest. During this time, patient's pulse rate, blood pressure and ECG were within normal limits. No desaturation and mucosal bleeding occurred during intubation. Endotracheal tube was secured in place and the surgeons were asked to proceed with the surgery. General anesthesia was maintained with propofol infusion and mixture of O_2 and nitrous oxide and neuromuscular blockade using vecuronium. The procedure lasted 2 hours; residual neuromuscular paralysis was reversed with neostigmine and glycopyrrolate, after which she was successfully extubated with an uneventful recovery. Patient maintained saturation in head-up position in the post-operative period on O_2 through mask. The patient exhibited only mild symptoms of sore throat that improved within 2 days without any intervention; otherwise, the post-operative period was uneventful. No hoarseness and other airway complications were noted.

DISCUSSION

Obesity can be a potential cause of complications after induction of anesthesia resulting from rapid desaturation,[4] limited mobility of atlanto-occipital and temporomandibular joints, narrowed upper airway, shortened distance between the mandibular and sternal fat pads, and delayed gastric emptying with gastro-esophageal reflux leading to pulmonary aspiration.[5]

AQL is a new device providing direct view of the glottis, with minimal maneuvering of patient for optimal positioning. There are reports demonstrating successful intubation using AQL in normal airways,[6] simulated difficult airways[7] and in a clinically difficult airway.[8,9] It has been used electively[10] as well as a rescue device[11] after failed attempt with conventional laryngoscopy.

Our patient, a morbidly obese woman (BMI, 41 kg/m^2) was successfully intubated with AQL in 12 seconds. Ndoko *et al.* (2008) also demonstrated that AQL shortened the duration of tracheal intubation and prevented reduction in O_2 saturation.

Hemodynamic changes (heart rate, blood pressure) were minimal during intubation using AQL. Similar findings have also been shown by Maharaj *et al.* (2007) and Ndoko *et al.* (2008).

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Screening for mrsa as a preventive approach prior to nasotracheal intubation

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ABSTRACT

Objective: This study was undertaken to determine the carriage of MRSA strains due to nasotracheal intubation into the lower respiratory tract where they can be a potential source of infection leading to high morbidity and mortality. **Materials:** Study was done on 100 patients (50 intubated nasally and 50 intubated orally). Swabs were taken from the anterior nares, throat and tip of the endotracheal tube (ETT tip), cultured on conventional media and sensitivity was determined.**Results:** In study group 1, nasal swabs showed growth of MRSA in 21 (42%) patients and out of these 16 (76%) patients showed growth of MRSA strains from ETT tip. MRSA was not detected from ETT tip in any of the patients in study group 2. Screening for MRSA should be done before intubation by nasal route.

1. Introduction

Nasotracheal intubation is a procedure commonly required for patients undergoing maxillofacial and dental surgeries [1]. There are well documented complications of this procedure like nasal sinusitis, nasal septal and parapharyngeal abscesses [2,3]. Nosocomial pneumonia and septicemia are more frequent in patients with nasotracheal intubation than those intubated orotracheally [4,5].

MRSA is the term used for Methicillin Resistant Stapyhlococcus Aureus which are relatively difficult to treat pathogens. If resistant to Methicillin, these strains are also resistant to Flucloxacillin and all β-lactam antibiotics. Upto 40% of the normal population carry *S.aureus* in the anterior nares for periods ranging from a few weeks to many years and this carriage rate is often increased in hospitalized patients. The increasing incidence of MRSA has been associated with hospital outbreaks leading to considerable morbidity and mortality[6]. Patients with compromised immune systems are at a greater risk of symptomatic secondary infection. MRSA can be detected by swabbing the nostrils of patients and isolating the bacteria found inside. At risk populations include : people with weak immune system (people with HIV/AIDS, transplant recipients, severe asthmatics etc.), diabetics, i.v drug users, use of quinolone antibiotics, young children, elderly, college students living in dormitories and people who spend time in confined spaces.

The present study was done to determine intubation related carriage of bacteria, especially MRSA into trachea mainly on nasotracheal intubation.

2. Material and methods

The study was done in departments of Anesthesiology and Microbiology of J.N. Medical College and Hospital. Hundred patients were included in the study.

Study group 1 comprised of 50 patients who were intubated by nasotracheal route due to conditions that led to difficult mouth opening or requiring more space for the surgical procedure. Study group 2 comprised of 50 patients who were intubated by oral route. Detailed history regarding prior use of antimicrobial agents like β-lactamase inhibitor combination, Fluoroquinolones, Macrolides, Cephalosporins and Vancomycin, steroid therapy, bronchoscopy, diabetes

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and dialysis was recorded from all patients. History of hospitalization was also taken.

2.1. Anaesthetic technique

Informed consent was taken from all the patients. Patients were intubated by nasal route using standard protocol [7]. Difficult airway cart including the instruments of surgical airway techniques (cricothyrotomy, tracheostomy) were kept ready. Nasal patency was checked on both sides and the right naris was selected for Nasotracheal intubation as the bevel of most of the ETT will face the flat nasal septum minimizing damage to the turbinates. We instilled cotton-tip pledgets soaked with 2 % Lignocaine with 1:200000 epinephrine in both the nasal passages 10-15 minutes prior to intubation. Premedication was done with Inj. Ondansetron 0.1 mg/kg intravenous (IV), Inj. Tramadol 2 mg/kg IV and Inj. Midazolam 0.04mg/kg IV. Patients were pre-oxygenated with 100% Oxygen for 3 minutes and induced with Inj. Thiopentone 3-5 mg/kg IV and relaxed with Inj. Succinylcholine 1-1.5 mg/kg IV. Cuffed endotracheal tube PVC type lubricated with sterile cotton soaked Lignocaine jelly was introduced to the half of its length into right nasal passage. The blade of MacIntosh laryngoscope was introduced into the mouth from the right side and advanced upto the faucial pillars. Next the tongue was swept and the blade was moved further to position its tip in the vallecula for lifting the epiglottis. Under visual guidance, Nasotracheal intubation was done pushing the endotracheal tube through the abducted vocal cords with the help of Magill's forceps. Correct placement of the tube was confirmed by capnography and auscultation. Patient was maintained on Oxygen and Nitrous Oxide mixture, Inj. Propofol and Inj. Vecuronium. Vital parameters including the pulse rate, blood pressure and pulse-oximetry were monitored in all patients. After the surgical process, the patients were successfully extubated. Sterility was fully maintained throughout the procedure.

Three swabs were taken from each patient - nasal, pharyngeal and swab from the tip of tube (ETT tip). Throat and nasal swabs were taken prior to intubation and swab from tube tip after procedure was completed and sent to microbiology laboratory in Brain-Heart infusion broth. All three swabs were inoculated on blood agar and McConkey's agar at 37 degree Celsius overnight. The isolates were identified by their characteristic morphological features and by battery of standard biochemical reactions for identification of gram-positive and gram-negative cocci.

MRSA detection was done using Oxacillin disc susceptibility testing using CSLI guidelines (8). A bacterial suspension adjusted to 0.5 MacFarland was inoculated onto Muller-Hinton agar. A filter paper disc containing Oxacillin (Hi-media, India) was placed on the inoculated agar and plates were incubated overnight. The diameter of zone of inhibition was measured and standard criteria for interpretation of results were employed (8). Antimicrobial susceptibility pattern of isolates was determined using Kirby-bauer disc diffusion technique.

3. Results

A total of 100 patients included in the study belonged to different age groups. Thirty-three patients (21 in study group 1 and 12 in study group 2) had shown positive culture for MRSA from nasal swab specimen.

Table 1.
Showing distribution of patients positive for MRSA growth on nasal swab according to rate of isolation from ETT tip after different routes of intubation

Intubation Procedure	MRSA carriage into trachea		Total
	Yes	No	
Nasal intubation	16 (76%)	5 (24%)	21
Oral intubation	0 (0%)	12 (100%)	12
Total	16	17	33

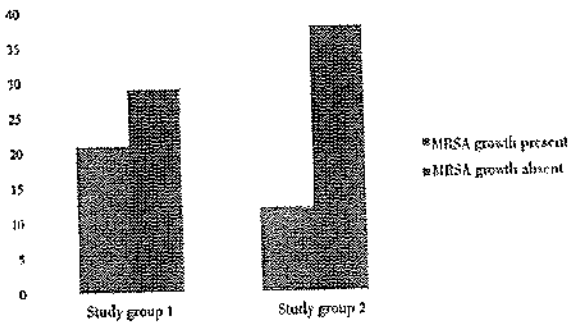

Figure 1. Distribution of MRSA strain in nasal swab specimens

In study group 1 (comprising of 50 patients intubated nasotracheally), general nasal commensal microflora was present on culture examination of their nasal swab specimens. Twenty-one patients (42%) showed colonization with MRSA. Throat swabs of these patients had commensal growth while Streptococcus pyogenes was isolated from throat of 1 patient. On culture examination from ETT tip, MRSA was detected in 16 (76%) patients whose nasal swab culture also showed MRSA. Streptococci were detected in 8 patients.

In study group 2 (comprising 50 patients intubated orotracheally), the ETT tip showed growth of staphylococcus sp and streptococcus sp in 5 patients. Nasal swabs of 12 patients in this group had shown MRSA growth, while none of them had shown MRSA growth on ETT tip culture.

4. Discussion

The results of this study indicate that bacteria are being carried into the trachea more frequently by intubation via nasal route than oral route. Satoshi Takahashi et al 2003 (9) reported carriage of bacteria from nasal cavity into trachea

because of nasal intubation. Other investigators reported that nasal cannulation for endotracheal and gastric intubation is a major risk factor for Nosocomial infection [9-11]

In this study, the nasal carriage rate of MRSA was found to be 33%. Dupeyron et al [12] reported nasal carriage rate of MRSA of 16.3% while Corbella et al (13,14) and Satoshi Takahashi et al [9] reported nasal carriage rate of 22.1% and 13.2% respectively. The high rate of nasal carriage of MRSA found in our study may be due to random selection of patients.

In this study, we found that the transfer rate of MRSA from nares into the lower respiratory tract was 76% (16 out of 21 patients) in patients intubated nasally while none (0 out of 12) of the patients intubated orally showed MRSA growth on ETT tip culture. In study done by Corne P et al (2005) showed nasal carriage of MRSA to be the causative agent of Staphylococcal pneumonia in critically ill patients[15]

MRSA which are carried in anterior nares of normal humans can be carried to trachea during nasotracheal intubation. Chances of transfer of other micro-organisms to trachea are higher when intubation is done by nasal route. To conclude, we suggest screening for MRSA strains by nasal swabs prior to nasal intubation to prevent complication associated with carriage of these organisms to trachea.

Conflict of interest statement

We declare that we have no conflict of interest.

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A RANDOMIZED, DOUBLE BLIND, PLACEBO-CONTROLLED STUDY OF PERI-OPERATIVE PREGABALIN FOR POST-OPERATIVE PAIN RELIEF IN PATIENTS UNDERGOING LOWER LIMB ORTHOPAEDIC SURGERY UNDER SPINAL ANAESTHESIA.

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SUMMARY

Introduction: Spinal anesthesia is the preferred technique for lower limb orthopaedic surgeries providing excellent operative conditions but with limited post-operative analgesia. Pregabalin is being used in the chronic pain arena for quite some time now but role in acute pain is not yet well defined.

Method: A randomized double-blind placebo controlled study including a total of 60 patients was designed to find the efficacy and safety of Oral Pregabalin as a protective analgesic.

Results: The time to rescue analgesic (VAS > 3) was 372.33±100.46 minutes in study group and 278.2±69.19 minutes in control group ($p < 0.0001$). The total dose of analgesics required (mg of Diclofenac) in study group (125 ± 49.57 mg) was less than the control group (162.5 ± 39.8 mg) but not statistically significant.

Conclusion: Oral Pregabalin was effective in increasing the duration of post-operative analgesia and reducing the dose of rescue analgesic required.

KEY-WORDS: Pregabalin, protective analgesia, post-operative analgesia

INTRODUCTION

"All is well that ends well". The reverse is also true as far as anesthesia and post-operative analgesia is concerned "Nothing is well if the end is not well". Acute post-operative pain (APOP), if untreated or inadequately treated can result in problems that can be a night-mare both to the patient and the attending doctor.

In an attempt to assert its significance, the Joint

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Committee for Accreditation of Healthcare Organization has declared "pain as the fifth vital sign"; keeping in view the bensfits of aggressive management of APOP. Out of the desire to have a comfortable and pain-free patient in the post-operative period, efforts have been made and are going on throughout the world.

One such effort is the development of the concept of 'Preemptive analgesia', which aims at preventing the sensitization of the nervous system [1, 2]. This can be achieved by providing analgesia prior to the pain stimulus and continuing the same in the intra- and post-operative periods.

'Protective analgesia' is a technique that has grown as a part of preemptive analgesia wherein the drugs used are not primary analgesics but adjuvant drugs used in non-acute pain arena. Gabapentin and Pregabalin are being explored as protective analgesics [1,2].

Pregabalin is a synthetic analogue of GABA, acting as the $\alpha_2\delta$-subunit calcium channel ligand. Clinically it has analgesic, anti-convulsant, anxiolytic and sleep-modulating activities. By reducing the hyper-excitability of dorsal horn neurons that follows surgical trauma, Pregabalin does pose as an effective protective analgesic [3,4].

Majority of lower-limb orthopaedic surgeries are conducted under spinal anesthesia that provides profound analgesia. Untreated APOP may develop into chronic persistent neuropathic pain.

This study, therefore, was designed to evaluate the efficacy of peri-operative Pregabalin as protective analgesic in patients undergoing lower-limb orthopaedic surgeries under spinal anesthesia.

MATERIAL AND METHODS

After approval by the Institutional Ethics Committee, 60 ASA I/II adult (18-60 years) patients of either sex were enrolled in this prospective, randomized, double-blind, placebo-controlled study. They were to undergo elective lower-limb orthopaedic surgery under spinal anesthesia. Informed consent was obtained from all patients. All patients were examined in the PAC clinic/Bedside as per the Department's protocol.

Exclusion criteria for the study included patients having neurological or coagulation disorder, abnormal liver or renal function tests, valvular heart disease, hypotension, diabetes mellitus, Body mass index (BMI>30), emotional instability, unwillingness and any anticipated difficulty in regional anesthesia along with other contraindications of central neuraxial blockade.

Patients were then assigned to either of the two groups of 30 patients each with computer-generated randomization. They were to receive either study drug (Pregabalin 150 mg) or matching placebo at 1 hour before the spinal anesthesia and 7 hours after the first dose.

Anesthesia technique was standard for both the groups and started with pre-loading (500 ml of Ringer's lactate) over 15-20 minutes. Inj. Ondansetron 0.1 mg/kg was administered intravenously. Technique for spinal anesthesia included aseptic preparation and draping of the lower back. After identification of L_3-L_4 intervertebral space, lumbar puncture was done using 26 or 23 G Quincke spinal needle in sitting position. After confirmation of CSF flow, Inj. Bupivacaine 0.5% heavy, 2.5 ml was injected in subarachnoid space. Patient was then turned supine and monitors were attached (Pulse-oximeter, ECG and NIBP) and vitals recorded.

Parameters recorded

1. Pulse - Bradycardia was considered when pulse rate <

50/minute and was treated with Inj. Atropine 0.5 mg, if accompanied with hypotension.

2. BP - Hypotension was considered when systolic blood pressure showed a fall of more than 20% of the pre-operative level and was treated with Inj. Mephentermine 6 mg i.v. and crystalloid infusion.

3. SpO_2

4. Level of Sedation - This was noted as 4 point verbal rating scale

0 – No sedation
1 – Drowsiness
2 – Asleep but arousable
3 – Unarousable with loss of verbal contact

5. Total i.v. fluids and vasopressor required were noted.

6. VAS - In the post-operative period, pain was assessed using the Visual Analogue Scale at 30 minutes for the first 2 hours and then at 2 hourly intervals and next morning at 8 a.m.

7. Rescue analgesic - The time when the patient first complained of pain was noted and VAS score was assessed. VAS score more than 40 was considered significant and patient was given Rescue analgesic in the form of Inj. Diclofenac Sodium 1 mg/kg intravenous infusion.

8. Total analgesic required in the first 24 hours was noted.

9. Side Effects – Patients were asked for the following complaints: Nausea, Vomiting, Somnolence, Diplopia, Confusion and Urinary retention.

Statistical analysis was done using SPSS version 15. Since no previous data was available, sample size of 30 was taken as the minimum so as to ensure that the results were statistically significant (Central Limit Theorem). Student's t-test and Fisher's exact test were employed to find the significance of the results obtained. p-value < 0.05 was considered statistically significant. Power analysis was done post-hoc using the power and sample size calculator using the time to rescue analgesia and maximum pain scores. Cut-off limit for power of test was 80% ($\beta = 0.8$).

Aims of this study were to evaluate:

1. The duration of post-operative analgesia
2. Total dose of analgesics required in first 24 hours
3. Effect on hemodynamics
4. Side effects, if any, attributable to the drug

RESULT

Sixty patients were analyzed for the study in two groups of 30 each.

There was no statistically significant difference amongst the two groups with respect to age, sex or duration of surgery. (TABLE-1)

There was no difference amongst the two groups with respect to the site of surgery. (TABLE-2)

The hemodynamic parameters (intra and post-operatively) and the fluid and vasopressor requirement were comparable in the two groups. (FIGURES-1 & 2)

The time to rescue analgesic (VAS > 3) was 372.33±100.46 minutes in study group and 278.2±69.19 minutes in control group ($p < 0.0001$). The difference was extremely significant. (FIGURE – 3)

The total dose of analgesics required (mg of Diclofenac) in study group (125 ± 49.57 mg) was less than the control group (162.5 ± 39.8 mg) but not statistically significant. (FIGURE – 4)

Of the noted complications; nausea (3 patients in control group and 1 patient in study group), vomiting (1

in control), confusion (none), diplopia (0 in control, 1 in study), and urinary retention (1 in control, 2 in study), the two groups did not differ significantly. However, the incidence of Somnolence (2 patients in control group and 10 patients in study group) was significantly higher in study group.

TABLE - 1: DEMOGRAPHIC DATA

Parameter	Control group	Study group	p-value
Age (years)	33.47 ± 13.66	32.03 ± 11.35	0.5145
Sex	M-22/F-8	M-20/F-10	0.7787
Duration (minutes)	78.17 ± 23.76	79.67 ± 30.51	0.4119

TABLE- 2: DISTRIBUTION OF PATIENTS ACCORDING TO SITE OF SURGERY

Site of surgery	Control group	Study group
Hip & thigh	16	17
Knee & leg	10	9
Ankle & foot	4	4

FIGURE – 1:

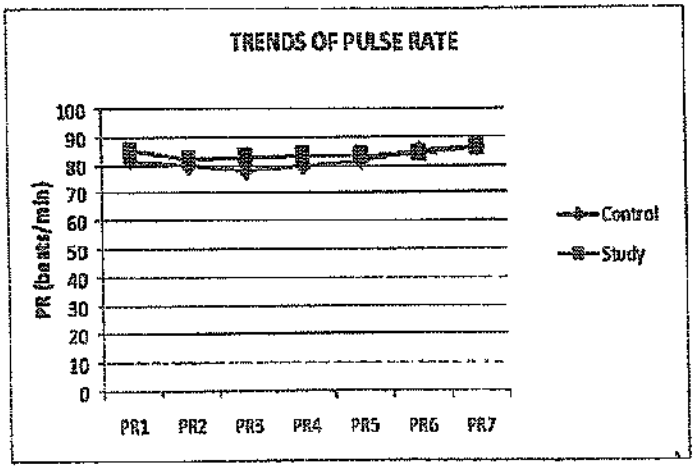
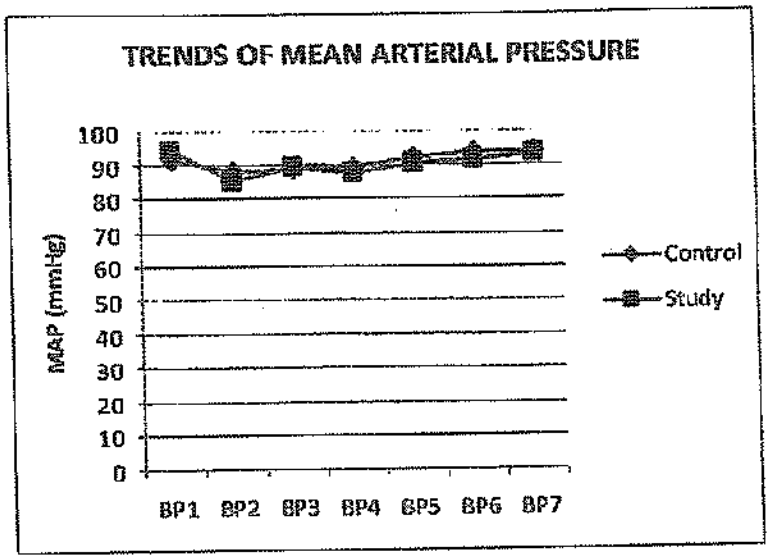


FIGURE – 2:



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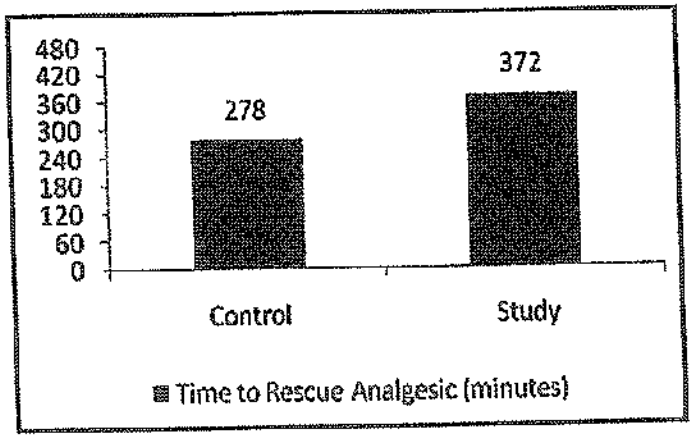
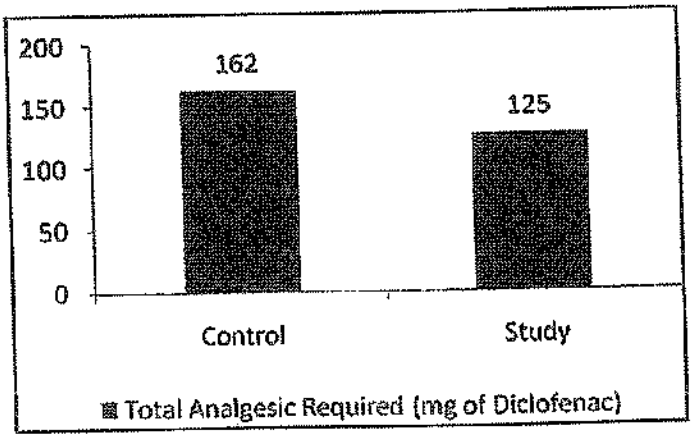


FIGURE – 4:



CONCLUSION

We conclude that peri-operative Pregabalin has been effective in increasing the duration of post-operative analgesia and decreasing the total dose of analgesics required in early post-operative period without any significant changes in hemodynamic parameters or side-effects.

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SUCCESSFUL SPINAL ANESTHESIA AFTER 'DRY TAP' IN A PATIENT HAVING CIRRHOSIS OF LIVER

Pratik Tantia[1], Sunny Malik[2], Mozammil Shafi[1], S. Bano[2]

SHORT TITLE: Spinal anesthesia after dry tap lumbar puncture in a patient with cirrhosis of liver and portal hypertension.

SUMMARY: We report a case of successful spinal anesthesia in a patient with cirrhosis of liver and portal hypertension. Attempts at lumbar puncture by an experienced anesthesiologist produced the typical 'give-in' feeling of dural puncture without obvious Cerebrospinal fluid (CSF) flow. At this point, it was decided to proceed and hyperbaric Bupivacaine was injected. Patient had successful neuraxial block within five minutes. The surgical and post-operative periods were uneventful.

KEY-WORDS: spinal anesthesia, dry tap, cirrhosis of liver

INTRODUCTION: Spinal (intrathecal) anaesthesia is generally regarded as one of the most reliable of regional block methods: the needle insertion technique is relatively straight-forward, with CSF providing both a clear indication of successful needle placement and a medium through which local anaesthetic solution usually spreads readily [1]. What if an experienced anesthesiologist, with all the precautions is unable to achieve the end point i.e. obvious CSF flow? 'Dry tap' on lumbar puncture has been reported previously; the usual cause being faulty technique. Causes include a blocked needle, needle in the wrong space, post-spinal surgery and low CSF pressure [2]. With some pathologic conditions, such as lumbar spinal-canal stenosis and adhesive arachnoiditis, a spinal puncture may result in a dry tap[3].

CASE HISTORY: 50-year-old female patient presented to the Emergency Room with complaint of pain in right hip-joint region following a trivial fall. X-ray examination confirmed the diagnosis of inter-trochanteric fracture of right femur. After initial conservative management, patient was to be operated for Dynamic-Hip-Screw fixation. On pre-anesthetic evaluation, significant history included low-grade fever, pedal edema and abdominal distension for the past 7 days and post-menopausal status for the past 4 years. On examination, patient was cachexic with moderate pallor, pedal edema and abdominal distension. Blood pressure (BP) was 200/110 $mmHg^{-1}$. Other examinations including airway and lumbar spine were normal. Investigations were ordered to find out the cause of hypertension and ascites. Hematological investigations: Hemoglobin-9 gdl^{-1}, Platelet count160,000 mm^{3}, Total Leucocyte count8000 mm^{3} and normal Differential Leucocyte count. Renal function tests: serum Creatinine1.3 $mgdl^{-1}$ and blood Urea-50 $mgdl^{-1}$. Chest X-ray showed evidence of cardiomegaly. Electrocardiogram findings were suggestive of Left Axis Deviation. Echocardiography

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findings were suggestive of Left ventricular hypertrophy with normal valves and no regional wall motion abnormality. Ultrasonography showed free fluid in abdominal cavity with cirrhotic changes in the liver. Liver function tests: total serum Bilirubin-1.8 $mgdl^{-1}$, Enzymes in high normal range, serum Proteins-5 gdl^{-1}, Albumin: Globulin2.1:1. Tests for coagulation: Prothrombin time20 seconds with International Normalized Ratio1.6. The physician prescribed Amlodipine 10 mg, Torsemide 5 mg and Spironolactone 25 mg to be taken once daily. These medications along with abdominal paracentesis helped resolve the ascites and optimize the BP within 7 days. Patient was then taken up for surgery. Informed consent was taken. Accordingly a plan for spinal anesthesia was made and patient was directed about the fasting status. Pre-operatively, patient had a pulse rate of 90 min^{-1}, regular and BP of 120/70 $mmHg^{-1}$.

Patient was taken first in the morning and after premedication with Ondansetron 4 mg and preloading with 500 ml 0.9% Sodium Chloride solution; she was shifted to the Operating Room. Monitors attached included Pulse-oximeter, Non-invasive Blood Pressure (NIBP) and Cardioscope. She was put in sitting position for spinal anesthesia and under strict aseptic precautions the back was prepared. An experienced anesthesiologist attempted Lumbar puncture in L_3-L_4 intervertebral space (IVS) with 23 guage Quincke spinal needle. Even after three attempts that produced the typical 'give-in' feeling of dural puncture and changing the IVS to L_2-L_3 no CSF was seen. Negative aspiration failed to show CSF flow. It was then decided to inject 2.5 ml of hyperbaric Bupivacaine 0.5% at this point of 'give-in' feel, with the realization that even if the needle was not in the subarachnoid space, the low amount of drug would not cause a major problem. Patient was then immediately put in supine position and all the pressure points were adequately padded. Assessment of motor and sensory blocks was confirmatory. A sensory block (assessed using pin-prick method) upto T_6 was attained within 5 minutes and the surgeons were asked to proceed. Surgery lasted for 60 minutes and completed uneventfully. Sensory block regression was adequate, reaching L_1 level after another 90 minutes. The post-operative period was uneventful over the next 48 hours.

DISCUSSION: Regional anesthesia in the form of central neuraxial blockade has definite advantage over general anesthesia for patients undergoing lower-limb orthopedic surgery. This includes reduction in the incidence of major peri-operative complications with certain surgical procedures including deep vein thrombosis, pulmonary embolism, blood loss, respiratory complications and death [4]. Post-operative pain management, a significant problem after orthopedic procedures, with regional anesthetic techniques, leads to superior pain relief [5]. Also, no airway manipulation, minimal drug use and a conscious patient was of utmost importance in our case.

Spinal anesthesia is a reliable and relatively simple technique of central neuraxial blockade for lower limb orthopedic surgeries. A major advantage of spinal anesthesia is its definitive endpoint i.e., the free flow of CSF [6]. Two conditions are, therefore, absolutely necessary to produce spinal anesthesia: puncture of the duramater and subarachnoid injection of an anesthetic agent[7]. This is possible only when CSF flow is seen.

However, sometimes one may not get an obvious CSF flow on lumbar puncture, i.e. 'dry tap'. Usual causes include faults in the technique employed and can be corrected by adhering to the basic rules. Occasionally, the dry tap may be genuine, wherein after the typical 'give-in' feeling of dural puncture, no CSF flow is seen. Causes include previous spinal surgery, low CSF pressure or pathologic conditions like adhesive arachnoiditis and lumbar spinal-canal stenosis.

Our patient, middle aged postmenopausal female, presented with fracture of femur after a trivial injury. Incidentally, she was found to have anemia, systemic hypertension and cirrhosis of liver with portal hypertension and ascites. After optimizing the patient's condition with anti-hypertensives and diuretics, she was to be operated under spinal anesthesia. An experienced anesthesiologist was faced with 'dry tap'. Keeping in view the patient's request to be operated under regional anesthesia and the negligible risk involved with injection of small quantity of local anesthetic in wrong space, it was decided to inject Bupivacaine at the point where the typical 'give-in' feeling of dural puncture was appreciated. The subarachnoid block was successful with adequate sensory and motor block leading to an uneventful surgery. The patient had excellent pain relief in the early post-operative period which was later supplemented with systemic analgesics.

The possible causes of 'dry tap' in our patient could have been low CSF pressure [8] resulting from diuretic

therapy as other pathological causes could be ruled out on the basis of absence of symptoms, negative history and absence of infectious etiology. Epidural could have been an option, but accidental dural puncture would go unrecognized. Other techniques for verification of needle location include radiological imaging with contrast studies or real-time stimulation testing with insulated needle [9], both of which were not feasible in our case.

CONCLUSION: To conclude, it is not intended that local anesthetic be given in every case of dry tap, as most often the cause is a faulty technique. We report this case, as 'dry tap' had been encountered and spinal anesthesia was successful suggesting that the 'dry tap' was genuine.

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(1)

Original Research Article

Role of clonidine premedication as a part of hypotensive anaesthesia during functional endoscopic sinus surgery: A placebo-controlled study

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Abstract

Objective: The present study was performed to evaluate the effectiveness of intravenous Clonidine as a part of premedication in controlled hypotensive anaesthesia during functional endoscopic sinus surgery (FESS). **Material & Methods:** It was a prospective study carried out in the department of Anaesthesia of a tertiary care centre of Rajasthan, India. 50 patients undergoing FESS surgery for chronic sinusitis were included in the study and were divided into two groups viz. group I, who were given normal saline and group II, who were given intravenous Clonidine 3µ/kg as a part of premedication prior to induction. The outcomes were measured by estimation of mean arterial pressure (MAP), extra requirement of isoflurane and nitroglycerine (NTG) to achieve target MAP, blood loss during the surgery, duration of surgery and post-operative complications. **Results:** Both the groups were matched in terms of age, sex and weight parameters. There was statistically significant difference between MAP in group I and group II before induction, average intra-operative and during immediate post-operative period. The requirement of extra isoflurane or NTG to achieve target MAP was high (in 56% patients) and moderate (in 44% patients) in group I while low requirement was needed in 60% of group II cases and rest 40% cases didn't required any extra isoflurane or NTG. The average amount of blood loss in group II was significantly less (230±66 ml) than group I (356±75 ml). Similarly, the duration was 76±16 minutes in group I surgery and 59±12 minutes in Clonidine group. Quality of surgical field as per Boezart score was significantly better in Clonidine group. The incidence of postoperative complications like bradycardia, hypotension and prolonged sedation were not significant in both the groups. **Conclusion:** Clonidine is cheap and safe drug to use for controlled hypotensive anaesthesia without any significant side effect in FESS.

Key Words: Clonidine, Controlled anaesthesia, Hypotension, Sinus surgery, Bradycardia

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INTRODUCTION

Functional endoscopic sinus surgery (FESS) has been emerged as treatment of choice for chronic rhinosinusitis with or without nasal polyp refractory to medical treatment. During the surgery, even a small amount of bleeding can decrease visibility of the surgical field and is directly related to increased risk of complications and surgery failure.[1] Hence it is important to minimize bleeding during the surgery. Preoperative preparation using antibiotic and steroid medications, intra-operative use of local decongestant and hypotensive anaesthesia by an expert anaesthetist are the methods which are being

used to control bleeding during FESS and better visualization of surgical field. Many drug combinations and protocols for controlled hypotensive anaesthesia have been used and compared in past years. Two main strategies being used for hypotensive anaesthesia are (a) deep anaesthesia with strong analgesia and (b) standard anaesthesia with hypotensive drugs. The first strategy may result in prolonged recovery while second strategy may result in postoperative hypotension. Hence, achieving controlled hypotensive anaesthesia in FESS is challenging and important for surgeon as well as anesthetist.Alpha2 agonists have been used in controlled hypotensive anaesthesia for decades. In addition to their antihypertensive and sympathicolytic effect, they are known to have effective sedative and analgesic effect with hemodynamic stability.[2] In present study, we are assessing the effect of single iv dose of Clonidine for controlled hypotensive anaesthesia in FESS surgery. The results were compared with placebo group.

MATERIAL AND METHODS

The present study was a prospective study carried out in the department of anaesthesia, Ananta Institute of Medical sciences, Rajsamand during the period of 1 year from December 2017 to December 2018.50 patients of chronic rhinosinusitis with or without nasal polyposis who were to undergo functional endoscopic sinus surgery (FESS) were included in the study. Patients were randomly allocated to two groups with 25 members in each group. Pre- anaesthesia examination of all the patients was done a day before surgery.

Group I- received 20 ml of normal saline in premedication.

Group II- received 3µg/kg body weight in 20 ml normal saline in premedication.

Exclusion criteria:

1. Patient with history of hypertension, cardiovascular accidents, ischaemic heart disease, hepatic and/ or renal dysfunction or poor respiratory reserve.
2. Pregnant or lactating female.
3. History of allergy to any of the drugs to be used during the study.
4. Patients already using the drugs that may affect the results of present study (anticoagulants, calcium channel blockers, beta-blockers, clonidine).
5. Obese patients weighing > 90 kg.
6. Patients having history of FESS done in the past.
7. Patients refused to give consent.

Ethical clearance: approval from institutional ethical committee was taken before starting the study and well informed consent was also taken from all the patients involved in the study.

RESULTS

The study was conducted during the period of 1 year from December 2017 to December 2018.50 patients of chronic rhinosinusitis with or without nasal polyp who were to undergo FESS surgery and who met the inclusion criteria were included in the study. Patients were randomly divided into two groups. Group I was the placebo group in which the patients were given 20 ml of normal saline as part of premedication while in group II, patients were given Clonidine 3µg/kg in 20 ml of normal saline as part of premedication. Both the groups were matched in terms of age and sex and weight parameters. (Table 1)

Table 1: Age, sex and weight of the patients included in present study

Parameters	Group I	Group II
Age (mean age in years)	42.62	44.91
Sex (M:F ratio)	16:9	17:8
Weight (mean weight in kg)	67.97	63.88

There was statistically significant difference between MAP in group I and group II before induction, average intra-operative and during immediate post-operative period. The MAP after induction in group I and II were 83±12 mmHg and 79±11 mmHg respectively but the difference was not statistically significant. (Table 2)

Table 2: Mean Arterial Pressure of the patients of two groups in the study

Mean Arterial Pressure (MAP)	Group I	Group II	p-value
Before induction	102±14	89±12	0.0009
After induction	83±12	79±11	0.2252
Average intra-operative	73±6	68±4	0.0011
Immediate post-operative	101±8	84±7	0.0001

The requirement of extra isoflurane or NTG to achieve target MAP was high (in 56% patients) and moderate (in 44% patients) in group I while low requirement was needed in 60% of group II cases and rest 40% cases didn't required any extra isoflurane or NTG. (Table 3)

Table 3: Extra requirement of isoflurane or NTG in two groups of the study

Requirement	Group I	Group II
High	14	0
Moderate	11	10
Low	0	15

The average amount of blood loss in group I surgery was 356±75 ml while in group II surgery, it was 230±66 ml and the difference was statistically significant. Similarly, the duration was 76±16 minutes in group I surgery and 59±12 minutes in group II surgery and the difference was statistically significant. (Table 4)

Table 4: Amount of blood loss and duration of surgery in two groups of the study

	Group I	Group II	p-value
Blood loss (ml) (Mean±SD)	356±75	230±66	0.0001
Duration of surgery (Mean minutes±SD)	76±16	59±12	0.0001

Quality of surgical field as measured by Boezart score was good in 8% of group I cases and 32% of group II cases, fair in 80% of group cases and 64% of group II cases, poor in 20% of group I cases and only 4% of group II cases. (Table 5)

Table 5: Quality of surgical field in two groups of the study

Grade	Group I	Group II
Good (0-1)	2	8
Fair (2-3)	20	16
Poor (4-5)	5	1

20% of group I patients had complications (hypotension 8%, Bradycardia 8% and prolonged sedation 4%) and 28% of group II patients developed complications (hypotension 12%, bradycardia 8% and prolonged sedation 8%). (Table 6)

Table 6: Incidence of post-operative complications in present study

Complications	Group I	Group II
Hypotension (< 50mmhg)	2	3
Transient Bradycardia	2	2
Prolonged sedation	1	2
Total	5	7

DISCUSSION

FESS is the preferred surgical method to treat chronic sinusitis which are refractory to medical treatment. Bloodless field is often required in FESS for better visibility of surgical field and to avoid complications and failure. Many pre-operative and intra-operative strategies have been explored till now to minimize the risk of bleeding in patients undergoing FESS. The success of these strategies is determined based on their impact on amount of blood loss during surgery, duration of surgery, quality of surgical field explained by surgeon and post-operative complications. Various methods are pre-operative antibiotics and steroids, position of the patient (reverse Trendelenburg position), intra-operative use of local decongestant, local vasoconstrictor injections, warm saline irrigation, controlled hypotensive anaesthesia and use of tranexemic acid.[4] The present study is a placebo-controlled study performed to assess the hypotensive effect of intravenous Clonidine in FESS surgery. In present study, we successfully achieved the target MAP between 50-70 mmHg in all the patients. The average MAP during intra-operative period in group I and group B were 73±6 mmHg and 68±4 mmHg respectively. Thus, it was observed that average MAP was significantly lower in Clonidine group than placebo group. Further, to achieve the target MAP, there was high to moderate requirement of extra isoflurane or NTG in placebo group while very less requirement was there in Clonidine group. (Table 3)Similar results were observed in a study done by V. A. Praveen and R. Krishna Prabu in 2016. They studied the effect of Clonidine as a part of hypotensive anaesthesia for FESS and found that 60% patients of placebo group required high amount of extra isoflurane and NTG while in clonidine group, there was very less requirement of extra isoflurane and NTG to achieve target MAP. [5] Similar results were obtained in other studies by Jabalameli *et al*, Hackmann *et al*, Howie *et al*. and Engelman E *et al*. [6, 7, 8, 9] The average amount of blood loss in Clonidine group (230±66 ml) was significantly less than placebo group (356±75 ml) in present study. The results were similar to another study done by Okuyama *et al* in 2005. They studied the effects of clonidine and prostaglandin E1 on blood loss during FESS and concluded that Clonidine constricts peripheral blood vessels and reduces nasal mucous blood flow which accounts for the reduction of blood flow. [10] Jabalameli *et al* also had the similar results with their studies on effect of Clonidine on reducing bleeding in FESS. The average duration of surgery was also very less in Clonidine group (59±12 min) as compared to placebo group (76±16 min). The results were similar to studies done by Nair S *et al* and Wawrzyniak *et al*. [11, 12] In present study, the surgical field grading showed that Clonidine group had better grading than the placebo group. The results were highly correlated with results of past studies done by Jabalameli M *et al* and Anvari *et al*.[6,13] 28% cases from clonidine group developed complications like hypotension (in 12% cases), bradycardia (in 8% cases) and prolonged sedation (in 8% cases) but the complications were not severe and relieved without any treatment. 20% cases from placebo group developed similar complications. The incidence of complications was similar in both the groups. Similar results were obtained by Meghna Jivanmall *et al* in their study to assess the effect of intravenous Clonidine in FESS. They also used 3µg/kg Clonidine in premedication and compared the results with placebo group. The incidence of complication between two groups was statistically insignificant. Out of 30 patients in Clonidine group, 3 patients had prolonged sedation, 10 patients had hypotension and 1 patient had bradycardia. The results were highly correlated with the results of present study. [14]Similar results were obtained by Sahajananda and Rao *et al* and Samantaray *et al*. They also used 3µg/kg Clonidine as a part of premedication and observed no significant incidence of complications like hypotension,

bradycardia which required treatment and thus correlates better with the results of present study.[15,16]

CONCLUSION

A single intravenous dose of Clonidine (3μ/kg) as a part of premedication is effective to achieve controlled hypotensive anaesthesia in FESS. It maintains the mean arterial pressure within limits without additional requirement of isoflurane or NTG. It significantly reduces the amount of blood loss and provides a better field of visibility for surgery and thus shortens the duration of surgery. Clonidine is cheap and safe drug to use for controlled hypotensive anaesthesia without any significant side effect.

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Original Research Article

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Caudal Epidural Injection of Steroid and Local Anesthetic in the Management of Chronic Low-Back Pain

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Abstract

Objectives: The present study was carried out to assess the role of caudal epidural injections of steroid with local anesthtic in the management of chronic low-back pain. *Materials and Methods:* Fifty patients of chronic low-back pain were included in the study. Epidural injections of steroid with local anesthetic were administered to them via caudal approach. Follow up was scheduled after 1 month, 3 months, and 6 months. Assessment was done by using VAS score and ODI. *Results:* Fifty patients of chronic low-back pain were included in the study. 31 (62%) patients were male and 19 (38%) were female. Age of the patients ranges from 30 to 70 years with the mean age of 55.21 years. Mean VAS score of the patients before the intervention was 7.91 ± 1.60 which was reduced to 3.87 ± 1.21 at 1 month follow-up, 3.46 ± 1.32 at 3 months follow-up and 4.66 ± 1.56 at 6 months follow-up. Similarly, mean ODI of the patients before the treatment was 53.81 ± 6.12 which was reduced to 33.67 ± 4.89 at the end of 1 month, 32.65 ± 5.11 at the end of 3 month and 28.80 ± 4.71 at the end of 6 month. *Conclusion:* Caudal epidural injection of steroid with local anesthetic is an effective method for the management of chronic low-back pain in terms of pain relief and functional improvement in both short- and long-term results.

Keywords: Chronic low back pain; Steroid; Local anesthetic; Epidural; Radiculopathy; Spinal stenosis.

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Introduction

Chronic low-back pain is a common community health problem worldwide. Over 70% people in developed countries experience low-back pain at sometime in their lives.[1] In India, this figure is even more around 80%. Every year, around 3–4% of population in India is temporarily disabled, and 1% of working age population is disabled totally and permanently because of low-back pain.[2]

Low-back pain is defined as pain, muscle tension or stiffness localized below the costal margin and above the inferior gluteal folds with or without leg pain and it is defined as chronic when the duration of pain is 12 weeks or more.[3]

The origin of low-back pain can be various anatomic structures like muscles, fascial structures, nerve roots, bones, joints, intervertebral discs, and abdominal organs. Many times, the pain can arise from aberrant neurological pain processing which causes neuropathic low-back pain.[4,5]

Furthermore, low-back pain can also be influenced by psychological factors (like anxiety, depression and stress, etc.) and psychosocial factors.[6–8]

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Hence, the diagnosis of low-back pain is very challenging and must include thorough history taking about the symptoms as well as about psychological and psychosocial factors. A proper clinical examination and identification of origin of pain is the mainstay of diagnosis. Radiological investigations including MRI/CT scan should be advised wherever necessary.

Till now, various conservative, surgical and non surgical methods have been used for low-back pain with variable results.[9-13] Every patient with low-back pain is not a candidate for surgery and, in fact, surgery had been proven failure in approximately 25% of well selected cases.[14]

A cornerstone of non-surgical treatment for low-back pain is epidural steroid injection and still is the most commonly performed procedure for low-back pain.[10-13]

There are three different ways to perform epidural injection, viz. caudal block, translumbar approach and transforamial approach. In present study, we are using caudal epidural injection (CEI) approach to administer steroid and local anesthetic (LA) agent for the management of low-back pain.

Materials and Methods

The present study is a prospective study carried out in the department of anesthesia, Ananta institute of medical sciences, Rajsamand during the period of 1 year from January 2018 to January 2019. Fifty patients attended orthopedic OPD with the complaints of low-back pain were included in the study.

Sample size and sampling: Fifty patients of chronic low back pain.

Study type: Quantitative, Prospective

Duration of study: 1 year

Inclusion criteria

1. Pain on the low-back region, buttock and/or lower extremities while standing, walking and/or spinal extension.
2. Mild-severe lumbar central canal spinal stenosis identified by CT/MRI.
3. Lower extremity symptoms consistent with neurogenic claudication.
4. Must provide consent for study and should be able to complete the assessment instruments.
5. Age ≥ 30 years.

Exclusion criteria

1. Other comorbidities that could interfere with the results of the study concerning pain and function like painful peripheral neuropathy, fibromyalgia, Parkinson disease, dementia, stroke, amputees, other neurological disorders
2. Spinal instability requiring surgical fusion.
3. Severe osteoporosis
4. Known hip joint pathology
5. Bone metastasis
6. Allergy to local anesthetic and/or steroid.
7. Tuberculosis or other bone infection
8. Any other systemic disorder that limits ambulation of patient

Technique

The procedure was carried out in the operation theater. The patients were laid in prone position with a pillow in their inguinal region. Sacral hiatus was palpated and a 22G spinal needle was preceded into the hiatus at an angle of 45. Reaching the bone structures, the angle reduced to 10 and after preceding about 5 cm, hiatus was entered and epidural region was attained. Injection containing 2 ml (80 mg) methyl prednisolone with 4 ml of 2% xylocaine was injected into the epidural space without fluoroscopic guidance.

Data collection tool (score) used: Pain was assessed by using visual analogue scale (VAS) score (1-10). Functional status was assessed by using Oswestry disability index 2.0 (ODI).[15]

Follow-up: Follow up was scheduled at 1, 3 and 6 months.

Ethical clearance was taken from institutional ethical committee. Informed written consent was obtained from all the patients involved in the study.

Results

Fifty patients of chronic low back pain who met the inclusion criteria were included in the study. 31 (62%) patients were male and 19 (38%) were female. Age of the patients ranges from 30 to 70 years with the mean age of 55.21 years.

Mean VAS score of the patients before the

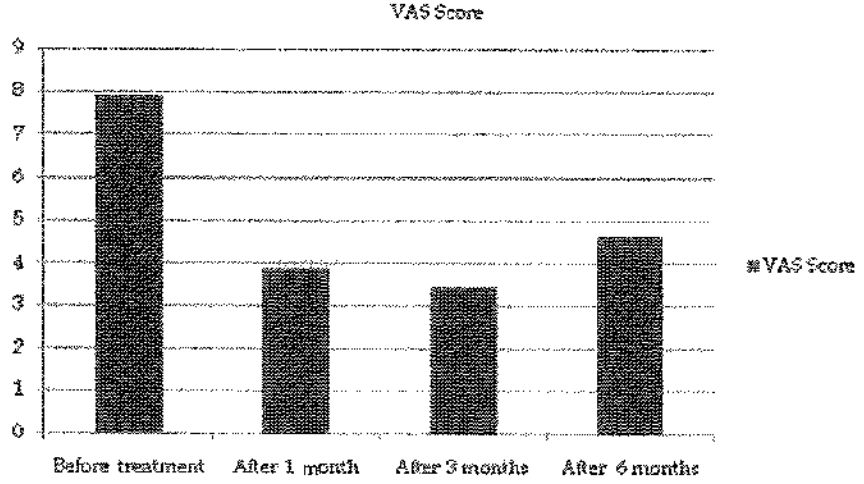

Fig. 1: MeanVAS score of the patients before treatment and at 1, 3, 6 month follow up.

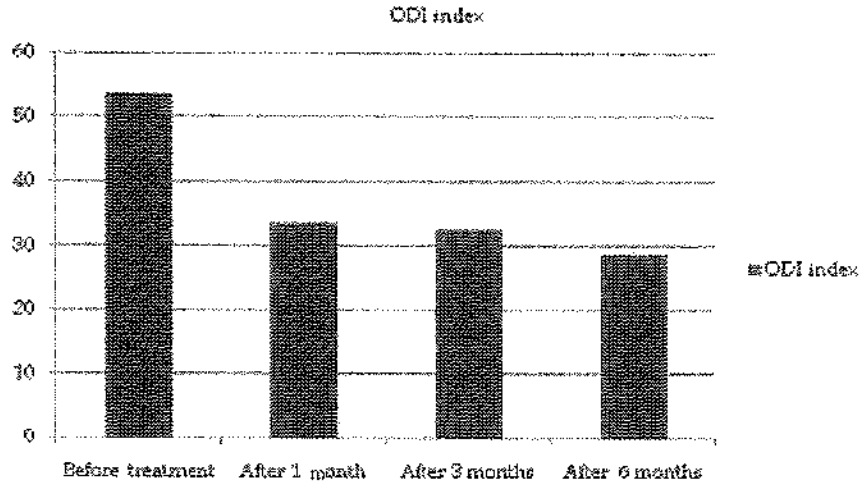

Fig. 2: Mean ODI before treatment and at 1, 3, 6 month follow up.

intervention was 7.91 ± 1.60 which was reduced to 3.87 ± 1.21 at 1 month follow-up, 3.46 ± 1.32 at 3 months follow-up and 4.66 ± 1.56 at 6 months follow-up. When compared to the VAS score before the treatment, the results were statistically significant (p-value < 0.05). Mean VAS score at six months follow up was higher than previous follow up values but the difference was not found to be statistically significant (p-value > 0.05) (Fig. 1).

In present study, mean ODI of the patients before the treatment was 53.81 ± 6.12 which was reduced to 33.67 ± 4.89 at the end of 1 month, 32.65 ± 5.11 at the end of 3 month and 28.80 ± 4.71 at the end of 6 month. When ODI values at each follow up was compared with ODI before treatment, the difference was statistically significant (p-value < 0.05) but when the ODI values at each follow up were compared with each other, the difference were not significant (p-value > 0.05) (Fig. 2).

Discussion

The present study was carried out to assess the role of caudal epidural injections of steroid with local anesthtic in the management of chronic low-back pain. The study showed positive outcome in both short- and long-term results in terms of reduction

in pain as well as good functional outcome.

The improvement in pain after epidural injections was assessed using VAS score. The mean VAS score of the patients before the intervention was 7.91 ± 1.60 which was reduced to 3.87 ± 1.21 at 1 month follow-up, 3.46 ± 1.32 at 3 months follow-up and 4.66 ± 1.56 at 6 months follow up. When compared with initial VAS score, the difference at follow up was statistically significant (p-value < 0.05), suggestive of positive outcome in both short- and long-term period. The VAS score at 6 months follow up was little higher than the previous follow up but the difference was not statistically significant (p-value > 0.05).

The improvement in mobility and function was assessed using ODI (Oswestry Disability Index).

ODI is calculated based on each score of the ODQ (Oswestry Disability Questionnaire), which consists of ten items. Each of the ten items is scored from 0 to 5, and the total is added and multiplies by 2. Therefore, the ODI ranges from 0 to 100.[15]

In present study, mean ODI of the patients before the treatment was 53.81 ± 6.12 which was reduced to 33.67 ± 4.89 at the end of 1 month, 32.65 ± 5.11 at the end of 3 month and 28.80 ± 4.71 at the end of 6 month. The difference was found to be statistically significant when ODI at each follow up was compared with ODI before treatment (p-value <0.05). The results are suggestive of good positive outcome in both short- and long-term follow up.

Manchikanti *et al.* performed a similar study in 2010 which included 70 patients of discogenic low-back pain. They compare the effect of caudal epidural injections (CEIs) of steroid and LA with CEIs of LA alone. Results were assessed using VAS, ODI, employment status and opioid intake. They got positive outcome for both short- and long-term results in both the groups. (86% in steroid + LA group and 74% in LA alone group). The results suggested that CEIs of steroid with LA are more effective than CEIs of LA alone in treatment of discogenic low-back pain.[16]

Ghahreman *et al.* also performed a comparative study in 2010 with 150 patients of low-back pain radiating to lower limb and concluded that CEIs of steroid with LA were effective than intramuscular injections in pain reduction secondary to radiculopathy.[17]

Wilson-Macdonald *et al.* performed a study in 92 patients of disc prolapse or spinal stenosis. They compared the effect of CEIs of steroid and LA with that of intramuscular injection of the same in the management of chronic low-back pain due to disc prolapsed or spinal stenosis. The assessment methods used were Oxford pain chart and ODI. They concluded that CEIs of steroid with LA was more effective in short-term results but was not found beneficial over intramuscular injections in long-term results.[18]

Iversen *et al.* also performed a study in 2011 to compare the effect of CEIs of steroid with that of placebo. 133 patients with unilateral lumbar radiculopathy were included in their study. The results were in contrary to our findings. They concluded that CEIs of steroid had no benefit over placebo in treating lumbar radiculopathy.[19]

Arden *et al.*, in 2005, studied the effect of CEIs of steroid with LA in 228 patients of sciatica and concluded that CEIs of steroid with LA had only short-term benefit over placebo in treating sciatica. Thus the results were partially in favor of present study.[20]

Bush K and Hillier S performed a placebo controlled study to assess the effect of CEIs of steroid with LA in the management of intractable sciatica and found that after 1 year follow up; subjective and objective measures were improved in both the groups. The improvement was greater in actively treated group but only the objective assessment, i.e. straight leg raise, was statistically significant.[21]

Another study done was by Breivik H *et al.* in the year 1976. Thirty-five patients of chronic lumbar radiculopathy were included in the study and a comparative assessment was done between the effect of CEIs of bupivacaine and methylprednisolone with bupivacaine followed by saline. They found improvement in both the groups but the improvement was greater in treatment group.[22]

In present study, caudal epidural injections of steroid with local anesthetic were found to be highly effective in both short- and long-term follow up. Both the VAS and ODI were improved till the 6 months follow up. ODI was slightly reduced at 6 months follow up than the previous value but the difference was not statistically significant.

An important limitation of present study was that we did not extend our treatment to control items for the comparison due to limitations of the time course. Replication of treatment results with the use of other control items would have provided a strong demonstration of experimental control,

strengthening the results of the study.

Conclusion

The results of the present study showed that caudal epidural injections of steroid with local anesthetic is an effective method for the management of chronic low-back pain in terms of pain relief and functional improvement. The results of present study are in favor of many studies done in the past but in contrary to some other studies. An important limitation of present study was that control items were not included in the treatment strategy. In future, controlled studies with large sample group and systematic reviews of various such studies are expected for further useful outcomes in the management of chronic low-back pain.

What this study adds to existing knowledge

The present study advocates the use of epidural steroid with local anesthetic injections for the management of chronic low-back pain. In comparison to previous study of using steroid alone or LA alone, the combination of steroid and LA have better results in both short- and long term follow up. Further, many patients in developing countries live with disability to avoid surgery but CEIs can be an effective alternative for them.

Conflict of interest: No conflict of interest exists. No financial relationship exists between authors and products or procedures related to the article.

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Original Research Article

Comparative Study of Using Intrathecal Clonidine and Fentanyl as an Adjuvant to Hyperbaric Bupivacaine (0.5%) in Lower Abdomen Surgeries

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ABSTRACT

Objective: The present study was carried out to compare the effect of intrathecal Clonidine and intrathecal Fentanyl as an adjuvant to hyperbaric Bupivacaine in terms if efficacy, safety and post-operative analgesia in patients undergoing lower abdominal surgeries.

Material and methods: 100 patients planned for elective lower abdominal surgery under spinal anaesthesia were included in present study. The patients were divided into two groups viz. group I (n=50) in which patients were given 2.5 ml of hyperbaric Bupivacaine (0.5%) with 50µg of Clonidine intrathecally and group II (n=50) in which patients were given 2.5 ml of hyperbaric Bupivacaine (0.5%) with 25µg of Fentanyl intrathecally. Assessment was done in terms of time taken for onset of sensory and motor blockade, duration of sensory and motor blockade and requirement of rescue analgesia.

Results: Patients' age, height, weight, sex ratio, mean arterial pressure during surgery (MAP), heart rate (HR) and duration of surgery were not significantly different between two groups. Onset of sensory blockade was significantly lower in Fentanyl group (group II) (2.02±0.15 min) while onset of motor blockade was significantly lower in Clonidine group (group I) (4.62±1.21 min). Duration of sensory and motor blockade was significantly less in Fentanyl group. Time for requirement of first dose of analgesia was also significantly longer in clonidine group (490.55±28.98 min) when compared to fentanyl group (421.19±26.64 min).

Conclusion: addition of 50µg Clonidine to hyperbaric Bupivacaine as an adjuvant in spinal anaesthesia for lower abdominal surgeries offers longer post-operative analgesia than Fentanyl with no side effects.

Keywords: Clonidine, Bupivacaine, Spinal, Fentanyl, abdominal surgery

INTRODUCTION

Bupivacaine is most commonly used local anaesthetic for spinal anaesthesia but the duration of anaesthesia is short and limited. Short duration of action can be overcome by using large doses of Bupivacaine but it can produce serious cardiac toxicity. Perioperative hemodynamic stability is also a concern. Hence, to address the problem of short duration of action and to improve perioperative hemodynamic status and quality of analgesia, various adjuvants are being used intrathecally along with Bupivacaine. [1,2] Various adjuvants used are Midazolam, opioids, neostigmine, Dexmedetomidine, and Clonidine. [3]

Fentanyl (µ1- and µ2- receptor agonist) is most common opioid used as an adjuvant to local anaesthetic in spinal anaesthesia. It has rapid onset and short duration of action along with minimal cephalic spread. However, it also has some side effects like nausea, vomiting, pruritis, respiratory depression and urinary retention. [4,5]

Clonidine is a selective alpha-2 receptor agonist agent, routinely used as

premedication agent for general anaesthesia. It prolongs sensory and motor block in spinal anaesthesia and provides prolonged postoperative analgesia. It acts by indirectly inhibiting the activity of wide dynamic range (WDR) neurons.

In present study, we have compared the effect of intrathecal Clonidine and intrathecal Fentanyl as an adjuvant to hyperbaric Bupivacaine in terms if efficacy, safety and post-operative analgesia in patients undergoing lower abdominal surgeries.

MATERIALS AND METHODS

The present study is a prospective study carried out during the period of one year from October 2016 to October 2017, after obtaining approval from institutional ethical committee and properly informed written consent from all the participants.

100 patients planned for elective lower abdominal surgery under spinal anaesthesia were included in present study. The patients were pre-medicated with glycopyrrolate 0.2 mg intravenous (IV) and ondansetron 4mg (IV). Sedatives were not used during whole procedure. In the operation theatre, the baseline parameters (pulse, blood pressure, SpO2, electrocardiogram) were recorded and preloading was done with Ringer lactate solution 10-15/kg. The patients were divided into two groups:

Group I (n=50): patients were given 2.5 ml of hyperbaric Bupivacaine (0.5%) with 50µg of Clonidine intrathecally.

Group II (n=50): Patients were given 2.5 ml of hyperbaric Bupivacaine (0.5%) with 25µg of Fentanyl intrathecally.

Exclusion criteria:

1. Patients with systemic disorders like diabetes, hypertension, and heart disease with ASA grade more than II.
2. Allergy to drugs used in the study.
3. Patients with contraindication to spinal anaesthesia like spine deformity raised intracranial pressure, neurological disorders, bleeding disorders or infection at puncture site.
4. Patient's refusal to give consent for the procedure.

Procedure: Under all aseptic precautions, subarachnoid block was administered with 23 G spinal needle through mid-line approach in sitting position. Intrathecal (IT) drug was injected in L3-L4 intervertebral space over 30 seconds. After the block was performed, the patients were made supine and were given supplemental oxygen. Bradycardia and hypotension were treated with IV atropine and ephedrine, respectively.

The following parameters were noted after subarachnoid block:

- Time of onset of sensory block (tested by pinprick method)
- Time taken for onset of motor blockade (assessed by modified Bromage scale: Bromage 0: Patients able to move hip, knee, and ankle, Bromage 1: Patients unable to move hip but able to move the knee and ankle, Bromage 2: Patient unable to move hip and knee but able to move the ankle, Bromage 3: Patient unable to move hip, knee, and ankle). [6]
- Intra operative haemodynamic monitoring (heart rate (HR), systolic blood pressure (SBP) measured immediately after subarachnoid block, 2nd min, 5th min, 10th min and every 5 min till the end of surgery)
- Total duration of analgesia (time from the onset of analgesia to the point where the patient complained of pain at the surgical site requiring rescue analgesia)
- Duration of motor block (complete recovery of motor power).

RESULTS

100 patients undergoing lower abdominal surgery under spinal anaesthesia were included in the study and divided into two groups viz. group I, in which Clonidine was used along with hyperbaric Bupivacaine and group II, in which Fentanyl was used along with hyperbaric Bupivacaine.

Patients' age, height, weight, sex ratio, mean arterial pressure during surgery

(MAP), heart rate (HR) and duration of surgery were not significantly different between two groups. (Table 1)

Table.1 Baseline characteristics of the study participants in two groups

S. No.	Parameters (Mean±SD)	Group-I	Group-II	P-value
1	Age (years)	38.61±9.22	40.01±10.48	0.4799
2	Height (cm)	148.77±9.47	146.89±9.09	0.3114
3	Weight (Kg)	61.09±6.21	62.98±6.66	0.1454
4	Sex (M:F)	36:14	38:12	1.0000
5	MAP (mmHg)	84.68±5.87	85.43±5.32	0.5048
6	HR (bpm)	82.11±4.97	83.01±4.34	0.3372
7	Duration of Surgery (min)	92.56±12	95.44±65	0.7587

Table 2 shows the comparison of blockade between two groups in terms of onset and duration of sensory and motor blockade and requirement of first dose of rescue analgesia. Onset of sensory blockade was significantly lower in Fentanyl group (group II) while onset of motor blockade was significantly lower in Clonidine group (group I). Duration of sensory and motor blockade was significantly less in Fentanyl group. Time for requirement of first dose of analgesia was also significantly less in Fentanyl group when compared to Clonidine group. (Table 2)

Table.2 Comparison of blockade and analgesia effect of two groups

S.No.	Parameters	Group-I	Group-II	P-value
1	Onset of sensory blockade (min)	2.11±0.12	2.02±0.15	0.0013
2	Onset of motor blockade (min)	4.62±1.21	5.36±1.45	0.0067
3	Duration of sensory blockade (min)	170.87±14.43	129.32±11.31	0.0001
4	Duration of motor blockade (min)	193.61±17.22	170.43±16.43	0.0001
5	Time for first dose rescue analgesia	490.55±28.98	421.19±26.64	0.0001

Intra-operative incidences of hypotension, bradycardia, respiratory depression, nausea/vomiting and dry mouth were comparable in both the groups.

DISCUSSION

Clonidine and Fentanyl are used to prolong the postoperative analgesia effect of intrathecal Bupivacaine. In present study, we compared the efficacy of intrathecal Clonidine and intrathecal Fentanyl when used along with hyperbaric Bupivacaine in spinal anaesthesia.

In present study, we found that onset of sensory blockade was earlier in Fentanyl group (2.02±.15 min) than in Clonidine group (2.11±0.12 min). Onset of motor blockade was earlier in Clonidine group. Duration of sensory and motor blockade was also for longer duration in group I than group II. These findings were similar to the findings of previous similar studies.

Clonidine is believed to prolong the motor blockade produced by local anaesthetic agents. [7] Clonidine produces local vasoconstriction by acting on vascular smooth muscle (α-receptors), which decreases absorption of local anaesthetics from sub-arachnoid space thereby prolonging the duration of action. [8-10]

In present study, mean time taken for onset of motor blockade was significantly shorter than the Fentanyl group. Similar results were obtained by Bajwa et al in their study of comparison of intrathecal Clonidine and fentanyl in hyperbaric bupivacaine for spinal anesthesia and postoperative analgesia in patients undergoing lower abdominal surgeries. [11]

In present study, duration of sensory and motor blockade was also for longer duration in group I than group II. Similar results were obtained by Chhabra et al. in their study of comparison between intrathecal Clonidine and Fentanyl as an adjuvant to intrathecal Ropivacaine for major lower limb surgeries. They concluded that clonidine 60 µg has advantage over fentanyl and it prolonged the duration of the subarachnoid block and postoperative analgesia, similar to our study. [12] Sharan et al. compared intrathecal Clonidine 30 µg

with fentanyl 25 µg and concluded that Clonidine had advantage over fentanyl which is in agreement with our study. [13]

In present study, group I patients required significantly longer time than group II for first dose of rescue analgesia. Khezri et al. in their study concluded that intrathecal clonidine 75 µg with Bupivacaine prolonged the time to first analgesia request compared to fentanyl which was similar to our study. [14]

The dose of clonidine was limited to 50 µg in our study to decrease the side effects. Kothari et al. compared different doses of clonidine as an adjuvant to intrathecal bupivacaine for spinal anesthesia in patients undergoing cesarean section aiming to find out the lowest possible effective dose and found that the incidence of both hypotension and bradycardia more in bupivacaine group than in bupivacaine with clonidine group which was not in agreement with our study. [15] Bhure et al. demonstrated that addition of clonidine, fentanyl, and midazolam to Bupivacaine significantly improves the onset and duration of sensory and motor block with relative hemodynamic stability, prolongs the duration of analgesia, and reduces the consumption of systemic analgesics in comparison to bupivacaine alone. They concluded that clonidine is an excellent additive to bupivacaine in spinal anesthesia and provides prolonged duration of analgesia without any deleterious effects on the mother and baby. [16]

No systemic side effects such as bradycardia, hypotension, or sedation were observed in both groups of our study. Sethi et al. [17] and Shah et al. [18] observed very few incidences of hypotension and bradycardia by using 1 mcg/kg of intrathecal clonidine for non-obstetric surgeries, whereas Kothari et al. [15] found the increased incidence of both hypotension and bradycardia in bupivacaine group than in bupivacaine with clonidine group.

CONCLUSION

Both Clonidine and Fentanyl are effective in prolonging the duration of analgesia in adjuvant to intrathecal hyperbaric Bupivacaine in spinal anaesthesia for lower abdominal surgeries. 50µg Clonidine is superior to 25µg Fentanyl intrathecally in terms of longer duration of sensory and motor blockade and longer post-operative analgesia.

Conflict of interest

No conflicts of interest exist for these authors. No relevant financial relationship exists between the authors and procedures or products used in this manuscript.

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Section Anaesthesiology

Original Article

A Comparative Analysis on Anaesthetic Requirement and Peri-Operative Hemodynamic Stress Response after a Single Dose of Dexmedetomidine and Fentanyl: A Hospital Based Study

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ABSTRACT

Background: *Fentanyl which is a short acting, synthetic opioid delivers cardiac stability at therapeutic doses and effectively blocks the sympathetic stress response to surgical stimulus. It also provides further hemodynamic stability. The Bispectral Index (BIS) is a derived electroencephalographic parameter. It has been widely validated as a monitor for depth of anesthesia.*

Methods: *99 patients of either sex, between age Group of 18 – 60 years, ASA Grade I and Grade II, scheduled for surgery under general anesthesia were randomly selected and included in this study. The duration of study was over a period of one year. This study was conducted in the Department of Anesthesia in Ananta Institute of Medical Sciences and Research Centre*

Results: *In this study we were included two groups. 34% male & 66% female were included in Group I. While in Group 2 33% male & 67% female were included. Baseline characteristics of both the groups were not significantly different. There were no significant differences in age & sex& mean duration of surgery between two groups. (p>0.05)*

Conclusions: *This study colludes that, it was inferred that Fentanyl can also help to attenuate laryngoscopic stress response, as the rise in hemodynamics after laryngoscopy and intubation was within the normal limits of heart rate.*

Keywords: *Hemodynamic Stress Response, Laryngoscopic, Intubation*

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INTRODUCTION

During induction of general anesthesia, the stimulation of sympathetic nervous system by laryngoscopy and intubation causes release of catecholamines. It leads to increase in arterial blood pressure, tachycardia and arrhythmia causing hemodynamic instability. After intubation, its maximum level within 1 min and ends within 5-10 min.[1] Due to anesthesia and surgery in the form of endocrine or autonomic disturbances may increase the risk during perioperative period. In past few years, the rate of peri- operative morbidity and mortality have been reduced due to the knowledge of the precipitating factors and applying modulatory therapeutic methods in time.[2] For effective blockage of the pressor response, many techniques and methods like increasing depth of anesthesia, topical spray of local anaesthetic agent (lignocaine), intravenous drugs like (lignocaine, esmolol, Fentanyl, Clonidine), etc have been carried out.[3] though, inhalation anesthesia is used but requires deep levels. It may take time to recover after short operation and can cause cardiovascular depression. Although adrenergic blockers are effective but longer acting agents and may cause hypotension and bradycardia.[4] Fentanyl which is a short acting, synthetic opioid delivers cardiac stability at therapeutic doses and effectively blocks the sympathetic stress response to surgical stimulus. It also provides further hemodynamic stability. The Bispectral Index (BIS) is a derived electroencephalographic parameter. It has been widely validated as a monitor for depth of anesthesia. The

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recommended range of BIS is 40–60. It is an indicator of adequate depth of general anesthesia and may be used to guide titration of anesthetic agents, instead of routine clinical signs.[5] The purpose of this study is to compare the effects of Dexmedetomidine and Fentanyl given as a bolus dose prior to induction in blunting the hemodynamic stress response to laryngoscopy and endotracheal intubation and to provide peri-operative hemodynamic stability as well as to reduce intraoperative anesthetic requirement and provide smooth recovery profile with the usage of BIS monitoring.

METHODS

Study population:- 99 patients of either sex, between age Group of 18 – 60 years, ASA Grade I and Grade II, scheduled for surgery under general anesthesia were randomly selected and included in this study

Study duration:-The duration of study was over a period of one year.

Study Area:-This study was conducted in the Department of Anesthesia in Ananta Institute of Medical Sciences and Research Centre

Data collection:- All patients were confirmed for nil by mouth status and were premedicated with injection Glycopyrrolate 5-10 µg/kg i.m. 30 minutes before induction of anesthesia. Pre-operative vitals and BIS values were noted in the operation room before giving the study drug and considered as baseline. Patients were randomly divided into 2 Groups.Group1- Received Inj. Dexmedetomidine 1 µg/Kg 10 and Group 2- Received Inj. Fentanyl 2 µg/kg 10 minutes before induction. In both the Groups general anesthesia was administered after preoxygenation for 3 minutes with Inj. Sodium Thiopentone (2.5%) 4-
6 mg/kg to produce loss of eyelash reflex followed by Inj. Succinylcholine 1.5-2 mg/kg. Patients were ventilated with 100% O 2 and on achieving complete relaxation intubation was done with appropriately sized cuff portex endotracheal tube. Anesthesia was maintained in both the Groups with O (66%), N O (33%), Isoflurane, 2 2 Inj. Vecuronium 0.1 mg/kg as initial dose and 0.02 mg/kg as maintenance dose, and ventilation was continued with IPPV (intermittent positive pressure ventilation). Pulse, blood pressure Spo and BIS value were recorded before 2 induction, during laryngoscopy, every 1-minute upto 5 minutes after intubation and then every 10 minutes till extubation. Volatile anesthetics were titrated to maintain BIS value between 40-60, ideal for surgical plane of anesthesia. Patients were reversed with injection Glycopyrrolate (0.008mg/kg) and injection Neostigmine (0.05mg/kg) intravenously at the end of the surgery. Duration of surgery, duration of anesthesia, total dosage of Vecuronium (mg) was recorded. Total dosage of Isoflurane (ml/hr) was measured by using EHRENWORTH AND EISENKRAFT formula. (3 x FGF x Volume%) Post-operative vitals, Ramsay sedation score and Visual Aaxnalouge Score for pain were recorded. Patients were observed for adverse effects like nausea, vomiting, bradycardia, and hypotension.

Data Analysis: -Data were analyzed by using Microsoft excel & statistics.

RESULTS

In this study we were included two groups. 34% male & 66% female was included in Group I. While in Group 2 33% male & 67% female were included. Baseline characteristics of both the groups were not significantly different. There were no significant differences in age & sex& mean duration of surgery between two groups (p>0.05). Usage of isoflurane was very less in dexmedetomidine group as compared to fentanyl group with BIS monitor, hence it was possible to maintain adequate depth of anesthesia and reduce requirement of anesthetic agents. Thus, using BIS monitor, during surgery and anesthesia, proves cost-effective. In Fentanyl Group, 11 patients had mild to moderate pain (VAS score 1) in the immediate post-operative period, while in Dexmedetomidine Group none of the patient had pain post-operatively (P <0.05). None of the patients was sedated after discontinuation of anesthesia.

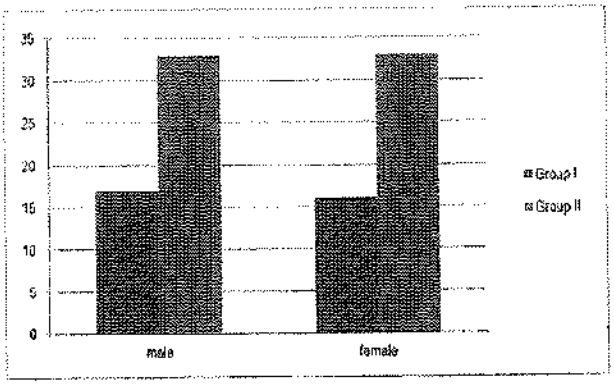

Chart: -1 Distribution of cases according to gender

Table 1: Distribution of cases according to Age & weight

Variables	Group I	Group 2
Age	33.16±9.8	36.84±11.38
Weight	58.4±7.63	54.69±8.8

Table 2: Distribution of cases according to duration of surgery

Duration of surgery	Group I	Group 2	P value
Mean	109	101.63	>0.05
SD	20.4	21.3	>0.05

Table 3: Volume (ml/hr) of Isoflurane usage:-

Group	MEAN±SD	P value
Group 1	7.41±1.34	<0.001
Group 2	14.25±2.43	

Table 4: This table showing Adverse effect

Adverse effect	Group I	Group 2
Nausea/ Vomiting	0	0
Shivering	0	0
Hypotension	0	0
Bradycardia	1	0

DISCUSSION

In modern era, it is very essential to have knowledge regarding the series of physiological changes during and after laryngoscopy. Under anesthesia, stress response has been universally recognized phenomenon. Due to stress, the adrenergic response leads to release of catecholamines in the circulation. It can cause severe hypertension, tachycardia, cardiac arrhythmias, myocardial ischemia, left ventricular dysfunction and rupture of cerebral aneurysm in susceptible individuals.[6] Direct laryngoscopy and intubation are deadly stimuli that can provoke stress response in the cardiovascular, respiratory and other physiological system. If the force and time of laryngoscopy is increased, the magnitude of the response is greater. The maximum level of response is within 1 min and ends in 5-10 min after intubation.[7] Therefore, we should limit the time for laryngoscopy to prevent rise in blood pressure. These changes are well borne by healthy individual, but may prove fatal in patients with hypertension, coronary artery disease and cerebrovascular disease.

This study was undertaken to evaluate and compare the effects of Dexmedetomidine and Fentanyl on laryngoscopic stress response and hemodynamic stability during general anesthesia conducted double-blind placebo-controlled study in 1997 to explore the effect of a single pre-induction intravenous dose of Dexmedetomidine 2 µg/kg on anesthetic requirement and peri-operative hemodynamic stability. Results showed that laryngoscopy and tracheal intubation resulted in 0 and 31 mm of Hg increase in the mean systolic blood pressure, 1 and 26 mm of Hg increase in the mean diastolic blood pressure and 13 and 29 beats/minutes increase in the mean heart rate in Dexmedetomidine and Placebo Groups, respectively. During first 51 minutes after tracheal intubation, the two groups were compared. Mean of systolic blood pressure, diastolic blood pressure and heart rate were significantly lower in the Dexmedetomidine Group in comparison to placebo Group($P<0.001$). In the post anesthesia care unit, over a three hour period, the mean systolic blood pressure, mean diastolic blood pressure and mean heart rate were significantly lower in Dexmedetomidine Group.($P<0.001$).[8] Dexmedetomidine has sedative and analgesic property through central actions in the locus coeruleus and in the dorsal horn of the spinal cord. The main action of all α adrenergic agonist is an inhibition of 2 norepinephrine release producing an attenuation of central nervous system excitation. Thus, it will cause dose dependent decrease in the heart rate and blood pressure and also has dose sparing capacity of anesthetic agent.[9] Dexmedetomidine has also been administered in normal adult as well as in patients having coronary heart disease. It provides hemodynamic stability perioperatively. During intubation, narcotics may block afferent nerve impulses resulting from stimulation of pharynx and larynx. Atweh and kuhar (1977) had observed high concentration of opiate receptors in the solitary nuclei of the 9th and 10th cranial nerves, related with visceral afferent fibers of these nerves which originate in the pharynx and larynx. Further, vagal motor nuclei intricate in monosynaptic pharyngeal and laryngeal motor reflex, also have a high concentration of opiate receptors. These receptors provide a possible mechanism for the blunting of the response to laryngeal stimulation. Fentanyl, which is a short acting, synthetic opioid, preserves cardiac stability at therapeutic dosages. It also effectively blocks the sympathetic stress response to surgical stimulus and delivers further hemodynamic stability. Fentanyl produces analgesia, sedation and in large doses unconsciousness. Anesthesia by virtue of its agonist effect on opioid receptor that is located in thalamus, hypothalamus, reticular system and gamma neurons. It prevents release of substance-P along with pain pathway and release dopamine and acetylcholine in central nervous system. High dose of opioids blunts the neuroendocrine stress response to surgery.[10-11] It was contingent that Dexmedetomidine an α agonist agent, when used 2 as a pre-induction drug, attenuates stress response to laryngoscopy and tracheal intubation. Thus, decreases heart rate and blood pressure perioperatively. Though, Fentanyl increases the heart rate & blood pressure during laryngoscopy and tracheal intubation, but it was significant when compared with the baseline value of that group. Increase in mean heart rate was maximum up to 23% in Group 2 (Fentanyl) and mean systolic blood pressure was 8% and mean diastolic pressure was 1.51% when compare to the baseline value. Though, the rise was not significant when compare with the control group of the other studies where it was found that the mean heart rate was approximately 29%, mean systolic blood pressure was 21% and mean diastolic blood pressure was 46%.

CONCLUSION

This study colludes that, it was inferred that Fentanyl can also help to attenuate laryngoscopic stress response, as the rise in hemodynamics after laryngoscopy and intubation was within the normal limits of heart rate.

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Review Article

Perils of paediatric anaesthesia and novel molecular approaches: An evidence-based review

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ABSTRACT

Evolution of anaesthesia has been largely helped by progress of evidence-based medicine. In spite of many advancements in anaesthesia techniques and availability of newer and safer drugs, much more needs to be explored scientifically for the development of anaesthesia. Over the last few years, the notion that the actions of the anaesthesiologist have only immediate or short-term consequences has largely been challenged. Evidences accumulated in the recent years have shown that anaesthesia exposure may have long-term consequences particularly in the extremes of ages. However, most of the studies conducted so far are *in vitro* or animal studies, the results of which have been extrapolated to humans. There have been confounding evidences linking anaesthesia exposure in the developing brain with poor neurocognitive outcome. The results of animal studies and human retrospective studies have raised concern over the potential detrimental effects of general anaesthetics on the developing brain. The purpose of this review is to highlight the long-term perils of anaesthesia in the very young and the potential of improving anaesthesia delivery with the novel molecular approaches.

Key words: Apoptosis, brain, general anaesthesia, neurodegeneration, paediatric anaesthesia, synaptogenesis

INTRODUCTION

Paediatric patients range from preterm infants to teenagers, and it would not be appropriate to call them miniature adults. There exist definite anatomical, physiological, pharmacological and psychological differences among the different paediatric age groups and between the paediatric and adult patients, which makes the safe anaesthetic delivery extremely challenging. Recently, there have been conflicting reports over the potential neurotoxicity of the general anaesthetics on the developing brain. Particularly intriguing are the long-term neurocognitive outcomes of anaesthesia in the very young.[1] This has generated a lot of concern because anaesthesia delivery among paediatric patients is no longer confined to the operation theatres and intensive care units but is also being increasingly used in the non-surgical settings such as long diagnostic procedures, radiological and interventional studies, to allay pain and anxiety and to maintain stable vitals. This has resulted not only in a tremendous increase in the number of anaesthetics being administered but also increased anaesthetic exposure in progressively younger age groups.[1]

Research articles, meta-analyses and systematic reviews and studies in various international and national bibliographic indices were extensively searched with emphasis on key words 'apoptosis, synaptogenesis, neurodegeneration, neurotoxicity, general anaesthesia (GA) in paediatric patients' published between the period of 1994 and 2014. The various search engines included Entrez (including PubMed), NIH.gov, Cochrane database for systematic reviews, Science direct, Scopus, WebMD.com, MedHelp.org, Searchmedica, MD consult and Google.com. The inclusion criteria was mainly focused on extraction of full text articles containing literary

Original Article

The effect of anesthetic technique for transvaginal ultrasound-guided oocyte retrieval on reproductive outcomes: A systematic review and meta-analysis

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ABSTRACT

The effects of various anesthetic techniques used for transvaginal ultrasound-guided oocyte retrieval (TUGOR) on reproductive outcomes remain controversial. Some studies have reported adverse effects due to nitrous oxide, propofol, and other general anesthetic drugs, whereas others have found them to be safe. The aim of the current meta-analysis is to pool the data available from studies comparing effects of a loco-regional technique against general anesthesia (GA)/intravenous sedation on reproductive outcomes when used for TUGOR. We searched PubMed, EMBASE, Cochrane Register, Google Scholar, and Scopus for studies that evaluated loco-regional anesthesia against GA and reported data on fertilization rate, cleavage rate, and pregnancy rate. A total of eight studies involving 1416 women undergoing TUGOR were identified. The risk of bias was high in most studies, and only two were randomized controlled trials. The loco-regional and the general anesthetic techniques used in these studies varied widely. Pooled odds ratio comparing general versus loco-regional groups for the fertilization rate was 0.939 (95% confidence interval [CI] 0.812-1.086; $P > 0.05$) and for the cleavage rate was 1.046 (95% CI 0.907-1.213; $P > 0.05$). Loco-regional anesthesia was found to be favorable to GA with regard to the pregnancy rate (pooled odds ratio was 0.701 (95% CI 0.543-0.905; $P < 0.05$). No serious complication was reported. Though the pregnancy rate was found to be higher in the loco-regional group, the superiority of one technique over the other cannot be confirmed based on the available quality of evidence and requires further well-conducted trials.

Key words: *Infertility anesthesia, ovum pickup anesthesia, sedation for in vitro fertilization*

INTRODUCTION

In vitro fertilization (IVF) started more than 30 years ago and has undergone numerous advances leading to improved patient outcomes. Ovarian stimulation, oocyte retrieval, IVF after sperm processing, and embryo transfer constitute the major steps of IVF. Oocyte retrieval is an important step that requires an anesthesiologist's involvement. Though initially performed by laparoscopy, egg collection is now universally done by the transvaginal ultrasound-guided oocyte retrieval (TUGOR) technique. TUGOR is minimally invasive and requires shorter time compared to previous techniques. Yet, it is a potentially stressful and painful procedure and thus requires some form of analgesia with or without sedation. Anesthetic

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ORIGINAL ARTICLE

A RETROSPECTIVE STUDY OF 26 CASES OF ANAESTHESIA FOR AWAKE CRANIOTOMY

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ABSTRACT:

Background: Awake craniotomy is performed for localization and resection of epileptic focus or for resection of tumours located near the eloquent areas of brain. This study was carried out to record the cases and complications occurred in awake craniotomy in 5 years. **Materials & Methods:** This study was conducted in the department of anesthesia in year 2010-2015. It included 26 cases of awake craniotomy over the period of 5 years. Data pertaining to pre-anaesthetic evaluation, intraoperative management, and post-operative course were collected. The pre-operative data included age, sex, weight, American Society of Anesthesiologists (ASA) physical status, airway status with Mallampati (MP) grade was also noted. Intraoperative data such as anaesthetic technique and duration of surgery was recorded. The intraoperative complications such as bradycardia, tachycardia, hypotension, and hypertension, pain, hypoxia (SpO2 ≤ 90%), tight brain, seizure, cough, and any other complications were recorded. Post-operative data such as nausea, vomiting, seizures, fever, surgical and neurological complications, progression or occurrence of new deficits, histopathological character of lesion, and duration of Intensive Care Unit and hospital stay was also recorded. **Results:** Out of 26 patients, 12 were males and 14 were females. The difference was statistical non significant (P-1) The mean age of male patients was 38±2.4 years and in females was 40±1.6 years. The mean weight in males was 60.24±3.2 Kg and in females was 56.08±1.7 Kg. The difference was statistical non significant (P > 0.05). ASA status 1 was seen in 17 patients and 2 in 9 patients. Right lesions were seen in 15 patients and left lesions were seen in 11 patients. 1 case of recurrent lesions was recorded. The mean duration of surgery was 240±12.6 minutes. ICU stay days were 2.4±1.3 days. Hospital stay days were 8±4 days. Propofol and fentanyl combination was the most commonly used anaesthetic regimen to provide MAC in 20 patients (propofol-fentanyl group). Dexmedetomidine was used for conscious sedation in 6 patients. We reported intra- operative complications such as tachycardia (1) in each group. Hypertension was the most common complication recorded with Propofol and fentanyl group while no cases was seen in dexmedetomidine group. Other complications were desaturation (2), apnea (2), movement (3), tense brain (3), shivering (2) and snoring (1) in propofol-fentanyl group. While hypotension (1), pain (1), seizures (3) and cough was seen in dexmedetomidine group. Total number of intra – operative complications such as desaturation (2), apnea (2), movement (3), tense brain (3), shivering (2) and snoring (1), hypotension (1), pain (1), seizures (3) and 6 cases of cough was seen. **Conclusion:** Conscious sedation is the technique of choice for awake craniotomy. For conscious sedations, Fentanyl, propofol, and dexmedetomidine are important agents used. Case selection should be carefully done. Appropriate use of sedatives or anesthetic agents is key to the success for awake craniotomy.

Key words: Awake craniotomy, Anaesthetic, Conscious sedation

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INTRODUCTION

There is continues debate over the advantages of regional anaesthesia versus general anaesthesia for many forms of surgery, there is an increasing number of indications in intracranial surgery for the patient to be awake during some or all of the operation. This may be a daunting prospect for the neuroanaesthetist who is inexperienced in the technique of awake craniotomy. However, with a sound anatomical knowledge of the nerve blocks and the knowledge to anticipate certain predictable

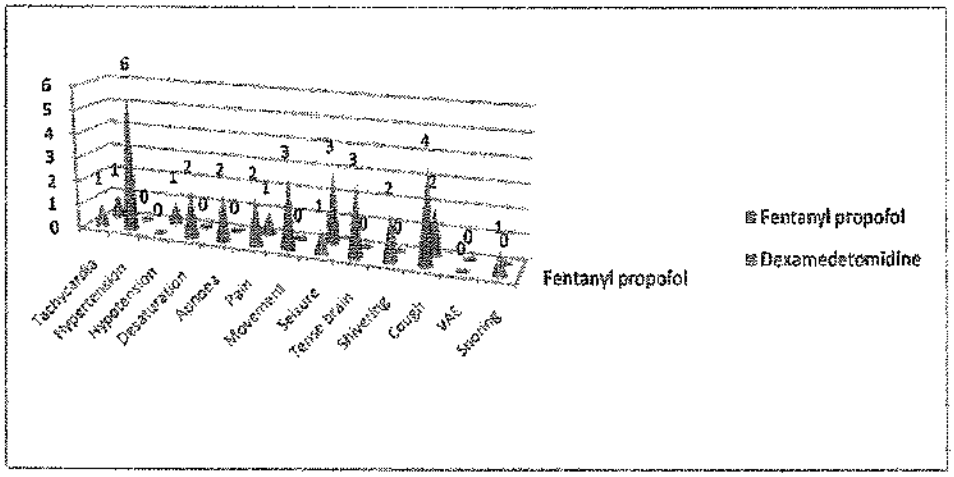
Table II Mean age and weight of patients

Gender	Male	Female	P value
Age (mean)	36±2.4 years	40±1.6 years	0.3
Weight (mean)	60.24±3.2 Kg	56.08±1.7 Kg	0.1

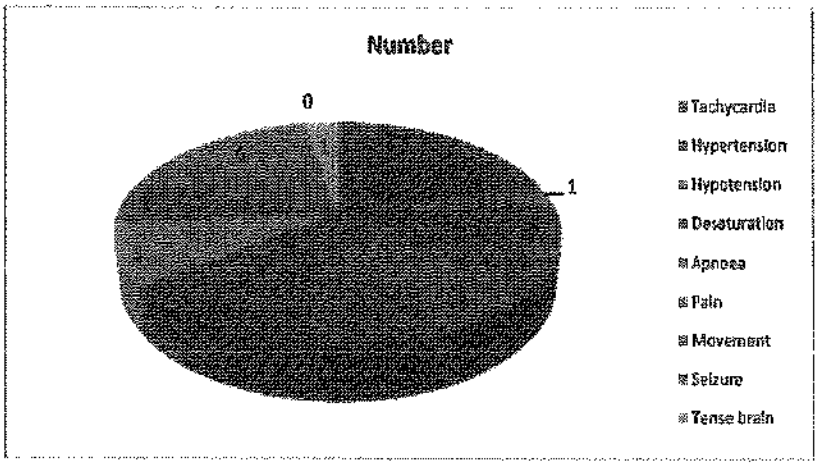
Table III Relevant data

	Number
ASA physical status	
1	17
2	0
Laterality of lesions	
Right	15
Left	11
Recurrent tumour	1
Duration of surgery (min)	246±12.6
ICU stay (days)	2.4±1.5
Hospital stay (days)	8.0±4.0

Graph I Intra-operative complications in both groups



Graph II Intra - operative complications



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ORIGINAL ARTICLE

ANALYSIS OF CRITICAL INCIDENTS IN PEDIATRIC ANAESTHESIA - A CLINICAL STUDY

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ABSTRACT:

Background: Critical incident monitoring is important in quality improvement and patient safety as it identifies potential risks to patients by analyzing adverse events or near-misses. The present study was conducted to report the incidence of critical events occurring in the department of anesthesia during surgery in children.

Materials & Methods: This study was conducted in the department of anesthesia in Jan 2015 to Dec 2015. It included 1050 children upto 15 years of age who underwent any procedure in pediatric surgery OT. Children undergoing Cardiac and ear, nose, throat (ENT) surgeries, thoracic, abdominal, genitourinary procedures, neurosurgeries and paediatric surgeries such as circumcision, examination and dressing under general anaesthesia, lymph node biopsy. Children having pre-operative cardiovascular compromise (hypotension, hypertension, arrhythmias) were excluded from cardiovascular adverse events. Those having pre-operative desaturation/hypercarbia (congenital diaphragmatic hernia [CDH], tracheoesophageal fistula) were excluded from respiratory adverse events. <94% Oxygen saturation was considered as desaturation and >50 mm Hg end-tidal carbon dioxide (ETCO2) was considered as hypercarbia. For laparoscopies, ETCO2 values <60 mm Hg was not considered as a critical incident. Pre-anaesthetic check (PAC), intraoperative and postoperative check was done in the post-anaesthesia care unit (PACU). Electrocardiogram (ECG), and pulse rate, pulse oximetry, ETCO2, blood pressure and temperature was monitored. **Results:** Out of 1050 patients, 250 were neonates, 300 were infants, 340 were toddlers and 160 were other children. We found that 25 neonates, 33 infants, 44 toddlers and 24 other children had critical events. The incidence rate was 12%. Respiratory incidents reported were laryngospasm (20), SGD related incidents (12), inappropriate size ETT (3), difficult neonatal intubation (5), difficult mask ventilation (6), accidental extubation (8), upper airway obstruction (8), urgent reintubation (5), bronchospasm (7) and hypercarbia (6). Associated desaturation was seen in laryngospasm (11), SGD related incidents (3), inappropriate size ETT (2), difficult neonatal intubation (6), difficult mask ventilation (3), upper airway obstruction (6), urgent reintubation (2), bronchospasm (2) and hypercarbia (1). Cardiovascular incidents were bradycardia seen in 7 patients, inferior vena cava rupture in 3 patients and accidental carotid punctures in 2 patients. The degree of harm recorded was no harm in 8 patients, low harm (31), moderate harm (68), severe harm (18) and 1 case of reported death. Critical incidents occurred in less than 2 hours (68), 2-6 hours (44) and more than 6 hours (14). **Conclusion:** Critical incident reporting is useful in perioperative safety of children. The anaesthesiologists can play important role in recording critical incidents. There is need to established critical incident monitoring system.

Key words: Bronchospasm, Critical incident, Hypercarbia

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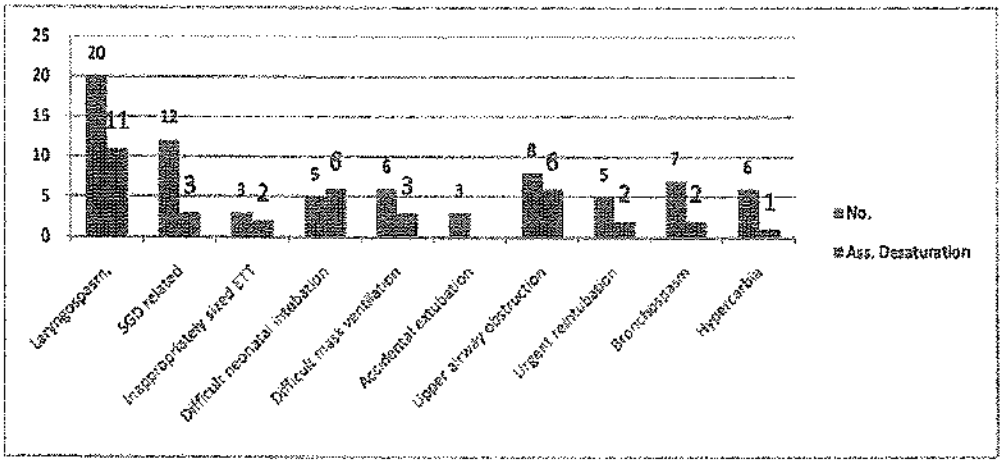
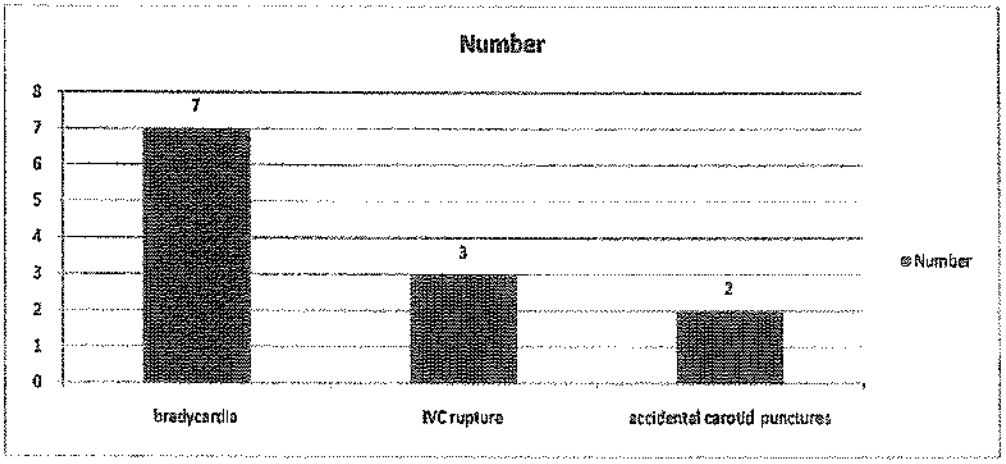
INTRODUCTION

Critical incident monitoring is important in quality improvement and patient safety as it identifies potential risks to patients by analyzing adverse events or near-misses. Flanagan[1] in 1954 first described critical incident technique to improve safety among military pilots, and was subsequently refined for nonmedical and medical uses. Later, this technique was adapted by Cooper et al.[2] in 1978 to uncover patterns of frequently occurring incidents in an anesthesia department. The original definition of a critical incident by Cooper and colleagues was an occurrence that could have led or did

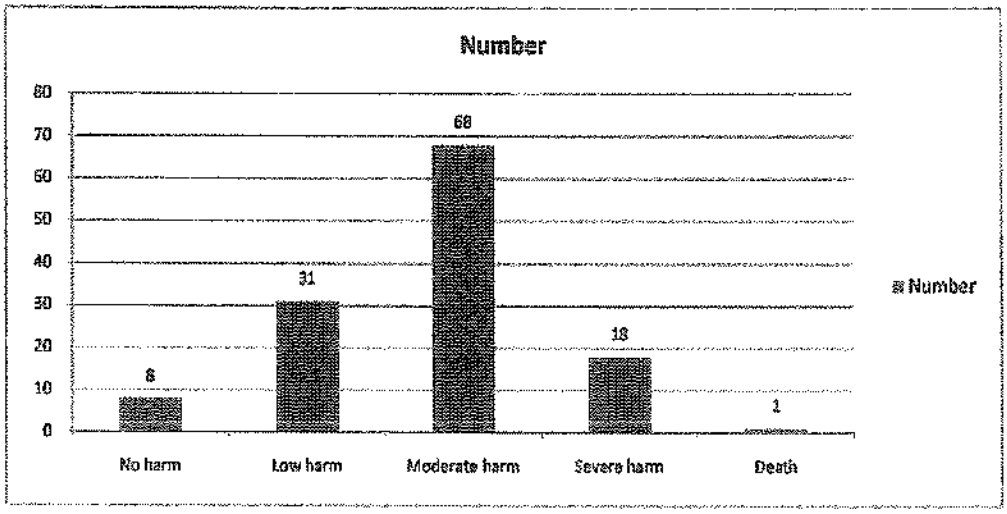
Graph I Distribution of respiratory and airway critical incidents



Graph II Cardiovascular incidents



Graph III Degree of patient harm



Review Article

Perils of paediatric anaesthesia and novel molecular approaches: An evidence-based review

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ABSTRACT

Evolution of anaesthesia has been largely helped by progress of evidence-based medicine. In spite of many advancements in anaesthesia techniques and availability of newer and safer drugs, much more needs to be explored scientifically for the development of anaesthesia. Over the last few years, the notion that the actions of the anaesthesiologist have only immediate or short-term consequences has largely been challenged. Evidences accumulated in the recent years have shown that anaesthesia exposure may have long-term consequences particularly in the extremes of ages. However, most of the studies conducted so far are *in vitro* or animal studies, the results of which have been extrapolated to humans. There have been confounding evidences linking anaesthesia exposure in the developing brain with poor neurocognitive outcome. The results of animal studies and human retrospective studies have raised concern over the potential detrimental effects of general anaesthetics on the developing brain. The purpose of this review is to highlight the long-term perils of anaesthesia in the very young and the potential of improving anaesthesia delivery with the novel molecular approaches.

Key words: Apoptosis, brain, general anaesthesia, neurodegeneration, paediatric anaesthesia, synaptogenesis

INTRODUCTION

Paediatric patients range from preterm infants to teenagers, and it would not be appropriate to call them miniature adults. There exist definite anatomical, physiological, pharmacological and psychological differences among the different paediatric age groups and between the paediatric and adult patients, which makes the safe anaesthetic delivery extremely challenging. Recently, there have been conflicting reports over the potential neurotoxicity of the general anaesthetics on the developing brain. Particularly intriguing are the long-term neurocognitive outcomes of anaesthesia in the very young.[1] This has generated a lot of concern because anaesthesia delivery among paediatric patients is no longer confined to the operation theatres and intensive care units but is also being increasingly used in the non-surgical settings such as long diagnostic procedures, radiological and interventional studies, to allay pain and anxiety and to maintain stable vitals. This has resulted not only in a tremendous increase in the number of anaesthetics being administered but also increased anaesthetic exposure in progressively younger age groups.[1]

Research articles, meta-analyses and systematic reviews and studies in various international and national bibliographic indices were extensively searched with emphasis on key words apoptosis, synaptogenesis, neurodegeneration, neurotoxicity, general anaesthesia (GA) in paediatric patients' published between the period of 1994 and 2014. The various search engines included Entrez (including PubMed), NIH.gov, Cochrane database for systematic reviews, Science direct, Scopus, WebMD.com, MedHelp.org, Searchmedica, MD consult and Google.com. The inclusion criteria was mainly focused on extraction of full text articles containing literary

Original Article

The effect of anesthetic technique for transvaginal ultrasound-guided oocyte retrieval on reproductive outcomes: A systematic review and meta-analysis

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ABSTRACT

The effects of various anesthetic techniques used for transvaginal ultrasound-guided oocyte retrieval (TUGOR) on reproductive outcomes remain controversial. Some studies have reported adverse effects due to nitrous oxide, propofol, and other general anesthetic drugs, whereas others have found them to be safe. The aim of the current meta-analysis is to pool the data available from studies comparing effects of a loco-regional technique against general anesthesia (GA)/intravenous sedation on reproductive outcomes when used for TUGOR. We searched PubMed, EMBASE, Cochrane Register, Google Scholar, and Scopus for studies that evaluated loco-regional anesthesia against GA and reported data on fertilization rate, cleavage rate, and pregnancy rate. A total of eight studies involving 1416 women undergoing TUGOR were identified. The risk of bias was high in most studies, and only two were randomized controlled trials. The loco-regional and the general anesthetic techniques used in these studies varied widely. Pooled odds ratio comparing general versus loco-regional groups for the fertilization rate was 0.939 (95% confidence interval [CI] 0.812-1.088; $P > 0.05$) and for the cleavage rate was 1.046 (95% CI 0.907-1.203; $P > 0.05$). Loco-regional anesthesia was found to be favorable to GA with regard to the pregnancy rate (pooled odds ratio was 0.701 (95% CI 0.543-0.905; $P < 0.05$). No serious complication was reported. Though the pregnancy rate was found to be higher in the loco-regional group, the superiority of one technique over the other cannot be confirmed based on the available quality of evidence and requires further well-conducted trials.

Key words: *Infertility anesthesia, ovum pickup anesthesia, sedation for in vitro fertilization*

INTRODUCTION

In vitro fertilization (IVF) started more than 30 years ago and has undergone numerous advances leading to improved patient outcomes. Ovarian stimulation, oocyte retrieval, IVF after sperm processing, and embryo transfer constitute the major steps of IVF. Oocyte retrieval is an important step that requires an anesthesiologist's involvement. Though initially performed by laparoscopy, egg collection is now universally done by the transvaginal ultrasound-guided oocyte retrieval (TUGOR) technique. TUGOR is minimally invasive and requires shorter time compared to previous techniques. Yet, it is a potentially stressful and painful procedure and thus requires some form of analgesia with or without sedation. Anesthetic

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RESEARCH ARTICLE

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Small Dose Intrathecal Clonidine and Hyperbaric Bupivacaine for Gynaecological Procedure: A Dose Response Study

Smriti Saraf[1*], Mahima Batra[1], M R Gaikwad[1], Vaishali Waindeskar[1], Krishan Kumar Thakur[1]

Abstract: Clonidine when added to intrathecal bupivacaine, prolongs the duration of analgesia. Our aim was to assess the effect of different dose of clonidine on duration of sensory motor blockade and hemodynamic parameters. 120 patients of ASA grade I and II, aged 20-60 years scheduled for elective gynaecological surgeries were divided into four groups. Group 'B' being the control and received only 0.5% hyperbaric bupivacaine 15 mg. Group BC1, BC2, BC3 received injection clonidine 30, 45, 60 microgram respectively with 15 mg hyperbaric bupivacaine intrathecally. Patients were observed for duration of two segments regression of sensory block, recovery of motor block and duration of analgesia. Mean blood pressure, heart rate, oxygen saturation and sedation scores were monitored. The mean duration of sensory block was significantly longer in the group BC3 (232±13.49 min) as compared to BC2 (185±30.93 min) and BC1 (149±25.91 min) ($p<0.001$) respectively. While in B group it was (104±11.01 min). The mean duration of motor blockade was also found to be longer in group BC3 (334.0±22.06 min) as compared to BC2 (266±33.79 min) and BC1 (238±20.24 min) ($p<0.0001$) and in B group it was (165±22.39 min). Incidence of side effects was non-significant. Addition of clonidine to hyperbaric bupivacaine through intrathecal route increases the duration of sensory motor blockade with postoperative analgesia in a dose dependent manner without increasing the side effects.

INTRODUCTION

Spinal anaesthesia is widely used for gynaecological procedures. Various adjuvants are being used to increase the duration of blockade for prolonged surgeries as well as for postoperative pain relief. Clonidine is an imidazoline derivative with alpha 2 adrenergic agonistic prolongs the duration of intrathecally administered local anaesthetics and has potent antinociceptive properties. The analgesic effect of clonidine is more potent after intrathecal administration because of the lipophilicity than by epidural route. [1] Smaller doses of intrathecally clonidine less than 150 micro gm produces minimal side effects as compared to other adjuvents like opiods [1] and other techniques to prolong analgesia like epidural analgesia which have their adverse effects and risks.

In this study clonidine 30, 45, 60 micro gm was added to 0.5% bupivacaine (15 mg) intrathecally in patients undergoing elective gynaecological procedures. The objectives of this randomised study are to evaluate the dose response of intrathecal clonidine on haemodynamics and analgesic profiles, when added to bupivacaine for gynaecological procedures.

METHODOLOGY

Present study was conducted at PCMS and RC after obtaining approval from Institutional Ethical Committee on total of 120 patient belonging to ASA grade I and II between 20-60 years of age scheduled for elective gynaecological procedures like total abdominal hysterectomy, vaginal hysterectomy, tubo ovarian mass, exploratory laparotomy etc. Patients with hypertension, DM, infection at injection site, coagulation disorders, cardiac disease, neurological disorders, hepatic and renal diseases were excluded from the study. Patients were explained about the procedure and after obtaining informed consent patients were randomly allocated into four study groups of 30 each.

1. Group B: Patients received 0.5% hyperbaric bupivacaine 15 mg + NS 1 ml - 3.5 ml
2. Group BC1: Patients received 0.5% hyperbaric bupivacaine 15 mg + 30 µg clonidine - 3.5 ml
3. Group BC2: Patients received 0.5% hyperbaric bupivacaine 15 mg + 45 µg clonidine - 3.5 ml
4. Group BC3: Patients received 0.5% hyperbaric bupivacaine 15 mg + 60 µg clonidine - 3.5 ml

A preoperative assessment was done in all patients. All patients were kept fasting overnight on the day of surgery patients were put with monitor for monitoring NIBP, SPO_2 and heart rate. An intravenous assess was secured with 18 G intravenous cannula and was preloaded with lactated ringer's solution at the rate of 10 - 15 ml/kg. Under all aseptic precautions dural puncture was performed at L3-L4 interspace with 25 G spinal needle in lateral recumbent position. There after the drug was pushed slowly and the patient turned supine. Above mentioned observations were recorded, oxygen was supplemented through face mask at the rate of 3-4 litres/min. Patients were monitored for adverse effect like nausea, vomiting, pruritis, respiratory depression, hypotension, bradycardia and sedation.

Bradycardia and hypotension were treated (when more than 20% from the baseline) with intravenous administration of injection atropine and ephedrine respectively.

RESULTS

A total of 120 Patients (30 Patients in each group) were recruited for the study. The duration of sensory and motor block was prolonged by the addition of intrathecal clonidine in a dose dependent manner.

The mean duration of sensory block as assessed by regression of level till L1 was significantly longer in the group BC3 (232±13.49 min) as compare to group BC1 (149±25.91 min) and BC2 (185±30.93 min) ($P<0.001$) respectively. While in group B it was (104±11.01 min).

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Research Paper Medical Science

Comparison of 0.75% Ropivacaine with Bupivacaine and Lidocaine for Peribulbor Anesthesia

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Dr. Abhilekh Jain — Associate Professor, Peoples Medical College, Bhopal, MP, India
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ABSTRACT

Aim:The objective of this study was to compare the rapidity of onset and efficiency of peribulbar block produced with 0.75% Ropivacaine alone with the traditional mixture of 0.5% Bupivacaine and 2% Lidocaine for cataract Surgery.

Methods: A total number of 60 patients scheduled for cataract surgery with peribulbar anesthesia were randomly allocated into two groups of 30 patients each, who receive mixture of 0.5% 2 ml + Lidocaine 2% 3 ml (Group I) or 0.75% Ropivacaine 5 ml (Group II). Hyaluronidase was added to both the groups. Ocular and eyelid movement scores were evaluated at 2,4,6,8 minutes after injection. Intraoperative analgesia was evaluated by verbal pain scores, need for supplementary anesthesia, hemodynamic parameters and incidence of perioperative complications were recorded.

Results: The ocular movement scores at 2,4,6 and 8 min was significantly lower in Group I than in Group II, however there was no significant difference between both the groups at 8 min. Duration of surgery and hemodynamic parameters did not differ among the groups.

Conclution: 0.75% Ropivacaine alone is an effective alternative to 0.5% Bupivacaine and 2% Lidocaine for peribulbar anesthesia. Although the traditional mixture of Bupivacaine and Lidocaine resulted in significantly lower ocular movement scores at 2,4 and 6 minutes ;at 8 minute both anesthetic solutions provide similar anesthetic conditions to perform cataract surgeries.

KEYWORDS : Cataract surgeries, peribulbor block, Ropivacaine, Bupivacaine, Lidocaine.

Introduction: Regional anesthesia with peribulbar block is anaesthetic technique of choice in cataract, by most of ophthalmic surgeons. Peribulbar anaesthesia form cataract surgery was described by Davis & Mande in 1986. Even Retrobulbar block provides faster and reliable anaesthesia than peribulbar block, it is performed over retrobulbar block because it has higher margin of safety. In our Institution a mixture of Bupivacaine and Lidocaine is used routinely, lidocaine providing a rapid onset and Bupivacaine a long duration of action

Ropivacaine is an amide local anesthetic agent with a greater margin of safety i.e less central nervous system and cardiac toxicity than other amide local anaesthetics.

We have shown that 0.75% Ropivacaine is an effective alternative to 0.5% Bupivacaine when used with 2 % Lidocaine for peribulbar anesthesia (Nicholason G, Sutton B, Hall GM: Ropivacaine for Peribulbar Anesthesia 1999). The objective of our study was to compare the onset, quality of ocular and lid akinesia and need for supplementary anesthesia and risk of complications if any. We found that 0.75% Ropivacaine 5ml alone is an effective alternative to 0.5% Bupivacaine 2 ml and 2% Lidocaine 3 ml for peribulbar anesthesia. Although the Bupivacaine, Lidocaine mixture resulted in significantly lower ocular movement scores at 2,4 and 6 min at 8 min both anesthetic solutions provided similar anesthesia . The faster onset with Bupivacaine-Lidocaine group is probably due to lidocaine.

Methodology: After obtaining approval from Ethics Committee and taking written consent informed Institutional Consent we studied 60 patients (Age 20-70 yrs) posted for cataract surgery under local anesthesia i.e peribulbar block. Patients were divided into 2 groups of 30 patients in each group. Patients were excluded if there was a history of allergy to amide type local anesthetic and patients wit ASA Grade III and IV. After obtaining history and thorough physical examination patients were randomly allocated into two groups. One group received Ropivacaine 0.75% 5 ml with hyaluronidase (15 microgram/ml) while the other group received a mixture of 3 ml 2% Xylocaine and 2 ml 0.5 % Bupivacaine with Hyaluronidase (15 microgram/ml), by ophthalmic surgeon.

Patients were not fasted and did not receive any premedication, perioperative sedation or supplementary oxygen. On receiving patients standard monitoring was started and I/V access with 20 G canula was established. Peribulbar block was carried out by Ophthalmic surgeon in our institute as a routine practice with 24 G needle transcutaneously at lateral 1/3rd and medial 2/3rd junction. After test aspiration 5 ml local anesthetic mixture was injected. Manual compression and gentle massage of the eyeball was performed for 5 min. Patients were assessed for eyelid and ocular movements at 2,4,6,8 and 10 minutes(Bramha et al) until the block was considered adequate for surgery. Eyelid movement score=0 and ocular movement score < 2. If block was inadequate after 10 minutes supplementary anesthesia was provided with another injection using similar technique. Complications during or after injection were recorded and the patients were asked specifically about pain while performing the block and during surgery. The main outcome criteria were difference in median ocular and eyelid movement scores at 8 minutes and time needed to obtain adequate block to start surgery.

TABLE 1. SCORING SYSTEM FOR DEGREE OF OCULAR MOVEMENT Brahma et al

Ocular Movement	Score
Full Movement	3
Moderate Movement	2
Quivering	1
No Movement	0

Table 2: Demographic Characteristics of Study Subjects.

Patient Characteristic	Group I	Group II
Age(Years) Mean± SD	70 ± 5	69 ± 7
Sex (Male/Female)	17/13	16/14
Weight	60 ± 7	62 ± 7
Duration of Surgery	20 min.	20 min.

Table 3: Movement Scores at various intervals.P <0.05 between groups

Scores	Bupivacaine 0.5% and 2 % Lidocaine (n=30)	Ropivacaine 0.75% (n=30)
Ocular Movement Scores		
2min	5 [3-7]	7[5-8]
4 min	3[2-6]	5[3-7]
6 min	2[1-5]	4[2-6]
8 min	2[0-4]	2[1-5]
Eyelid Movement Scores		
2 min	1[1-2]	1[1-2]
4 min	1[0-2]	1[0-2]
6 min	0[0-2]	1[0-2]
8 min	0[0-1]	0[0-1]
Supplementary Anesthesia	5	7
Complication		
Hematoma	0	1
Chemosis	7	6
Pain	11	13

STATISTICAL ANALYSIS

Statistical analysis was done by using SPSS software .There were 30 patients in each group,groups were comparable with respect to age ,height ,weight and sex of the patients.The main criteria were difference in median ocular and eyelid movement scores at 8 min. and time needed to obtain adequate block to start surgery.Median eyelid movement scores were not significantly different between the groups,ocular movement scores were significantly decreased in bupivacaine group campared with ropivacaine group at 2 min (P=0.011),4 min(P =0.022)and 6 min (P =0.047),but not significant at 8 min (P =0.13).The delay to start surgery and occurance of complications were compared using 'chi –square test'.

DISCUSSION

In our study we compared .75% ropivacaine with .5% Bupivacaine & 2% lignocaine in peribulbar block for cataract surgeries. Johnson RW in 1995 described the anatomy of opthalmic anaesthesia and approaches to various techniques [1]. Eke T & Thompson JR et al studied the safety profiles of local anaesthesia in a national survey study [2]. Wang DH also studied role of regional anaesthesia for intraocular surgeries.[3]

Peribulbar block was the anaesthesia technique used in our study as it is much safer; but it requires large volume of local anaesthetic solution . S Ahmed also shared his experiences with peribulbar block and its safety profile. Shreen Ahmed, Afzal Ahmed et al in their clinical experience with peribulbar block found it to be safe & reliable. They studied 2600 patients and found only 5 patients with minor peribulbar haemorrage and 3% patients needed supplemental block.[4]. Oksana Demediuk Ranjit Dhaniwal et al compared peribulbar & retrobulbar anaesthesia and concluded that both provide equal levels of akinesia and analgesia and each requires intra opertive supplementation in 32% cases. Similar students were done by MB Al Hassan,F, Kyari et al who compared the two block techniques for cataract surgeries & found similar results. [5,6] Dempsey, Jul et al added hyaluronidaze as adjuvent in bupivacaine/lidocaine mixture. Lidocaine has advantage of early block but adding bupivacaine prologs the block. Combination has its advantages but sometimes prolonged block causes drying and irritation in the eyes.[7,8]

Nicholson added rupivacaine ;Brahama et al studies prilocaine [9,10]. Than researchers with advent of newer & safer drugs studied the comparison of ropivacine with (bupivacaine/lidocaine) mixture. JR Nociti et al did a comparative study on 80 patients between ropivacaine & bupivacaine in peribulbar block. They inferred that ropivacaine had a faster onset, with low systemic toxicity & slightly lower potency as compared with bupivacaine [11]

Gioia et al studied peribulbar anesthesia with either 0.75% ropivacaine or a 2% lidocaine and 0.5% bupivacaine mixture for vitreoretinal surgery surgeries. Gioia, Prandi et al did a study very similar to our study in which they compared ,75% ropavacine with 2% lidocaine & .5% bupivacine mixture (1:1) only difference was that they studied vitreoretinal surgeries. Surgical block was achived in 8±5 minutes in lido/bupivacine group & 10±5 min in ropivacaine on Post operative day one, 87% of patients in ropavaicaine group reported no pain as compared to 60% in lido- bupavacaine group.[12] Nicholson also did a similar study [13] Our study was similar to Croke PJ/Baker J/et al [14]

JH Loots & Koots et al JH did a study, the objective of which was to determine the efficacy in peribulbar block of bupavacaine .5% , .75% and combination of bupivacaine .5& lig 2%. They found that akineria was not achieved in 54% of the cases; in contract; our study had akinesia in 100% in 8 min in all patients.[15] ; Huha also studied clinical efficacy & Kinetics of 1% ropavacaine & 75% bupivacaine for peribulbar anaesthesia in cataract surgery.[16] Complication were studied by Rubin et al and Baker J P et al. Baker et al compared post operative symptoms such as pain nausea & vomitting in patients undergoing cataract surgery in either General anaesthesia or local anaesthesia. While Rubin studied complications & post op morbidity follow cataract surgeries [17,18]

David B et al did a huge study in which they studied the efficacy & complication rate in 16224 consequtive peribulbar blocks in 12 center of United States , Gemany & Chile. Degree of akinesia, amaurosis, percentage of supplemental block & complication for 6 weeks were noted. Peribulbar block is as effective as retrobulbar block with fewer site & life threatening complications. The observations ,results and complication rate much similar to our study.[19]

CONCLUTION

0.75% Ropivacaine alone is an effective alternative to 0.5% Bupivacaine and 2% Lidocaine for peribulbar anesthesia. Although the traditional mixture of Bupivacaine and Lidocaine resulted in significantly lower ocular movement scores at 2,4 and 6 minutes ;at 8 minute both anesthetic solutions provide similar anesthetic conditions to perform cataract surgeries.

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Research Article

To evaluate and compare analgesic effects of wound infiltration with voveron with intravenous injection in cesarean section

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Abstract

Objectives: Postoperative pain mostly results from sensitization of afferent fibers at injury sites driving central sensitization. Recently, peripheral processes have gained attention as mechanism of hyperalgesia, and prostaglandins are among highly sensitizing agents. To date, postoperative administration of a one single intravenous dose of voveron has shown inconclusive efficacy. Rather than a single intravenous dose, the current study evaluates the postoperative analgesic effect of local injection of voveron sodium after cesarean delivery. **Methodology:** In a prospective randomized, controlled study, 60 patients age group between 18-35 years, scheduled for routine and emergency cesarean surgery were distributed into two groups of 30 patients each. Postoperatively, group [B] was given voveron in wound local injection and group [A] received voveron 75 mg conventionally as intravenous injections. Pain intensity score, onset of analgesia, rescue analgesia doses and overall patient satisfaction score were recorded. **Results:** Mean onset of analgesia was 8.31 ± 1.5 min with group A as against 4.23 ± 1.2 min with group B. Pain Intensity (PPI) score ≤ 1 was observed in 78.21% observations belonging to group A and in 50 % observations of group B. Twenty five patients (71.4%) from group A and 30 patients (85.7%) from group B required rescue analgesia. The patient's feedback was graded as very good or good by 78.5% of the patients in Group-A and 69% patients in Group-B. **Conclusion:** Though both drugs are equally safe, Voveron in local wound infusion is faster acting, more potent and efficient analgesic than intravenous. voveron when used for postoperative pain

Key words: Postoperative analgesia, Voveron, local injection.

Introduction

Postoperative pain and hypoxemia are common complications following cesarean sections. Inadequately treated pain results in an increased incidence of complications and morbidity[1]. An ideal analgesic regimen should provide pain relief with minimal side effects and should allow early return of normal function. Local analgesia provides superior quality of pain relief after surgery and avoids many of the side effects of conventional narcotic analgesics [2]. The primary outcome measure compared was quality of analgesia expressed as Present Pain Intensity (PPI) score [3].

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Methodology

A prospective, randomized, study design with two parallel groups was used. After prior approval from Institutional Ethics Committee, this study was conducted at Peoples Medical College and associated Hospital, Bhopal during a period of 3 months on 60 patients, aged group between 18-35 years, scheduled for routine and emergency cesarean sections. Informed written consent was obtained from all patients. Exclusion criteria were severe systemic disorders including diabetes mellitus, hypertension, heart disease; addiction to narcotic drugs; chronic alcoholism; psychiatric disorders; allergy to study drugs and known contraindications to spinal. Patients were randomly

distributed into two groups of 30 patients each and randomization was concealed.
Group-B (n=30): received voveron intrawound local injection
Group-A (n=30): received voveron intravenously.

Method of Randomization was Blocked randomization. Thirty blocks of two each with treatment allocation of 1:1 for Group- A and Group-B were created with the help of computer software. Coded envelopes (total 30) were used and each envelope was used for two patients leading to random assignment of one subject to one group. For sample size calculation a pilot study was done on 20 patients (each group containing 10 patients). Present Pain Intensity (PPI) score was recorded. PPI score ≤ 1 was observed in 34(42.5%) observations in Group-B as against 69(86.25%) observations from Group-A, out of total 80 observations made in each group. Sample size was calculated to detect effect size of 43.75% between two groups accepting alpha error 0.05 and β error 0.90 was 28.

In the operating room pre-operative parameters (pulse rate, blood pressure, respiratory rate and oxygen saturation) were noted. Patients were placed in sitting position and under aseptic precautions; a 25G spinal needle was inserted through the median approach at a suitable space between L3-L4. Physiological parameters e.g. pulse rate, blood pressure, respiratory rate and oxygen saturation, were recorded every 5 min during operative period and before shifting to postoperative ward. At the end of operation before dressing is done, a bolus of 75 mg voveron diluted in 10 ml of saline was injected in the wound when the patient complained of pain. Group A was given 75 mg injections intravenously. Pulse rate, blood pressure and respiratory rate were recorded along with present pain intensity (PPI) score. The degree of pain was assessed by using the Present Pain Intensity (PPI) scale; 0=no pain; 1=mild pain; 2=discomfort; 3=distress; 4=horrible pain and 5=excruciating pain. Highest PPI score was noted. Thus, Percentage of different PPI scores out of total number of observations was used for comparison of two groups.

During this interval if any patient had PPI >3, 'rescue top' doses were noted. Any side effect e.g. nausea, vomiting, backache, sedation or drowsiness, hypotension, sign of excessive block or numbness / weakness in limbs was observed. On 2nd postoperative day each patient was interviewed regarding feedback on overall pain relief during the postoperative Period as very good, good, fair or poor. This scale was used to compare both groups as secondary outcome measure regarding quality of analgesia.

Statistical Analysis: Statistical analysis was done using Stata 11 software. Demographic characteristics, hemodynamic parameters, onset of analgesia, quality of analgesia, level of sedation and side effects were compared between two groups and data was analyzed statistically. For continuous variables descriptive statistics (mean and standard deviations) were computed. Comparison of means in Group-B and Group-A was done using unpaired t-test. For categorical data chi-square test was applied. $P < 0.05$ was considered significant.

Results

Both groups were comparable in respect of demographic characteristics as shown in Table 1 .Table 2 shows the proforma used to note down our readings .Each patient, after giving analgesia was followed up for 2 hours. Rescue analgesia was given if PPI score was >3. Table 3 compares the quality of analgesia among the groups. Voveron when given in wound was found to be faster in action as compared to intravenous group. Mean onset of analgesia was 4.31 ± 1.5 min with local injection group as against 8.23 ± 1.2 with intramuscular group (p value < 0.05). Quality of analgesia was also better with voveron local injection reflected by the fact that Present Pain Intensity (PPI) score was zero (means no pain at all) in only 3.93% observations belonging to intramuscular group as against 17.5% observations belonging to local injection group. PPI Score 1 (meaning slight pain) was observed in 46.07% observations belonging to intramuscular group as against in 78.21% observations belonging to local injection group. PPI score 3 and 4 was found in 105 and 35 observations respectively belonging to intramuscular group as against in 49 and 12 observations respectively belonging to local injection group. Twenty five patients out of 30 from Local injection group required rescue analgesia as against 30 patients from intravenous group. Overall feedback was graded as very good or good by 78.5% patients in Group-B and 69% patients in Group-A. Only one patient from Group-B and 4 from Group-A have graded analgesia as poor. Mild

hypotension was seen in 5 patients from Group-B and 8 patients in Group-A, which was easily corrected with crystalloid infusions.

Table 1: Patient characteristics

Characteristics	Group-B (n = 30) Mean ± SD	Group-A (n = 30) Mean ± SD	P value
Age (in years)	20.86 ± 13.17	21.57 ± 10.27	> 0.05
Height (in cm)	159.14 ± 6.86	161.29 ± 5.26	> 0.05
Weight (in Kgs)	62.57 ± 5.91	63.83 ± 6.82	> 0.05

Table 2: Quality of analgesia

Quality of analgesia		Group-B (n = 30)	Group-A(n = 30)	p Value
Onset of analgesia in min (Mean ± SD)		**8.23 ± 1.2**	**4.31 ± 1.5**	**< 0.05**
Rescue analgesia*	0	10	5	> 0.05
	1	5	2	
	2	12	10	
Overall satisfaction regarding analgesia*	Very Good	1	5	> 0.05
	Good	10	15	
	Fair	15	9	
	Poor	4	1	
PPI Score ≤ 1 [n(%)]		50%	78.21%	< 0.05
PPI Score 0 [n(%)]		3.93%	17.5%	< 0.05

Table 3: Incidence of side effects Data given as n(%)

Side effect	Group-B (n = 30)	Group-A (n = 30)
Hypotension	8(22.86)	5(14.29)
Nausea and vomiting	5(14.29)	3(8.57)
Respiratory depression	3(8.57)	2(5.71)
Sedation	0	2(5.71)
Gastrointestinal discomfort	1(2.86%)	0
Total	22(62.86%)	16(45.71)

Two patients from Group-B and 3 patients from Group-A had transient fall in oxygen saturation that responded to an increase in FiO_2. No significant difference was observed between the two groups. Table 4 shows the incidence of side effects in both the groups.

Discussion

Although different pain mechanism participate in incisional pain,[3,4] acute postoperative pain results in part from sensitization of primary afferent pain receptors at the site of injury, which in turn drives pain and enhanced responsiveness of central neurons [5]. The current results show that postoperative wound local injection of voveron displays a significant morphine sparing effect at 12 and 24 h after cesarean delivery when compared with the 24 h after cesarean delivery when compared with the same dose administered intravenously. After cesarean delivery, systemic administration of voveron (150- to 300-mg daily dose) reduces other analgesic needs by 39–46% [6-9] using a wound infiltration has allowed a further decrease in morphine use. In the postoperative context, specifically

in obstetrics, where women want to recover quickly to take care of their baby, an analgesic-sparing effect, which reduces nausea and vomiting as well as sedation, might be beneficial and hasten recovery [9,10]. These results contrast with most of those already published on wound infiltration with NSAIDs [11,12]. Although none of these clinical trials involved cesarean delivery or hysterectomy, they all reported the effect from a single dose of NSAID either before or immediately after completion of the surgical procedure. In contrast, our patients benefited from 10ml postoperative wound local injection.

To date, the modulation of peripheral pain transduction has usually been accomplished by wound infiltration with long-lasting local anesthetics, [13,14] and only a few studies report the use of voveron infiltration. After cesarean delivery [15, 16] such local anesthetic infusion provides a mild and short-lasting decrease in pain scores and a significant reduction in postoperative analgesic requirements. Our findings show a short-lasting (12-h) reduction in pain scores but no significant decrease in analgesic needs with intramuscular injection when compared with local saline with voveron local injection. It is possible that the concomitant use of systemic voveron blunted the opioid-sparing effect afforded by the infusion of local anesthetic in our patients.

The current results suggest that local infiltration of voveron allows a better management of postoperative pain than the usual systemic route using intramuscular administration of the drugs. Therefore, these findings questions the relative contribution of central and peripheral mechanisms involved in the postoperative analgesic effect of NSAIDs. In an experimental human model, the central effect accounts for 40% of the total analgesic effect of systemic voveron [17]. Systemic administration of therapeutic doses of COX inhibitors of associated with a significant reduction in prostaglandin E2 levels both locally at the site of injury and centrally in the cerebrospinal fluid [18,19]. Consequently, the reduction of both local and spinal prostaglandin E2 concentrations is associated with a decrease in postoperative pain [18]. Systemic absorption may have partly accounted for the beneficial effect observed on visceral pain. In a previous clinical trial, [19] small doses of either local or systemic ketorolac, surprisingly, demonstrated delayed but comparable analgesic effect to that of a analgesic of the systemic and the local effect on peripheral prostaglandin E2 levels at the site of injury.[19] These observations suggest not only a central site of action for NSAID analgesia, which is highly sensitive to the effects of NSAIDs and which mediated central hypersensitivity after tissue injury is present, but also that NSAID analgesia might be mediated through local mechanism unrelated to peripheral prostaglandin suppression.

Finally, in addition to the different routes of diclofanec administration, the design of our study, which compared wound infiltration with voveron to systemic administration, did not allow us to exclude an impact of the timing of NSAID administration on the observed analgesic effects. It is possible that circulating sub therapeutic doses of voveron administered at wound reduced postoperative neuronal sensitization more than systemic therapeutic doses.

Beyond the sensitization of damaged tissue, surgical incision also induces central neuronal sensitization and probably the development of residual pain after surgery [20]. Recent studies mention cesarean delivery as a cause of chronic pain [21] representing a significant problem in 6-12% of patients 10 month after the procedure [22].

Among the established risk factors for development of chronic pain after surgery, the severity of acute postoperative pain is one of the most striking [20,22]. Although this study was not powered to evaluate the incidence and severity of residual pain after cesarean delivery, our results are in agreement with the risk for development of persistent pain after cesarean delivery (an average incidence for the three group of 14% residual pain at 6 months).

In summary, our results demonstrate that local wound local injection of voveron affords better postoperative pain management after cesarean delivery (greater morphine-sparing effect and decreased early PPI scores) without adverse effects than the same dose administered systemically by intermittent intravenous injections. The current results suggest the presence of peripheral analgesic properties of voveron apart from the systemic effect, mediated either through COX 2 inhibition and decrease of prostaglandin production or through other local mechanisms. In our study, no difference was observed between groups regarding patient satisfaction. All patients had stable vital parameters. The incidence of side effects was remarkably minimal and both groups had comparable in this regard.

Conclusion

In conclusion, local local injection is faster acting, more potent and efficient analgesic than intramuscular voveron when used for postoperative pain relief in lower segment cesarean sections.

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Paper acceptance letter

To,

Date: 16/06/2019

Dr Ajay Singh Chundawat,

Dear Author,

After a thorough double-blind review, I am pleased to inform you that your revised manuscript entitled **"Comparative Evaluation of Two Approaches Of Brachial Plexus Anesthesia"** (IJMSE3032019109), 1st submission received: *12/05/2019 was* reviewed by reviewer and got positive opinion. This paper has been accepted on **16/06/2019** for publication in original research article category at the peer-reviewed **"International Journal of Medical Science and Education"** which is a quarterly publication of **Association of Scientific and Medical Education"**, Jaipur, Rajasthan to be published in Vol. 6, Issue No.3.

Kindly acknowledge receipt of this acceptance letter.

With regards and wishes,

IJMSE Journal Management Team

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Original Research Article

COMPARATIVE EVALUATION OF TWO APPROACHES OF BRACHIAL PLEXUS ANESTHESIA

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ABSTRACT

Background: The brachial plexus blockade of is a proven and very effective method for achieving anesthesia for the upper limb which involves shoulder to fingertips. There are multiple theories and various approaches for achieving brachial plexus blockage which are varies on the block indication, procedure of surgery which being performed, specific patient-body habitus, associated medical comorbidities and anatomical individual variations. **Material & Methods:** The present single Centre observational study was conducted in department of anesthesia at our tertiary care hospital. The study was conducted in duration of one year, after seeking approval from the Institutional Ethics Committee. Calculated Sample size of study was 100, and patients who had American society of anesthesiologists (ASA) physical status I to II and in the age group of 18 to 65 years, who were scheduled for surgery of the upper limb under brachial plexus anesthesia, were enrolled for the study. **Results:** The block performance time (min) was 3.8±0.90 in supraclavicular brachial plexus block (group I) and block performance time (min) was 5.4±0.7 in infraclavicular brachial plexus block (group II) ($P < 0.05$). The Onset time for sensory and motor block was 29 and 30 minutes for supraclavicular brachial plexus block (group I) and Onset time for sensory and motor block was 30 and 31 minutes for infraclavicular brachial plexus block (group II) ($P > 0.05$). The most common complication after supraclavicular brachial plexus block was Horner syndrome 31 (62%) and Vascular puncture 3 (6%). Complication after infraclavicular brachial plexus block was Horner syndrome 3 (6%) and Vascular puncture 3 (6%). **Conclusion:** The supraclavicular brachial plexus block was easier to perform compared to the infraclavicular brachial plexus block. Both the approaches of the brachial plexus block have nearly similar duration of onset. The infraclavicular brachial plexus block approach had minimal complications.

Keywords: Brachial plexus block, Supraclavicular block, Infraclavicular block.

INTRODUCTION

The anatomy of brachial plexus is well described and it formed by nerve roots from the C5 to T1. These nerve roots join to form three trunks above the clavicle namely superior trunk (C5, C6), middle trunk (C7), and inferior trunk (C8, T1). These trunks then further descend downwards and pass beneath the clavicle, here they are situated in close proximity to each other and that's why at this level they blocked easily. Further downwards, the brachial plexus divided into the three cords namely lateral (C5-C7), medial (C8, T1) and posterior (C5-T1), they are situated in close proximity of the axillary artery (1). At last, the end nerve branches of the plexus are formed by the cord branches in the axilla. Similarly, the median nerve is form by brachial plexus from the continuation of medial and lateral cords which are situated superficial to the axillary artery. Likewise, ulnar nerve is form by brachial plexus from the continuation of medial cord and it is situated lateral to the axillary artery. Radial nerve is situated lateral and deep to the axillary artery. The musculocutaneous nerve is branches off the lateral cord and pierces by the coracobrachialis muscle located in the proximal axilla (2).

The brachial plexus blockade of is a proven and very effective method for achieving anesthesia for the upper limb which involves shoulder to fingertips. There are multiple theories and various approaches for achieving brachial plexus blockage which are varies on the block indication, procedure of surgery which being performed, specific patient-body habitus, associated medical comorbidities and anatomical individual variations (3). This study was tried to address all the indications and including, probe placement, superior trunk block, ultrasound-guided interscalene block, supraclavicular brachial plexus block, axillary brachial plexus block and infraclavicular brachial plexus block (4). The brachial plexus blockade can be provided at multiple sites for varying wanted effect. It is useful to be study the various approaches of brachial plexus blockade given patients who have varying anatomy and different indications (5). In the present study, we tried to research the two approaches of brachial plexus block, which were supraclavicular block and infraclavicular block approaches and compared them in the terms of the block performance time, onset of motor and sensory block, by using neurostimulation among patients who were undergoing upper limb surgery.

MATERIALS & METHODS

The present single Centre observational study was conducted at our tertiary care hospital. The study was conducted in Department of anesthesia. The study was conducted in duration of one year, after seeking approval from the Institutional Ethics Committee. All protocols of ethical conduct including written and informed consents of the patients enrolled for the study was strictly complied. Calculated Sample size of study was 100, and patients who had American society of anesthesiologists (ASA) physical status I to II and in the age group of 18 to 65 years, who were scheduled for surgery of the upper limb under brachial plexus anesthesia, were enrolled for the study. Detailed socio-demographic data were taken and recorded along with general physical and clinical examination. Patient who had disorders of hemostasis, major systemic illness, localized sepsis, systemic infection, pregnancy, allergy to local anesthetics, previous clavicle fractures, chest deformities, neurological disorders and patients who had chronic pain were excluded from the study.

Patients were randomly divided in two equal groups, who received supraclavicular and infraclavicular brachial plexus block. In both the groups 30 ml of 0.5% ropivacaine was used and injected slowly (over 1 minute) with intermittent aspiration. The block performance time was noted. Block performance which was related to pain was assessed by using a VAS pain score between 0 and 10 (0 -no pain and 10 -excruciating pain). The sensory block was evaluated by alcohol-soaked gauze and graded from 0-2 (0 means no difference from an unblocked area; 1means comparative less cold than unblocked area; 2 means no sensation of cold). The motor block was assessed by; forearm flexion, thumb and second digit pinch, thumb abduction and finger abduction and graded from 0-2 (0 means no loss of force; 1means reduced force compared to other arm; and 2 means inability of movements). The results thus obtained shall be subjected to statistical analysis. The data were analyzed by using software's MS Excel 2010, Epi Info v7 and SPSS v22.

RESULTS

Total 100 patients were enrolled for the study. Out of them 50 participants were selected from patients who had given supraclavicular brachial plexus block (group I) and 50 participants were selected from patients who had given infraclavicular brachial plexus block (group II). Both the groups were demographically nearly similar in characteristics. Likewise, both the groups had nearly similar characteristics on ASA evaluation. Similarly, both the groups showed comparative characteristics on evaluation of surgical profile. (Table 1)

Table 1: Distribution of study participants according to study parameters

Parameters		Group I (n = 50)	Group II (n = 50)
Demographic distribution	Age (years)	44±8	45±7
	Sex (M/F)	32/18	35/15
	Weight (kg)	63±4	61±6
	Height (cm)	165±14	162±18
ASA (I/II)		29/11	30/11
Distribution according to surgery	Hand	17	15
	Wrist	10	12
	Forearm	11	9
	Elbow	12	14
	Surgery duration (min)	70±26	68±24

In the present study the block performance time (min) was 3.8±0.90 in supraclavicular brachial

plexus block (group I) and block performance time (min) was 5.4±0.7 in infraclavicular brachial plexus block (group II). It was found statistically highly significant by applying Chi square test (P <0.05). The Onset time for sensory and motor block was 29 and 30 minutes for supraclavicular brachial plexus block (group I) and Onset time for sensory and motor block was 30 and 31 minutes for infraclavicular brachial plexus block (group II). It was found statistically non-significant by applying Chi square test (P >0.05). (Table 2)

In the present study, the most common complication after supraclavicular brachial plexus block was Horner syndrome 31 (62%) which was followed by Vascular puncture 3 (6%). The most common complication after infraclavicular brachial plexus block was Horner syndrome 3 (6%) and Vascular puncture 3 (6%). (Table 3)

Table 2: Distribution of study participants according to block

Parameters	Group I (n = 50)	Group II (n = 50)	P value
Block performance time (min)	3.8±0.90	5.4±0.7	**< 0.05**
Onset time for sensory block (min)	29	30	> 0.05
Onset time for motor block (min)	30	31	> 0.05

Table 3: Distribution of study participants according to complications

Complications	Group I (n = 50)	Group II (n = 50)
Horner syndrome	31 (62%)	3 (6%)
Dyspnea	0	0
Pneumothorax	0	0
Vascular puncture	3 (6%)	3 (6%)

DISCUSSION

In the present study, two approaches of the brachial plexus block were studied, namely supraclavicular block and infraclavicular block approach. We evaluate results by using the neurostimulation and it was found that there was significant difference in the block performance time and there was similar duration of onset of sensory and motor blockade. In the present study the block performance time (min) was 3.8±0.90 in supraclavicular brachial plexus block (group I) and block performance time (min) was 5.4±0.7 in infraclavicular brachial plexus block (group II). It was found statistically highly significant by applying Chi square test (P <0.05). The Onset time for sensory and motor block was 29 and 30 minutes for supraclavicular brachial plexus block (group I) and Onset time for sensory and motor block was 30 and 31 minutes for infraclavicular brachial plexus block (group II). It was found statistically non-significant by applying Chi square test (P >0.05).

In the present study, higher incidence of complication namely Horner's syndrome was reported specialy with supraclavicular block. The most common complication after supraclavicular brachial plexus block was Horner syndrome 31 (62%) which was followed by Vascular puncture 3 (6%). The most common complication after infraclavicular brachial plexus block was Horner syndrome 3 (6%) and Vascular puncture 3 (6%). We applied peripheral nerve stimulation technique in present study for brachial plexus block because there was limited data available on researches among Indian population on the comparison of supraclavicular with infraclavicular brachial plexus block **(6)**. In comparative studies of brachial plexus block for axillary approach and supraclavicular approach it was reported in previous studies that to provide adequate anaesthesia for upper-limb surgeries, with the gain of faster onset & denser block after a single injection of local anesthetic **(7)**.

In previous studies it was reported that incidence of iatrogenic pneumothorax following the Kulenkampf technique for supraclavicular brachial plexus block, makes this technique less preferable among anesthesiologists. The reported prevalence of pneumothorax after a supraclavicular brachial plexus block was 1% to 6.1% **(8)**. However, in the present study there was not a single incidence of iatrogenic pneumothorax was reported. The prevalence of vascular puncture in both the groups of supraclavicular or infraclavicular brachial plexus block in present study was equal and didn't result in any haematoma or intravascular injection. Similarly, in the present study there was not a single incidence of dyspnea was reported. We reported a 100% success rate for supraclavicular block and infraclavicular block in present study.

A study done by Kilka et al on brachial plexus block reported that 95% success rate for vertical infraclavicular approach which was achieved using 40 ml of (1.5%) Prilocaine and 10 ml of (0.5%) Bupivacaine; block assessment time was 30 minutes **(9)**. A study conducted by Franco et al on brachial plexus block reported that 97.2% success rate was achieved with the supraclavicular brachial plexus block using perivascular technique among one thousand patients **(10)**. The main reasons behind the lower success rates of brachial plexus block reported in above mentioned two studies was mainly because of operator inexperience, different local anesthetic used in above studies different than used in present study, the definition used for a successful block and fewer number of study participants studied in present study.

CONCLUSION

We concluded from the present study that the supraclavicular brachial plexus block was easier to perform compared to the infraclavicular brachial plexus block. Both the approaches of the brachial plexus block have nearly similar duration of onset. The infraclavicular brachial plexus block approach had minimal complications. However large population based studies are needed for further evaluation.

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Paper acceptance letter

To,

Date: 25/11/2019

Dr Ajay Singh Chundawat ,

Dear Author,

After a thorough double-blind review, I am pleased to inform you that your revised manuscript entitled "Comparative assessment of local anesthesia and spinal anesthesia for hemorrhoidectomy" (IJMSE132119104), 1st submission received: 12/10/2019 was reviewed by reviewer and got positive opinion. This paper has been accepted on **25/11/2019** for publication in original research article category at the peer-reviewed **"International Journal of Medical Science and Education"** which is a quarterly publication of **Association of Scientific and Medical Education"**, Jaipur, Rajasthan to be published in Vol. 6, Issue No.4.

Kindly acknowledge receipt of this acceptance letter.

With regards and wishes,

IJMSE Journal Management Team

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Original Research Article

COMPARATIVE ASSESSMENT OF LOCAL ANESTHESIA AND SPINAL ANESTHESIA FOR HEMORRHOIDECTOMY

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ABSTRACT

Background: Various researchers had clinically classified piles or hemorrhoids into four grades. For the treatment of piles or hemorrhoid the most commonly used and widely considered operative technique is open hemorrhoidectomy and reported to be the most effective operative technique for grade III and IV hemorrhoids among various studies **Material & Methods:** Patients who were diagnosed clinically as third- and fourth-degree hemorrhoids and planned for conventional hemorrhoidectomy were enrolled by simple random sampling and randomized for two equal groups. Clearance from hospital ethics committee was taken before start of study. Written informed consent was taken from each study participant. **Results:** Out of the total study participants of group 1 10 (40%) were females and 15 (60%) were males. The mean age of study population was 36.2 ± 5.8 years. On the basis of degree of hemorrhoids 14 (56%) patients had third degree piles and 11 (44%) patients had fourth degree piles. The need for general anaesthesia was reported among 2/25 (8%) patients. The mean operative duration (minutes) was 22.54 ± 6.98. Out of the total study participants of group 2, 9 (36%) were females and 16 (64%) were males. The mean age of study population was 38.4 + 6.2 years. On the basis of degree of hemorrhoids 13 (52%) patients had third degree piles and 12 (48%) patients had fourth degree piles. The need for general anaesthesia was reported among 1/25 (4%) patients. The mean operative duration (minutes) was 21.32 ± 5.21. **Conclusion:** Local anesthesia for hemorrhoidectomy along with intravenous sedation is a safe procedure and should be considered as an alternative to spinal anesthesia. Present study reported that it has lesser postoperative pain scores, no hypotension, no headache and no urine retention in comparison to spinal anaesthesia.

Key words: Hemorrhoidectomy, Local anesthesia, Spinal anesthesia.

INTRODUCTION

Piles or hemorrhoids are a common disease diagnosed among adults. Previous studies reported that more than half population of males and females who aged 50 years and above were diagnosed with piles or hemorrhoid signs and symptoms **(1)**. Piles or hemorrhoids are characterized as the distal displacement and/or the symptomatic enlargement of the normal anatomy of anal cushions **(2)**. Various researchers had clinically classified piles or hemorrhoids into four grades. For the treatment of piles or hemorrhoid the most commonly used and widely considered operative technique is open hemorrhoidectomy and reported to be the most effective operative technique for grade III and IV hemorrhoids among various studies. The open hemorrhoidectomy operative technique was firstly used and operated by Milligan and Morgan, surgeons in the United Kingdom in 1937 **(3)**.

Excisional operative techniques for hemorrhoidectomy including the open hemorrhoidectomy technique and its other modifications are reported in various studies as a painful operative procedure. In previous studies, various attempts were made to reduce the postoperative pain such as suturing the vascular pedicle without incisions, limited incisions and stapled hemorrhoidectomy. Along with these modification in operative procedures various medications were also studied for postoperative pain such as local anesthesia, suppositories and oral medications **(4)**.

Among several studies local anesthesia was studied to decrease the postoperative pain after hemorrhoidectomy under general anesthesia or in some studies it was the only anesthesia applied for hemorrhoidectomy **(5)**. The benefits reported of local anesthesia includes reduction in postoperative pain, early recovery and reduction in hospital stay. However, the major complaint reported of local anesthesia for performing hemorrhoidectomy is severe pain during the injection of the local anesthesia because of the sensitive anoderm **(6)**. Various studies also conducted for evaluation of the effects and benefits of the general and spinal anesthesia along with their complications and need of preoperative preparation and duration of hospitalization till complete recovery. We conduct the present study to assess the benefits and complications of local anesthesia and spinal anesthesia for hemorrhoidectomy.

MATERIALS & METHODS

The present prospective study was conducted at our tertiary care hospital and the study duration was one year from January 2018 to December 2018. A sample size of 50 was calculated at 95% confidence interval at 5% of maximum allowable error. Patients who were diagnosed clinically as third- and fourth-degree hemorrhoids and planned for conventional hemorrhoidectomy were enrolled by simple random sampling and randomized for two equal groups. Clearance from hospital ethics committee was taken before start of study. Written informed consent was taken from each study participant.

All the data were recorded related to detailed clinical history, cause of admission, APACHE -2 scores, and co-morbidities. Patients with cardiovascular, renal disease, neurologic disease, hepatic diseases, diabetic mellitus, patients with associated anorectal problems, history of anorectal operations, patients who were taking anti-hypertensive, analgesics, antipsychotics or sedative medicines and pregnant or breast-feeding females were excluded from the present study. Study participants were divided in two groups 1st Group had surgery under local anesthesia with IV sedation and 2nd group underwent surgery under spinal anesthesia. All the study participants were subjected to electrocardiography, end tidal CO2, temperature and baseline cardio-respiratory parameters were also recorded. Data analysis was carried out using SPSS v22. All tests were done at alpha (level significance) of 5%; means a significant association present if p value was less than 0.05.

RESULTS

In the present study, we enrolled 50 patients who were who were diagnosed clinically as third- and fourth-degree hemorrhoids and planned for conventional hemorrhoidectomy and randomized for two equal groups. Out of the total study participants **(19)** 38% were females and (31) 62% were males. The mean age of study population was 37.55 ± 5.9 years. Study participants were divided in two groups 1st Group had surgery under local anesthesia with IV sedation and 2nd group underwent surgery under spinal anesthesia. Out of the total study participants of group 1 10 (40%) were females and 15 (60%) were males. The mean age of study population was 36.2 ± 5.8 years. On the basis of degree of hemorrhoids 14 (56%) patients had third degree piles and 11 (44%) patients had fourth degree piles. The need for general anaesthesia was reported among 2/25 (8%) patients. The mean operative duration (minutes) was 22.54 ± 6.98. Out of the total study participants of group 2, 9 (36%) were females and 16 (64%) were males. The mean age of study population was 38.4 ± 6.2 years. On the basis of degree of hemorrhoids 13 (52%) patients had third degree piles and 12 (48%) patients had fourth degree piles. The need for general anaesthesia was reported among 1/25 (4%) patients. The mean operative duration (minutes) was 21.32 ± 5.21. (Table 1)

Table 1: Distribution of study participants according to study parameters.

Study parameters		Group 1 (n=25)	Group 2 (n=25)
Mean age (years)		36.2 ± 5.8	38.4 ± 6.2
Gender	Male	15 (60%)	16 (64%)
	Female	10 (40%)	9 (36%)
Piles degree	Third	14 (56%)	13 (52%)
	Fourth	11 (44%)	12 (48%)
Need for general anaesthesia		2/25 (8%)	1/25 (4%)
Mean operative duration (minutes)		22.54 ± 6.98	21.32 ± 5.21

In the present study, out of the total study participants on the basis of Post-operative pain scores (determined by NRS), it was found that Post-operative pain scores were collectively less in local anaesthesia group. Out of the total study participants of group 1 the mean values of post-operative pain score, determined by NRS after 1st hour was 0.67, after 2nd hour was 0.91, after 4th hour was 2.0, after 6th hour was 2.2 and after 12th hour was 2.0. Out of the total study participants of group 2 the mean values of post-operative pain score, determined by

NRS after 1st hour was 0.42, after 2nd hour was 1.18, after 4th hour was 2.6, after 6th hour was 2.9 and after 12th hour was 2.8. These differences were statistically non-significant (p value > 0.05). (Table 2)

Table 2: Distribution of Post-operative pain Score among study groups.

Post-operative pain Score	Group 1	Group 2	p value
1st hour	0.67	0.42	>0.05
2nd hour	0.91	1.18	>0.05
4th hour	2.0	2.6	>0.05
6th hour	2.2	2.9	>0.05
12th hour	2.0	2.8	>0.05

In the present study, out of the total study participants on the basis of adverse effects, we found that bleeding was the most common adverse effect reported among the study groups of group 1st which was reported among 6(24%) patients. Delayed healing was present among 1 (4%) patients. None of the patient was reported for hypotension, headache, urine retention and deep infection. Out of the total study participants on the basis of adverse effects, we found that hypotension was the most common adverse effect reported among the study groups of group 2nd which was reported among 8 (32%) patients. Headache was present among 7 (28%) patients, bleeding was present among 5 (20%) patients, urine retention was present among 3 (12%) patients and delayed healing was present among 2 (8%) patients. None of the patient was reported for deep infection. (Table 3)

Table 3: Distribution of study participants according to adverse effects.

Adverse effects	Group 1	Group 2	p value
Hypotension	0	8 (32%)	< 0.05
Headache	0	7 (28%)	< 0.05
Bleeding	6(24%)	5(20%)	> 0.05
Urine retention	0	3(12%)	< 0.05
Delayed healing	1(4%)	2(8%)	> 0.05
Deep infection	0	0	> 0.05

DISCUSSION

In the present study, we enrolled 50 patients who were who were diagnosed clinically as third- and fourth-degree hemorrhoids and planned for conventional hemorrhoidectomy and randomized for two equal groups. Out of the total study participants (19) 38% were females and (31) 62% were males. The mean age of study population was 37.55 ± 5.9 years. Study participants were divided in two groups 1st Group had surgery under local anesthesia with IV sedation and 2nd group underwent surgery under spinal anesthesia. Similar results were obtained in a study conducted by Bansal H,et al for the Comparative study of assessment of the benefits and complications of local anesthesia and spinal anesthesia for hemorrhoidectomy. They reported similar results as the present study (7). Similar results were obtained in a study conducted by et al for the Comparative study of assessment of the benefits and complications of local anesthesia and spinal anesthesia for hemorrhoidectomy. They reported similar results as the present study (8).

In the present study, out of the total study participants of group 1 10 (40%) were females and 15 (60%) were males. The mean age of study population was 36.2 ± 5.8 years. On the basis of degree of hemorrhoids 14 (56%) patients had third degree piles and 11 (44%) patients had fourth degree piles. The need for general anaesthesia was reported among 2/25 (8%) patients. The mean operative duration (minutes) was 22.54 ± 6.98. Out of the total study participants of group 2, 9 (36%) were females and 16 (64%) were males. The mean age of study population was 38.4 ± 6.2 years. On the basis of degree of hemorrhoids 13 (52%) patients had third degree piles and 12 (48%) patients had fourth degree piles. The need for general anaesthesia was reported among 1/25 (4%) patients. The mean operative duration (minutes) was 21.32 ± 5.21. Similar results were obtained in a study conducted by D. G. Jayne,et al for the Comparative study of assessment of the benefits and complications of local anesthesia and spinal anesthesia for hemorrhoidectomy. They reported similar results as the present study (9).

In the present study, out of the total study participants on the basis of Post-operative pain scores (determined by NRS), it was found that Post-operative pain scores were collectively less in local anaesthesia group. Out of the total study participants of group 1 the mean values of post-operative pain score, determined by NRS after 1st hour was 0.67, after 2nd hour was 0.91, after 4th hour was 2.0, after 6th hour was 2.2 and after 12th hour was 2.0. Out of the total study participants of group 2 the mean values of post-operative pain score, determined by NRS after 1st hour was 0.42, after 2nd hour was 1.18, after 4th hour was 2.6, after 6th hour was 2.9 and after 12th hour was 2.8. These differences were statistically non-significant (p value > 0.05). Similar results were obtained in a study conducted by Craig T. Hartrick,et al for the Comparative study of

assessment of the benefits and complications of local anesthesia and spinal anesthesia for hemorrhoidectomy. They reported similar results as the present study **(10)**.

In the present study, out of the total study participants on the basis of adverse effects, we found that bleeding was the most common adverse effect reported among the study groups of group 1st which was reported among 6(24%) patients. Delayed healing was present among 1 (4%) patients. None of the patient was reported for hypotension, headache, urine retention and deep infection. Out of the total study participants on the basis of adverse effects, we found that hypotension was the most common adverse effect reported among the study groups of group 2nd which was reported among 8 (32%) patients. Headache was present among 7 (28%) patients, bleeding was present among 5 (20%) patients, urine retention was present among 3 (12%) patients and delayed healing was present among 2 (8%) patients. None of the patient was reported for deep infection. Similar results were obtained in a study conducted by Younes Hassan et al for the Comparative study of assessment of the benefits and complications of local anesthesia and spinal anesthesia for hemorrhoidectomy. They reported similar results as the present study **(11)**.

CONCLUSION

We concluded from the present study that use of local anesthesia for hemorrhoidectomy along with intravenous sedation is a safe procedure and should be considered as an alternative to spinal anesthesia. Present study reported that it has lesser postoperative pain scores, no hypotension, no headache and no urine retention in comparison to spinal anaesthesia.

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Original Article

A descriptive survey of tracheal extubation practices among Indian anaesthesiologists

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ABSTRACT

Background and Aims: This study assesses the extubation practices of anaesthesiologists and whether these practices differ from existing guidelines. **Methods:** The literature related to tracheal extubation was searched and a validated questionnaire was designed to assess practices of tracheal extubation. The questionnaire included techniques, manoeuvres, preparation, timing and plan of extubation. The survey link was shared with eligible participants. The responses were assessed using Statistical Package for Social Sciences (SPSS) software. **Results:** Of the 1264 respondents, 66.8% keep difficult airway cart ready only when difficult extubation is anticipated. Only 12.3% of respondents perform deep extubation with supraglottic airway device (SAD) exchange while 73.3% of respondents perform awake extubation with pharmacological control for preventing haemodynamic fluctuations. In the case of anticipated difficult extubation, 48.3% anaesthesiologists prefer the airway exchange catheter (AEC) exchange technique. Of all, 84.8% anaesthesiologists administer 100% oxygen before performing extubation and 81.7% continue to oxygenate during and 83.9% provide oxygen after extubation in all patients. In the case of suspected airway edema or collapse or surgical cause for airway compromise, 70% anaesthesiologists perform a leak test. The most preferred plan of extubation in patients with suspected airway collapse after surgery is direct extubation in fully awake position (54.6%). In patients with anticipated difficult extubation, 50.8% anaesthesiologists prefer to ventilate for 24 hours and reassess. **Conclusion:** We observed that the extubation practices vary widely among anaesthesiologists. Almost half of the anaesthesiologists were unaware of extubation guidelines.

Key words: Difficult airway, difficult extubation, difficult intubation, extubation, surgical airway

INTRODUCTION

Tracheal extubation after completion of surgery is an important aspect of perioperative care for uneventful patient recovery. Tracheal intubation has always been given much emphasis, but extubation remains an ignored aspect in literature and clinical practice. Adverse events related to extubation include airway obstruction, laryngospasm, bronchospasm, aspiration, airway edema and so on which may lead to emergency reintubation. These events increase the risk of morbidity and mortality. Proper planning and its execution before extubation are of utmost importance, especially in the difficult airway. Various guidelines have been formulated to provide a structured approach and proper technique for extubation.[1,2] The knowledge and practice of these guidelines are important to optimise extubation practices for different scenarios to improve patient outcomes and minimise postoperative complications.

We designed a survey to assess the extubation practices among anaesthesiologists with regards to techniques, manoeuvres, timing, and plan of extubation in various situations and whether there were any differences in their practices from the existing guidelines.

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METHODS

The literature related to tracheal extubation was searched in various databases including Pubmed/ Medline, Cochrane, Scopus and Google Scholar. The existing difficult airway guidelines by All India Difficult Airway Association (AIDAA) and Difficult Airway Society (DAS) were also referred.[1,2] The keywords 'difficult airway', 'extubation', 'difficult intubation', 'difficult extubation', 'extubation and surgical airway', 'extubation and haemodynamics' in various combinations were used for literature search. The bibliography of the retrieved manuscripts was searched manually for any missing manuscripts.

Based on this literature, a questionnaire was designed to cover various aspects related to tracheal extubation. The questionnaire was designed as per the format for the online (web-based) survey.[3,4] A total of 25 questions were designed in the English language and all of them were closed-ended questions (multiple-choice or checkbox) except one open-ended question at the end of the survey. The questionnaire collected data about the experience and working place of anaesthesiologists, their techniques, manoeuvres, preparation, timing, and plan of extubation in various scenarios. The questionnaire was reviewed by 5 independent experienced anaesthesiologists (with experience of >10 years) and comments related to ambiguity, clarity, and relevance were sought. The questionnaire was revised accordingly as per the comments. In case of a difference in opinion among these, the consensus was achieved among the three researchers for the final survey question. The final survey was also shared with non-anaesthesiologists and three other experienced anaesthesiologists for a final review. The comments were requested about any ambiguity in words, language and understanding. The final revision of the questionnaire was thus made for its distribution.

The google form-based questionnaire was made and its web-based link was shared via e-mail and WhatsApp among anaesthesiologists working in India. One anaesthesiologist could participate once in the survey. Only anaesthesiologists who have completed their post-graduation in anaesthesia were included. The response was voluntary, and the anonymity of the participants was maintained. Their responses were recorded and assessed using Statistical Package for the Social Sciences (SPSS) software. The data collected about practice patterns were analysed using descriptive analysis.

RESULTS

We analysed the responses from 1264 respondents. Majority of the respondents (45.6%) had experience of more than 10 years and 55.2% were from the academic institutes [Table 1].

According to the data collected, it was observed that 66.8% of respondents keep difficult airway cart ready only when difficult extubation is anticipated while 30.4% keep difficult airway cart ready for all patients. In case of low risk for extubation (normal airway and intubation), where pharmacological control of haemodynamic parameters is required, only 12.3% of respondents perform deep extubation with supraglottic airway device (SAD) exchange, 73.3% of respondents perform awake extubation with pharmacological control for preventing haemodynamic fluctuations, and 14.4% perform direct extubation in a patient with low risk of extubation failure. During extubation in a deep plane of anaesthesia, the most common technique used was direct extubation followed by mask ventilation [Table 2]. In the case of anticipated difficult extubation, the majority (48.3%) anaesthesiologists prefer the airway exchange catheter (AEC) exchange technique for extubation [Table 2]. Most of the anaesthesiologists (60.3%) keep AEC for <2 h and few keep it for 2-12 h in situ. Very few (4.6%) keep it for >12 h.

Regarding oxygen supplementation, 84.8% anaesthesiologists administer 100% oxygen in all patients before performing extubation, 81.7% continue to oxygenate during the extubation process, and 83.9% provide oxygen after extubation in all patients [Table 3]. A time-based (for a fixed period) technique is most commonly used for delivery of 100% oxygen before performing extubation [Table 3].

The routine use of recruitment maneuvers before extubation was low and 54.7% of anaesthesiologists apply positive pressure in all patients during the

Table 1: Demographic profile of the respondents (*n*=1264)

Parameter	Options	Response *n* (%)
Experience in Anaesthesiology (after completing post-graduation)	<3 years	265 (21.1%)
	3-5 years	214 (16.9%)
	6-10 years	208 (16.4%)
	>10 years	577 (45.6%)
Workplace	Academic Institute	698 (55.2%)
	Corporate Hospital	318 (25.2%)
	Freelance practice	207 (16.4%)
	Others	41 (3.2%)

Table 2: Use of various techniques for difficult extubation (*n*=1264)

Parameter	Options	Response *n* (%)
Which technique do you perform for airway management during extubation in deep anaesthesia?	Supraglottic airway device (SAD) exchange (Bailey manoeuvre)	340 (26.9%)
	Direct extubation followed by mask ventilation	742 (58.7%)
	Extubation over airway exchange catheter	128 (10.1%)
	Other	54 (4.3%)
In case of anticipated difficult extubation, which advanced technique do you prefer for awake extubation?	Airway Exchange Catheter (AEC)	611 (48.3%)
	Laryngeal mask airway exchange/Bailey manoeuvre	289 (22.9%)
	Fiberoptic bronchoscope/Video endoscope exchange	120 (9.5%)
	Direct Extubation	243 (19.2%)
	Other	1 (0.1%)

Table 3: Peri-extubation oxygen supplementation (*n*=1264)

Parameter	Options	Response *n* (%)
Do you administer 100% oxygen before performing awake extubation?	All patients	1072 (84.8%)
	Selected patients (e.g.in anticipated difficult extubation)	154 (12.2%)
	Administer the same % of oxygen as intraoperatively	38 (3%)
Do you continue to oxygenate with 100% oxygen at the extubation process?	Yes	1032 (81.7%)
	No	88 (7%)
	Selected patients (e.g.in anticipated difficult extubation)	144 (11.4%)
Do you routinely provide oxygen supplementation after extubation?	Yes	1060 (83.9%)
	No	86 (6.8%)
	Selected patients (e.g.in anticipated difficult Extubation)	118 (9.3%)
Which technique do you use for delivery of 100% oxygen before performing extubation?	Time-based -for a fixed period (e.g., 1,2,3 minutes)	792 (62.6%)
	End-tidal oxygen (EtO_2) monitoring based	423 (33.5%)
	Other	49 (3.9%)

extubation process [Table 4]. The survey revealed that 62% of anaesthesiologists suppress haemodynamic responses in selected patients with normal airway and 8.3% suppress in the difficult airway. In the case of suspected airway edema or collapse or surgical cause for airway compromise, 70% anaesthesiologists perform a leak test and 17% were not sure. The qualitative method is used by most of them (47%) for the leak test.

The most preferred plan of extubation in patients with suspected airway collapse after surgery is direct extubation in a fully awake position (54.6%). In patients with anticipated difficult extubation (difficult mask ventilation/difficult intubation, delayed recovery because of pre-existing diseases), 50.8% anaesthesiologists prefer to ventilate for 24 hours and reassess [Table 5]. In difficult extubation cases with surgical cause for airway compromise/suspected airway edema/collapse, 65.2% prefer to ventilate for 24 hours [Table 5]. In case of high suspicion of airway edema, manoeuvre or drugs used before extubation were steroids (48%), nebulised epinephrine (28%), and head-up position (23%). Among the participants, 37.6% follow DAS guidelines, 19.8% follow AIDAA guidelines whereas 42.6% follow department protocol-based algorithms for extubation. As far as awareness of the difficult airway algorithm is concerned, 44% of anaesthesiologists were unaware of the extubation guidelines/algorithms. Various suggestions were invited to improve airway algorithms. Some of them were the inclusion of obstetric and paediatric extubation in difficult airway algorithms.

DISCUSSION

This survey focused on various practice patterns related to extubation planning, extubation techniques, and awareness of the extubation algorithm among anaesthesiologists. There is a scarcity of such information from anaesthesiologists. The reported data related to knowledge and awareness of extubation practices have not focused on techniques and plans of extubation.[5,6]

According to the data collected from all anaesthesiologists, it was observed that 66.8% of respondents keep difficult airway cart ready only when difficult extubation is anticipated while 30.4% of people keep difficult airway cart ready always in all patients.

We observed that the availability of difficult airway cart was not universal even when difficult extubation

Table 4: Use of recruitment manoeuvre and positive pressure for extubation (*n*=1264)

Parameter	Options	Response *n* (%)
Do you perform a recruitment manoeuvre (if not contraindicated) before extubation?	All patients	321 (26.4%)
	Selected patients (e.g. in anticipated difficult extubation)	541 (42.9%)
	Do not perform	402 (31.6%)
Do you apply positive pressure during the extubation process (endotracheal tube removal)?	All patients	691 (54.7%)
	Selected patients (e.g. in anticipated difficult extubation)	278 (22%)
	Don't apply	295 (23.3%)

Table 5: Extubation strategies in difficult extubation (*n*=1264)

Parameter	Options	Response
What is your preferred plan of extubation in patients with suspected airway collapse (leak absent/equivocal) after surgery?	Extubate under deep inhalational anaesthesia directly	28 (2.2%)
	Extubate under deep inhalational anaesthesia over AEC/FOB	430 (34%)
	Direct extubation in fully awake and observe	690 (54.6%)
What is the plan for extubation in difficult extubation cases with difficult mask ventilation/Difficult intubation/Delayed recovery/difficulty because of pre-existing disease?	Tracheostomy	116 (9.2%)
	Upfront tracheostomy	88 (7%)
	Extubate over Airway Exchange Catheter (AEC)/Fiberoptic bronchoscope (FOB)	471 (37.3%)
	Ventilation for 24 h and reassess	643 (50.8%)
	Other	62 (4.9%)
What is the plan for extubation in difficult extubation cases with surgical cause for airway compromise/ suspected airway edema/suspected airway collapse?	Upfront tracheostomy	215 (17%)
	Extubate over AEC/FOB	192 (15.2%)
	Ventilation for 24 Hours and reassess	824 (65.2%)
	Other	33 (2.6%)

is anticipated. Although ready access to alternative airway devices reduces risk and complications in the unanticipated difficult airway, according to guidelines difficult airway cart should be readily available in case of anticipated difficult extubation.[1,2,5,6]

In patients who require obtundation of haemodynamic responses like ocular, intracranial surgeries, etc., most of the anaesthesiologists (73%) prefer to do awake extubation with pharmacological control while only 12% prefer deep extubation. Both are the techniques described in low-risk algorithms of airway guidelines.[1,2] But most anaesthesiologists do not prefer deep extubation which may either be because of lack of expertise or lack of regular practice. Although deep extubation has many advantages e.g., decreased cardiovascular sympathetic stimulation, lesser incidence of cough, and laryngospasm, there is an increased incidence of respiratory complications after extubation under deep anaesthesia.[7,8] The anticipated respiratory complications may be one of the reasons for low rates of deep extubation.

In case of anticipated difficult extubation, AEC is the most preferred advanced technique followed by laryngeal mask airway (LMA) exchange (Bailey's manoeuvre) followed by direct extubation. AEC use has been supported by various airway guidelines and the evidence of successful reintubation through AEC is also sufficient.[1,2,5,9,10] LMA exchange is the first and most useful advanced technique described in DAS as well as AIDAA guidelines.[1,2] The safety and efficacy of this technique are well described in the literature.[11,12] A fibreoptic bronchoscope (FOB) is the least preferred technique for extubation in anticipated difficult extubation in our survey. This finding is also supported by a recent survey in the Indian scenario and most likely due to lack of expertise and less availability.[13] FOB may be of limited use because of its inherent limitation when used as an exchange catheter due to its stabilisation, expense, and risk of its breakage. It is also limited in its ability to oxygenate and monitor capnography through it because of its small lumen.[14] That may be the reason for not preferring FOB for difficult extubation. The AEC can be retained up to 72 hours as described in the literature.[5,6,12] However, the timing of retaining AEC should be individualised. In our survey, 60.4% of anaesthesiologists prefer to keep it *in situ* for <2 hours and 19% prefer to keep it from 2-12 hrs.

As far as oxygenation is concerned, 84% anaesthesiologists administer 100% oxygen before performing extubation in all patients and 82% continue to oxygenate throughout the extubation process and after extubation too. Extubation guidelines recommend providing preoxygenation with an inspired fraction of oxygen (FiO_2) 1 to build oxygen stores to provide

safe apnea time.[1,2,5,6] Although studies show that 100% oxygen increases the chances of atelectasis, the clinical significance is controversial.[15,16] During extubation, improving oxygen reserve takes a priority. To assess the delivery of oxygen before performing extubation, a time-based technique is most commonly employed (63%) in this survey followed by end-tidal oxygen (EtO_2) monitoring (33%). Although EtO_2 >90% is a better endpoint for the adequacy of oxygenation than a fixed period, its lesser utilisation maybe because of lack of availability and unfamiliarity of the technique and high cost associated with the technology.[1,2,18] AIDAA and DAS recommend applying recruitment manoeuvre (if not contraindicated) and positive pressure before extubation. However, only 43% of anaesthesiologists perform recruitment manoeuvres in selected patients and 55% apply positive pressure in all patients. Although reports of recruitment manoeuvre and positive pressure in the prevention of atelectasis have contradicting results, still guidelines have emphasised its importance in pre-extubation period.[17-20]

Haemodynamic responses secondary to extubation need to be obtunded and pharmacological measures like opioids are usually used. However, it can lead to sedation and respiratory depression post-extubation. Therefore, it should be done cautiously. AIDAA recommends haemodynamic suppression to be mandatory in the normal airway in a selected group of patients undergoing eye surgeries, vascular surgeries, intracranial surgeries, or thoracic surgical procedures in whom awake extubation is to be performed.[1] Only, 61% of anaesthesiologists perform haemodynamic suppression in the normal airway in a selected group of patients and 19% in all patients. The extubation failure may be seen in the difficult airway due to surgical cause (structural damage or nerve injury) or there is suspicion of postoperative airway edema or collapse (e.g., long-standing thyroid tumors, swelling, or another neck mass excision, obese patients or airway-related surgeries). A leak test is recommended in this group of patients to assess airway calibre and collapsibility.[1,21,22] In the present survey, 70% anaesthesiologists always perform, and 18% anaesthesiologists probably perform leak tests in such cases of suspected airway compromise. We observed that 47.5% prefer to perform qualitative tests and 33% prefer quantitative tests. Although the quantitative test is more accurate in identifying cuff leak, it is still not practised much probably because of the lack of proper techniques or lack of knowledge.[23,24] In patients with negative or equivocal leak test (suspected airway collapse), 55% anaesthesiologists prefer extubation when fully awake followed by extubation in deep inhalational anaesthesia over AEC/FOB (34%) followed by tracheostomy (9%). Both the techniques (awake as well as deep inhalational over AEC/FOB) have been described in AIDAA guidelines[1] whereas DAS guidelines[2] do not specify the technique for this specific group of patients, rather they have grouped such patients in 'at-risk group' for which awake extubation or advanced techniques are advised if it is safe to remove the tube. American Society of Anesthesiologists (ASA) taskforce recommends consideration of merits and demerits of deep extubation versus awake extubation in the difficult airway.[9] Deep extubation has been advocated to decrease the occurrence of coughing and laryngospasm. However, it may be associated with the risk of airway obstruction due to the decreased tone of the pharyngeal muscle.[25] Difficulty airway has been reported as one of the contraindications for deep extubation and thus avoided and awake extubation remains the preferred technique.[26,27] In difficult extubation cases with difficult mask ventilation/difficult intubation/delayed recovery/difficulty because of preexisting disease, 51% anaesthesiologists prefer delaying extubation and ventilate for 24 hours and reassess; 37.3% prefer to extubate over AEC/FOB and 6.7% prefer upfront tracheostomy. Even in patients with surgical cause for airway compromise, suspected airway edema, and collapse, 65.1% anaesthesiologists prefer to ventilate for 24 hours and reassess followed by 17% preferring upfront tracheostomy and 15.2% preferring extubation over AEC/FOB. Keeping asleep and intubated in the postoperative period and transfer to a critical care unit appears to be the safest option in anticipated difficult extubation cases provided proper precautionary measures are taken during transfer.[5,6,9] This is the most preferred option in our survey too. In case of high suspicion of airway edema, management options include head-up position, steroids, and nebulised epinephrine.[28-30] The most common method employed in our survey is steroids (48%) followed by nebulised epinephrine (28%) and head-up position (23%). Most of the anaesthesiologists may be using all simultaneously but steroids seem to be the first choice for airway edema.

Most of the anaesthesiologists follow departmental protocol-based algorithms for extubation (43%) followed by DAS (38%) and AIDAA guidelines (19.7%). It was observed that 44% of anaesthesiologists are unaware of the presence of extubation guidelines.

This depicts the need of improving awareness about the extubation guidelines to promote uniform and safe extubation practices. Some contraries to the present guidelines were also depicted in this survey. Aintree catheter guided extubation needs to be added to AIDAA guidelines. In case of the decision to delay extubation, extubation time may be shorter also (6-8 h) rather than 24 hr.

To conclude, we observed that the availability of difficult airway carts at extubation is not universal, the use of the pharmacological technique is a commoner technique to obtund haemodynamic response at extubation. The use of AEC is seen in half of the anaesthesiologists in anticipated difficult extubation. The majority provide 100% oxygen supplementation in the perioperative period. Almost half of the anaesthesiologists were unaware of extubation guidelines.

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Conflicts of interest

There are no conflicts of interest.

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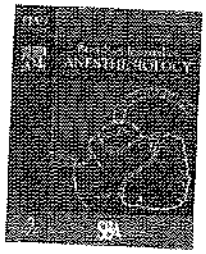

CASE REPORTS

Near ideal anesthetic technique for tracheal stenting in central airway obstruction with dexmedetomidine-ketamine infusion: a case report

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KEYWORDS
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Abstract Central airway obstruction presents as an emergency with dyspnea and stridor. Anesthetic management of rigid bronchoscopy-guided tracheal stenting is highly stimulating procedure requiring general anesthesia. But it may lead to life threatening airway obstruction and cardiovascular collapse after induction. Total intravenous anesthesia based on propofol-remifentanil is an optimal anesthetic technique, but remifentanil is not available in many countries. Although dexmedetomidine-ketamine has been used for procedural sedation, its use for rigid bronchoscopy in the setting of central airway obstruction has not been described in literature. We describe near ideal anesthetic technique for management of central airway obstruction using dexmedetomidine-ketamine combination.

Introduction

Anesthetic management of Rigid Bronchoscopy (RB) guided tracheal stenting in patients with Central Airway Obstruction (CAO) poses unique challenges because the patient present as an emergency with high grade dyspnea and stridor with impaired oxygenation which provides us minimal time for optimization. It is a highly stimulating procedure and requires General Anesthesia (GA). But it may lead to life-threatening airway obstruction and cardiovascular collapse after induction of anesthesia. Total Intravenous Anesthesia (TIVA) based on propofol and remifentanil combination (intermittent boluses or continuous infusion)[1-3] is an optimal anesthetic technique but remifentanil is not available in many countries like ours. Remifentanil and propofol both cause hypotension and bradycardia and the effect

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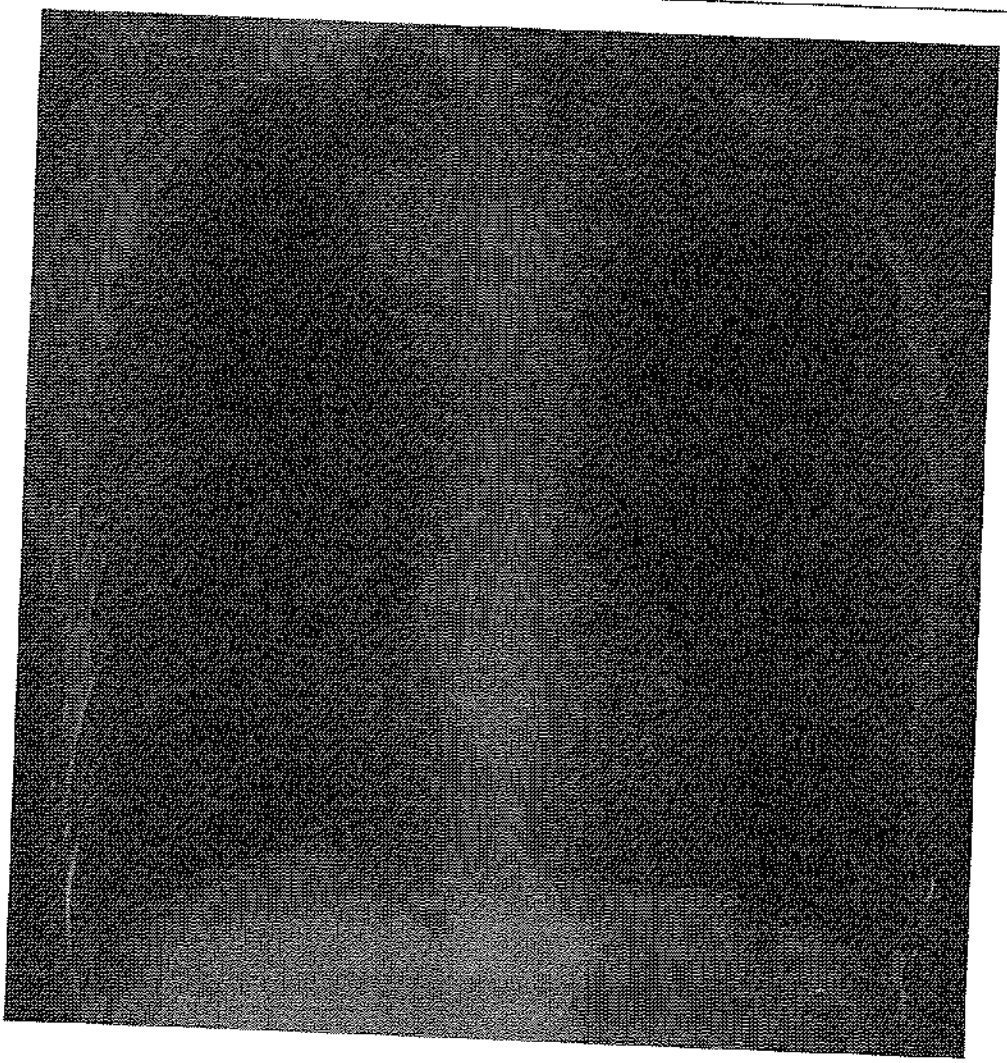

Figure 1

of their combination on hemodynamics can be synergistic. Ketamine, on the other hand, increases blood pressure and heart rate and is a good bronchodilator and analgesic but causes delirium, hallucinations, and increased salivation. Dexmedetomidine (DXM) reduces the side effects of ketamine and their combination provides hemodynamic stability. There are a few reports on the use of ketamine and DXM combination for procedural sedation.[4] DXM-ketamine infusion has not been reported to be utilized for GA in the setting of rigid bronchoscopy. We describe the use of combination of DXM-ketamine infusions for RB guided tracheal stenting in a patient with CAO.

Case report

A 55-year-old American Society of Anesthesiologists (ASA) physical status II patient weighing 56 kg presented to the emergency with cough, breathlessness (modified medical research council Grade 3)[5,6] and stridor. He was in respiratory distress with tachypnea (respiratory rate 22/minute) and usage of accessory muscles for respiration. On auscultation, patient had decreased air entry with bilateral inspiratory crackles with expiratory wheeze and audible stridor. Hemodynamic parameters were stable except tachycardia (pulse rate 120/min). Arterial Blood Gas (ABG) exhibited pH 7.31, PaO_2 63 mmHg, $PaCO_2$ 58 mmHg, and oxygen saturation (SpO_2) 89% on room air. Chest X-ray revealed mediastinal mass with tracheal compression and homogenous opacity in right middle lobe (Fig. 1). Computed Tomography (CT) scan demonstrated a large conglomerated lymph nodal mass in right paratracheal location (7 × 5 cm) infiltrating into tracheal lumen with significant narrowing of tracheal lumen with minimum diameter 3.5 mm (Grade 3 tracheal stenosis)[7] (Fig. 2). He was posted for RB-guided tracheal stenting under GA.

After confirming fasting status (6 hours) and obtaining written informed consent, the patient was taken to operation theatre. Preoperative counselling was done, and anesthesia risks related to loss of airway control, need of intubation and mechanical ventilation, need of intensive care unit, and perioperative pulmonary complications were explained to relatives. He was started on nebulization with salbutamol (2 mL, 2.5 mg) and budesonide (2 mL, 0.5 mg), and standard ASA monitors including Bispectral Index (BIS) monitor were attached. Preoxygenation was done with 10 L of 100% oxygen for 5 minutes in head-up position.

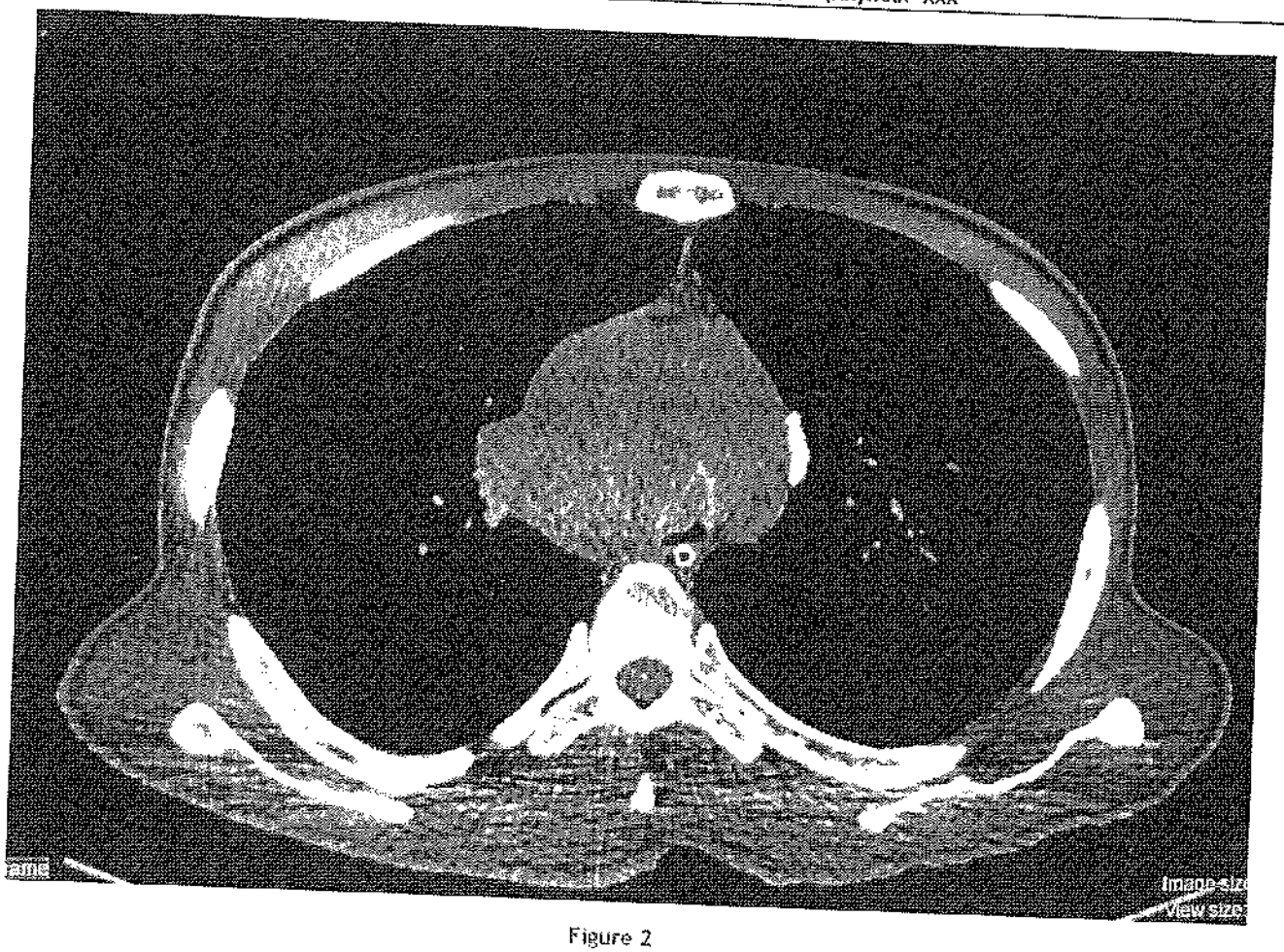

Figure 2

He received 0.2 mg glycopyrrolate, 8 mg dexamethasone and 75 μg fentanyl intravenously (IV). Thereafter, 0.5 $\mu g.kg^{-1}$ DXM was given over 10 minutes, and anesthesia was induced with 75 mg IV ketamine. Subsequently, 1 $mg.kg^{-1}$ intravenous (IV) succinylcholine was given and RB (Karl storz, size 11) was introduced in the trachea 60 seconds later. During maintenance phase, DXM (0.2–0.5 $mcg.kg^{-1}.h^{-1}$) and ketamine (0.5–1 $mg.kg^{-1}.h^{-1}$) infusions were titrated to achieve a BIS between 40–60. The patient was ventilated intermittently through anesthesia circuit attached to the ventilating port of the RB. Intraoperative ABG revealed improvement in oxygenation (PaO_2 75 mm) with slight increase in $PaCO_2$ (63 mm). The procedure lasted for 30 minutes and the patient was hemodynamically stable throughout the procedure. After the stent was placed, bronchoscope was removed, and I-gel size 4 was inserted. The infusion of DXM and ketamine was stopped, and the patient was extubated after ensuring good respiratory efforts with BIS of 80 after about 6 minutes of stopping the infusions. Postoperative ABG revealed Ph 7.37, PaO_2 80 mm, $PaCO_2$ 52 mm, and SpO_2 95%. He was conscious, oriented, pain free and was following commands. He was shifted to post anesthesia care unit for one day. Patient remained stable while maintaining SpO_2 95–96% on room air with normal neurocognition in the postoperative period. He was discharged the next day. His immediate postoperative period and follow up at one week was uneventful.

Discussion

Tracheal stenting in CAO is an emergency procedure and may not give enough time for preoperative optimization. It can lead to life threatening respiratory complications due to nature of disease, decreased oxygen reserve, or sudden airway collapse after anesthesia induction.

Propofol and remifentanil based TIVA is preferred technique over inhalational anesthesia.[2,6] Propofol is an IV hypnotic agent with short context sensitive half-life but it is painful on injection and does not provide analgesia. It may also cause suppression of airway reflexes, apnea, and hemodynamic instability due to vasodilatation and negative inotropy. Ketamine is an IV anesthetic agent with N-Methyl-D-Aspartate (NMDA) receptor blockade as the primary mechanism of action. Ketamine is a good analgesic with rapid onset of action (30 s) and causes bronchodilatation. But its usefulness is limited as it may cause delirium, hallucinations, emergence reactions, increased salivary secretions and hemodynamic instability (tachycardia and hypertension) due to sympathetic stimulation.[8]

DXM is a centrally acting alpha-2 adrenergic receptor agonist and produces sedation, anxiolysis and analgesia without respiratory depression. It enhances anesthesia produced by other anesthetic drugs, preserves airway reflexes and reduces delirium.[9–11] However, it may cause bradycardia and hypotension and has slow onset of action when used

as sole agent. A combination of DXM and ketamine may provide ideal anesthetic conditions like rapid onset, sedation, analgesia, amnesia, bronchodilation, hemodynamic stability, and maintenance of spontaneous respiration with minimal side effects. It may be an alternative to propofol and remifentanil in countries where remifentanil is not available. Moreover, it obviates the need of additional opioids and opioid related side effects.

DXM-ketamine combination has been used for procedural sedation with minimal cardiorespiratory adverse effects in patients undergoing esophago-gastro-duodenoscopy, in children undergoing minor cardiac procedures, and in pediatric dentistry.[11-13] Tobias has demonstrated descriptive accounts of reports from literature regarding the use of this combination for procedural sedation.[4] Apart from sedation, the effective and safe use of this combination has also been described for anesthesia in patients with uncorrected congenital cyanotic heart disease presenting for non-cardiac surgery.[14]

DXM-ketamine combination provided adequate sedation and comfort[15] with better hemodynamic stability than DXM alone[16] for awake fiberoptic intubation. RB procedure is associated with greater hemodynamic response for a longer time and optimum depth of anesthesia should be maintained throughout the procedure. Our patient presented in CAO with severe dyspnea and had low oxygen saturation that did not improve with any bronchodilators or steroids. As insertion of RB is highly stimulating, therefore depolarizing muscle relaxant was used for providing relaxation[17] due to its rapid onset, short duration, low cost, and better intubating conditions. So, emergency tracheal stenting was planned under general anesthesia with short acting neuromuscular block for induction followed by continuous infusion of DXM-ketamine combination that provided good anesthetic depth (objectively measured by BIS values) and hemodynamic stability without the need of additional doses of muscle relaxants. Further randomized studies are required to validate these findings in such category of patients.

Conclusion

DXM-ketamine based total intravenous anesthesia provides good analgesia, anesthesia, and hemodynamic stability with rapid, smooth induction, and emergence with minimal side effects. Hence it can be an ideal anesthetic technique for rigid bronchoscopic guided tracheal stenting.

Conflicts of interest

The authors declare no conflicts of interest.

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Original Article

Evaluating the Efficacy of Low-Dose Hyperbaric Levobupivacaine (0.5%) versus Hyperbaric Bupivacaine (0.5%) along with Fentanyl for Subarachnoid Block in Patients Undergoing Medical Termination of Pregnancy and Sterilization: A Prospective, Randomized Study

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Abstract

Background: Spinal anesthesia using low doses of local anesthetics with opioids is emerging as a useful technique for day care surgeries. Levobupivacaine, a lesser toxic enantiomer of bupivacaine, has now been increasingly used in various gynecological surgeries. However, its use has not been demonstrated in medical termination of pregnancy (MTP) with sterilization (a kind of day care surgery). This study was performed to compare analgesic and anesthetic effectiveness of low-dose hyperbaric 0.5% levobupivacaine and hyperbaric 0.5% bupivacaine in combination with fentanyl in spinal anesthesia in patients undergoing MTP with sterilization. **Methods:** A comparative, randomized, double-blind study was conducted in 90 patients scheduled to undergo elective MTP with sterilization. Group levobupivacaine (L) (n = 45) received 7.5 mg (1.5 mL) of 0.5% isobaric levobupivacaine + 1 mL of 5% dextrose and fentanyl 25 mcg (0.5 mL), while group bupivacaine (B) (n = 45) received 7.5 mg (1.5 mL) of 0.5% hyperbaric bupivacaine + 1 mL of normal saline and fentanyl 25 mcg (0.5 mL). They were compared with respect to onset and duration of sensory and motor block, time to reach highest sensory level, time to two segments' regression, and total duration of analgesia. **Results:** Sensory and motor block onset and time to achieve highest level of sensory block were significantly delayed in group L ($P < 0.05$). Duration of sensory block and duration of analgesia was longer in group L than group B. Motor block duration was significantly shorter in L group (88.4 ± 12.4 min in group L and 133.9 ± 28.1 min in group B). Both groups were comparable in terms of hemodynamic parameters and adverse effects. **Conclusion:** This study suggests that 7.5 mg of 0.5% levobupivacaine usage in spinal anesthesia provides longer duration of analgesia and better sensory blockade with minimal motor block when compared with 0.5% bupivacaine along with fentanyl and may be a better alternative to bupivacaine in day care surgeries.

Keywords: *Bupivacaine, fentanyl, hyperbaric, levobupivacaine, medical termination of pregnancy, spinal anesthesia, sterilization*

Introduction

Spinal anesthesia is one of the anesthesia technique for medical termination of pregnancy (MTP) with sterilization.[1] It offers the advantage of patient being awake, oriented, breathing spontaneously, reduced postoperative pain, minimal postoperative nausea vomiting (PONV), and fast-track recovery and has emerged as a useful technique for day care surgeries.[2,3] For sterilization procedure, sensory level of at least T5-T6 is necessary to prevent discomfort from peritoneal traction, but increasing the dose of long-acting local anesthetics may produce extensive sensory and motor block as well as hypotension and this might result in delayed discharge from hospital.[4] Long-acting amide local anesthetics such as bupivacaine are used at low doses for outpatient spinal anesthesia.[5,6] Levobupivacaine is the S(-)-enantiomer of bupivacaine and is less toxic to heart and central nervous system.[7] It produces less motor block than bupivacaine when administered intrathecally at low doses.[8] Intrathecal fentanyl added to low-dose local anesthetics produces a synergistic effect without increasing the sympathetic block or delaying discharge.[9]

The aim of the study was to compare anesthetic and analgesic efficacy of

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low-dose hyperbaric levobupivacaine versus bupivacaine along with fentanyl in subarachnoid block in MTP with sterilization surgery. We hypothesize that levobupivacaine provides similar duration of analgesia without affecting duration of sensory and motor block when compared with bupivacaine.

Methods

This study was performed from February 2013 to January 2014. The study was registered with the Clinical Trials Registry of India (CTRI) with CTRI number 2016/12/007516.

After obtaining permission from the institutional ethical committee and written informed consent from the patients, this randomized, double-blind study was conducted in 90 patients. Inclusion criteria were american society of anesthesiologists (ASA) physical status I–II females between 20 and 50 years of age, weighing between 40 and 70 kg, and height >145 cm scheduled to undergo elective MTP with sterilization (tubal ligation) with gestation maximum up to 12 weeks. Patients with uncontrolled hypertension, infection at the injection site, disorders of coagulation, history of headache, reluctance to the procedure, neurologic disease, or hypersensitivity to amide local anesthetics or fentanyl were excluded from the study. All patients underwent a thorough preanesthetic checkup at least 24 h prior to surgery and were advised fasting 6 h before the procedure. Visual Analog Scale (VAS) was explained to patients.

In operation theater, electrocardiograph, noninvasive blood pressure (NIBP), and pulse oximeter were attached, and preoperative baseline readings of NIBP, pulse rate (PR), and oxygen saturation (SpO_2) were noted. A wide bore cannula was secured and preloading was done with Ringer lactate at 10 mL/kg. Patients were randomly allocated to two groups using computer-generated random number table and numbers concealed in opaque envelope to be opened after recruitment. This trial was so planned that neither the doctor nor the participant was aware of the group allocation and the drugs received.

Group A (n = 45) received 7.5 mg (1.5 mL) of 0.5% isobaric levobupivacaine (Levo-Anawin-Neon Laboratories Limited, Palghar Maharashtra, India) +1 mL of 5% dextrose and fentanyl 25 mcg (0.5 mL), while group B (n = 45) received 7.5 mg (1.5 mL) of 0.5% hyperbaric bupivacaine (Anawin Heavy-Neon Laboratories Limited, Palghar Maharashtra, India) +1 mL of normal saline and fentanyl 25 mcg (0.5 mL) making a total volume of 3 mL each. The intrathecal drugs were prepared by an independent anesthesiologist not involved in the conduct of case as per randomization and administered by another anesthesiologist blinded to group allocation. Under all aseptic precautions, spinal anesthesia was performed in the operating room at the L3–L4 or L2–L3 interspace, with the patient in the left lateral position. A total volume of 3 mL was injected slowly through a 25-G spinal needle. The patient was placed in supine position with a slight head down tilt immediately after spinal injection to achieve block level of T6.

Intraoperative vitals (blood pressure, PR, saturation and respiratory rate) were recorded at 2, 5, 10, 15, 30, 40, 50, 60 min, and postoperatively at 30 min interval or until rescue analgesic was given.

The primary outcome measure was comparison of analgesic efficacy of low-dose intrathecal levobupivacaine (7.5 mg) versus bupivacaine (7.5 mg) when combined with fentanyl 25 mcg. Secondary outcome measures were to compare sensory and motor block characteristics and hemodynamic effects of low-dose (7.5 mg) hyperbaric levobupivacaine (0.5%) and bupivacaine (0.5%) when they were combined with fentanyl (25 μg) in spinal anesthesia for MTP with sterilization surgery.

Total duration of analgesia was defined as time from intrathecal administration of drugs to patient's demand of rescue analgesic or VAS >3. It was recorded following pain scoring system – VAS. The VAS consisted of a 10-cm horizontal paper strip with two endpoints labeled 0 = "No pain" and 10= "Worst pain ever." VAS was serially assessed after completion of surgery at half an hour interval till 300 min or till the patient complained of pain (VAS >3). Patient's VAS >3 and administration of rescue analgesia constituted the end point of the study. Inj. diclofenac (75 mg) IV through infusion was given as rescue analgesic and 100 mg inj. tramadol IV through infusion if required.

The level of sensory block was tested by pinprick bilaterally at mid-clavicular line which was done every 2 min after spinal injection until it stabilized for three consecutive tests, and then every 15 min until S2 segment regression was achieved. "Onset of sensory block" was taken as the time taken to attain sensory level of T10 dermatome. Degree of motor block was assessed using modified Bromage scale (0: Able to move the hip, knee and ankle, 1: Unable to move the hip but is able to move the knee and ankle, 2: Unable to move the hip and knee but is able to move the ankle, 3: Unable to move the hip, knee, and ankle)[10] "Onset of motor block" was taken as the time taken to achieve Bromage scale 1 from the time of subarachnoid injection. "Onset of highest motor block" was recorded as time to reach highest scale of motor block (Bromage scale 2/3). "Motor block duration" was recorded as time to complete termination of motor block (Bromage scale 0). "Maximum motor block level" was recorded as highest motor block scale (Bromage scale) that was reached. Side effects recorded were hypotension (mean arterial pressure <60 mmHg or greater than 25% below the baseline), bradycardia (pulse <50/min), respiratory depression (oxygen saturation less than 90% or respiratory rate ≤8/min), and pruritus.

Episodes of intraoperative hypotension were managed with crystalloids 5 mL/kg, colloids, and if required with bolus doses of inj. mephenteramine 6 mg intravenously. Bradycardia was treated with 0.01 mg/kg of inj. atropine intravenously. Intraoperative nausea was treated with inj. ondansetron 4 mg and any pruritus was treated using antihistaminics. Oxygen (3 L/min) through face mask was applied if pulse oximeter reading decreased below 90%.

The surgical technique used was dilation and evacuation in lithotomy position followed by tubal ligation through minilaparotomy approach through suprapubic incision in supine position. On completion of the surgery, the patients were shifted to the recovery unit. These patients were discharged home once the complete resolution of motor and sensory blockade was achieved and they were able to stand on their feet with minimal or no assistance.

Statistical assessment of data was done using Statistical Package for the Social Sciences statistical software (version 17.0). The calculation of the required sample size was based on the mean and standard deviation (SD) of time to first rescue analgesia requirement after spinal anesthesia with bupivacaine (305 ± 50 min) and levobupivacaine (389 ± 189 min) as reported in previous trial,[10] and 36 patients were required for each group to reject null hypothesis of equality of means of two groups with alpha = 5% and power (1- β) = 90%. A total of 95 patients were assessed for eligibility and after exclusion and dropouts, 90 patients were analyzed (45 per group). Independent sample *t*-test was used to assess some of the demographic data (age, weight, and height), time to reach T10 dermatome, time to achieve highest sensory level, time to two segments' regression, time to onset of motor block, motor block regression time, and time to first dose of rescue analgesic. The changes in blood pressure and heart rate over time were tested with analysis of variance for repeated measures. Categorical variables such as ASA physical status and complications were analyzed by Chi-square test of significance. A value of <0.05 was considered significant and <0.001 was considered highly significant. Data were expressed as mean ± SD or median (range) or number of patients (*n*) or percentage (%).

Table 1: Demographic profile of the two groups

	Group L (*n*=45)	Group B (*n*=45)	*P* between groups
No. of Patients	45	45	
Age (yr)	27.5±3.4	28.7±3.5	0.1136
Weight (kg)	50.7±6.6	51.4±8.3	0.6646
Height (c.m)	155.2±3.0	154.8±2.9	0.4976
ASA Grade (I/II)	36/9	34/11	0.6121
Duration of surgery (min.)	26.7±8.5	28.8±9.9	0.2909

Results

A total of 90 patients were analyzed in the study. Two patients in levobupivacaine group failed to achieve adequate surgical block within 30 min after spinal injection and performed under GA, and therefore withdrawn from the study. One patient in bupivacaine group had bladder perforation in which surgery was prolonged and GA had to be given, and therefore excluded from the study. The two groups were comparable with respect to age, gender, weight, height, ASA grade, and duration of surgical procedure [Table 1].

The duration of analgesia was significantly prolonged in levobupivacaine–fentanyl group than bupivacaine–fentanyl group ($P < 0.05$). Sensory and motor block onset and time to achieve highest level of sensory block were delayed in group L (levobupivacaine) when compared with group B (bupivacaine) with *P* value <0.05 (significant). Duration of sensory block was also longer in group L than group B. On the other hand, duration of motor block was significantly shorter in levobupivacaine group ($P < 0.001$) [Table 2]. There was no significant difference in terms of two segments' regression time and highest level of sensory block in both groups [Table 2]. T6 was the highest level of block achieved in a majority of patients in both groups, whereas few patients also achieved T8 level of block.

There was highly significant difference in maximum motor block achieved. In group B, The percentage of patients with complete motor block (Bromage scale 3) was significantly higher than group L ($P < 0.001$) [Table 3 and Figure 1].

Both groups were comparable with respect to mean arterial blood pressure, heart rate, and SpO_2 values over different time intervals [Figures 2 and 3]. There was no significant fall in MBP in both groups at any time interval. There

Table 2: Characteristics of Spinal Anesthesia

Characteristics	Group L (Mean±SD)	95% Confidence Interval (Group L)	Group B (Mean±SD)	95% Confidence Interval (Group B)	*P*
Duration of Analgesia (min.)	222.6±26.2	170.2-275	206.1±35.3	135.5-276.7	0.0133
Sensory Onset T 10(min.)	4.7±1.2	2.3-7.1	4.0±1.3	1.4-6.6	0.0097
Time to achieve Highest Level of Sensory Block (min.)	8.9±2.6	3.7-14.1	7.4±2.0	3.4-11.4	0.0029
Duration of Sensory Block (min.)	185.9±25.7	134.5-237.3	175.2±21.7	131.8-218.6	0.0361
Two Segment Regression time (min.)	89.9±14.8	60.3-119.5	86.3±16.9	52.5-120.1	0.2851
Motor onset (min)	3.2±1.3	0.6-5.8	2.3±1.0	0.3-4.3	0.0011
Duration of Motor block (min.)	88.4±12.4	63.6-113.2	133.9±28.1	77.7-190.1	0.0000

was no significant difference in the incidence of side effects (e.g. hypotension, bradycardia, nausea, vomiting, shivering, pruritus) in both groups ($P > 0.05$) [Table 4].

Discussion

We observed that 7.5 mg 0.5% hyperbaric levobupivacaine in spinal anesthesia can provide adequate sensory blockade with minimal motor block with longer duration of analgesia and stable hemodynamic profile when compared with similar dose and concentration of bupivacaine in MTP with sterilization surgery. Comparison of levobupivacaine and bupivacaine has been performed in various studies, but the results of them are inconsistent. Some studies have demonstrated equal effectiveness of levobupivacaine and bupivacaine, whereas others have shown different block characteristics. This is the first study performed in MTP

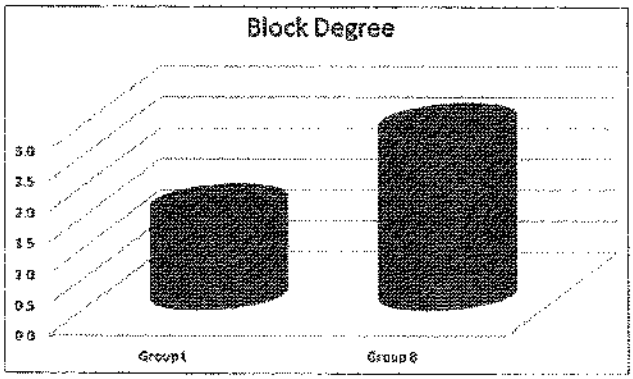

Figure 1: Comparison of block degree between two groups

Table 3: Degree of motor block achieved

Block degree	Group L		Group B		*P*
	No.	Percentage	No.	Percentage	
1	8	17.8	0	0	<0.0001
2	23	51.1	8	17.8	
3	14	31.1	37	82.2	
Grand total	45	100.0	45	100.0	

Table 4: Complications (Intra operative and early post-operative)

Side effects	Group L *n* (%)	Group B *n* (%)	*P*
Hypotension	4 (8.89%)	5 (11.11%)	0.936 184
Bradycardia	1 (2.22%)	2 (4.44%)	
Ponv	2 (4.44%)	2 (4.44%)	
Shivering	2 (4.44%)	3 (6.67%)	
Pruritus	2 (4.44%)	1 (2.22%)	

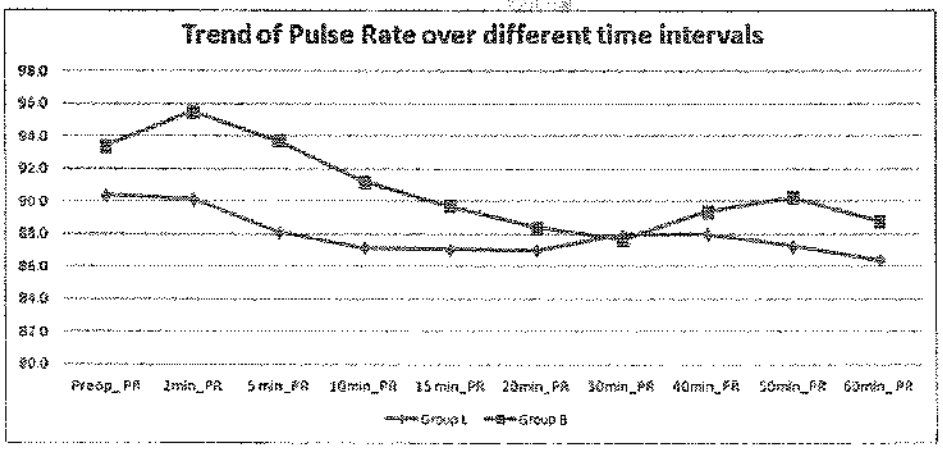

Figure 2: Trend of pulse rate over different time intervals

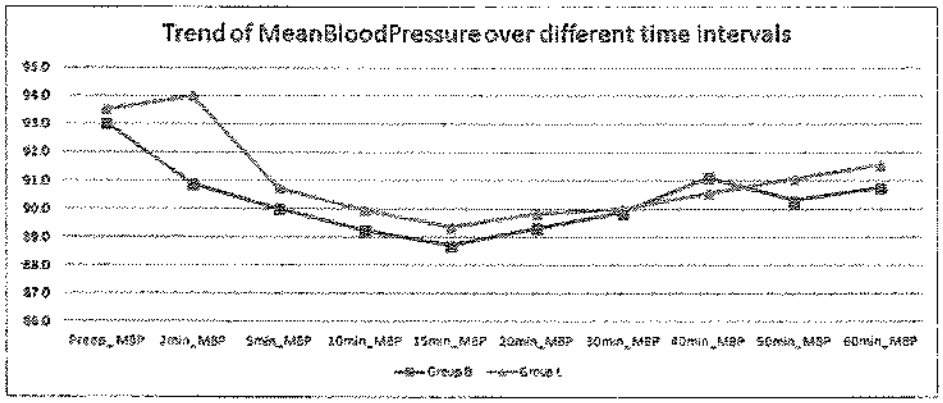

Figure 3: Trend of mean blood pressure over different time intervals

with sterilization surgery which is a type of ambulatory day care surgery.

Low-dose spinal anesthesia has been performed in this study which is the practice of using minimal dosing of intrathecal drugs to ensure that only the nerve roots supplying the specific area get blocked. According to a meta-analysis of 12 studies performed in 693 patients, a cut-off value was defined for "conventional dose" as >8 mg bupivacaine (which many would consider a low cut-off value) and "low dose" <8 mg.[12]

We have used hyperbaric solutions of levobupivacaine and bupivacaine in our study. Since literature describes use of various concentrations (mg/mL) of dextrose (3%[10]–50%[13]) to make solutions hyperbaric, we have used minimally concentration of dextrose (5%) using readily available solution to make levobupivacaine hyperbaric. We performed specific gravity testing on the mixtures before starting the study. The values of specific gravity of solutions were 1.015 in group L and 1.020 in group B, at 25°C respectively. As the specific gravity of cerebrospinal fluid (CSF) ranges from 1.0063 to 1.0075[14] and the mean CSF density of pregnant women was found to be 1.00033 ± 0.00010 g/mL,[15] both solutions were hyperbaric compared with CSF.

This study demonstrated longer duration of analgesia and longer duration of sensory block in levobupivacaine–fentanyl group. It may be related to vasoconstrictive properties of levobupivacaine at lower doses than bupivacaine.[3] Consistent with our study, Hakan Erbay *et al*.[11] and Erkili *et al*.[15] found that first analgesic requirement and duration of sensory block were longer in levobupivacaine than bupivacaine group. Long duration of sensory block in levobupivacaine group was also observed by Casati *et al*.[6] In contrast to this, Mehta *et al*.,[16] Lee *et al*.,[12] and Misirlioglu *et al*.[18] have demonstrated similar sensory block characteristics, whereas Duggal *et al*.[19] have revealed shorter duration of sensory block in levobupivacaine group which may be related to the fact that they have used isobaric levobupivacaine to compare with hyperbaric bupivacaine.

Studies performed by Misirlioglu *et al*.,[18] Erdil *et al*.,[20] and Vellosillo *et al*.[21] showed results similar to the present finding of delayed time to reach T10 level and highest level of sensory block in levobupivacaine group which again may have been the result of the vasoconstrictor properties of levobupivacaine.

The duration of the block is dependent on the type of the drug used and the volume. In our study, the effective concentration of the local anesthetic in both the groups was 0.25% and the volume was limited to 3 mL for both. Thus, the only difference was characteristic of the drug used. We found no significant difference in two segments' regression time and highest level of block achieved in both the groups ($P > 0.05$). In 2006, Vanna *et al*.[22] studied 70 patients undergoing elective transurethral endoscopic surgery who received 2.5 mL of either 0.5% isobaric levobupivacaine ($n = 35$) or 0.5% hyperbaric bupivacaine ($n = 35$) intrathecally and found that two groups were similar in terms of time to block suitable for surgery, duration of sensory block, time to two segments' regression, and time to T12 regression. In a recent study by Dar *et al*.,[23] 2 mL each of isobaric levobupivacaine 0.5% and hyperbaric bupivacaine 0.5% in combination with fentanyl 15 mcg were compared in spinal anesthesia in cesarean section and there was no significant difference in time to achieve highest level of block, two segment regression times, and incidence of side effects.

Our findings of delayed onset and short duration of motor block in levobupivacaine group are in congruence with Hakan Erbay *et al*.[11] and Duggal *et al*.[19] Erdil *et al*.[20] also illustrated delayed onset in group L, but similar degree and duration of motor block between two groups. Studies performed by Lee *et al*.[17] and Alley *et al*.[24] demonstrated no difference in motor block characteristics between levobupivacaine and bupivacaine.

We observed lesser percentage of patients with complete motor block in levobupivacaine group when compared with bupivacaine group. This was probably because levobupivacaine is less potent than bupivacaine. In the study of Camorcia *et al*.,[8] the potencies for motor block of intrathecal ropivacaine, levobupivacaine, and bupivacaine were compared, and weaker motor block potency and shorter duration of motor block were reported with levobupivacaine group. Dar *et al*.[23] also observed that regression time of motor block was significantly lesser in levobupivacaine group correlating with this study.

No clinically significant changes were observed in hemodynamic parameters (heart rate, mean blood pressure, peripheral oxygen saturation) throughout our study, and complications (hypotension, bradycardia, PONV, pruritus, shivering) were minimal and comparable in both groups. This may be related to usage of low doses of local anesthetics.[16]

There are certain limitations to our study. The sample size taken is small. Its implementation to a larger population group will need further research. In addition, since levobupivacaine was made hyperbaric by addition of 5% dextrose, whereas bupivacaine taken had 8% dextrose, the difference in the spinal characteristics may have been in part related to the difference in dextrose concentrations.

Conclusion

To conclude, 7.5 mg of hyperbaric levobupivacaine in addition to 25 mcg fentanyl provides adequate level of sensory blockade, with significantly lesser duration of motor blockade and longer duration of analgesia compared with similar dose of hyperbaric bupivacaine with the only disadvantage of delayed onset of sensory block. In addition,

low-dose levobupivacaine leads to a better hemodynamic profile compared with similar doses of bupivacaine. Thus, low-dose levobupivacaine plus fentanyl may be a better alternative to bupivacaine plus fentanyl owing to its longer duration of sensory block, good postoperative analgesia, and lesser degree and shorter duration of motor block allowing early ambulation and faster discharge.

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Conflicts of interest

There are no conflicts of interest.

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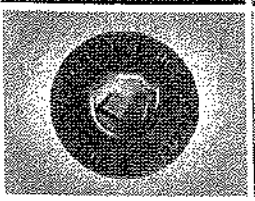

Comparison of intrathecal dexmedetomidine and buprenorphine as adjuvant to 0.5 % hyperbaric bupivacaine in spinal anaesthesia for orthopaedic surgery

KEYWORDS: bupivacaine, hyperbaric, dexmedetomidine, buprenorphine, orthopaedic, spinal, anesthesia

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ABSTRACT *Aims of Study : The aim of the study was to compare Intrathecal dexmedetomidine (Group D) and buprenorphine (Group B) in spinal anaesthesia for orthopaedic surgery in terms of onset and duration of sensory and motor block, haemodynamic parameters, post operative analgesia and side effects, if any.*

Methods : This comparative, randomized, double blind study was conducted in seventy patients scheduled to undergo elective orthopaedic lower limb surgeries. Group D (n=35) received 15 mg(3 ml) of 0.5 % hyperbaric bupivacaine + 5 mcg of dexmedetomidine + Normal saline to make the total volume 3.5 ml while Group B (n=35) received 15 mg(3 ml) of 0.5 % hyperbaric bupivacaine + 60 mcg of buprenorphine + Normal saline to make the total volume 3.5 mL Onset and duration of sensory and motor block, total duration of analgesia, hemodynamic parameters, post operative VAS score, number of rescue analgesics required and adverse effects were noted.

Results: There was no significant difference in sensory and motor block onset between 2 groups but significantly prolonged duration of sensory and motor block, and post operative duration of analgesia was seen in group D as compared to group B. Significantly reduced number of rescue analgesics were required in group D. Both groups were comparable in terms of hemodynamic parameters and no significant adverse effects were observed in both groups.

Conclusion : It was concluded that 5 µg dexmedetomidine as adjuvant to 0.5 % hyperbaric bupivacaine in spinal anesthesia provided prolonged duration of sensory and motor blockade and longer duration of analgesia and stable hemodynamic profile as compared to 60 µg buprenorphine.

INTRODUCTION

Spinal anesthesia is commonly employed technique for orthopaedic lower limb procedures and provides effective analgesia in early post operative period. Various adjuvants have been added to spinal local anaesthetic to prolong post operative analgesia.[1] Neuraxial adjuvants are utilised to increase the speed of onset of neural blockade (reduce latency), improve the quality and prolong the duration of neural blockade and for their dose sparing effects [2]. Buprenorphine is a mixed agonist – antagonist narcotic with high affinity at both mu (µ) and kappa opiate receptors. Lanz et al [3] demonstrated that buprenorphine is compatible with CSF and has no adverse effects when administered intrathecally. Intrathecal α2 receptor agonists have antinociceptive action for both somatic and visceral pain [4]. α2 receptor agonists administered intrathecally prolonged the analgesia provided by subtherapeutic doses of local anaesthetics like bupivacaine due to synergistic effects with minimal haemodynamic effects[5,6].

This study was aimed to compare the dexmedetomidine and buprenorphine as adjuvant in terms of onset and duration of sensory and motor block, haemodynamic parameters, post operative analgesia and side effects, if any.

METHODS:

After obtaining due permission from the institutional ethical committee and written informed consent from the patients, this hospital based, comparative, randomized , double blind study was conducted in seventy patients. Patients of ASA physical status I – II, age ranging between 30-50 years, height between 150-180 cm, who were scheduled to undergo lower limb elective surgeries. Patients with uncontrolled hypertension, infection at the injection site, disorders of coagulation, history of headache, reluctance to the procedure, neurologic disease or hypersensitivity to amide local anesthetics or dexmedetomidine and buprenorphine, were excluded from the study.

All patients underwent a thorough pre anesthetic checkup and were kept fasting overnight before the procedure. All routine monitoring were attached and preoperative baseline readings of Non Invasive Blood Pressure, Pulse Rate and Oxygen saturation were noted.

A good IV line was secured with 18G cannula and Ringer Lactate infusion was started. Patients were randomly allocated to two groups using chit in the box method. This trial was so planned that neither the doctor nor the participant was aware of the group allocation and the drugs received. Concept of VAS score was explained to patients.

Group D (n=35) received 15 mg(3 ml) of 0.5% hyperbaric bupivacaine + 5 mcg of dexmedetomidine + Normal saline to make the total volume 3.5 ml while Group B (n=35) received 15 mg(3 ml) of 0.5% hyperbaric bupivacaine + 60 mcg of buprenorphine + Normal saline to make the total volume 3.5 ml. The solutions were prepared by the anesthesiologist blinded to the study. Under all aseptic precautions, spinal anesthesia was performed in the operating room at the L3 – L4 or L2 – L3 interspace, with the patient in the sitting position. A volume of 3.5 ml was injected slowly through a 25-gauge spinal needle.

Intraoperative vitals (blood pressure, pulse rate, saturation) were recorded at 2,5,10,15,20,30,40,50,60 min interval and post operatively at 2, 4, 6, 8, 24 hr interval.

Onset of sensory block and motor block was noted using Modified Bromage score (0 : Able to move the hip, knee and ankle, 1 : Unable to move the hip but is able to move the knee and ankle, 2 : Unable to move the hip and knee but is able to move the ankle, 3 : Unable to move the hip, knee and ankle)

"Motor block duration" was recorded as time to complete termination of motor block.

"Maximum motor block level" was recorded as highest motor block

scale (Bromage score) that was reached.

Following side effects were recorded:

- Hypotension (MAP < 60 mmHg or greater than 20% below the baseline)
- Bradycardia (Pulse < 50/min)
- Respiratory depression (oxygen saturation less than 90%)
- Pruritus

Episodes of intra-operative hypotension were managed with intravenous fluids and if required, with bolus doses of inj. mephenteramine 6 mg intravenously. Bradycardia was treated with 0.01 mg/kg of inj. atropine intravenously. Intra-operative nausea and pruritus,if any, were planned to be treated using ondansetron and antihistaminics respectively.

Total duration of analgesia was defined as time from intrathecal administration of drug to patient's demand of rescue analgesic. It was recorded following pain scoring system - Visual analogue score. Patient's VAS>3 and administration of rescue analgesia constituted the end point of the study. Inj. diclofenac (75mg) IM was given as rescue analgesic.

STATISTICAL ANALYSIS:

The sample size was calculated 35 for each group at alpha error 0.05 and power 80 percent.

Statistical assessment of data was done by using SPSS Statistical software (ver. 17.0) Within group, paired t-Test and between groups, student t-Test were applied. For significance in difference in proportion of cases with complications, Chi - Square test of significance was applied. A value of <0.05 was considered significant and <0.001 was considered highly significant. Data were expressed as mean ± standard deviation (SD) or median (range) or number of patients (n) or percentage (%).

RESULTS:

A total of 70 patients were enrolled in the study and randomly assigned equally to one of two studied groups. The two groups were comparable with respect to age, gender, height, ASA grade. (Table 1,2)

Table 1

	Group-B		Group-D		P-Value between groups
	Group-B	SD	Group-D	SD	
Age (yrs)	40.3	6.6	38.6	4.8	0.2258
Height (cm)	158.3	4.3	160.3	5.7	0.1075
ASA	1.0	0.0	1.0	0.0	Not Significant

Table 2

	GROUP B	GROUP D
MALE	32	31
FEMALE	3	4
TOTAL	35	35

Characterstics of spinal anaesthesia: (Table 3)

Sensory and motor block onset were comparable in both groups with p value >0.05 (insignificant). Duration of sensory block and motor block was longer in group D than group B (p<0.001) and the difference was highly significant. Duration of analgesia was significantly longer in group D than group B (p<0.05).(Fig 1) Lesser number of rescue analgesics were required by the patients in dexmedetomidine group as compared to buprenorphine group. (Fig 2)

Fig 1. Duration of analgesia

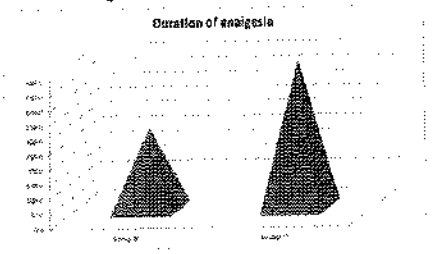


Fig 2. Number of rescue analgesics

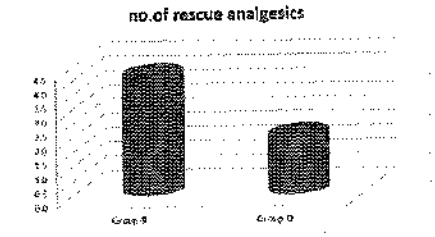


Table 3. Characteristics of spinal anaesthesia

	Group-B		Group-D		P-Value between groups
	Group-B	SD	Group-D	SD	
Onset in sensory block(minutes)	3.3	0.9	3.5	1.0	0.5289
Onset in motor block (minutes)	3.7	0.8	3.8	0.9	0.4724
Duration of sensory block (minutes)	223.9	36.9	449.8	27.7	0.0000
Duration of motor block (minutes)	199.8	35.9	398.8	20.2	0.0000
Duration of analgesia (minutes)	275.9	38.9	499.8	28.0	0.0000
Number of rescue analgesics	4.1	0.9	2.0	0.7	0.0001

Intraoperative and postoperative hemodynamic changes:

Both groups were comparable with respect to heart rate and mean arterial blood pressure values over different time intervals. (Fig.3,4) No significant difference was found between the two groups regarding fall in Mean Blood Pressure at different time intervals.

Fig 3. Trends of pulse rate in both groups.

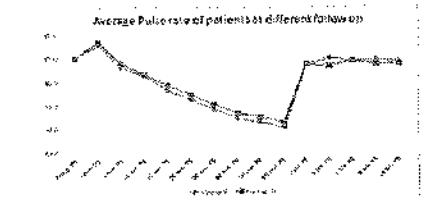
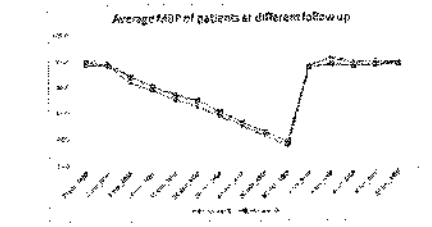


Fig 4. Trends of Mean Arterial Pressure in both groups.



Complications

There was no significant difference in the incidence of side effects

(e.g. hypotension, bradycardia, nausea, vomiting, shivering, pruritus) in both groups (p>0.05) In group D 34.3 % patients and in group D 37.1 % patients showed hypotension (Table 4)

Table 4. Percentage of patients showing hypotension.

Hypotension	Group B		Group D		P value
	Number	Percentage	Number	Percentage	0.803
Yes	13	37.1	12	34.3	
No	22	62.9	23	65.7	
	35	100.0	35	100.0	

DISCUSSION

70 patients of similar demographic profile and ASA physical status1 and 2 were studied. Using 5 mcg dexmedetomidine provided longer duration of analgesia,sensory and motor blockade as compared to the use of 60 mcg of buprenorphine when added to 15 mg 0.5% hyperbaric bupivacaine.

Different agents have been used as adjuncts for prolonging the duration of spinal anaesthesia. Al - Ghanem et al.'s[13] study concluded that 5mcg dexmedetomidine seems to be effective as adjuvant to spinal bupivacaine in surgical procedures and provided adequate post operative analgesia. Therefore dexmedetomidine in a dose of 5 mcg was used in the present study.

Narcotics co administered with local anaesthetics intrathecally have a potent synergistic effect[14] . Buprenorphine is a centrally acting partial opioid agonist and has both spinal and supraspinal component of analgesia. Added to Bupivacaine intrathecally, it improved the quality and duration of postoperative analgesia compared to Bupivacaine alone.[15]. Shaikh et al. showed that 1 µg/kg Buprenorphine to a maximum of 50 µg when added to 15 mg of 0.5% heavy Bupivacaine intrathecally provides analgesia for 476.6±93.7 minutes.[16] .So in present study, buprenorphine in the dose of 60 mcg was used.

The duration of analgesia in buprenorphine group in present study was found to be 275.9 minutes which is lesser than the results observed by Capogna et al.,[17] where the duration of analgesia was 430 minute in the buprenorphine group. This could be because Capogna studied elderly patients. In present study,we found that the duration of analgesia in the dexmedetomidine group was 499.8 minutes. This is comparable with studies done by Shah et al.[18], where 5µg dexmedetomidine had a duration of analgesia 474 minutes. Duration of analgesia was significantly prolonged with the addition of 5µg dexmedetomidine to 478 minutes in the study done by Gupta et al[19]. In a similar study done by Nayagam et al[20], the duration of analgesia after addition of 5 mcg of dexmedetomidine was found to be 8.20 +/- 2.78 hrs which is found to be in resonance with our results.Study done by Eid et al.[11], showed that duration of analgesia with dexmedetomidine is proportional to its dose.

The onset of sensory and motor block in present study was comparable with the studies done by Shukla et al.,[12] and Shaikh and Kiran [16] for dexmedetomidine and buprenorphine respectively. The onset of sensory block in buprenorphine group according to a study done by Fauzia A. Khan et al [15] showed it to be 4.3 +/- 1 min where they used a buprenorphine dose of 30 mcg. The duration of sensory block in present study was 223.9 min in Buprenorphine group and 449.8 min dexmedetomidine group. Similar results have been shown in the study done by Mahima Gupta et al. [19]

The duration of motor block in present study was 398.8 minutes in the dexmedetomidine group which is comparable with the studies done by Gupta et al.,[19] where duration of motor block was 421 minutes.In a study done by Yektas et al [21], the duration of motor block with dexmedetomidine was found to be 226.5 min. This is probably because a lower dose of dexmedetomidne, 4mcg, was used in their study. The duration of motor block is significantly prolonged in comparison to duration of motor block in the buprenorphine group, 199.9 minutes which is in accordance with the study done by Mahima Gupta et al[22]

α2-adrenoceptor agonist bind to pre-synaptic C-fibres and post-synaptic dorsal horn neurons. Their analgesic action is due to depression of the release of C-fibre transmitters and by hyperpolarisation of post-synaptic dorsal horn neurons.[23] It may be an additive or synergistic effect secondary to the different mechanisms of action of the local anaesthetics and the α2-adrenoceptor agonist as studied by Salgado et al. [24] This antinociceptive effect may explain the prolongation of the sensory block when added to spinal anaesthetics. The prolongation of the motor block of spinal anaesthetics is due to the binding of α2-adrenoceptor agonists to motor neurons in the dorsal horn.[25,26]

A trend of decrease in pulse rate was observed in both the groups after the subarachnoid block was performed. But none of the patients in present study needed any intervention in the form of iv atropine throughout the surgery. This is in accordance with the study done by Dixit et al [27] where no case of bradycardia was seen in the buprenorphine group. In a study conducted by Mahmoud M. Al-Mustafa et al [28] only 1 case of bradycardia was reported when a 5 mcg dose of dexmedetomidine was used while no case of bradycardia was seen when a dexmedetomidine dose of 10 mcg was used and this supports the results of present study. Dexmedetomidine causes bradycardia but the effect is more prominent when administered intravenously and with a higher dose[29].

A trend of decrease was observed in the MAP readings in both the groups of present study. Hypotension was observed in 13 patients in buprenorphine group and 12 patients in dexmedetomidine group. The fall in MAP observed in the Dexmedetomidne group is similarly shown in the study conducted by Nayagam et al [11]. The fall in MAP observed in the Buprenorphine group is similarly shown in the study done by Fauzia A. Khan et al[15]. Sedation scores for dexmedetomidine were observed in a study done by Rajni Gupta et al [18] This action of dexmedetomidine is attributed to its action on the α-2 receptors in locus ceruleus. Sedative effects of Dexmedetomidine are prominent when given as intravenous bolus, continuous infusion, or Intramuscular injections[27].

Lesser number of rescue analgesic doses were required by the patients in dexmedetomidine group (2+/- 0.7) as compared to buprenorphine(4.1+/-0.9). Gupta et al[14] also concluded that after addition of dexmedetomidine 5 mcg to ropivacaine,less number of rescue analgesics were required in the first 24 hrs. The α-2 adrenergic agents also have antishivering property as observed by Talke et al.,[28] but no incidence of shivering was found in both the groups in present study. No incidences of nausea, vomiting, respiratory depression were observed in any of the patients in present study. Buprenorphine is partial agonist with high molecular weight and lipophilic, which may prevent its rostral spread and thus respiratory depression, prolongs the duration of sensory block and hence decreases the need for postoperative analgesia [29]. It was concluded that, the onset of sensory and motor blockade with both dexmedetomidine and buprenorphine were comparable. The duration of motor and sensory block in dexmedetomidine group was significantly longer as compared to buprenorphine group. Similarly duration of analgesia was also significantly longer in dexmedetomidine group as compared to buprenorphine group.

CONCLUSION:

Hence we concluded that intrathecal dexmedetomidine 5µg when compared to intrathecal buprenorphine 60µg caused prolonged duration of sensory and motor block and duration of analgesia. The requirement of rescue analgesia was lesser in dexmedetomidine group and the haemodynamics are similar in both the groups without causing any significant side effects.

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CASE REPORT

Use of i-gel for laser ablation of a bronchial lesion

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SUMMARY

The use of laser for airway lesions requires airway management. Usual options include special laser-resistant endotracheal tubes. The use of supraglottic devices have been described in the literature. Laryngeal mask airway carries the risk of cuff damage during the use of laser. i-gel is made of thermoplastic material and does not require air inflation and thus potentially reduce the risk of cuff rupture. i-gel use in laser surgeries has not been described in the literature. We present successful airway management in laser surgery for bronchial tumour using i-gel.

BACKGROUND

Light amplification by simulated emission of radiation (laser) has been used for treatment of benign (colon and rectal polyps) and malignant conditions (head and neck cancers, lung cancer, liver tumours). The use of laser for airway lesions requires anaesthesia and a secured airway. Various options for securing the airway include laser-resistant endotracheal tubes, wrapped tubes and jet injector. Laryngeal mask airway (LMA) has also been described for airway management.[1] LMA allows uninterrupted ventilation along with the use of fibreoptic bronchoscope through it.[1 2] In spite of the benefits, LMA carries the potential risk of cuff damage during laser use leading to inadequate ventilation and thus risk of hypoxia. i-gel has the specific advantages of non-inflatable cuff and the possibility of tracheal intubation through it, if required. Until now, i-gel use in laser surgeries has not been described in the literature. We describe successful airway management in laser surgery for bronchial laser ablation of a lung tumour using i-gel. Written consent was taken for publication of this case from the patient.

CASE PRESENTATION

A 61-year-old man presented with chief complaints of cough, haemoptysis and fever since 1 year. Contrast enhanced CT scan revealed heterogeneously enhancing mass lesion in lingular lobe of left lung, upper lobe collapse and multiple enhancing mass lesions in both lobes of liver. Positron emission tomography CT findings revealed somatostatin expressing disease in left upper lobe bronchus and liver metastasis. Flexible video-bronchoscopy performed under local anaesthesia revealed left upper lobe occluded by a vascular tumour along with purulent secretions. Bronchial washings confirmed the diagnosis of neuroendocrine tumour of left upper lobe bronchus.

DIFFERENTIAL DIAGNOSIS

In view of respiratory distress caused by proximal bronchus obstruction by tumour mass, laser debulking of tumour was planned. Pulmonary function test demonstrated moderately restrictive defect.

TREATMENT

In the bronchoscopic suite, after securing the intravenous access, intravenous hydrocortisone 100 mg was administered. Standard monitors including 5-lead ECG, pulse oximeter (SpO_2) and non-invasive blood pressure were attached. The patient was preoxygenated with 100% oxygen for 5 min at a flow rate of 15 L/min in 40° head up position. Anaesthesia was induced in head up position (40°) using intravenous fentanyl 100 µg, propofol 100 mg and rocuronium 60 mg. A continuous intravenous infusion of propofol 200–300 µg/kg/min was started. Lungs were ventilated using positive pressure ventilation. Three minutes later, rigid bronchoscope was inserted. On evaluation, growth was visualised in left upper lobe bronchus. Intermittent manual jet ventilation was started through side port (ventilating port) of rigid bronchoscope. Because of excessive air leak from and around the rigid bronchoscope, ventilation was ineffective. The pulmonary interventions of laser ablation required period of apnoeas and low inspired fraction of oxygen (FiO_2). So the ventilatory strategy was required to be changed. We modified our plan to perform ventilation through i-gel (supraglottic airway device) and perform laser ablation of tumour by inserting laser probe through flexible fibreoptic bronchoscope which is in turn inserted through the i-gel using an swivel connector (figure 1). I-gel (figure 2) of size 4 was inserted and positive pressure ventilation was initiated. The procedure was started with continued ventilation. During laser ablation, to minimise the risk of airway fires, FiO_2 was reduced to 0.30 and fresh gas flow was increased to 10 L to expedite clearance of oxygen in the airway. All routine laser safety precautions were followed including draping the patient with moist towels and eye pads, and antiglare glasses were worn by all the personnel. Flexible fibreoptic bronchoscopy was performed through swivel catheter mount and endobronchial neodymium-doped yttrium aluminium garnet (Nd:YAG) laser (23 W/cm^2, continuous mode) applied. During laser ablation, intermittent apnoea was provided. High-force suction was applied through bronchoscope to remove laser fumes. During desaturation episodes below 90% of oxygen saturation as assessed by SpO_2, use of laser was stopped and intermittent positive

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23 Anesthesia for Interventional Pulmonology

— *Dr. Sakshi Thakore, Dr. Sachidanand Jee Bharati, Dr. Karan Madan, Dr. Vinod Kumar*

INTRODUCTION

Interventional pulmonology is a rapidly evolving field of pulmonary medicine. The role of pulmonologists involves not only early diagnosis, risk stratification and management of lung disorders using minimally invasive techniques but also palliative procedures for inoperable and long standing diseases and their complications. The need of advanced bronchoscopic and pleuroscopic techniques for the diagnosis and treatment of a wide spectrum of thoracic disorders has increased in recent past.[1-4] Many of these procedures can be performed without anesthesia but others require varying levels of anesthesia ranging from local anesthesia to conscious sedation under monitored anesthesia care (MAC) for short and simple procedures to general anesthesia for complex and long duration procedures.

INTERVENTIONAL PULMONOLOGY SUITES

Disease processes requiring interventional pulmonology include complex airway pathologies, benign and malignant central airway obstruction, pleural diseases, and pulmonary vascular procedures.[5] Central airway obstruction (CAO) is a common clinical condition that leads to significant morbidity and mortality. CAO refers to obstruction in trachea and mainstem bronchi resulting from malignant or non malignant causes. The most common cause of malignant CAO is direct extension from an adjacent tumor most commonly bronchogenic carcinoma, followed by esophageal and thyroid carcinoma. The nonmalignant causes include infection, trauma, granulation tissue, vascular lesions and other entities like Sarcoidosis, Wegner's Granulomatosis, lymphadenopathy, tracheomalacia, post intubation tracheal strictures and bronchomalacia.[6]

Diagnostic and therapeutic procedures pertaining to these suites include, but are not limited to, rigid bronchoscopy, transbronchial needle aspiration (TBNA), endobronchial ultrasound (EBUS), transthoracic needle aspiration and biopsy, laser bronchoscopy, endobronchial electro surgery, argon-plasma coagulation, cryotherapy, airway stent insertion, balloon bronchoplasty and dilatation techniques, endobronchial radiation (brachytherapy), photodynamic therapy, percutaneous dilatational tracheotomy, transtracheal oxygen catheter insertion, medical thoracoscopy, and image-guided thoracic interventions (Table 1)

Table 1: Interventional Procedures Organized by Disorders of the Chest[12]

Central Airway Obstruction	Diagnosis of Pulmonary Lesions	Artificial Airway	Pleural Disease
Mechanical Debulking / Dilation o Flexible bronchoscopy o Rigid bronchoscopy o Microdebridement o Airway Dilation o Stent placement Metallic vsSilicone **Ablation Therapies** o Endobronchial laser (Nd:YAGvs YAP) o Argon Plasma Coagulation (APC) o Electrocautery o Cryotherapy o Brachytherapy o Photodynamic therapy (PDT)	**Peripheral Lung Lesion** o Transthoracic Needle Aspiration / Biopsy (TTNA) o Electromagnetic Navigational Bronchoscopy o Radial Endobronchial Ultrasonography **MediastinalAdenopathy** o Transbronchial Needle Aspiration / Biopsy (TBNA) o Linear Endobronchial Ultrasonography **Early Detection of Lung Cancer** o Autofluorescence bronchoscopy o Narrow band imaging o Confocal bronchoscopy	o Percutaneous tracheostomy o Minitracheostomy o Transtracheal oxygen catheter	o Medical pleuroscopy and pleurodesis o Indwelling pleural catheter o Thoracic ultrasonography

Anesthesia for Interventional Pulmonology

Introduction:

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Need of Anesthesia:

The field of interventional pulmonology involves diagnostic as well as therapeutic approaches. Whether there is need of anesthesia or not, it is usually decided by the pulmonologist and depends on the operators experience and level of comfort with a particular technique. It depends upon many factors which include type of procedure, its complexity and duration, patient's general condition and associated co-morbidities, patient's level of cooperation and consent. Anesthesia had not been discovered at the time when the rigid bronchoscope was discovered in 1865 by Dr. Killian (7), and the procedure was performed in conscious patients. In 1884, cocaine was introduced (first local anesthetic) which improved patient's comfort as well as physician's

methodology. But the effectiveness of local anesthetic is limited by its absence of anti anxiety properties and incomplete patient satisfaction [8,9]. Moreover, local anesthetics can't be used repeatedly for prolonged procedures because of possible toxicity with high doses. Conscious sedation with anti anxiety and/or analgesic drugs, alone or in combination with local anesthesia, has become the preferred method of anesthesia for routine outpatient diagnostic bronchoscopy procedures[10]. However, there is wide variation in drug doses required to achieve the desired effect. Complications related to conscious sedation are also variable and include prolonged period of amnesia, hypoventilation, hypoxemia, loss of airway patency, and hemodynamic instability [11]. As the field of interventional pulmonology is expanding, general anesthesia is emerging as a safe technique in patients undergoing long duration and technically complex procedures especially in patients with severe comorbidities and compromised central airway.

Anesthetic Challenges:

Although procedures requiring GA are performed in OR, many of the procedures performed through flexible bronchoscope in diagnostic bronchoscopy are carried out outside operating rooms. Many of the patients planned for an IP procedure are high risk patients either because of underlying lung condition or presence of co-morbidities. Secondly, anesthesia for interventional pulmonology requires sharing of airway with pulmonologist, the dynamic nature of the procedure given the continuously changing airway, fraction of inspired oxygen (FiO2) and finally, the ventilation mode to accommodate the procedure being performed. All these represent a unique challenge to the anesthesiologist. The anesthesiologist needs to be familiar with the different IP procedures (Table 1) and needs to develop an anesthetic and airway management plan specific for these airway interventions especially in high-risk patients.

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Coagulation (APC) o Electrocautery o Cryotherapy o Brachytherapy o Photodynamic therapy (PDT)	Endobronchial Ultrasonography **Early Detection of Lung Cancer** o Autofluorescence bronchoscopy o Narrow band imaging o Confocal bronchoscopy		

Preoperative Evaluation:

Preoperative evaluation has several important considerations. Important facts to consider are whether the procedure is elective or emergent and how stable the airway is. In elective cases, preoperative assessment is usually conducted with special attention to the following:

• Evaluation of airway, symptoms of compromise: dysphagia, hoarseness, orthopnea, stridor, the use of accessory muscles of respiration

• Review of the pulmonologist's notes on the size, extent and location of the lesion or tumor and the intended procedure(s).

• Review of computerized tomographic scan of the neck and chest to find out extent of airway obstruction and presence of any mediastinal masses.

•Review of pulmonary function tests (if available), extent of obstruction/restriction. In patients with significant airway compromise or respiratory distress, PFT's are usually not performed.

- Flow volume loop is simple and readily available tool to assess any form of airway obstruction. Special attention should be focused on inspiratory curve to suspect upper or central airway obstruction. However, clinician should comment on serial and repeatable inspiratory curve abnormalities as isolated abnormal inspiratory curve may suggest poor inspiratory effort rather than CAO.[13] Another limitation of flow volume loops is that characteristic blunting of flow volume loops can not be appreciated until tracheal lumen has narrowed to <8mm (≥ 80% tracheal narrowing).[14]

- Most studies have demonstrated low sensitivity of morphological criteria, but quantitative criteria has shown to have high sensitivity and high specificity in detecting CAO. Two ratios: a) Mid-vital capacity ratio (FEF50%/FIF50%) ≥ 1 and b) Empey's index which is the ratio of forced expiratory volume in 1s (FEV_1) and peak expiratory flow (PEF); (FEV1/PEF) ≥ 8 $mL \cdot L^{-1} \cdot min^{-1}$ are associated with the location, type and degree of central airway obstruction. Therefore, quantitative evaluation is extremely important to assess CAO.[15,16]

• Prior chemotherapy and any effects on vital organs (especially the heart and lungs)

• Commonly associated conditions, such as heavy smoking, tobacco chewing and alcohol use

• Common comorbidities: coronary artery disease, chronic obstructive/restrictive pulmonary disease, chronic alcoholism, malnutrition and aspiration pneumonitis.

Premedication:

In presence of significant airway obstruction, premedication with sedatives and anxiolytics should be minimized as many of these are known to have respiratory depressant effects. International guidelines suggest benzodiazepines to be the preferred agent for sedation during flexible bronchoscopy because of their favorable benefits of sedation, anterograde amnesia, decreased patient anxiety, improved tolerance of procedure, willingness of patients to undergo a repeat procedure, and improved working conditions for physicians.[17] Among benzodiazepines, midazolam is the most commonly used owing to its quick onset of action, rapid peak effect, and relatively short duration. Dose recommended for midazolam is 0.06 to 0.07 mg/kg according to International guidelines.[17] However, midazolam premedication must be carefully considered in hypoxemic critically ill patients because of persistent drowsiness and episodes of desaturation [18]

Atropine and glycopyrrolate have been used as premedication in bronchoscopic procedures because of their potential effects including drying of secretions to allow better examination of the tracheobronchial tree, protection against vasovagal reaction and bronchospasm. They also improve pulmonary function when given prior to bronchoscopy by either IV or IM route, however, this sustained effect is not seen through the post bronchoscopy period. [19,20] International guidelines have discouraged their use because of no clinically significant improvement in lung function or drying of bronchial secretions with atropine or glycopyrrolate. [17] In view of the available evidence, their use cannot be recommended at present.

Many clinicians use corticosteroids, particularly dexamethasone, as a premedication to decrease airway edema after airway surgery prophylactically. Common scenario when steroids may help reduce postoperative vocal cord edema include: cases where there are multiple attempts of insertion and removal of flexible fiberoptic bronchoscope (alone or through an LMA and in the absence of ETT), leading to friction of bronchoscope against the vocal cords, or prolonged continuous use of rigid bronchoscope. There is literature supporting the prophylactic administration of IV steroids in a multidose regimen before planned extubation in decreasing the global incidence of laryngeal oedema and subsequent need for reintubation, with minimal adverse events.[21] However, other studies have shown prophylactic administration of steroids to be ineffective in reducing airway edema. [22] But, evidence of the real advantage of steroids is still controversial. During central airway interventions with rigid bronchoscope, we usually administer parenteral steroids to reduce the likelihood of laryngeal edema.

Anesthetic management of cases depends on the specific procedures and the patient's pathophysiology. Various planning issues deserve individualized consideration including:

- Location (OR vs Out-of-OR suite)
- Depth (sedation vs GA)
- Ventilation (spontaneous, intermittent apnea, Positive pressure ventilation, jet ventilation, etc.)
- TIVA vs Inhalation
- Plan for Fire Prevention and Response (if laser or electrocautery used)

- Plan for Distal Airway Obstruction (tumor, folded stent, extrinsic compression, etc)
- Plan for Massive Hemoptysis

Anesthetic management of commonly performed procedures:

1. RIGID BRONCHOSCOPY

Rigid bronchoscopy (RB) was initially performed under local anesthesia. Today, general anesthesia and appropriate ventilation method are recommended. The main indication for rigid bronchoscopy is the diagnostic and treatment of intra- and/or extraluminal obstruction of the airway. The beveled tip can help pass obstructing tumors in the airway and the large working channel can allow for passage of debrider instruments, laser equipment, balloons, stents and valves. The following interventional pulmonology techniques are usually employed through the rigid bronchoscope:

1.1) Tracheobronchial stenting:

Stent is a commonly employed procedure for the treatment of central airway obstruction. Currently, metallic stents are only licensed for malignant conditions, On July 29, 2005, the US Food and Drug Administration (FDA) issued a Public Health Notification recommending against the use of both covered and uncovered self-expanding metallic tracheal stents for benign lesions unless absolutely necessary. However, unlicensed use of stents has increased significantly because of either significant morbidity associated with other therapeutic options or exhaustion of other options. (Table 2)

Table: 2 Indications for stents Placement [23,24]
o Lung Cancer: small cell, non-small cell, metastatic, lymphoma
o Carcinoma esophagus
o Tracheobronchomalacia: Considered when patients are symptomatic and airway collapse > 60%
o Tracheo-oesophageal and bronchopleural fistulae
o Strictures: postintubation, post-traumatic
o Post anastomotic: tracheobronchial resection; heart, lung transplantation
o Inflammatory/Fibrous stenoses: post intubation, post-tuberculous, granulomatosis with polyangiitis, amyloidosis
o Laryngeal web/atresia
o Extrinsic compression: neoplastic, vascular oesophageal stenting, kyphoscoliosis, iatrogenic obstruction

The Montgomery T-tube was the first successful airway stent described in 1960s, which was designed for stenting the airway after repair of stenosis in the subglottic region. [25] It involved an external side limb protrusion through a tracheostomy. The first straight Intratracheal silicone

stents without side limbs were inserted in 1965 by Anderson and Egnud. [26] In 1990, Dumon presented the first distal airway stent which was used in the treatment of external compression of the main airway. [27] The Dumon stents were made of molded silicone and were relatively easy to place. These prevent tumor in-growth and cause minimal local tissue inflammation.
Broadly stents are divided into four categories [28] :
a) Silicone stents such as the Dumon stent or the Polyflex stent;
b) Metallic stents such as the Palmaz stent or the uncovered Wall stent
c) covered metallic stents such as the covered Ultraflex stent
d) hybrid stents such as the Dynamic stent (silicone stent with metallic rings)

Currently, Silicone (Dumon-type) stents are most popular and most frequently used worldwide. Their placement results in rapid relief of respiratory symptoms. They result in lesser inflammatory response and are easier to remove. Therefore, they can be deployed in any benign and malignant condition where expected survival is > 6months as well as palliation of critical respiratory obstruction.[29]They can be used for stenting of any structural stenosis of the trachea or bronchi except for tracheobronchomalacia. However, the silicon stents can only be deployed through a rigid bronchoscope and prior to their deployment, the airway needs to be dilated to a sufficient degree. They are predisposed to migration and have a smaller internal diameter to a similarly sized metal stent. This is one of the major limitations to the use of silicon stents as compared with metallic airway stents.

Metallic stents are self-expanding and made of metal (nitinol – nickel titanium alloy) in a mesh structure, which can be either uncovered or covered with silastic or polyurethane. Metallic stents with uncovered mesh become epithelialized after about 8 weeks. There is also high chance of tissue re-growth through the mesh leading to re-obstruction. Other complications include stent fracture, granulation formation and secretion inspissation. Metal stents can be deployed through both rigid or fiberoptic bronchoscope but are difficult to remove. They are primarily indicated in malignant conditions where predicted survival is limited.[24,29]

Anesthetic management:

Preoperative evaluation: Underlying lung condition affects the anesthetic management of the patient. Stent placement for the relief of an obstructed airway (tumor, stricture or stenosis) results in release of copious thick or even purulent secretions. Tracheobronchomalacia can become more severe when stenting induces frequent coughing episodes. Coughing and movement during procedure may result in total airway obstruction or worsening of SVC obstruction. Therefore, such issues should be anticipated and need of post operative ventilation should be explained to the patients beforehand.
Monitoring: Routine monitoring should be performed which include electrocardiography, non-invasive blood pressure, pulse oximetry and neuromuscular monitoring. Capnography is not reliable owing to inadequate ventilation. Alternatively, transcutaneous CO2 measurement, intermittent blood sample analysis through an eventual arterial line, aspiration of CO2 through the injector of HFJV after having provoked apnea may be used.[30,31] Depth of anesthesia monitoring is useful, as there is risk of intraoperative awareness during interventional RB.[32]

Anesthetic technique: Intravenous (IV) induction alongwith muscle relaxant provides the best operating conditions. TIVA is preferred over inhalational technique because it ensures continuous controlled delivery of anesthetic agent compared to an inhalation anesthetic-based technique even when there are ventilation leaks occur around the rigid bronchoscope [33]. It prevents operating room pollution by inhalational anesthetic agents and also avoids the risk of sedating operating room personnel. Propofol 100–200μg/kg per min and remifentanil 0.1–0.3mg/kg per min or fentanyl infusions 0.015-0.025 mcg/kg/min can be administered. Succinylcholine 1-1.5 mg/ kg can be administered in order to facilitate the passage of the rigid bronchoscope. Dexmedetomidine infusions have also been employed in pediatric rigid bronchoscopy in randomized controlled trials and it provides adequate anesthesia with less coughing and minimal respiratory depression or hemodynamic instability [34]. A maintenance dose of a nondepolarizing muscle relaxant, such as rocuronium 0.3-0.45 mg/kg or atracurium 0.08-0.1 mg/kg or vecuronium (0.04–0.06 mg/kg) IV repeated PRN, helps to maintain adequate levels of relaxation [35]. The 'pressor response' to rigid bronchoscopy can be attenuated, by the use of short acting agents like remifentanil/ fentanyl/ esmolol/ lignocaine. However, it critically narrowed airway, muscle relaxant administration should be considered very cautiously. In case of operator inexperience, muscle relaxant administration should preferably be avoided until a patent airway has been secured.

Ventilation strategy: The methods of ventilation [36] that are available include:

A) Apneic oxygenation

B) Spontaneous assisted ventilation

C) Controlled ventilation (closed system)

D) Manual jet ventilation

E) High-frequency jet ventilation (HFJV).

A) Apneic oxygenation: Some designs of rigid bronchoscopes feature a port on the direct conduit orifice, allowing intermittent airway instrumentation during apnea followed by instrument removal, sealing the port and positive pressure ventilation either manually or with a standard "anesthesia" ventilator delivering fresh gas via an anesthesia circuit connected to the side port. This technique relies on preoxygenation of the patient with 100% FIO2 with a brief period of time used to perform an intervention, followed by removal of the instruments from the bronchoscope and capping the proximal end, enabling the anesthetist to ventilate the patient. Given the limitations of this approach, apneic oxygenation has largely been abandoned by most centers except for very brief procedures in selected patients.

B) Spontaneous assisted ventilation: It is a total intravenous anesthetic technique whereby the level of sedation is closely titrated throughout the procedure to maintain spontaneous ventilation

by the patient. Supplemental oxygen is supplied through the rigid bronchoscope, and ventilation is maintained by the patient, with assistance from the anesthetist via bag ventilation attached to the rigid bronchoscope during periods of deeper sedation and apnea.

C) Controlled Ventilation (Closed System) An alternative to spontaneous assisted ventilation is controlled ventilation. In this technique, the rigid bronchoscope is used similarly to an endotracheal tube to provide inhaled anesthetic under positive pressure ventilation. This technique requires use of silastic caps on the ports of the rigid scope as well as packing the mouth with gauze to minimize air leaks from the uncuffed rigid tube. This technique can be challenging to perform due to the operating characteristics of common anesthetic equipment leading to circuit leaks and requirement of high fresh gas flows. Despite these challenges, controlled ventilation is the method of choice in some centers.

D) Jet Ventilation: Jet ventilation uses a high-pressure gas source that is applied to an open airway in short bursts via a small-bore catheter. Two modes of jet ventilation are currently available. The technique as originally described by Sanders[37] in 1967, uses a hand-operated valve (manual jet ventilation) connected to 100% oxygen and a pressure-limiting device to deliver gas to the patient at 50 psi or less with a respiratory rate usually in the range of 10 to 14 breaths/min. This mode of ventilation is especially useful in management of critical tracheal stenosis

E) High Frequency jet ventilation: The second mode of jet ventilation uses an automated system at respiratory rates substantially higher than physiologic (between 60 and 300 breaths/min, often termed HFJV) to allow for a nearly motionless operative field as well as freeing the anesthesiologist from ventilation during the procedure. The operator controls the applied pressure, respiratory rate, and inspiratory time to maintain adequate oxygenation [26]. HFJV is the most widely accepted alternative ventilation method in the context of interventional rigid bronchoscopy, creating high-quality and safe working conditions for the operator and the patient. [13] The injector catheter can be placed within the side arm of the bronchoscope. The HFJV advantages include the delivery of small respiratory volumes, often smaller than the dead space, limited movements of the diaphragm, the creation of a positive end expiratory pressure, which improves oxygenation by reducing the alveoli shunt, and the expulsion of laser generated smoke. Expiration occurs through the lumen of the bronchoscope and its surroundings The main risk of HFJV is pulmonary barotrauma, which occurs when expiration of the injected gas is impaired by upper airway obstruction. Other possible complications caused by jet ventilation include hypercapnia, hypertension, hypotension, hypoxemia and bronchospasm.

In the case of a metallic stent placement using a flexible bronchoscope, this can be done under laryngeal mask airway (LMA) or ETT in general anesthesia. The TIVA or inhalation anesthesia can be used. Sevoflurane causes least coughing and is preferred agent for this procedure. The patient may be able to breathe spontaneously during the procedure. Metallic stents can also be deployed using flexible bronchoscope without any airway conduit by experienced operators.

Complications: In cases of anterior mediastinal mass, there can be cardiovascular collapse at the time of induction or when the patient is made supine, because of tracheal obstruction. [5] Others include perforation of the airway (causing pneumothorax or pneumo mediastinum), airway obstruction caused by a malpositioned stent or edema and dissemination of pneumonia after relief of an obstruction in case of presence of localised distal infection. [38]

1.2) **Tissue resection and removal**: It includes Transbronchial Needle Aspiration (TBNA), line washings, lavage, debridement, resection, excision, and cauterization and cryoablation. The common aim of the removal of tissue is to relieve the obstruction or cancer or the acquisition of tissue to make a diagnosis. All of these techniques share the common complications of bleeding and perforation in the form of subcutaneous emphysema, pneumothorax or pneumomediastinum. Air can also embolize into the vascular system.

The type of technology used to manipulate tissues can determine the potential complications as well. Electrocautery can pose as a risk to the operating room personnel with the vaporization of carcinogens and the aerosolization of viruses. The argon beam coagulator has been associated with venous air (or argon) emboli, some of which have been seen to reach the left heart and coronary arteries. [39] Cryoablation has affected the nerve conduction of adjacent structures such as the vagus nerve, causing bradycardia.
Radiofrequency ablation also has been associated with nerve conduction as well as with local damage to instruments in adjacent structures; such as transesophageal echocardiography probes in the distal esophagus.

Brachytherapy, which involves the local implantation of radioactive implants, can lead to delayed hemoptysis and fistula formation.

Photodynamic therapy, which relies on the increased ability of neoplastic cells to incorporate and retain hematoporphyrin compounds, uses these compounds as photosensitizing agents. When exposed to monochromatic light via multiple bronchoscopic treatments, the neoplastic cells lyse. As such, hemoptysis can result from this extensive tumor necrosis. [40]

Anaesthetic Considerations:

Most cases of tissue washings and biopsies are performed through flexible bronchoscopy and require only conscious sedation. Certain biopsies, such as fine needle aspirations that require localization using endobronchial ultrasound (EBUS), usually happen under general anesthesia, which allows for a more precise movement of the ultrasound instrument and location of the fine needle. This general anesthetic often involves an LMA with either TIVA using propofol as described above or the continuous administration of an inhalational anesthetic, such as sevoflurane in 2–3%. However, moderate sedation is an equally well established and extensively used modality for performance of both linear and radial EBUS.

Another important but infrequently encountered clinical scenario is when bronchoalveolar lavage (BAL) is employed therapeutically for pulmonary alveolar proteinosis (PAP), a procedure known as Whole Lung Lavage. The BAL in this setting requires the administration of 10–50 liters of irrigating fluid, a procedure that takes several hours. Thus, the patient is

given general anesthesia and is intubated with a double lumen tube to accomplish lung isolation. The lungs are lavaged sequentially, with the ventilating lung as the nondependent lung and with the appropriate endobronchial cuff inflated to safeguard the ventilating lung. Warmed lavaging solutions are essential to prevent hypothermia.[40]

1.3) **Dilation of tracheal stenosis:**

Usual causes of tracheal stenosis are post intubation/post tracheostomy, neoplasm, trauma, chronic inflammatory disease, collagen vascular disease (such as granulomatosis with polyangiitis) and infection. The patient with tracheal stenosis often presents with obvious dyspnea at rest, audible stridor, and use of accessory muscles for adequate ventilation. Usually, these symptoms occur after an obliteration of at least 70% of the cross-sectional area of the airway. Dilatation can be performed with smooth round dilators, gradual dilation with ventilating bronchoscopes of increasing diameter, rigid bronchoscopes of increasing diameters or dilating balloons passed through flexible bronchoscopes. [41] In severe stenosis, a wire is passed across the narrowed area followed by a balloon advanced over the wire, carefully to expand the proximal portion of the stenosis first. Complications from balloon dilation include bleeding, airway perforation and fracture. Steroids can be used to minimize edema after these dilatations. They can delay the synthesis of collagen in the early stages of scar formation. However, they can also delay wound healing and cause cartilage resorption.[42] The smallest size rigid bronchoscope should be used initially for securing the airway. Then serial dilatation can be performed by rigid bronchoscopes of increasing sizes. Electrocautery knife is also a very useful accessory for initial incisions on the stenosis. Care should be taken during any heat generating procedure in the airways like electrocautery and laser as they carry the risk of 'endobronchial ignition'. To prevent the same, FiO2 should be kept below 40% while performing these procedures.

2. **FLEXIBLE FIBEROPTIC BRONCHOSCOPY:**

Conduction of Flexible fiberoptic bronchoscopy (FFB) usually requires minimal to moderate level of anesthesia alongwith topical anesthesia. In patients with limited cardiovascular or pulmonary reserve or anticipated prolonged procedures, deep sedation or GA may be required. According to British Thoracic Society (BTS) guidelines (2001), sedation should be offered to all patients undergoing FFB when there are no contraindications (Level B evidence).[43] The preferred mode of anesthesia for FFB is TIVA with LMA because it induces minimal pressor response and also allows for the examination of laryngeal apparatus. Benzodiazepines, opioids, and propofol have been preferable used for sedation during FFB owing to rapid onset and recovery and minimal respiratory depression or hemodynamic instability. Midazolam can be safely given iv in 0.5mg to 1mg increments at five minute intervals until desired level of sedation achieved. Commonly used opioids are fentanyl, alfentanil, remifentanil, meperidine and less frequently morphine. Studies comparing midazolam, alfentanil and combination have demonstrated that alfentanil group had lesser coughing but greater degree of desaturation

in combination group. However, there was no difference in the level of discomfort between the groups.[44]

Propofol provides dose dependent degree of sedation from conscious sedation to general anesthesia which can be administered as 0.5-1 mg/kg bolus followed by infusion at 25-75 mcg/kg/min for minimal to moderate sedation or 40-200 mcg/kg/min for deep sedation or anesthesia.[35] Propofol can also be administered as intermittent boluses, a single intravenous dose of 0.5–1.0mg/kg given slowly with top-up doses of 25–50mg every few minutes. Studies investigating the effect of the addition of alfentanil to propofol have shown greater respiratory depression in combination group than propofol alone.[45] Another study comparing propofol with a combination of midazolam and hydrocodone has demonstrated that propfol is as effective and safe as combined sedation in patients undergoing flexible bronchoscopy and represents a valid alternative to combined sedation with a benzodiazepine and an opiate.[46]

For topical anesthesia, it is recommended that total dose of lidocaine should be limited to 8.2 mg/kg in adults (approximately 29 ml of a 2% solution for a 70 kg patient) with reduction of dosage in the elderly or those with liver or cardiac impairment. The minimum amount of lidocaine necessary should be used when instilled through the bronchoscope.[43]

3. LASER BRONCHOSCOPY

Laser bronchoscopy is the delivery of laser energy via laser fibers passed through the working channel of standard bronchoscopes in order to treat a variety of endobronchial lesions.

Lasers suitable for laser bronchoscopy include the potassium titanyl phosphate (KTP), argon dye, yttrium aluminium pevroskite (YAP), Nd-YAG (neodymium-yttrium aluminium garnet) and diode lasers. The Nd-YAG laser is most widely used for airway resection[47] because depending on the amount of energy applied, its effects on living tissues (i.e. photocoagulation or vapourization) are predictable. It can be performed through flexible or rigid bronchoscopes. However, most surgeons prefer rigid bronchoscopy for all but the smallest lesions because the open tube allows for the simultaneous passage of the laser fibre, suction catheters, and forceps; adequate tracheobronchial toileting and the better management of hemorrhage within the airway.

Indications: The most common indication is inoperable cancer, either primary lung cancer (non small cell type) or endobronchial metastasis. Other indications include benign endobronchial tumors (e.g. papilloma, lipoma, leiomyoma), tumours of uncertain prognosis (adenoid cystic carcinomas, carcinoid tumours), and postinfectious or postintubation stenosis of the trachea or main stem bronchi.

Anesthetic Technique: Choice of anesthesia for laser bronchoscopy depends on the surgical technique. Rigid bronchoscopy usually demands general anesthesia, while fiberoptic bronchoscopy can be managed with either topical anesthesia and sedation or general anesthesia. For G.A., either inhalational or TIVA can be used; however TIVA is preferred over inhalational in laser surgery for two reasons. Firstly, there are leaks around bronchoscope which leads to inappropriate delivery of volatile anesthetics to the patient, and OR pollution. Secondly, inhalational anesthetics after flame exposure pyrolyse to potentially toxic compounds. ANSI Z136.3–2011 standard conservatively recommends not to use volatile anesthetics during airway laser surgery. There should be good coordination between the anesthesia and surgical teams so that need for an ETT, which tube type to use, the oxygen enrichment plan, and mode of ventilation can be discussed with surgeon. For jet ventilation catheter may be placed in either supraglottic or infraglottic position. For fiberoptic bronchoscope, either LMA or Laser resistant endotracheal tube can be used. In case of cuffed ETT, the cuff should be filled with saline rather than air whenever feasible. Methylene blue–dyed saline is another option which helps early identification of cuff breaches. Water-soaked sponges may be used which seal leaks of oxygen around an ill-fitting ETT cuff.

Laser Safety Precautions: These include: a) draping the patient with moist towels and eye pads in order to minimize risk of fires to patient's body b) Warning signs must be posted for persons entering the operating room. c) Laser goggles should be worn by all the persons in that area. d) Inspired oxygen concentration (FiO2) should be kept <40% to reduce the risk of ignition of flammable devices. [48]

4. THORACOSCOPY:

Medical thoracoscopy or pleuroscopy is a commonly performed pleural intervention by interventional pulmonologists that is different from Video assisted thoracoscopic surgery (VATS). It is usually performed as a single port technique.

Anesthetic considerations

Whereas simple diagnostic procedures can be conducted under local anesthesia by chest wall infiltration in combination with light sedation, more complex procedures that require sampling of tissue are best performed under regional (epidural, intercostals blocks) or general anesthesia. Most VATS procedures are performed under general anesthesia through one-lung ventilation (OLV) techniques using either double lumen tube or bronchial blockers or rarely, endobronchial tube. OLV allows for better exposure and guarantees a secure airway in the lateral decubitus position.[49]

SUMMARY and CONCLUSION :

Interventional pulmonology is a rapidly evolving field which includes variety of simple and complex procedures. It presents many challenges to anesthesiologists owing to sharing of airway with pulmonologists, already compromised lung condition of patients and dynamic nature of the procedures. A good preoperative evaluation in advance and anticipation of possible complications is essential for the successful anesthetic management. Choice of anesthesia whether general anesthesia or conscious sedation depends upon the type of procedure and patient's pathophysiology. TIVA is the preferred anesthetic technique for general anesthesia. Team approach, relying on good communication between surgeon, anesthesiologist and nursing staff is necessary for the success of a procedure. Anesthesiologist should be prepared with alternative airway management plan in case of failure of plan A. Ventilatory techniques should be planned and preparation should be done accordingly. Therefore, there is need to stay updated about the newly emerging IP procedures as well as various anesthetic and ventilation techniques.

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CASE REPORT

Use of i-gel for laser ablation of a bronchial lesion

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SUMMARY

The use of laser for airway lesions requires airway management. Usual options include special laser-resistant endotracheal tubes. The use of supraglottic devices have been described in the literature. Laryngeal mask airway carries the risk of cuff damage during the use of laser. i-gel is made of thermoplastic material and does not require air inflation and thus potentially reduce the risk of cuff rupture. i-gel use in laser surgeries has not been described in the literature. We present successful airway management in laser surgery for bronchial tumour using i-gel.

BACKGROUND

Light amplification by simulated emission of radiation (laser) has been used for treatment of benign (colon and rectal polyps) and malignant conditions (head and neck cancers, lung cancer, liver tumours). The use of laser for airway lesions requires anaesthesia and a secured airway. Various options for securing the airway include laser-resistant endotracheal tubes, wrapped tubes and jet injector. Laryngeal mask airway (LMA) has also been described for airway management.[1] LMA allows uninterrupted ventilation along with the use of fibreoptic bronchoscope through it.[1 2] In spite of the benefits, LMA carries the potential risk of cuff damage during laser use leading to inadequate ventilation and thus risk of hypoxia. i-gel has the specific advantages of non-inflatable cuff and the possibility of tracheal intubation through it, if required. Until now, i-gel use in laser surgeries has not been described in the literature. We describe successful airway management in laser surgery for bronchial laser ablation of a lung tumour using i-gel. Written consent was taken for publication of this case from the patient.

CASE PRESENTATION

A 61-year-old man presented with chief complaints of cough, haemoptysis and fever since 1 year. Contrast enhanced CT scan revealed heterogeneously enhancing mass lesion in lingular lobe of left lung, upper lobe collapse and multiple enhancing mass lesions in both lobes of liver. Positron emission tomography CT findings revealed somatostatin expressing disease in left upper lobe bronchus and liver metastasis. Flexible video-bronchoscopy performed under local anaesthesia revealed left upper lobe occluded by a vascular tumour along with purulent secretions. Bronchial washings confirmed the diagnosis of neuroendocrine tumour of left upper lobe bronchus.

DIFFERENTIAL DIAGNOSIS

In view of respiratory distress caused by proximal bronchus obstruction by tumour mass, laser debulking of tumour was planned. Pulmonary function test demonstrated moderately restrictive defect.

TREATMENT

In the bronchoscopic suite, after securing the intravenous access, intravenous hydrocortisone 100 mg was administered. Standard monitors including 5-lead ECG, pulse oximeter (SpO_2) and non-invasive blood pressure were attached. The patient was preoxygenated with 100% oxygen for 5 min at a flow rate of 15 L/min in 40° head up position. Anaesthesia was induced in head up position (40°) using intravenous fentanyl 100 µg, propofol 100 mg and rocuronium 60 mg. A continuous intravenous infusion of propofol 200–300 µg/kg/min was started. Lungs were ventilated using positive pressure ventilation. Three minutes later, rigid bronchoscope was inserted. On evaluation, growth was visualised in left upper lobe bronchus. Intermittent manual jet ventilation was started through side port (ventilating port) of rigid bronchoscope. Because of excessive air leak from and around the rigid bronchoscope, ventilation was ineffective. The pulmonary interventions of laser ablation required period of apnoeas and low inspired fraction of oxygen (FiO_2). So the ventilatory strategy was required to be changed. We modified our plan to perform ventilation through i-gel (supraglottic airway device) and perform laser ablation of tumour by inserting laser probe through flexible fibreoptic bronchoscope which is in turn inserted through the i-gel using an swivel connector (figure 1). I-gel (figure 2) of size 4 was inserted and positive pressure ventilation was initiated. The procedure was started with continued ventilation. During laser ablation, to minimise the risk of airway fires, FiO_2 was reduced to 0.30 and fresh gas flow was increased to 10 L to expedite clearance of oxygen in the airway. All routine laser safety precautions were followed including draping the patient with moist towels and eye pads, and antiglare glasses were worn by all the personnel. Flexible fibreoptic bronchoscopy was performed through swivel catheter mount and endobronchial neodymium-doped yttrium aluminium garnet (Nd:YAG) laser (23 W/cm^2, continuous mode) applied. During laser ablation, intermittent apnoea was provided. High-force suction was applied through bronchoscope to remove laser fumes. During desaturation episodes below 90% of oxygen saturation as assessed by SpO_2, use of laser was stopped and intermittent positive

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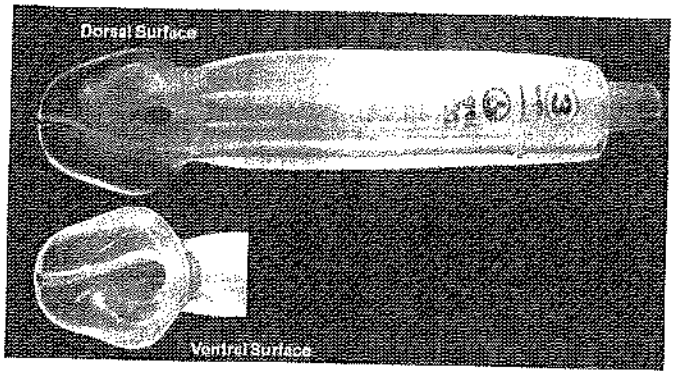

Figure 1 Use of i-gel during laser.

pressure ventilation was resumed. After adequate oxygenation, above steps were repeated until complete tumour carbonisation was achieved. Laser ablation lasted for 45 min and remained uneventful. After the procedure, the residual neuromuscular blockade was reversed with neostigmine 2.5 mg and glycopyrrolate 0.4 mg. Tracheal extubation was performed after adequate spontaneous respiratory efforts and when the patient regained consciousness.

OUTCOME AND FOLLOW-UP

Patient was shifted to high-dependency unit uneventfully for further management and observation. The patient was discharged on third postoperative day uneventfully.

DISCUSSION

Different types of lasers are used in clinical practice. Some lasers use a gaseous lasing media such as carbon dioxide, argon, krypton or helium–neon, while other lasers use solid rods of laser-passive material containing small quantities of ionic impurities, known as dopants. Dopants commonly used for their laser potential include chromium (as in the ruby laser), neodymium or holmium. Energy of an Nd:YAG beam is more widely disseminated, producing less vaporisation and more thermal coagulation. It can go deeper into tissue than light from other types of lasers, and it can make blood clot quickly. Nd:YAG lasers can be used through thin flexible tubes or optical fibres. Nd:YAG laser is used for lesions distal to larynx and for bulky, vascular endobronchial neoplasms because it can be used with a rigid bronchoscope or a flexible bronchoscope. In our case, we used it for debulking of neuroendocrine tumour of bronchus.

Laser surgeries are associated with specific hazards like airway fires, tissue and vascular perforation, eye injury, gas embolism, atmospheric contamination with laser fumes. Laser safety precautions should be used. Deposition of laser fume particulates in rat lung appears capable of producing interstitial pneumonia, bronchiolitis, reduced mucociliary clearance, inflammation and emphysema.[2 3] Nitrous oxide exothermically dissociates releasing heat and free oxygen. Nitrous oxide is thus a powerful oxidiser, and adding nitrous oxide as a diluent for oxygen is just as dangerous as having high FiO_2.[4] We avoided nitrous oxide for anaesthesia in our patient. Using an air–oxygen mixture appears to be acceptable. We used air–oxygen mixture to reduce the FiO_2 to prevent airway fires. Volatile anaesthetics when exposed to flame may pyrolyse to potentially toxic compounds.[5] Hence, we used propofol infusion rather than volatile agents to maintain anaesthesia.

Various airway management options are available which include jet ventilation with a modified Sanders venturi coupler, laser guard wrap around endotracheal tube, laser-resistant tubes like Norton, Laser-Flex tubes, Bivona Fome-Cuf and LMA. Studies with Nd:YAG laser has shown polyvinyl chloride, silicone and red rubber tubes to be vulnerable for damage because of ignition.[4–7] Covering of tubes with laser safe material such as copper and aluminium foil is an option, but wrapping is to be done very carefully with a 30% overlap, with no exposed tube, and adhesive used to stick foil is also flammable.[7] Commercially available laser-resistant tracheal tubes are expensive and their cuff is inflammable. Use of a metal endotracheal tube does not imply absolute protection from ignition as 50 W of Nd:YAG beam focused to 0.68 mm ignited a laser flex in 6 s.[6] Use of low FiO_2 (<30%) in lung with poor functional capacity poses a specific risk during laser surgery of a lung tumour as occurred in our case. Intermittent apnoea during use of laser also increases risk of desaturation. Jet ventilation is one of the modality in such situations but has the potential to produce barotrauma, pneumothorax or crepitus specially where in bronchial tumours require ablation. All these issues can be circumvented to large extent by using LMA. LMA has additional advantages of low frequency of coughing, better haemodynamic stability during insertion and improved oxygen saturation during emergence. LMA is an effective way to manage ventilation while simultaneously allowing unencumbered flexible bronchoscopic access for laser surgery.[1 6 7] Only few studies are performed about LMA in laser surgeries and use of i-gel is not reported yet.[7 8] The LMAs with air-filled cuffs are liable to get damaged with lasers.[9] Though silicone base cuff are reported to be more resistant to laser burns, but they are still not burn proof.[9] The use of saline for cuff inflation has been reported and may be of some use in laser surgery for prevention of cuff damage.[10] The occurrence of air leak from LMA damaged cuff would lead to difficulty in ventilation. i-gel has soft gel-like non-inflatable cuff which naturally positions itself over laryngeal framework providing a reliable perilaryngeal seal without the need of inflating cuff. It also provides conduit for intubation. It appears that the risk of cuff leak due to laser burn of the cuff should not be a concern as i-gel is made up of thermoplastic polymer (medical grade thermoplastic called styrene ethylene butadiene styrene) and does not require air inflation for making a good laryngeal seal. This technique would provide uninterrupted exposure to the airway lesion for ablation without compromising lung ventilation. The robust airway and gastric channel along with buccal cavity stabiliser of the i-gel would help in preventing potential of rotation

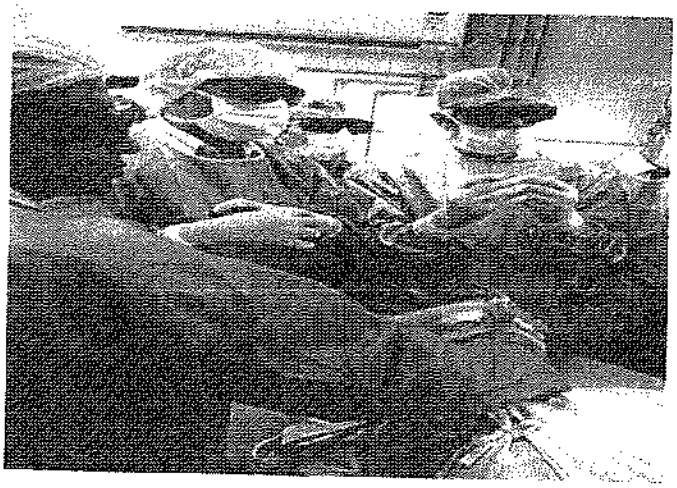

Figure 2 I-gel used for airway management.

and stability and its robust channel would prevent any accidental burn to it during the laser insertion or its removal. i-gel would easily accommodate the flexible fibreoptic scope for the laser procedures of the airway. The flammability of the i-gel itself has not been reported. The previous reported studies for use of LMA are usually with first generation device and has issues related to seal pressures, leak, prolonged positive pressure ventilation specially when airway pressure are high like in our case with bronchial lesions. The second-generation devices like i-gel have a better profile of its placement, better seal pressures and thus use of positive pressure ventilation effectively. The bronchial and lung tumours have increased airway resistance and thus require higher ventilatory pressures. Also, the better surgical condition with use of device would allow optimal tumour ablation and lesser chances of recurrence leading to airway compromise. The device not only provides continuous ventilatory support but also remains away from the surgical site of laser ablation and potentially lesser risk of fire. The conventional laser-resistant tubes are safer but would interfere in the laser ablation as they remain near to site of laser ablation and may interfere in optimal resection.

Learning points

- Patient undergoing laser surgery under anaesthesia remains challenging
- Airway management in patient requiring laser for bronchial tumour requires cautious selection of airway device.
- i-gel could be considered an airway management device for patients requiring neodymium-doped yttrium aluminium garnet (Nd-YAG) laser ablation of bronchial lesion in patient with lung cancer.
- Further testing may be warranted to evaluate the fire-resistant characteristics of the i-gel for its use during Nd-YAG laser surgery.

We conclude, the i-gel could be considered an airway management device for patients requiring Nd:YAG laser ablation of bronchial lesion in patient with lung cancer. It would be a good substitute for patients requiring laser ablation distal to glottis and other lower airway laser ablations. However, further testing may be warranted to evaluate the fire-resistant characteristics of the i-gel for its use during Nd:YAG laser surgery.

Contributors RG and ST: Conduct of the case, review of literature, writing of manuscript, revision and final approval of the manuscript. KM and MA: Conduct of the case and approval of the manuscript. All authors approve the final manuscript for submission.

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Anesthetic Management of an Ankylosing Spondylitis Patient with Normal Pressure Hydrocephalus for the Ventriculoperitoneal Shunt

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Ankylosing spondylitis (AS) poses unique challenges to anesthesiologists owing to difficult airway and cardiorespiratory compromise.[1–3] We describe the anesthetic management of a case of AS with normal pressure hydrocephalus (NPH) for lumbar puncture (LP) followed by ventriculoperitoneal shunt (VPS) surgery.

A 68-year-old male weighing 65 kg, case of AS for 25 years, American Society of Anesthesiologists (ASA) grade III presented with gradually progressive slowness of gait and urinary incontinence for 5 months. Computed tomography scan of head was suggestive of hydrocephalus. Magnetic resonance imaging cervical spine revealed ankylosis of cervical vertebrae with arthrosis of the atlantoaxial joint (►Fig. 1). LP was performed in left lateral position with limited hip and knee flexion. 40 mL cerebrospinal fluid (CSF) was drained at a pressure of 12 mm Hg. Patient showed significant improvement in gait and a diagnosis of NPH was established. He was then posted for VPS the next day. Preanesthetic evaluation of the airway revealed restricted mouth opening (2 cm), Mallampati class IV, fixed flexion deformity of neck, and loss of cervical and lumbar lordosis. Breath holding time was 20 seconds and pulmonary function test revealed severe restrictive lung disease (forced expiratory volume in 1 second [FEV1] 34%, forced vital capacity [FVC] 33%, FEV1/FVC 101%). Risks of anesthesia pertaining to difficult airway and perioperative pulmonary complications were explained and consent for anesthesia was obtained, but patient refused for awake fiberoptic bronchoscopic (FOB) intubation. He was taught deep breathing exercises (DBE) and incentive spirometry (IS).

On the day of surgery, standard ASA monitoring was applied and a stack of pillows and gel-ring were placed under the head and neck in Trendelenburg position (►Fig. 2). After preoxygenation with 100% oxygen for 5 minutes, induction was done with 100 mcg fentanyl and 20 mg graded boluses (total 60 mg) of propofol to preserve spontaneous breathing. However, breathing became shallow and jerky due to backward falling of tongue and airway obstruction. Bag mask ventilation (BMV) was inadequate with nasopharyngeal airway (NPA) (size 8.0) but became possible with oropharyngeal airway (OPA). Due to failed attempt through oral FOB, plan was changed to nasal FOB. Glottic opening could be visualized only after pulling the tongue anteriorly and 7.5 mm endotracheal tube was advanced under vision into the trachea. Anesthesia was maintained with oxygen, air, desflurane, and atracurium. Because of nonmaneuverability of the neck, conventional surgical position with neck rotation was not possible and shunt was manipulated from the cranial burr (Kocher's point) in three passes. Patient was shifted to intensive care unit postoperatively. After the reversal of neuromuscular blockade, he was extubated when fully awake, obeying commands with adequate spontaneous respiratory efforts. DBE and IS were continued in the postoperative period. He was discharged on second postoperative day and was doing well with improvement in symptoms at 2 weeks' follow-up.

Discussion

Anesthetic challenges in management of the rare cooccurrence of AS with NPH has not been reported, and is probably the first case in literature.[2,3] It imposed array of difficulties ranging from technically difficult LP, airway hazards, and positioning issues.

Fibrosis of the spine made LP more complicated. One interesting finding in our case was difficulty in ventilation with NPA but not with OPA. This could be due to the malleable nature of NPA, and larger nares to epiglottis distance. It indicates that a standard size NPA can be shorter in case of fixed flexion deformity of neck. Direct and video laryngoscopy was not possible due to shaft getting struck to the chest and misalignment of oropharyngeal axis with laryngeal axis. Oral FOB was unsuccessful because of decreased oropharyngeal

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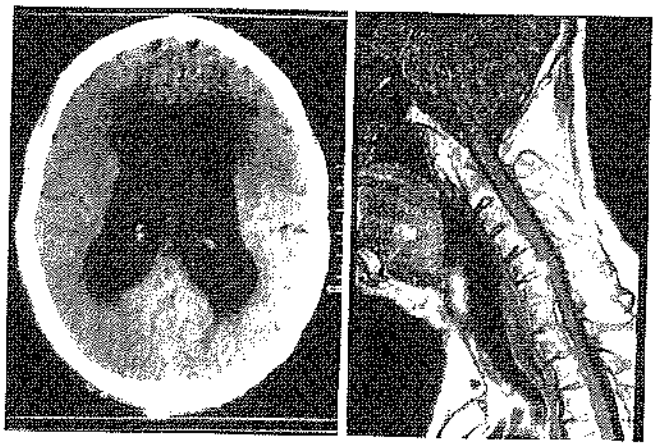

Fig. 1 Left side: Noncontrast computed tomography (NCCT) head (axial cut) showing hydrocephalus. Right side: Magnetic resonance imaging (MRI) cervical spine (T1 sequence sagittal) showing ossified vertebral column.

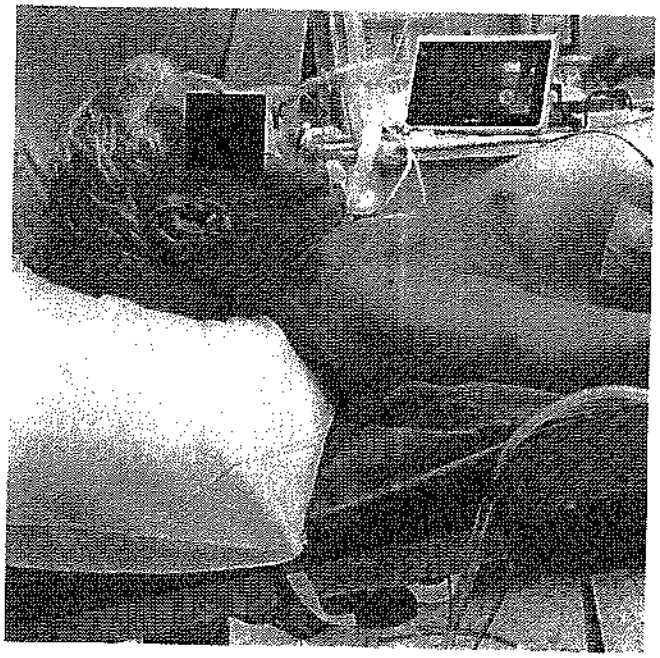

Fig. 2 Patient positioning (head low with pillows) to support head in fixed flexion deformity.

space and more acute angulation in approaching glottis via oral route, therefore nasal FOB was the better choice.[4] Lingual traction maneuver helped us in negotiation of FOB. Other airway supporting maneuvers like head tilt, chin lift, and jaw thrust were not possible because of probable ankylosis of the temporomandibular joint. Lung fibrosis leading to severe restrictive lung disease gave us only limited duration of apnea without desaturation for FOB. Adequate preoxygenation and oxygen insufflation through nasopharyngeal catheter during apnea period has been shown to increase the time to desaturation.[5] Careful positioning is imperative in AS because of high risk of spine fractures in osteoporotic bones.[6,7] Ideal positioning for intubation and procedure was not possible in our case due to fixity of the spine. A stack of pillows below the head helped to keep the head as in preoperative position.

To conclude, management of NPH with coexisting AS has its own challenges. Performance of LP to assess beneficence of a definitive CSF diversion procedure like VPS is difficult but necessary. OPA is a better choice for BMV. Nasal FOB with lingual traction while maintaining spontaneous respiration is the appropriate technique if the consent for awake FOB is not provided.[4] Restrictive lung disease and inappropriate posture add to the challenges. Preoperative lung expansion maneuvers and preparedness for the anticipated difficult airway is the key to successful management of this case.

Note

A written and verbal informed consent was taken from the patients' first degree relative (son).

Conflict of Interest

None declared.

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Original Research Article

MORPHOLOGICAL AND MORPHOMETRIC STUDY OF SUPRA SCAPULAR NOTCH AND INCIDENCE OF OSSIFIED SUPERIOR TRANSVERSE SCAPULAR LIGAMENT IN HUMAN DRY SCAPULAE AND ITS CLINICAL IMPLICATION

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ABSTRACT

Background: The supra scapular notch is the common site of supra scapular nerve entrapment causing supra scapular neuropathy. The supra scapular notch present in the superior border of the scapula is roofed by the Superior Transverse Scapular Ligament (STSL) which ossified in some scapulae and form supra scapular foramen.

Aim and objective: In present study we analyze, Morphological and Morphometric variations of supra scapular notch and ossified superior transverse scapular ligament in human dry scapulae.

Materials and Methods: In present study, we studied 136 dry human scapulae of unknown sex. We noted incidence of ossified superior transverse scapular ligament and Morphometric parameters analyzed.

Result: In present study we found 10 scapulae with complete ossified suprascapular ligament and 6 scapulae with partial ossified suprascapular ligament out of 136 dry human scapulae.

Conclusion: Ossified superior transverse scapular ligament is known factor for supra scapular nerve entrapment neuropathy so knowledge of incidence of STSL and anatomy of supra scapular region very useful for clinician, surgeons and orthopaedicians.

KEY WORDS: Supra Scapular Notch, Supra Scapular Nerve, Supra Scapular Neuropathy, Transverse Scapular Ligament.

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INTRODUCTION

The suprascapular notch is a depression or notch on the lateral part of the superior border of the scapula, medial to the coracoid process. This

structure is bridged by the superior transverse scapular ligament, which is sometimes ossified and the foramen which is thus completed, transmits the suprascapular nerve to the supraspinatus fossa [1].

The Suprascapular Nerve passes under the ligament and suprascapular vessels pass above the ligament. The Suprascapular Nerve gives motor nerve supply to the supraspinatus and infraspinatus muscles sensory nerve supply to the rotator cuff muscles and also supply the shoulder and acromioclavicular joint.

The suprascapular notch is frequently bridged by bone rather than a ligament, converting it into a bony foramen in some animals [2]. But in human, the STSL is sometimes ossified [1, 3].

The size and shape of suprascapular notch may be a factor in suprascapular nerve entrapment neuropathy because narrow notch has been found in patient with this neuropathy [4, 5].

The suprascapular notch is one of the potential site for compression of the nerve. Other causes associated with Suprascapular Nerve neuropathy include direct trauma, rotator cuff tear, ganglion cysts causing compression, sports injury due to repeated traction, variation of the SN morphology[6].

The presence of an ossified STSL may also pose a challenge during decompression of the suprascapular notch if the condition is not fully appreciated [7].

MATERIALS AND METHODS

In present study, we studied 136 dry human scapulae of unknown sex. This study carried out in Department of Anatomy of Pacific Medical College and Hospital and Pacific Institute of Medical Science Udaipur (Rajasthan). In this study damaged scapulae are excluded. We noted incidence of ossified superior transverse scapular ligament and following Morphometric parameters analyzed by digital Vernier caliper.

1. Vertical diameter of foramen
2. Transverse diameter of foramen
3. Area of supra scapular foramen
4. Superior maximal length of STSL
5. Inferior maximal length of STSL

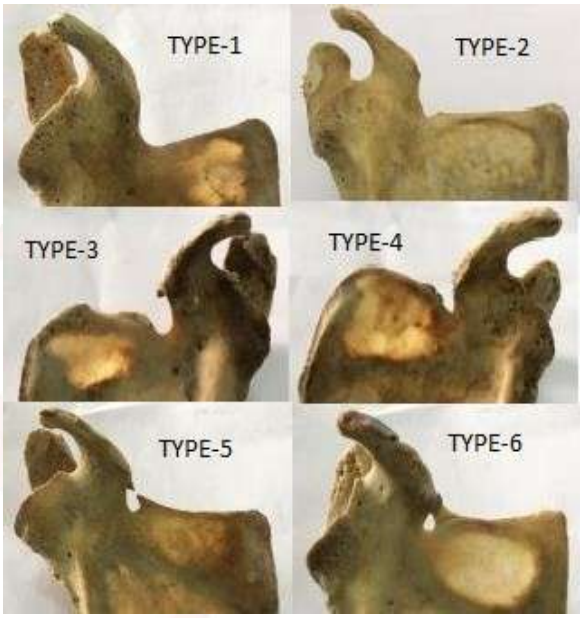
Area is count by area=π ×D1×D2/2

D1=Vertical diameter of suprascapular foramen

D2= Transverse diameter of suprascapular foramen

Also we classified suprascapular notch according Rengachary et al., Type I –complete absence of notch. Type II -wide blunted V shaped notch. Type III -symmetrical and U shaped notch with parallel lateral margins. Type IV -small V shaped notch. Type V- partial ossification. Type VI -complete ossified ligament

Fig. 1: Showing the different types of supra scapular notch.



RESULTS

In our study we used 136 dry human scapulae and measure various parameter, we found various types of suprascapular notch and shape of it noted in tables. We found 8% scapulae with complete suprascapular foramen and 5 % partial ossified suprascapular ligament. Other

Table 1: Showing the types of supra scapular foramen and its incidence.

	Type-1	Type-2	Type -3	Type-4	Type -5	Type -6
Number of scapulae	48	14	55	3	6	10
Percentage	35	10	40	2	5	8

Table 2: Morphometric Parameter of Supra Scapular Foramen and Superior Transverse Scapular ligament.

Parameters	Lt (mm)	Lt (mm)	Lt (mm)	Lt (mm)	Rt (mm)	Rt (mm)	Rt (mm)	Rt (mm)	Rt (mm)	Rt (mm)
Vertical diameter of foramen	8.2	7.8	9.6	8.8	6.8	14.2	7.1	8.2	10.2	9.6
Transverse diameter of foramen	7.1	4.62	5.1	4.3	4.1	7.39	5.4	6.5	8.3	6.4
Area of supra scapular foramen	46.2	57.1	38.8	29.7	21.8	82.4	30.4	83.9	132.9	48.6
Superior maximal length of STSL	10.2	9.1	9.3	8.9	8.9	11.72	9.6	11.2	10.1	9.6
Inferior maximal length of STSL	8.4	6.9	6.7	6.5	5.9	10.2	7.1	8.2	9.8	9.5

Table 3: Various study showing frequency of types of Suprascapular notch.

Study	Population	Type I (%)	Type II (%)	Type III (%)	Type IV (%)	Type V (%)	Type VI (%)
Paolo Albino et al 2013 [8]	Italian	12.4	19.8	22.8	31.1	10.2	3.6
Sinkeet et al. 2010 [9]	kenya	22	21	29	5	18	4
Khan, M. A. 2006 [2]	Indian	20	10	52	4	4	10
Rengachary et al., 1979 [5]	American	8	31	48	3	6	4
Sangam MR, et al 2013 [16]	Indian	21.15	8.65	59.61	2.88	5.76	1.93
Present study	Indian	35	10	40	2	5	8

DISCUSSION

In our study, we found the ossification of the STSL which convert notch in suprascapular foramen in 10 scapulae(8%) and partial foramen seen in 6 scapulae [5]. According to Paolo Albino et al,In Italian population complete foramen seen in 3.6 % of scapulae, same as in Kenyan population according to Sinkeet et al is 4%[9].

The suprascapular nerve entrapment may be due to traumatic or non-traumatic causes. The suprascapular nerve is commonly found to compress mainly at two sites, at the level of the suprascapular notch and the base of the scapular spine[10].

Compression and entrapment of the suprascaspular nerve at the suprascapular notch was first suggested by Kopell and Thompson and they also suggest Irritation of the SN gives rise to pain which is deep and poorly localized and because of this the cause of the pain and tenderness is difficult to discover in any individual and the muscle atrophy starts [11], According to ticker at al the shape of the suprascapular notch or the ossification of the STSL to predispose to suprascapular nerve entrapment.

Micha Polguj at al suggested that the mean area of the suprascapular foramen in the specimens with anossified band-shaped STSL is significantly smaller than in those with a fan-shaped STSL. Therefore, he confirm that band-shaped type of ossified STSL forms less space for the passage of the suprascapular nerve. Such an observation may explain why there is no increase in suprascapular nerve entrapment, even when the frequency of ossified STSL is very high, for example, 30.76% in the Brazilian population[12] According to Soni, G etal ,excessive movement of the shoulder exerts traction on the suprascapular nerve which leads to its compression-against the superior transverse scapular ligament[13]. Sandow & Ilic describe that specific volleyball movements and their implications at suprascapular nerve compression. The characteristically gestures e.g. of volleyball players as abduction associate lateral (external) rotation are factors that predispose the neuropraxis[14].

Gosk et al. state that peripheral nerves are highly susceptible to injury from stretching and compression. Both of these mechanisms result in nerve ischemia, edema, micro environmental changes, and conduction impairment [15].

Rengachary et al. first proposed an etiopathogenesis of suprascapular nerve entrapment known as the sling effect. It assumes that during maximum arm motioncause the irritates of nerve and induces microtrauma that can result in suprascapular[5]. Neuropathy, Most of studies showing incidence of suparascapular foramen but in our study we studied morphometric analysis of suprascapular notch and its suprascapular foramen knowledge is very important for decompression of suprascapular nerve.

Incidence of suprascapular foramen and STSL in other study are shown in table 3.

CONCLUSION

Ossified superior transverse scapular ligament is known factor for supra scapular nerve entrapment neuropathy so knowledge of incidence of STSL and anatomy of supra scapular region very useful for clinician, Surgeons and Orthopaedicians for diagnosis and treatment.

ABBREVIATIONS

STSL - Superior Transverse Scapular Ligament

Conflicts of Interests: None

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Original Research Article

A Morphological Study of Caudate Lobe in Human Cadaveric Liver

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Abstract

The liver is the largest abdominal visceral organ, occupying a substantial portion of the upper abdominal cavity. The liver has four lobes, Caudate lobe is a separate and distinct liver lobe. It is located on liver at the posterior surface. The caudate lobe has two portions joined by a narrow parenchymal bridge that is called the caudate isthmus. Caudate lobe also has its separate blood supply and biliary drainage. The complexity of liver function and its importance in body homeostasis has encouraged this study of morphology and variations of caudate lobe to better the diagnosis and analysis of clinico-pathological conditions. For present study 100 cadaveric livers were obtained. Caudate lobe was studied on various parameters such as shape, size and dimensions. Various measurements were taken and data was analyzed using descriptive statistics and relational statistics. 'Z' test was computed to find out the association between the parameters of the present study and the studies of similar background. It was found that majority of the caudate lobes in all livers are rectangular 67 (67%) in shape followed by pyriform 21 (21%) and irregular 12 (12%) shaped. The average transverse diameter of caudate was measured 28.69 ± 7.73.The average longitudinal diameter of caudate lobe was measured 54.67 ± 10.73. A sound knowledge of the normal and variant liver anatomy is a prerequisite to having a favorable surgical outcome and commonly occurring variations assumes even more significance in the era of diagnostic imaging and minimally invasive surgical approaches.

Keywords: Liver, Caudate Lobe, Surgical resection, Harbin's measurements.

INTRODUCTION

The liver is one of the largest abdominal organs, occupying a large portion of the upper abdominal cavity. It is present in right hypochondria and epigastrium, and extending into left hypochondria as far as left lateral line [1]. The liver has four lobes; gross anatomical appearance of the liver has been divided into the right, left, caudate and quadrate lobes by the surface peritoneal and ligamentous attachments [2]. Various ducts, veins and arteries are present on the surface of the lobes that allow the inflow and outflow of fluids [3]. Caudate lobe is a separate and distinct liver lobe. It is located on the posterior surface of the liver between the groove for inferior vena cava (IVC) to the right and fissure for Ligamentum venosum to the left and on the anterior side of porta hepatis. The caudate lobe has two portions joined by a narrow parenchymal bridge called the caudate isthmus. This lobe also has separate blood supply and biliary drainage [4].

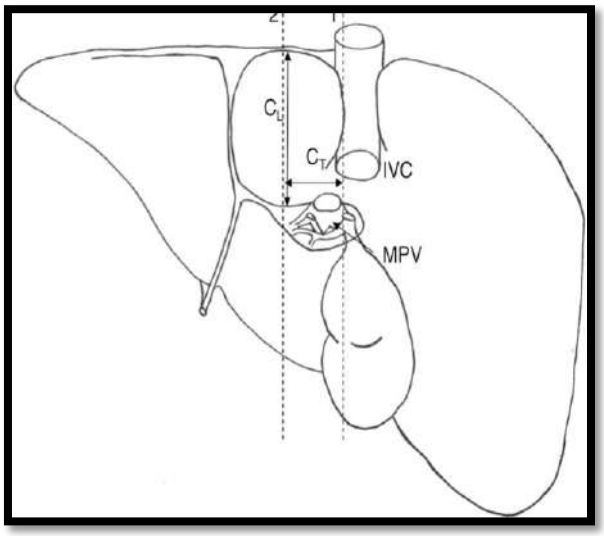
In man, the liver is essential for survival since there is currently no artificial organ or equipment that has the capacity to compensate for the absence of liver function [5]. The complexity of liver function and its importance in body homeostasis has encouraged many anatomists to study the morphological features of the organ in considerable detail [6]. For the surgeons it is of paramount importance to have clear knowledge of the structure of the normal organ and its variations during the period of growth and ageing.

MATERIAL & METHODS

The study was conducted on 100 cadaveric livers obtained from the Department of Anatomy, Baroda Medical College, Gujarat, India. Any liver from cadavers with previous history or appearance of cirrhosis, metastatic disease or other liver pathology and any cadavers with previous history of or an appearance suggestive of any trauma disease or abdominal surgery were excluded from the study. The approval was obtained from the Institutional Ethics Committee for Human research, Medical College Baroda, Gujarat prior to the commencement of the study. The liver specimens collected were allotted numbers from 1 to 100. The numbering to the specimens were given using synthetic thread and

laminated tags. Anatomy of the caudate lobe was studied after defining and cleaning lesser omentum covering its two of the four margins [7].

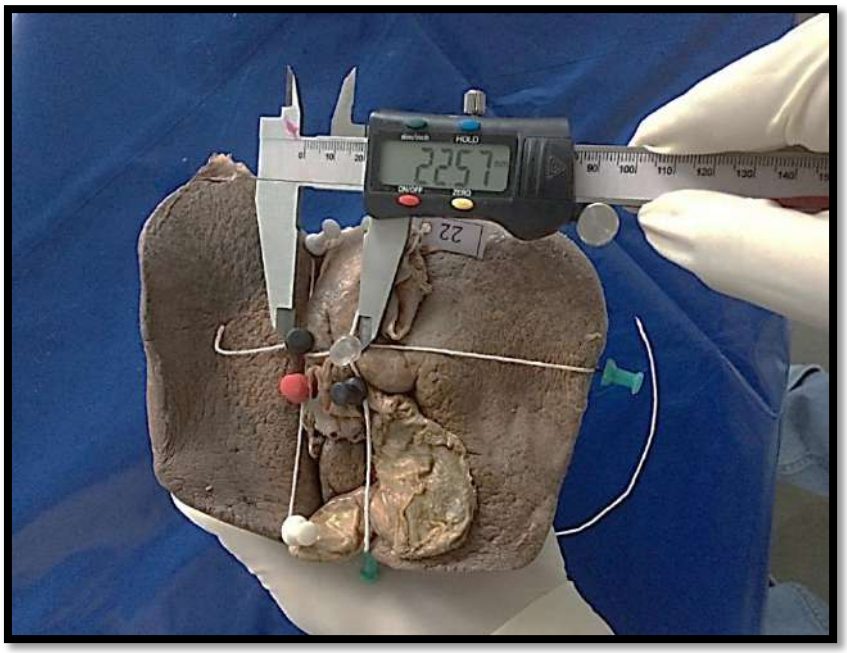
Each liver was placed in the anatomical position to facilitate visualization of the diaphragmatic and visceral surfaces, and morphometric measurements were performed with the aid of cotton threads and digital Vernier caliper in mm. Each liver was examined on three different occasions by the examiner and the mean of the three readings was derived. A line, L1 is drawn through the right lateral wall of the main portal vein. Another line, L2 was drawn parallel to L1 at the most medial aspect of the caudate lobe. Another line, L3 was drawn perpendicular to lines 1 and 2, midway between Main Portal Vein and the inferior vena cava, and extended out to the lateral margin of the right lobe. For consistency, in the present study the most medial aspect of the caudate lobe was considered as the medial extent of the transverse diameter of the porta hepatis in all livers [8, 9].



Visceral surface of the liver, demonstrating the greatest longitudinal diameter of the caudate lobe (CL) measured supero-inferiorly. CT transverse diameter of the caudate lobe, IVC Inferior Vena Cava, MPV Main Portal Vein

CT – Transverse diameter of caudate lobe: Measured from the most medial margin of the caudate lobe to the right lateral wall of the portal vein.

CL – Longitudnal diameter of caudate lobe: Measured at the level of the greatest longitudinal extension of the caudate lobe.



Transverse diameter of the caudate lobe measured on L3 between L1 and L2

The distinct morphological characteristics observed were recorded on individual data sheets in a form appropriate for posthumous analysis [3].

The data was analyzed using descriptive statistics (frequency, percentage, mean, median, standard deviation, skewness and kurtosis) and relational statistics i.e.'Z' test. Z' test was computed to find out the association between the parameters of the present study and the studies of similar background [10].

OBSERVATIONS AND RESULTS

In the present study, a total of 100 embalmed human livers evacuated were studied, 18 livers (18%) were normal in their external appearance. However, 82 (82%) specimens showed anomalies in lobes, fissures, shape and size of lobe. On examining the caudate lobe it was found that majority of the caudate lobes in all the livers are rectangular 67 (67%) in shape followed by pyriform 21 (21%) and irregular 12 (12%) shaped.

Table-1: Shape of Caudate lobe

Shape of Caudate lobe		
Type of Shape	No. of Liver specimen	Percentage %
Rectangular	67	67
Pyriform	21	21
Irregular	12	12

The average transverse diameter of caudate was measured 28.69 ± 7.73, while the values ranged between 14.68–50.81. The mean is more than median and $S^3 > 0$, which indicate positively skewed distribution of data because observations tend to concentrate more at the lower end of the possible values. The distribution is more spread out than normal as kurtosis is less than 3 (platykurtic). The average longitundal diameter of caudate lobe was measured 54.67 ± 10.73 and the values ranged between 35.41–74.24. The mean is less than median and $S^3 < 0$, which indicate negatively skewed distribution of data because observations tend to concentrate more at the higher end of the possible values. The distribution is more spread out than normal as kurtosis is less than 3 (platykurtic).

Table-2: Morphology of caudate lobe

Parameter	Mean (SD)	Median	Skewness (S^3)	Kurtosis (S^4)
Transverse Diameter (CT)	**28.69 (7.73)**	**27.97**	**0.75**	**0.15**
Longitudinal Diameter (CL)	**54.97 (10.73)**	**56.23**	**-0.91**	**-1.07**

Table-3: Morphology of Caudate Lobe comparing with other studies

Authors	Present study	Sahni *et al.*, [11]	Ahidjo *et al.*, [12]	Chavan *et al.*, [13]	Arora *et al.*, [14]	Sagoo *et al.*, [15]	Reddy *et al.*, [16]
Sample size	100	138	-	50	36	50	80
Transverse Diameter of caudate lobe	28.69±7.73	32.7± 7.6	34.1± 6.5	25.0	27.0	27.4± 12.2	25.4
Longitudinal diameter of caudate lobe	54.97± 10.73	-	-	81.5	50.3	57.4± 14.1	47.8

DISCUSSION

An attempt was made to find out the variations in the shape and size of caudate lobe to aid into clinical and surgical applications.

The findings of the present study for shape of caudate lobe are 67 (67%) rectangular, 21 (21%) pyriform and 12 (12%) irregular. Sahni et al. studied 200 specimens of liver. They observed that 189 (94.5%) were rectangular, 9 (4.5%) pyriform and 2 (1%) irregular. Sagoo et. al. also studied 50 specimens of liver for Northwestern Indian reported 45 (90%) rectangular, 03 (6%) pyriform and 02 (4%) irregular shapes of caudate lobe. In the Present study the average transverse diameter of caudate was measured 28.69 ± 7.73, while the values ranged between 14.68–50.81 and the average longitundal diameter of caudate lobe was measured 54.67 ± 10.73 and the values ranged between 35.41–74.24. Such measurements were compared with the studies done in the past as shown in Table-3.

CONCLUSION

A sound knowledge of the normal and variations in liver anatomy is a prerequisite to having a

favorable clinical outcome. The commonly occurring anatomical variations in liver have even more significance in the era of diagnostic imaging and minimally invasive surgical approaches. The absence of normal fissures or the presence of additional lobes might lead to confusion on a radiological diagnosis of a liver disorder. The modern era of imaging and minimally invasive liver surgeries have started after the intrahepatic segmentary anatomy was classified. It is very important on the part of both the radiologists and surgeons to have a thorough knowledge of the normal anatomy and the commonly occurring variations of this organ. The success of liver transplantation points towards an increase in liver operations in the future.

Conflict of Interest: None

ABBREVIATIONS

IVC: inferior vena cava
et.al: Et Alia (and others)
CT: Transverse diameter of caudate lobe
CL: Longitudinal diameter of caudate lobe
SD: Standard deviation

Authors' Contributions

JBC: Concept and design of study, Collection of data, Acquisition of data, analysis & interpretation of data, literature search, BBK: Concept and design of study, analysis & interpretation of data, literature search, drafting the article and final version to be published. VHV: Concept and design of study, Collection of data, Acquisition of data, analysis & interpretation of data, literature search.

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Section Anatomy

Original Article

Cephalic Index in Population of District Jhalawar, Rajasthan According to Food Habit and it's Significance

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ABSTRACT

Background: *Cephalic index exhibits sexual differences and different shapes of head. This information will be highly important for Plastic surgeons, Forensic Scientists, Anatomists, Human Biologists, Criminologists & Physical Anthropologists.*
Materials & Methods: *The present study was observed on 200 living subjects of Jhalawar district Rajasthan (100 male and 100 female) of 18 to 25 years in the year of 2013 with the objective to study the sex differences and food habitual in cephalic index. Cephalic index was investigated with the help of head length and width with the use of spreading caliper.*
Results: *The study showed that mean cephalic index was higher in females than in males.*
Conclusion*: Predominant head type was dolicocephalic in both sexes.*

Key words: *cephalic index, dolicocephalic, vegetarian, non-vegetarian*

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INTRODUCTION

Anthropometry is a technique of measuring the human body in terms of dimensions, proportions, and ratio such as those provided by cephalic index for determining various head. Cephalic index is the most frequently investigated craniofacial parameters as it utilizes the length and breadth of the head which are useful indices in the study of secular trend[1,2] Body dimension are affected by ecological, biological, geographical, racial, gender and age factors as quoted by Imami.[3] Lifestyle, nutrition, intercaste marriage, environment, geographical variation and ethnic composition of population lead to change in body dimension and require regular updating of anthropometric data. Ever since the human life came to existence, constant changes are occurring in morphological appearance.[4] Cephalic index is calculated as Maximum head breadth / Maximum head length x 100.[5] On basis of cephalic index head shapes classified four international categories Doliocephalic (CI up to 74.9), Mesocephalic (CI 75-79.9) Brachiocephalic (CI 80-84.9), Hyperbrachiocphalic (CI > 85).[6]

We in our study include Jhalawar region which is one of the biggest parts of Rajasthan. As no research, has been conducted in this area, we tried to establish and compare Cephalic Index of 18 to 25 years age of students of Jhalawar district (Rajasthan) with available data of various Indian populations. This study useful for Plastic surgeons, Forensic Scientists, Anatomists, Human Biologists, Criminologists & Physical Anthropologists.

METHODS

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This descriptive and cross sectional research was done on 200 students (100 Males and 100 Females). Students were selected because of the easy availability. The age of the students ranged from 18 to 25 years. The study was conducted on the Govt. PG College and Govt. Girls PG college Jhalawar (Raj.). All the measurements were taken with the subject sitting in chair, in relaxed condition and head in anatomical position. The method used for assessing the cephalic index is Hrdlicka's method.[7]

The head length from glabella to inion will measure with the help of spreading caliper. The head breadth will measure as the maximum transverse diameter between two fixed point.

Cephalic Index = Head Width/ Head Length x100

RESULTS

A total 200 adults were studied out which 100 (50%) were male and 100 (50%) were female. The male subject was divided in to out of 100; vegetarian male – 57 (57%) and non-vegetarian male-43(43%), and female subject were divided in to out of 100; vegetarian female-83 (83%) and non-vegetarian female-17 (17%). The study subjects were aged between 18 years to 25 years and Mean Cephalic Index was 74.23(SD=2.68; p=0.393).For Males, Mean Cephalic Index for Male was 74.07(SD=2.31; p=0.617).For Females, Mean Cephalic Index for Female was 74.39(SD=3.00; p=0.568).For Vegetarian Males Mean Cephalic Index was 13.73 (SD=.604).For Non-vegetarian Males Mean Cephalic Index for Non-vegetarian males was 74.20 -(SD=2.34).For Vegetarian males, Cephalic Index for Vegetarian females was 74.31 (SD= 3.091). For Non-vegetarian Females, Mean Cephalic Index for Non-vegetarian females was 74.77 (SD=2.581). Collected data of present study was statistically analysed. The observations and results are presented in the tabular form.

Table 1: Cephalic index of the study subjects according to gender

Cephalic index (cm)	M	F	Total (%)	Cephalic index (cm)	M	F	Total (%)
68.01 to 69	0	3	3 (1.5%)	75.01 to 76	14	8	22 (11%)
69.01 to 70	1	1	2 (2%)	76.01 to 77	7	14	21 (10.5%)
70.01 to 71	8	6	14 (7%)	77.01 to 78	9	6	15 (7.5%)
71.01 to 72	13	16	29 (14.5%)	78.01 to 79	3	12	15 (7.5%)
72.01 to 73	16	11	27 (13.5%)	79.01 to 80	2	2	4 (2%)
73.01 to 74	13	8	21 (10.5%)	80.01 to 81	1	1	1 (0.5%)
74.01 to 75	14	12	26 (13%)	Total	100	100	200 (100%)

M= Male, F= Female

Table 2: Comparative analysis of males and females cephalic index variable:-

Sr. No.		Male	Female
1.	No. of Case	100	100
2.	Cephalic Index Range (cm)	69.39-80	62.92- 80.11
3.	Mean	74.07	74.39
4.	S.D.	2.316	3.009

Table 3: Comparative analysis of Vegetarian males and Non-vegetarian males cephalic index variable

Sr. No.		Veg. Male	Nonveg. Male
1.	No. of Case	57	43
2.	Cephalic Index Range (cm)	69.39- 79.16	70.27- 80
3.	Mean	73.97	74.20
4.	S.D.	2.312	2.341

Table 4: Comparative analysis of Vegetarian females and Non-vegetarian females cephalic index variable

Sr. No.		Veg. female	Nonveg.female
1.	No. of Case	83	17
2.	Cephalic Index Range (cm)	62.92-80.11	71.03-78.44
3.	Mean	74.31	74.77
4.	S.D.	3.097	2.581

Table 5: Comparative analysis of Vegetarian females and Non-vegetarian females cephalic index variable

Variable in (cm)	N	Min. (cm)	Max. (cm)	Mean (cm)	S.D.	S.E.	P value
Cephalic index (male)	100	69.39	80	74.07	2.316	.231	
Cephalic index (female)	100	62.92	80.11	74.39	3.009	.300	
Cephalic index (male and female)	200	62.92	80.11	74.23	2.683	.189	0.393
Cephalic index (Veg.male)	57	69.39	80	73.97	2.31	.306	
Cephalic index (Nonveg.male)	43	70.27	78.21	74.20	2.34	.357	
Cephalic index (Veg.male and Nonveg.male)	100	69.39	80	74.07	2.31	.231	0.617
Cephalic index (Veg. female)	83	62.92	80.11	74.31	3.091	.340	
Cephalic index (Nonveg.female)	17	71.03	78.28	74.77	2.581	.626	
Cephalic index (Veg.female and Nonveg.Female)	100	62.92	80.11	74.39	3.00	.300	0.568

Table 6: Result from head shape classification for the male and female in percentage (%) based on cephalic index.

Head Shape	Male (%)	Female (%)
Dolichocephalic	60	56
Mesocephalic	39	33
Brachycephalic	1	1
Hyper brachycephalic	0	0

Table 7: Comparison of cephalic index (Mean) with other population

Sr. No.	People / Country	Reserch workers	Cephalic Index
1.	Bhils of central India (7)	Bhargava & Kher,1960	76.98
2.	Berelas of central India (8)	Bhargava & Kher,1961	79.80
3.	Gujrati Students (9)	Shah & Jadhav,2004	80.81
4.	Medical students of Panjab (10)	Anupama et al,2009	85.53
5.	Gujrati Population (11)	Jadav et al,2011	80.20
6.	North Indian Popn(Males) (12)	Anitha et al,2011	79.14
	North Indian Popn(Females)		80.74
7.	Indians students(Males) (13)	Yogain VK et al,2012	77.92
	Indians students (Females)		80.85
8.	Haryanvi Banias(Males) (14)	Mahesh Kumar et al,2012	66.72
	Haryanvi Banias (Females)		72.25
9.	Student of Jhalawar,Rajasthan (Male)	Present Study,2013	74.07
	Student of Jhalawar,Rajasthan (Females)		74.39

DISCUSSION

The variations in cephalic indices between and within population have been attributed to a complex interaction between genetics and environmental factors. In present study the mean cephalic index in males was 74.07 and in females 74.39. So the dominant type of head shape in male was dolichocephalic (60%) and in female was 56%. The findings of dolichocephalic was similar to study done on (Anitha et al, 2011)[4] North Indians in which 40.6 % was dolichocephalic and 15.6% was hyperdolichocephalic but

the percentage was more than this study & the mean cephalic index is more in previous study. North and central Indian population have Dolichocephalic predominance (Singh & Bhasin, 2006). This is in agreement with the present study.

In our study, dominant type of head shape in males was dolicocephalic (60%) and mesocephalic (39%) and the mean cephalic index was 74.07 (doliocephalic). This finding of dolicocephalic was similar to study done on Indian males (Bhatia *et al*., 1995) in which 58.5% of population was dolicocephalic, but not similar with the study by Shah & Jadhav[9] in Gujarati (41%) which showed Mesocephalic head shape was common. The dolicocephalic shape was a rare type found in 7% in Indian gujarati (Shah & Jadhav).[9]

The similar studies were conducted in different groups and Cephalic index was found to be different for different groups due to genetics and geographical factors. The value of mean cephalic index (males & females) in present study is lower as compared to other study however Bhils of central india, Haryanvi population have value close.[14]

CONCLUSION

The result of present study showed that all male and female of Jhalawar region students of age group of 18 years to 25 years of colleges of Jhalawar District (Rajasthan) are Doliocephalic according to classification based on cephalic index.

There was a significant difference ($p < 0.393$ & difference 0.32) between cephalic index of male and female of Jhalawar region. Thus, we can conclude that cephalic index of the female is some point higher than the male in Jhalawar region population.

There was a significant difference ($p < 0.617$ & difference 0.23) between cephalic index of Vegetarian male and Non-vegetarian male of Jhalawa region. Thus, we can conclude that cephalic index of the Non-vegetarian male is 0.23point higher than the Vegetarian male in Jhalawar region population.

There was a significant difference ($p < 0.568$ & difference 1.8) between cephalic index of Vegetarian female and Non-vegetarian female of Jhalawar region. Thus, we can conclude that cephalic index of the Non-vegetarian female is 1.8 point higher than the Vegetarian female in Jhalawar region population.

ABBREVIATION – CI – Cephalic Index

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Section Human Anatomy

Original Article

Morphological and Morphometric Study of Nutrient Foramen of Tibia and its Clinical Implication in the South Rajasthan Region

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ABSTRACT

Background: *Human body is made up of framework of variety of bones and make human body Bone is core structure of the human skeleton and form the framework of the human. During embryological and fetal life arteries enter into long bone through nutrient foramen and entry into medullary cavity, which is, require for growth long bone. Various surgical procedures like fracture reduction, bone grafting and joint replacement require sufficient knowledge of nutrient foramen and nutrient artery.*
Aim: *The Aim of the present study is: (A) To identify the position, number & direction of diaphyseal nutrient foramina of Tibia. (B) To identify any variations in number, location and position of diaphyseal nutrient foramina of tibia. (c) calculate the foramina index by Hughes formula.*
Materials and methods: *Present study was conducted on 100-dried Human Tibia with unknown age and sex, which was taken from the anatomy department of Geetanjali medical college & Hospital Udaipur and Pacific medical college & hospital, Udaipur and marked number on it. Morphological and pathological abnormal bones excluded from study. Help of vernier caliper and fine gauge needle, we observed location and distance from proximal end, number and direction of nutrient foramen and calculate foramina index.*
Results: *In present study we found single foramen present in 80 bone, Double foramen present 18 bone and in 2 bone there was triple foramen at different level. According direction: In upward direction of foramen found in 1 bone, horizontal direction found in 3 bone and most of bone have downward direction. According location: In most of bone Nutrient foramen was situated on posterior surface except in four bones where it was situated on lateral surface and In 66 bone Nutrient foramen present in upper 1/3 of bone except 34 bone where it present in middle 1/3.*
Conclusion: *In present study we found, Nutrient foramen was located mostly on the posterior surface and direction was downward. Nutrient artery is very important for blood supply of long bones. Therefore, it is very important for surgeons to have sound knowledge of precise morphology and morphometric of nutrient foramen*

Keywords: *Nutrient foramen, Nutrient artery*

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INTRODUCTION

Long bone of human body gets nutrition mainly from 3 artery 1) Nutrient artery, 2) Periosteal artery, 3) Epiphyseal Artery. But main source of blood derived from Nutrient artery, which supply diaphysis and metaphysis. During its course Nutrient artery first enters into the bone through nutrient foramen.[1] According to various cadaveric studies the Nutrient foramen is directed away from the growing end of in Adult the bone.[2,3] In lower limb leg bone, nutrient foramen is generally directed downwards because upper end is growing end, as it fuses with shaft in the 16 and 18 year in female and males respectively. While lower-end fuses with the shaft at about 15th year in females and 17th year in males. For tibia Nutrient artery derived from a branch of posterior tibial artery. Rarely it may arise from popliteal artery or anterior tibial artery.[3] Nutrient Artery is very important and vital for early embryogenic development and maturity of bone.[3] Nutrient artery provides 70-80% of blood supply to the long bones of human and if any deterioration in blood supply of long bone during early child and adult life, it may affect the growth of long bone if injury during fracture reduction, bone grafting

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and joint replacement lead to ischaemia of long bone resulting into less vascularisation of diaphysis, metaphysis and growth plate.[4] Because of this orthopedic and surgeons to have well knowledge of nutrient foramina before go to surgery to prevent catastrophic damage artery. The tibia is commonly involved in several surgical procedures like bone grafting, the knee replacement, external and internal fixation of fractures and bone resection for tumours.[5,6] Present study was conducted for knowledge of morphology and morphometric of nutrient foramen on tibia.

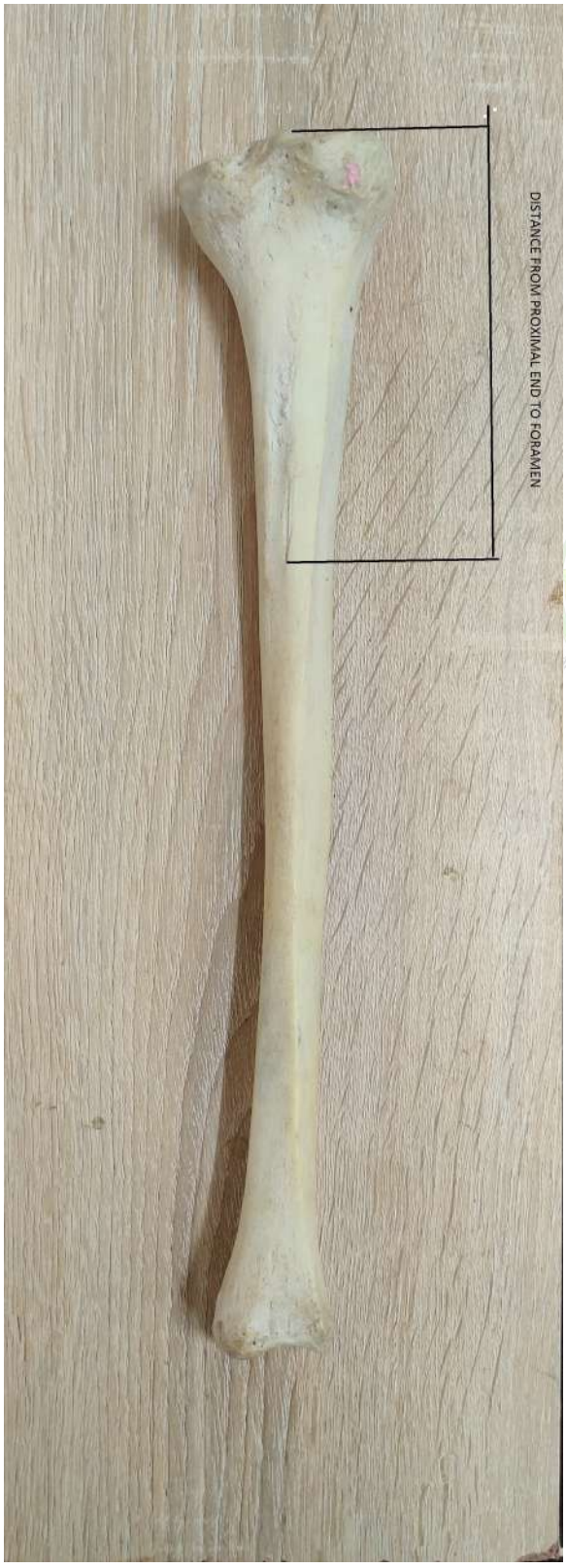

Fig 1: Showing distance from proximal end of Tibia to Nutrient Foramen

METHODS

The present study included 100 dried tibia bones with unknown age and sex, which was taken from the anatomy department of Geetanjali medical college & Hospital Udaipur and Pacific medical college & hospital, Udaipur and marked number on it. Morphological and pathological abnormal bones excluded from study.

Help of vernier caliper and fine gauge needle, we study 53 right sided tibia and 47 left sided tibia. We study A) Number of foramen present on bone. B) Location of foramen present on which surface. C) Nutrient foramen direction. D) Total Length (TL) of Tibia. E) Distance (PF) from proximal end of tibia. F) With Help of Hughes formula, we calculated Foramina Index.

Number, Location and Direction observed macroscopically with help of gauge needle and osteometric board was noted. Total length (From the Upper margin of the medial condyle and lower end of medial malleolus and Distance of Foramina measured from proximal end of Tibia.

Foramina Index: with help of Hughes formula, we calculated our data.

Foraminal index = PF/TL×100

According to index,

Position of foramen was determined Accordingly,

A) Foramen is in the Lower 1/3 of the bone if Index >66.66
B) Foramen is in the Middle 1/3 of the bone if Index between 33.33 to 66.66
C) Foramen is in the Upper 1/3 of the bone if Index < 33.33

RESULTS

In present study we found single foramen present in 80 bones, Double foramen present 18 bones and in 2 bones there was triple foramen at different level. According direction: In upward direction of foramen found in 1 bone, horizontal direction found in 3 bone and most of bone have downward direction. According location: In most of bone Nutrient foramen was situated on posterior surface except in four bones where it was situated on lateral surface and in 66 bone Nutrient foramen present in upper 1/3 of bone except 34 bone where it presents in middle 1/3.

Table 1: Showing average Total length, distance from proximal end and number of nutrient foramen of Tibia.

	Total length Tibia (TL) (Average in cm)	Distance from Nutrient foramen from Proximal end of Tibia (PF) (Average in cm)	Number of foramen present on bone		
			Upper 1/3	Middle 1/3	Lower 1/3
Rt	36.5	12.1	35	18	0
LT	36.8	11.92	31	16	0

Table 2 Showing direction and location of Nutrient foramen

	Number foramen			Direction of Foramen			Location of foramen (surface)	
	Single	Double	Triple	Downward	Upward	Horizontal	Posterior	Lateral
Rt	42	9	2	52	1	3	56	4
Lt	38	9	0	44	0	0	40	0

DISCUSSION

Long bone in human is mainly supply by Nutrient artery which enter into bone through nutrient foramen then it divided into ascending and descending branch then supply rest part of

bone and provide nutrients to bone which require for growth of bone. The entry point is present in diaphysis that why this artery also called diaphyseal artery. For any fracture surgery and reconstructive surgery there have very caution about this artery and its course. Any injury to nutrient artery during surgery which cause the catastrophic event which very dangerous to bone growth in child. Because of this depth knowledge of anatomy of this artery is very important for orthopedic and surgeon.

In our study, we studied many parameters.

Number of foramen: In present study we found single foramen in 80 bone and most authors study found same, our study noticed Double nutrient foramina were found in 18 numbers of bones. Zahra SU et al. found around 4.5 % bone have double foramen,[7] Seema et al. reported 10% bone have dual foramen,[8] other author like Roul B et al. and Udaya P et al., noted 16.2% and 23.8 % of double foramina in bone which higher than other study.[9,10] We have found triple foramen in our study was only 2 % it also less number in other study like Swapna SA and Udaya P found 3.80% and 2.70% in their studies.[10] In our study we have not found any bone without nutrient foramen but few study found absent nutrient foramen like Joshi P, Prashanth KU and Gupta RK observed there is no nutrient foramen in 6%, 1.4% and 6.20% of tibia respectively.[11-13] In this case blood supply carried by periosteal vessel.[13]

Direction of foramen: There are changing in direction of nutrient foramen during embryological and after birth. Starting period of life nutrient arteries going in caudal direction toward growing end but in long bone growth is different because of this nutrient artery is directed away from the growing end.[4] In our study mostly all bone has nutrient foramen direction was downward, only less 1 and 3 % bone have upward and horizontal direction. Also, Mazengenya P and Faremore MD, noted direction of foramen upwards in 0.6% and 1.7% of tibia in South Africans population.[14]

Location of Foramen: In our study, most bone's nutrient foramen was found on posterior surface the tibia 96 % except in 4% bones where it was found on the lateral surface, many textbooks and studies of various of authors also have noted the location of foramen on posterior surface in most of the bones but some author found on medial surface like Kamath V et al., found foramen on medial surface in 2.82% of bones.[6] Hiren Chavda found in 87.14% of bones, foramina were located lateral to vertical line; in two bones it was medial to vertical line and in four bones on the vertical line.[1] Seema et al., and Collipal E et al., found 3.77% and 4% of tibia having nutrient foramen on the soleal line.[8,15]

Total Length of tibia (TL): In our study we found total length of tibia was 36.5 and 36.8 on rt and Lt side. Hiren Chavda was found to be 35.1±2.3 cm on right side and 35.2±1.96 cm on the left side.[1] In black South Africans and white South African length were 38.44 cm and 37.12 cm observed by Mazengenya P and Faremore MD.[14] In Turkish population length of tibia was 35.8 cm noted by Kizilkanat E and Pereira GAM et al., found it to be 37.31 cm .[16,17]

Average distance of nutrient foramen from proximal end (PF); In present study we found there was distance between proximal end and foramen was 12.1 and 11.92 on Rt and Lt side respectively. According to Hiren Chavda observation, the distance was 11.8±1.93 cm on right side and 11.8±2.28 cm on left side.[1] Ankolekar VH et al., found distance was 13 cm and 13.4 cm on the right and left side respectively.[2] Joshi P and Mathur S, found on Rajasthani population, this distance was 14.53±3.77 cm on right side and 14.0±2.99 cm on left side.[11]

Distance of nutrient foramen from proximal end (PF): Average distance of nutrient foramen from proximal end in our study was 12.1 cm and 11.92 cm respectively on Right and left side. Hiren Chavda et al., observed in their study was 11.79 cm and 11.8 cm on the right and left side respectively.[1] Joshi P and Mathur S, found distance was as 14.53±3.77 cm on right side while 14.0±2.99 cm on left side.[11]

Foraminal Index (FI):

In our study was found to be it was in the middle 1/3. Gupta RK and Gupta AK also observed similar findings in Gujarati population.[13] Vadhel CR et al., in their study on Gujarati population found occurrence of nutrient foramen on upper 1/3 in 99.5% of bones, which was higher than the present findings.[18] Mohan K et al., found it on upper 1/3 in 42% of bones while in 52%, it was on middle 1/3.[19] No foramen was found in the lower 1/3rd of the tibia. Kamath V et al., reported nutrient foramen in upper 1/3rd in 74.65% of bones and in middle 1/3rd in 25.35% of bones.[6] Pereira GAM et al., and Mazengenya P and Faremore MD, in their studies also found nutrient foramen more commonly on upper 1/3rd more than on the middle 1/3rd.[14,17]

Table 3: Showing comparison of various study about Number of Nutrient foramen

Author (Year of study)	Number of Bone include in study	Nutrient foramen number (%)							
		1		2		3		Absent	
		Rt	Lt	Rt	Lt	Rt	Lt	Rt	Lt
Hiren S. Chavda et al. (2018)	70 (Rt-35, Lt-35)	100	100	-	-	-	-	-	-
Zahra SU et al. (2018)	91 (Rt-40, Lt-51)	97.5	96.0	2.5	1.96	-	-	1.96	
Joshi P et al. (2018)	50 (Rt-21, Lt-29)	94 -		-	-	-	-	6	
Udaya P et al. (2017)	151 (Rt-74, Lt-77)	83.70	89.6	13.51	10.3	2.70 -		-	-
Vinay G et al. (2017)	90 (Rt-45, Lt-45)	96.66		3.33		-	-	--	-
Mohan K et al. (2017)	150	98		2		-	-	-	-
Swapna SA et al. (2016)	-	94.30		1.90		3.80		-	-
Agarwal SA et al. (2016)	80 (Rt-40, Lt-40)	100		-	-	-	-	-	-
Seema et al.(2015)	60 (Rt-30, Lt-30)	93.34	96.6	6.60	3.30	-	-	-	-
Mazengenya P et al. (2015)	180 (Rt-90, Lt-90)	98.30		1.70		-	-	-	-
Roul B et al. (2015)	37	83.70		16.20					
Gupta RK et al. (2014)	312 (Rt-161,Lt-151)	97.51	94.7	0.62	-	-	-	1.86	4.34
Ankolekar VH et al. (2013)	50	98		0	2	-	-	-	
Present study (2019-20)	100 (Rt-53, Lt-47)	42	38	9	9	2	-	-	-

Table 4: showing comparison of various study in different parameter of location, length of bone and foramina index.

Author	Location Foramen % bone				Mean length of bone [cm]		Foraminal Index[cm]	
	Upper 1/3		Middle 1/3					
	Rt	Lt	Rt	Lt	Rt	Lt	Rt	Lt
Hiren S. Chavda et al	62.85	65.71	33.14	34.28	35.1±2.3	35.2±1.96	33.8±5.43	33.5 ± 5.56
Zahra SU et al.	72		28		35.54±2.53	36.17±2.96	32.39±2.21	32.05 ± 4.6
Joshi P et al.	88		6		32.84±8.4	34.46±8.1	31.85±1.8	31.67±2.83
Udaya P et al.	73.86	81.18	26.4	18.82	37.26±2.83	37.54±2.30	32.09±3.76	32.12±3.13
Mohan K et al.	42		58		36.58±2.38		34.74±4.08	-
Vinay G et al.	86.66		16.66		35.58		34.82	
Agarwal SA et al.	92.85		7.5		37.75 ±		32.96±6.06	
Lakshmi V et al.	58.82		41.17		37.4±2.61		33.7±3.32	
Roul B et al.	91.89		8.1		37.2		33.33	33.33
Gupta C et al.					37.75±3.45	37.68±1.61	34.66	34.83
Mazengenya P et al.					37.12		31.45±2.52	31.87±3.63
Gupta RK et al.	63.97	58	36.03	42	36.1	36.44	32.66	33.09
Ankolekar VH et al.	91.66	88.46	8.33	11.54	37.3	38.7	35.92	34
Present study	66.03	65.95	33.96	34.04	36.3±2.5	36.8±2.2	33.15	32.39

CONCLUSION

In present study we found, Nutrient foramen was located mostly on the posterior surface and direction was downward. Nutrient artery is very important for blood supply of long bones. Therefore, it is very important for surgeons to have sound knowledge of precise morphology and morphometric of nutrient foramen which will help in preserving vasculature of bone during various surgical procedures like bone grafting, the knee replacement, external and internal fixation of fractures and bone resection for tumors.

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Original Research Article

ANATOMICAL VARIATIONS OF THE DISTAL END OF HUMERUS

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ABSTRACT

Background: The study was aimed at determining the variations of lateral epicondyle, capitulum and lateral trochlear crest of humerus and finding out the prevelance of different forms.

Materials and Methods: 60 dried Human humeri were examined grossly from the collection of Anatomy department, Pacific Medical College & Hospital for the location of lateral epicondyle, extent and shape of distal margin of capitulum and for the lateral trochlear crest.

Results: In 76.67% of humeri, lateral epicondyle was located at the same level/ slightly below the level of capitulum whereas in 23.33% of humeri, it was located above the level of capitulum, Distal margin of capitulum was Flat and extending onto distal surface in 83.33% of humeri where as it was Convex and extending onto posterior surface in 16.67% of humeri. Lateral trochlear crest was pooriy developed in 10%, moderately developed in 85% and well developed prominent in 5% of humeri.

Conclusion: This study may help in repairing the fractures/reconstruction of trochlea and capitulum, designing of elbow prosthesis, repairing the damage to radial collateral ligament as well as lateral epicondyle surgeries of humerus.

KEY WORDS: Lateral epicondyle, Trochlea, Capitulum, Distal end of Humerus.

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INTRODUCTION

Humerus is the largest and longest bone in the upper limb, has expanded ends and a shaft. The lateral epicondyle occupies, lateral part of non articular portion of condyle. The capitulum is a rounded convex projection, considerably less than half a sphere which covers the anterior and inferior surfaces of the lateral part of the condyle of the humerus but does not extend onto its posterior surface. Trochlea is a pulley shaped structure that covers the anterior, inferior and posterior surfsces of the condyle of humerus medially and on its lateral side, it is

separated from capitulum by a faint groove [1].

Uptill now, distal end of the humerus was used by researchers for the studies like determination of Total length of humerus from the fragments of distal end of humerus, gender determination, forensic sciences and supratrochlear foramen studies [2-4]. These studies used complex statistics and measurements which were time consuming, so this study was conducted to determine different types of presentations of lateral epicondyle, capitulum and lateral edge of trochlea as well as their prevalence in dry human humerus by gross examination.

Knowledge of the these anatomical variations at the lower end of humerus is required to orthopaedic surgeons in repairing the fractures/ reconstruction of trochlea and capitulum, designing of elbow prosthesis, repairing the damage to radial collateral ligament as well as lateral epicondyle surgeries of humerus.

MATERIALS AND METHODS

This study was undertaken at Pacific Medical College and Hospital, Udaipur. A Total of 60 dry humeri were examined irrespective of their side and sex from the collection of Department of Anatomy, Pacific Medical College and Hospital, Udaipur. Distal end was examined for the following parameters:

1. Location of lateral epicondyle.
2. Shape and extent of distal margin of capitulum.
3. Lateral trochlear crest.

Fig. 1: (a) Lateral epicondyle at the same level of capitulum, (b) Lateral epicondyle above the level of capitulum.

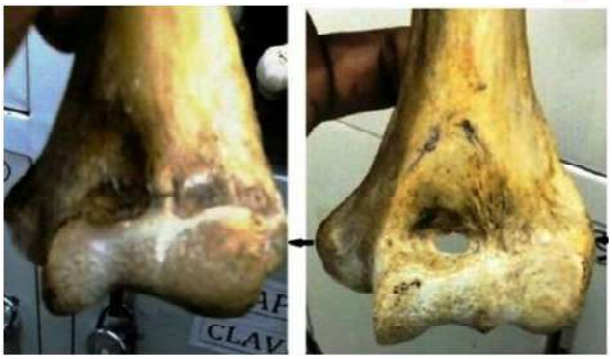


Fig 2: (a) Distal margin of capitulum flat and extending on to distal surface of lower end of humerus, (b) Distal margin of capitulum convex and extends on to posterior surface of lower end of humerus.

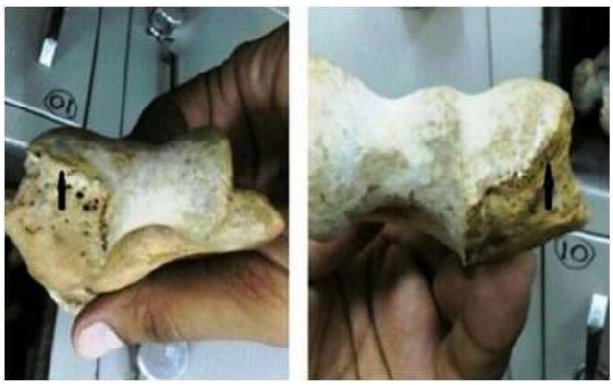
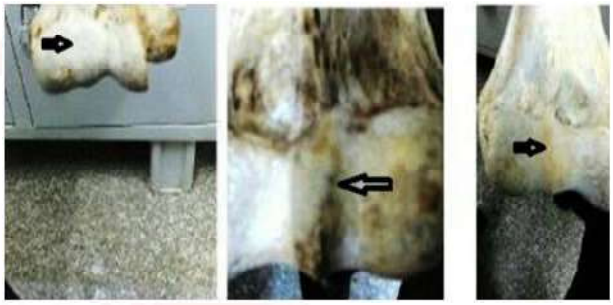


Fig. 3: Lateral trochlear crest (a)poorly developed, (b)well developed and prominent, (c)moderately developed.



RESULTS AND DISCUSSION

In our study, Lateral epicondyle of humerus was found at the same level of capitulum/slightly below the level of capitulum in about 76.67% of humeri where as in 23.33%, it was well developed and located above the level of capitulum which may prove advantageous for added lever action of long extensors of fingers and wrist. High placed lateral epicondyle makes the trochlea easily accessible during the Built-on surgical techniques for distal humerus shear fractures [5]. As the Radial collateral ligament is attached to distal surface of lateral epicondyle [6], knowledge of exact location of lateral epicondyle is important to diagnose Radial collateral ligament abnormalities [7]. Among the varieties of capitulum, capitula with flat distal margin extending onto distal surface were 83.33% whereas capitula with convex distal margin extending onto posterior surface were 16.67%. Flat distal margin extending onto distal surface only may prevent the hyper extension of elbow. These variations may help in designing elbow prosthesis and capitular reconstruction. Lateral trochlear crest was poorly

developed in 10%, moderately developed in 85% and well developed prominent in 5% of humeri. Any fracture of trochlea involving the lateral trochlear crest makes the person susceptible for the capitular fracture as well [8]. So the knowledge of variations of lateral trochlear crest may help in diagnosis of extent of fracture and thereby guiding the surgical procedure. Presentations of various types and their prevalence are illustrated in the Table-1.

Table 1: Presentations of various types and their prevalence.

PARAMETER	VARIATIONS		
Location of lateral epicondyle (60)	At same level/ slightly below the level of capitulum(46) – 76.67%	Above the capitulum(14)- 23.33%	
Distal margin of capitulum (60)	Flat and extending onto distal surface(50) – 83.33%	Convex and extending onto posterior surface(10) – 16.67%	
Lateral trochlear crest (60)	Poorly developed (6) – 10%	Moderately developed(51) – 85%	Well developed and prominent (3) – 5%

CONCLUSION

Lateral epicondyle, capitulum and lateral trochlear crest do exhibit variations. Such variations of distal humerus have been studied least in india so far.Knowledge of these variations having variety of clinical implications such as in making elbow prosthesis, to diagnose extent of fracture and to determine mode of surgeries etc.

Conflicts of Interests: None

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Original Research Article

A study on association of placental morphometry with newborn anthropometry

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ABSTRACT

Fetal improvement is the fundamental part of maternal supplement stores & compelling transportation through the placenta. Consequently, any distinction in the placenta brings about inconsistent fetal advancement results of expanded danger of delayed sicknesses in the neonatal. This investigation was expected to find the impact of placental morphometry on infant anthropometry.

Materials and Methods: In current study lacentae were obtained from Obstetrics and Gynecology Unit & pacific medical college & hospital Udaipur and study was conducted in the Dept. of Anatomy, Geetanjali M.C. and Hospital, Udaipur (Rajasthan) from August 2018 to November 2019, by using standard operating methods in a pre-designed & pre-tested format, distributions of placental morphology & newborn anthropometry are stated in percentage & box plots, evaluation of variance is used to study the differences in means of placental morphometry in various groups of newborn anthropometry.

Results: The Means & SD of placental morphometry; weight, volume, surface area & thickness were found to be 440 ± 100gm, 386 ± 101 ml, 230 ± 50 cm sq, & 2.1±0.4cm respectively, whereas Mean for birth weight & length found to be 2700±500 gm & 46.6 ±2.5cm of newborn. Placental morphometry & newborn anthropometry improved significantly with pregnancy.

Conclusions: The study extrapolates that maternal pre-pregnancy & during pregnancy condition status along with placental morphology determines neonatal health status. Hence, variations in the maternal nutrient status lead to an adverse gestational outcome.

1. Introduction

Placental advancement was perceived from fossil indication of Ichthyosaurus, in excess of 170 million years prior. Circle molded haemochorial placenta of various humans, happened all through the Eutherian ancestry.[1]

Chorionic plate resultant from the developing incipient organism & decidual plate resultant from a change of the uterine covering of the mother, Consequently, the human placenta develops from both uterus & creating embryo.[2–5] In beginning the placenta assesses the embryo in size & keeps on creating till term. As gestation propels, it grows moderately more modest & by term, the proportion of its weight to that of the baby is about 1:6 to 1:72.

The chorionic plate part expresses the placental surface part covering the uterus & depicts, the number of maternal winding courses & veins are plausible gives to surface area.[6] Placental turn of events & profitability are the main fetal wellspring of supplements & oxygen flexibly. Placental improvement is around achieved by beginning third trimester, while the thickness of placenta increments in last third trimester.[7–10]

Placental thickness, by distinction, denotes the measure of arborisation of the villous slender bed, the genuine locus of maternal-fetal trade.[11] Placental volume was clearly comparative with the birth weight of the baby.[12]

Unordinary chorionic plate shape regularly uncovers pathologic villous decay from the finish of the principal

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trimester or placental infarct. Subsequently, these boundaries of placental advancement might be crucial pointers of placental load at delivery.[13]

2. Materials and Methods

The current examination was coordinated in the Department of Anatomy, Geetanjali Medical College and Hospital, Udaipur (Rajasthan) and pacific clinical school and emergency clinic Udaipur. Placentae were assembled from Obstetrics and Gynecology Unit. Data was gathered from August 2018 to November 2019. The examination was directed to 391 mothers & their singleton posterity. Information about mothers & consent was taken starting the real examination. Subjects without antenatal enrollment during the principal trimester & with history of pre-pregnancy key & industrious ailments were banished. Placental morphometry & baby limits were noted on the predesigned & pretested design.

1. Techniques for example assortment, planning, & evaluation of placental morphometry:[14]
   a. Placentae were assembled not long subsequent to secluding the newborn from the umbilical rope, assembled placentae were assessed inside & out washed under the running water, starting there, layers were overseen.
   b. The models were marked with numbers for ID & were delivered to the capacity lab by setting in a 10% formalin compartment.
   c. The weight of each placenta of newborn was kept constrained by the automated measuring scale CS-8316(CE guaranteed) & recorded with an exactness of 1 gm.
   d. The maternal surface locale of the placenta was resolved using the formula.[15]
2. Boundaries of infant evaluated were:
   a. Gestational age, weight & height of the newborn.
   b. The G.A. was recorded from LMP & further insisted by USG as 28-34, 35-36, 37+ wk.
3. Birth weight calculated using Digital baby measuring scale CS-8316 (CE asserted) with an accuracy of 10 gm.

2.1. Statistical analysis

Statistical Analysis was carried out using Analysis of Variances and comparisons of means were studied by t-test was done utilizing SPSS-16, the Box plots were set up to examine the relative circulations placental morphometry & infant anthropometry.

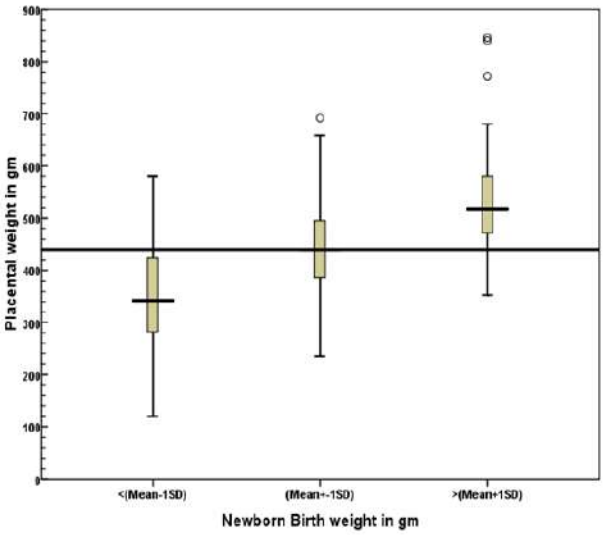

Fig. 1: Placental weight by birth weight

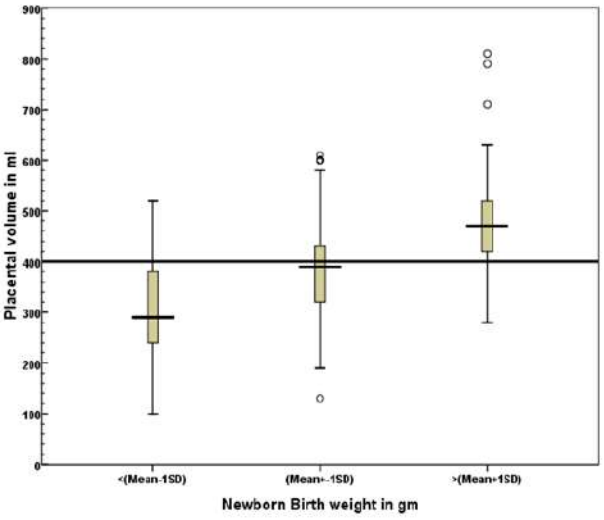

Fig. 2: Placental volume by birth weight

3. Result and Discussion

Mean birth weight if there should be an event of the current assessment was 2,700 gm, lesser than all recently referenced considers, yet practically like Mysore Parthenon study as they were from similar neighborhood belt of India.[16–18] Placental development is related with pregnancy results, as the placental morphology & its physiology decide the development direction of the embryo. Mean birth weight in the current assessment was nearer to that of Indian newborn children, it is decided the ideal extent of birth weight in made countries as 3000-4000 gm to keep up a key good ways from maternal & fetal mortality & morbidity[19] referred to the mean & SD of birth weight

Table 1: Distribution of gestation & birth weight

Variables	Percent	Cumulative Percent	
		Observed	Expected
a. Gestation in wks, Mean=38.3, SD=2.2			
28-32	4.1	4.10	0.87
33-36	10.7	14.80	28.00
37-40	78.5	93.40	88.70
41+	6.6	100.00	100.00
Total	100		
b. Birth weight in gm, Mean=2700, SD=500			
1000-1499	3.6	3.6	0.8
1500-1999	3.6	7.2	8.1
2000-2499	21	28.2	34.5
2500-2999	44.5	72.6	72.6
3000-3499	22.8	95.4	94.5
3500+	4.6	100	100
Total	100		

Table 2: Percentiles by birth weight groups

Newborn birth weight among groups (Mean=2700, SD=500)	Percent % (n=391)	Percentiles						
		5	10	25	50	75	90	95
a. Placental weight in gm								
<(Mean-1SD)	11.51	201.5	227.6	272.5	342.0	426.0	500.0	559.7
(Mean±1SD)	75.70	304.9	340.5	386.0	440.0	495.8	562.9	586.0
>(Mean+1SD)	12.79	373.1	402.1	469.8	517.5	580.0	649.8	802.6
b. Placental volume in ml								
<(Mean-1SD)	11.51	106.0	176.0	225.0	290.0	380.0	414.0	486.0
(Mean±1SD)	75.70	250.0	280.0	320.0	390.0	430.0	500.0	520.0
>(Mean+1SD)	12.79	300.0	371.0	420.0	470.0	520.0	609.0	746.0
c. Placental surface area in cm sq								
<(Mean-1SD)	11.51	106.5	127.0	154.0	187.0	213.7	243.3	262.4
(Mean±1SD)	75.70	164.8	176.8	200.4	226.3	253.8	282.9	314.3
>(Mean+1SD)	12.79	193.8	206.8	227.1	265.6	297.4	314.2	368.2
d. Placental thickness in cm								
<(Mean-1SD)	11.51	1.3	1.5	1.5	2.0	2.5	2.5	3.0
(Mean±1SD)	75.70	1.5	1.5	2.0	2.0	2.5	2.6	3.0
>(Mean+1SD)	12.79	1.5	1.6	2.0	2.1	2.5	3.0	3.0

of Malays, Chinese, & Indian youngsters as 3126±300gm, 3245±300gm & 2935±400gm respectively.[20]

In the current assessment birth weight indicated a dependably sure & tremendous connection with the going with limits: The current assessment declares the placental weight, volume, & surface domain are basic determinants of birth weight.[21] Placental morphometry: Weight ($p<0.001$), volume ($p<0.001$), surface zone ($p<0.001$), thickness ($p<0.05$), baby Length ($p<0.001$), current examination showed 28.2% LBW kids described as under 2500 gm.

LBW was identified with an extended risk of perinatal mortality & those youngsters who suffer are slanted to have hindered immune limit, diminished muscle quality, & bear cardiovascular diseases[22] so, birth weight can be used as a strong marker of newborn child unsullied perseverance.

A Norway based study declared the mean newborn child length of 50.8±SD 2.320cm. The placental weight mirrors the turn of events and capacity of the placenta and is corresponded with gestational age. The current examination indicated that placental weight expanded by birth weight and gestational age, which agrees with past perception. Another Indian assessment itemized the mean newborn child length of 47.06±1.18cm. The mean baby length from Malays 48.8 cm, Chinese 49.5 cm & Indians 48.1 cm, & assumed that Indian youngsters were more restricted than Malays & Chinese neonates.[23] The mean length 48.7 cm of newborn child & uncovered an immense positive association between's the placental weight & baby length.[24]

4. Conclusion

Maternal pre-pregnancy weight mean (48.4±8.9 kg) with 14.1% of women weighing less than 40 kg. Percentiles of birth weight & placental morphometry: weight, volume, & surface area with maternal pre-pregnancy

Table 3: Percentiles of birth weight & placental morphometry length among groups

Newborn length groups (Mean=46.6, SD=2.5 cm)	Percent (n=391)	Percentiles 5	10	25	50	75	90	95
a. Birth weight in gm								
<(Mean-1SD)	10.49	1100	1200	1372	1800	2000	2940	3100
(Mean±1SD)	79.28	2200	2300	2500	2700	2900	3000	3200
>(Mean+1SD)	10.23	3000	3000	3100	3325	3500	3698	3924
b. Placental weight in gm								
<(Mean-1SD)	10.49	196.5	225.2	261.5	334.0	430.0	511.4	560.9
(Mean±1SD)	79.28	307.2	344.4	388.0	440.0	496.0	560.0	583.5
>(Mean+1SD)	10.23	352.2	386.0	469.3	560.5	585.5	652.1	832.0
c. Placental volume in ml								
<(Mean-1SD)	10.49	102.0	172.0	210.0	290.0	370.0	426.0	479.0
(Mean±1SD)	79.28	260.0	280.0	320.0	400.0	430.0	500.0	520.0
>(Mean+1SD)	10.23	300.5	341.0	420.0	500.0	527.5	607.0	782.0
d. Placental surface area in cmsq								
<(Mean-1SD)	10.49	103.6	121.9	153.6	187.0	207.4	251.1	287.0
(Mean±1SD)	79.28	165.0	176.8	200.4	226.3	253.8	282.9	314.3
>(Mean+1SD)	10.23	177.3	212.3	235.7	267.1	298.5	314.2	329.5
e. Placental thickness in cm								
<(Mean-1SD)	10.49	1.2	1.4	1.5	2.0	2.5	2.5	2.6
(Mean±1SD)	79.28	1.5	1.5	2.0	2.0	2.5	2.6	3.0
>(Mean+1SD)	10.23	1.5	1.5	2.0	2.0	2.5	3.0	3.0

Table 4: Association of placental morphometry with birth weight

Birth weight groups	N	Percent	Mean	SD	SE	95% Confidence Interval Lower	Upper
Weight in gm;*; F2,388=49.94; p<0.001**							
<(Mean-1SD)	45	11.5	353.2	103.2	15.4	322.2	384.3
(Mean±1SD)	296	75.7	442.8	82.3	4.8	433.4	452.3
>(Mean+1SD)	50	12.8	533.4	103.8	14.7	503.9	562.9
Total	391	100.0	440.0	100.0	5.0	434.3	453.9
Volume in ml;*;F2,388=53.81; p<0.001**							
<(Mean-1SD)	45	11.5	296.1	98.8	14.7	266.4	325.8
(Mean±1SD)	296	75.7	384.2	82.8	4.8	374.7	393.6
>(Mean+1SD)	50	12.8	482.6	105.5	14.9	452.6	512.6
Total	391	100.0	384.6	101.0	5.0	376.8	396.5
Surface area in cm sq ;*; F2,388=38.13; p<0.001**							
<(Mean-1SD)	45	11.5	183.9	42.7	6.4	171.1	196.8
(Mean±1SD)	296	75.7	230.7	45.9	2.7	225.4	235.9
>(Mean+1SD)	50	12.8	266.1	48.8	6.9	252.2	279.9
Total	391	100.0	229.8	50.1	2.5	224.9	234.8
Thickness in cm;*;F2,388=4.12; p<0.05							
<(Mean-1SD)	45	11.5	2.0	0.5	0.1	1.9	2.2
(Mean±1SD)	296	75.7	2.1	0.4	0.0	2.1	2.2
>(Mean+1SD)	50	12.8	2.3	0.8	0.1	2.1	2.5
Total	391	100.0	2.1	0.5	0.0	2.1	2.2

Table 5: Association of placental morphometry with length of newborn

Newborn length groups		Percent	Mean	SD	SE	95% Confidence Interval	
						Lower Bound	Upper Bound
Birth weight in gm;*;F2,388=198.0; p<0.001**							
<(Mean-1SD)	41	10.5	1829	576	90	1647	2011
(Mean±1SD)	310	79.3	2685	312	18	2650	2719
>(Mean+1SD)	40	10.2	3341	270	43	3255	3427
Total	391	100.0	2700	500	25	2613	2711
Weight in gm;*;F2,388=46.7; p<0.001**							
<(Mean-1SD)	41	10.5	348.9	107.8	16.8	314.9	382.9
(Mean±1SD)	310	79.3	444.5	82.0	4.7	435.3	453.7
>(Mean+1SD)	40	10.2	538.7	112.2	17.7	502.8	574.6
Total	391	100.0	440.0	100.0	5.0	434.3	453.9
Volume in ml;*; F2,388=48.1; p<0.001**							
<(Mean-1SD)	41	10.5	291.2	101.3	15.8	259.3	323.2
(Mean±1SD)	310	79.3	386.6	83.7	4.8	377.2	395.9
>(Mean+1SD)	40	10.2	485.0	112.1	17.7	449.1	520.9
Total	391	100.0	384.6	101.0	5.0	376.8	396.5
Surface area in cm sq ;*; F2,388=30.30; p<0.001**							
<(Mean-1SD)	41	10.5	184.5	45.9	7.2	170.0	199.0
(Mean±1SD)	310	79.3	231.4	47.0	2.7	226.1	236.6
>(Mean+1SD)	40	10.2	264.2	45.2	7.1	249.8	278.6
Total	391	100.0	229.8	50.1	2.5	224.9	234.8
Thickness in cm;*; F2,388=3.91; p<0.05							
<(Mean-1SD)	41	10.5	2.0	0.4	0.1	1.8	2.1
(Mean±1SD)	310	79.3	2.1	0.5	0.0	2.1	2.2
>(Mean+1SD)	40	10.2	2.2	0.4	0.1	2.1	2.3
Total	391	100.0	2.1	0.5	0.0	2.1	2.2

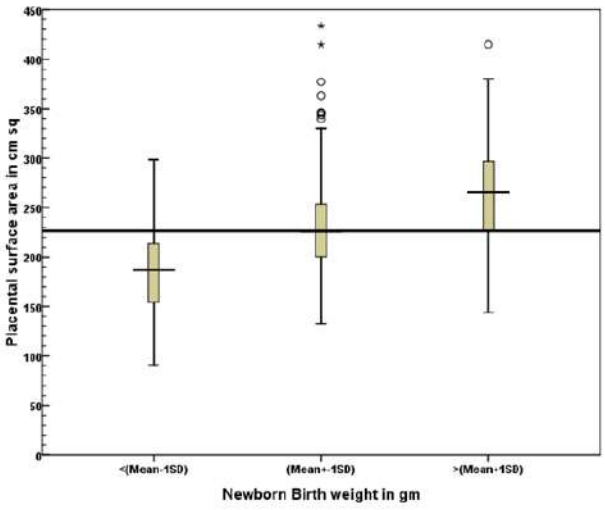

Fig. 3: Placental surface area by birth weight

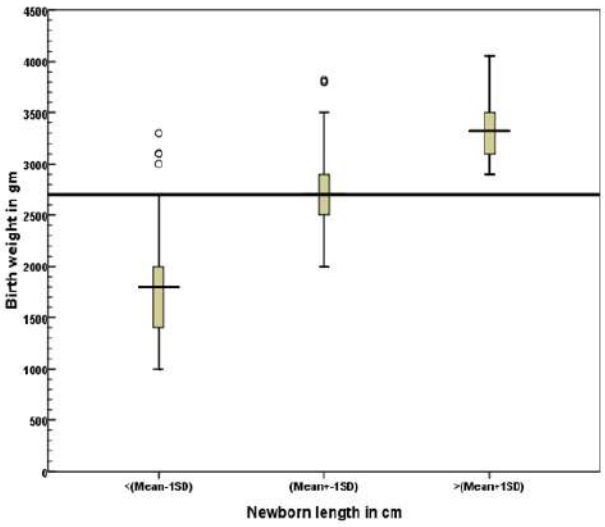

Fig. 4: Birth weight by newborn length

weight (p<0.001) & surface zone (p<0.05). Gestational weight gain was basically identified with birth weight (p<0.01) regardless, placental morphometry. Maternal height followed dissemination where 08.2% of pregnant women had height under 145 cm & 59.8% were from height pack 150-159 cm. The mean maternal height was 153.9±6.7cm. Percentiles of birth weight growing example with maternal height yet placental morphometry & Birth weight (p<0.05) extended dependably with the growing maternal height, nevertheless, placental morphometry didn't

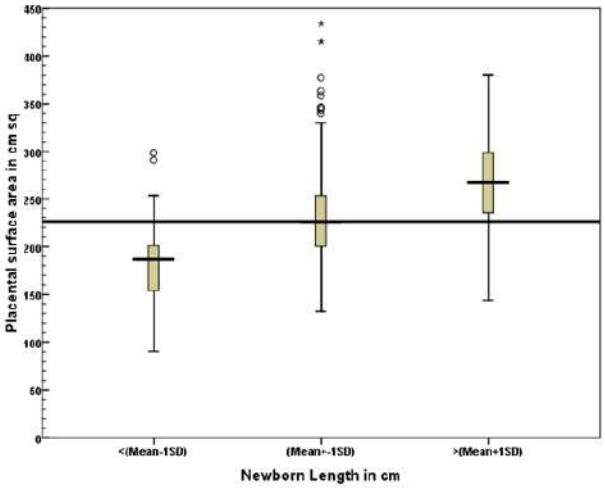

Fig. 7: Placental surface area by newborn length

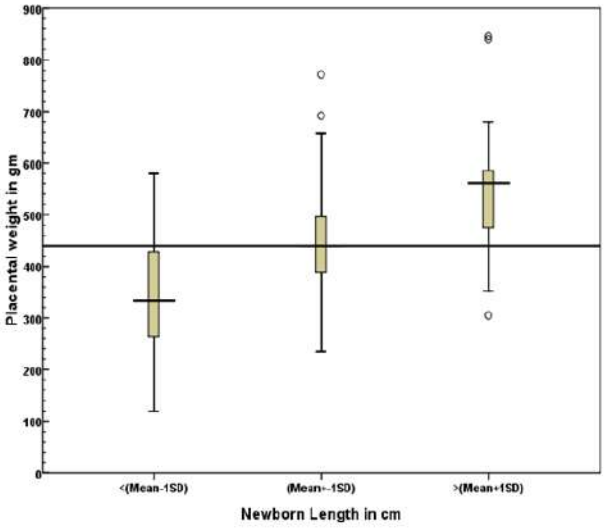

Fig. 5: Placental weight by newborn length

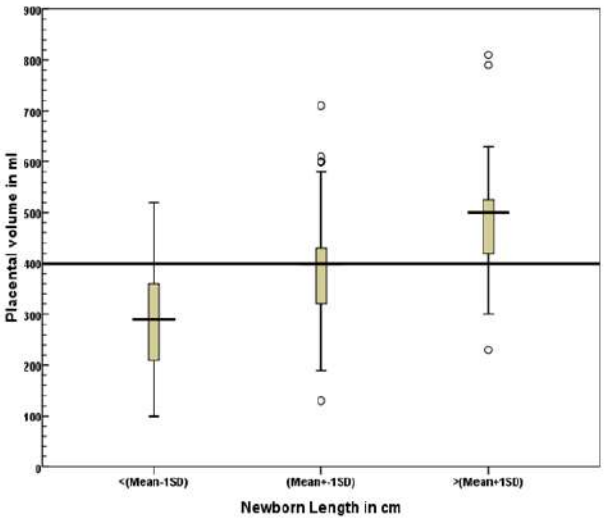

Fig. 6: Placental volume by newborn length

show any consistent association

5. Limitations

Placental morphometry determines the birth weight & newborn length. However, the results need further validation in other setups with a large number of subjects.

6. Source of Funding

None.

7. Conflict of Interest

The authors declare no conflict of interest.

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Original Research Article

A case-control study on relationship between dermatoglyphics and diabetes

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ABSTRACT

Background: Nowadays study of dermatoglyphics has an extraordinary significance in legal and criminal explores. Additionally, its investigation is identified with some hereditary sicknesses has an enormous application. Diabetes Mellitus is the silent killer of humanity and general medical issue. Dermatoglyphics might be viably utilized as a screening methodology in future and may help in the early recognition of instances of diabetes mellitus.

Materials and Methods: In our study, total of 100 patients were selected from the out door patient department from the hospital, out 0f 100 patients 50 patients those are suffering from diabetes made the experimental group and the other those are having no systemic condition made the other group or the control group. The establishment of the connection between the two groups by examining the each group the fact of presence or absence of dermatoglyphic design. In this total finger ridge count, indian ink technique was usd for taking up the hand, along with total ridge count of finger, absolute finger ridge count, ridge count for distal as well as lateral deviation along with palmer frequency design computerised along with lateral deviation with design frequency of the c- line and angles, which represent the qualitative boundary.

Results: The result that has been obtained from our study reveals that the total finger count of the ridge along with ridge count of the finer absolute, along with a-b count of the ridge were found to be higher in all the groups of the patient but found to be insignificant statistically. Angle "atd" that is present over both the sides of the hand in the patient were found to be expanded in all the groups that involve both the experimental groups and the control group, but with an exception in males that too in left side, but still they differ on the right side that too significantly ($p<0.01$, overall) and on the left side i.e. in case of females with $p<0.001$. The angles of tad and as well as 'tda' which were present over the two sides of the with respect to all the groups, that include the experimental one and the control one, but with an exception with respect to males with left 'tda' and in other case they significantly differ in case of females with left tad with $p<0.01$ and in case of right side tda with $p<0.001$ and with respect to all the groups with reference to right 'tda' with value of $p<.01$ the arch advanced frequencies along with the circle and the whorl in case of females with respect to the over all groups with an exception with loop were found to be increased significantly with p value i.e. $p<0.05$. The design of the spiral along with remnant were found to be totally limited to the thenar along with the hypothenar region in the male patients when get contrasted with the controls.

Conclusion: By the results of our study we concluded that, there is expansion in the radial variety and absence was found in case of proximal variety and the designs of the c – line in case of diabetics were reduced when it is compared to the control group. Our study results demonstrated that dermatoglyphic abnormalities can be utilized as a device which act as analytic for predicting the chance for the development of the disease known as diabetes in future.

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1. Introduction

Dermatoglyphics deals the logical investigation of epidermal ridge designs on the palmar and plantar part of fingertips, palms, soles and toes.[1] The term 'Dermatoglyphics was coined by Cummins and Midlo (1926) and was derived from the Greek words 'derma' signifies skin and 'glyphics' signifies carvings (Penrose LS, 1963).[2,3] The skin on the palmar and plantar surfaces of man not smooth. It is scored by inquisitive ridges, which form a variety of designs as the dermal ridges start developing during the third intrauterine week as a result of physical or topological power.[3] Dermal ridges along with the arrangements which are once framed are not influenced by the age, advancement and ecological changes in the postnatal life thus it can possibly anticipate different hereditary and obtained disorders with a hereditary impact.[4]

Broad clinical interest in epidermal ridges grew distinctly over the most recent couple of years when it became apparent that numerous patients with chromosomal variations had strange ridge design. Assessment of skin ridges, subsequently vowed to give a basic, reasonable methods for data to decide if a given patient could have a specific chromosomal deformity.

1.1. Dermatoglyphics offers at least two significant focal points.[5]

1. The epidermal ridge designs on the hand and sole are completely evolved at birth and so, stay unaltered forever.
2. Scanning of the ridge patterns or recording these perpetual impressions can be cultivated quickly, reasonably and with no injury to the patient.
3. Finally, the relevance of dermatoglyphics is not to diagnose, but it is preventive by predicting a disease. Similarly, it is not for defining an existing disease, but for identifications of people with the genetic predisposition to develop certain diseases.

Diabetes Mellitus is the silent killer of mankind and general medical issue. Accordingly, researchers are searching for new techniques for its initial diagnosis and management. Indeed, even before that the primary expectation of it might assist with taking some prophylactic measures. One of the aetiology of Diabetes Mellitus is genetic. In this investigation, we are attempting to indicate the dermatoglyphic attributes to see if some particular quality exists in the Diabetes Mellitus patients.

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2. Materials and Methods

Total number of patients included in the study is 60 and all these 60 patients were contrasted and 60 patients were taken as control group. Confirmation that the patient is having diabetes mellitus id totally depend upon the clinical signs and symptoms given by the patient along with there blood glucose levels.

2.1. The Indian Ink method (Cumins and Midlow, 1961)

The technique that was introduced by cumins and midlow in the year 1961 that is now known as indian ink technique was utilized totally in the process of impression making with the help of camel copying ink.

The material that is utilised in our study is a piece of glass plate with dimension of 8.5x11 inches along with two plain paper of dimension 8.5x11 inches, a bottle of dimension10x4 inches, roller which is used for the dispersion of the ink, table, scale, pointed HB lead pencil along with mercury light, pointer for marking and a protractor, chemicals for washing the hand like ether and a good quality of central focal point which is enhancing.

The hands should be washed thoroughly with the help of chemicals and water and chemical ether was used to clean the dampness. Very small amount of replicating ink crushed out from the roller on a thin film for the process of direct ink over the fingers. The palm was spreaded with the help of roller that is inked to cover the palm, that has to be printed for appraisal. The paper was engaged over the compartment that is in round shape and the fingers were open after than the palm should move by the application of force over them and in the mean time by permitting the paper along with container to move in forward direction [Figure 1]. The fingerprints that were taken by different turns of the fingers both in inking and priting to get the proper impression of the finger prints. This technique will help us in recording the complete impression of the palm. After than all these prints were concentrated by central focal point that is intensifying for all the observed observations with respect to and under different heads.

3. Obeservations and Results

All the findings were recorded in a careful manner to get the quantitative as well as qualitative highlights of the dermatoglyphic from the prints from different hand of the different patients, that constitutes total of 60 patients, out of 60 30 were male and 30 were female and total number of patient under control group is 60, which constitutes of 17 females and 43 males.

45 percent was the total whole finger ridge count of the different patient examined with a range of 150-200 and for the control group it was concluded as 43 percent with a range of 100 to 150 for the control group. Mean for the diabetic group is 143.12 and for the control group it was

Table 1: Distribution with respecttot total finger count in both the sexes i.e. male and female, both in control and experimental group.

	Male		Female	
	Diabetic	**Control**	**Diabetic**	**Control**
Mean ± SD	143.12 ± 37.27	134.23 ± 34.46	138.43 ± 35.38	148.54 ± 37.43
P-Value	> 0.05	> 0.05	> 0.05	> 0.05
Significant	NS	NS	NS	NS

NS = Not Significant.

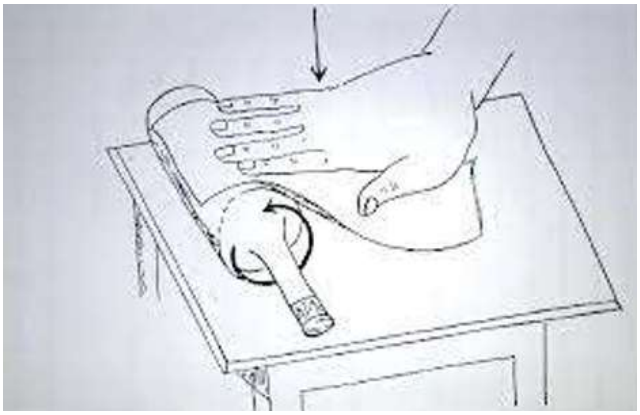

Fig. 1: Showing the technique used in taking a print

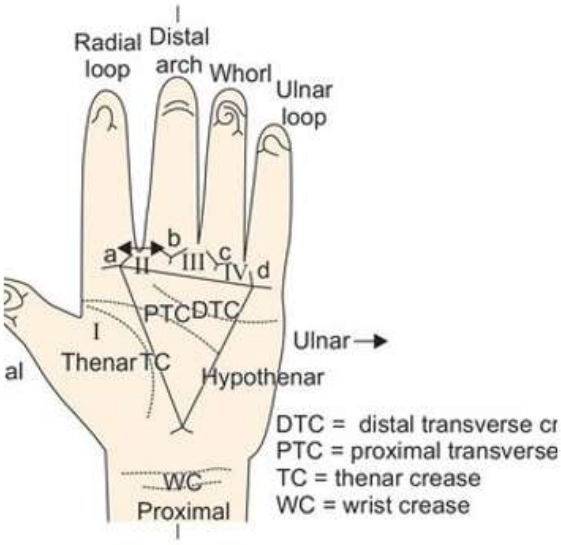

Fig. 2:

Fig. 3: Non significant type c line in case of diabetic patient.

134.23, which is found to be not differ significantly along with the above said comparative difference was additionally not significant in Table 1.

It was revealed that 43 percent was the absolute finger ridge count for the diabetic group with a range of 100 to 200 and the same is 45 percent for the control group with a range of 200 to 300. The difference which was found for their mean value is 211.48 for the experimental group i.e. the diabetic patient group and 196.43 for the other group i.e. the control group.

The point mean values of the patient with 'atd' of the right was revealed to be 43.92 and the same for the control group was revealed to be 39.41 and these two values were fond to be differed significantly with p<0.01. While we went for correlation regarding with sex wise, in case of females the mean values for left angle was found to be 41.68 in case of the experimental group i.e. the diabeteic group and 38.96 for the control group and a significant difference was found with p<0.001. on the other hand the angle distribution for the right side was in the range under 60 to 69 which constitutes about 46 percent when get contrasted with the other group thai is the control group. On the left side this was inverted on correlation with angle 'tda', both the groups i.e. experimental and control group revealed significant difference with p<0.01 over the right side. Distribution range on the right side was revealed to be 70-79 which is found to be 48% in case of experimental group i.e. diabeteic patient group, when get contrasted with 80-89 which constitutes about 66 percent in the other group

Table 2: Distribution of absolute Finger Ridge Count in both the sexes i.e. in male and female with the experimental and the control group.

	Male		Female	
	Diabetic	**Control**	**Diabetic**	**Control**
Mean ± SD	211.48 ± 54.48	196.43±41.38	192.76 ± 43.49	220.87 ±54.24
P	> 0.05	> 0.05	> 0.05	> 0.05
Significant or Not significant	Not Significant.	Not Significant.	Not Significant.	Not Significant.

Table 3: Frequency distribution ofRight and Left (A-B) Ridge Count between case and control group along with sex distribution

	Rt. (a-b) ridge count				Lt. (a-b) ridge count			
	Male		Female		Male		Female	
	Diabetic	**Control**	**Diabetic**	**Control**	**Diabetic**	**Control**	**Diabetic**	**Control**
Mean ± Standard deviation	38.7±42	37.3±4.32	37.9±4.24	36.9±4.29	38.4±3.12	38.2±3.29	37.4±43	35.5±4.2
P	> 0.05	> 0.05	> 0.05	> 0.05	> 0.05	> 0.05	> 0.05	> 0.05
Significant	Not Significant	Not Significant	Not Significant	Not Significant	Not Significant	Not Significant	Not Significant	Not Significant

Table 4: Frequency distribution of palmer between the two case and control group

Pattern Frequency			
Area	**Type**	**Right**	**Left**
	Diabetic	8	9
Thenar/I1	Control	9	10
	SignificanceX^2=0.063	df=1	P>0.05 NS
	Diabetic	4	4
I_2	Control	6	5
	Significance X^2=0.053	df=1	P>0.05 NS
	Diabetic	33	25
I_3	Control	32	12
	Significance X^2=1.642	df=1	P>0.05 NS
	Diabetic	22	24
I_4	Control	26	28
	Significance X^2=0.009	df=1	P>0.05 NS
	Diabetic	18	13
Hypothenar	Control	13	13
	Significance X^2=0.428	df=1	P>0.05 NS

P-Value Significance Of Palmer NS = Not Significant I1 = I Palmer area I2 = II Palmer area I3 = III Palmer area

Table 5: Frequency distribution of Angles between two groups i.e. diabetic and control group

Angles		**Mean ± SD**				**P-Value**		**Significance**	
		Diabetic		**Control**					
		Rt	**Lt**	**Rt**	**Lt**	**Rt Hand**	**Lt Hand**	**Rt Hand**	**Lt Hand**
'atd'	Male	43.32 ± 5.39	38.75 ± 4.42	38.84 ± 5.37	40.81±5.39	>0.05	> 0.05	NS	Ns
	Female	44.52 ± 5.63	44.61± 5.52	44.71±4.18	37.12±3.39	> 0.05	<0.001	NS	Sig.
	Total	43.92±5.51	41.68±4.97	41.77±9.55	38.96±4.39	< 0.01	> 0.05	Sig.	NS
'tad'	Male	57.43±5.63	46.31±4.86	58.26±5.32	55.62±6.32	> 0.05	> 0.05	NS	Ns
	Female	56.37±5.49	52.42±6.16	56.39±6.01	59.42±6.03	> 0.05	< 0.01	NS	Sig.
	Total	56.90±5.56	49.36±5.51	57.32±5.66	57.52±6.17	> 0.05	> 0.05	NS	NS
'tda'	Male	79.05±4.43	82.88±5.04	82.24±5.52	81.39±4.39	> 0.05	> 0.05	NS	NS
	Female	78.56±4.50	81.52±4.67	84.43±5.34	81.49±4.57	<0.001	> 0.05	HS	NS
Total	78.80 ±4.46	82.2 ±4.85	83.33±5.43	81.44±4.48	< 0.01	> 0.05	Sig.	NS	

P-Value Significance of Angles

Table 6: Digital Pattern Frequency of Finger Tip Pattern Distribution among different region with respect to the experimental as well as control group.

Digit	Type	Whorl	Loop	Arch	Whorl	Loop	Arch	Whorl	Loop	Arch
I	Diabetic group	53	38	8	28	22	3	28	19	6
	Control group	46	47	6	12	6	-	37	44	6
	Value of Significance	X^2=1.654	df=2	P>0.05 NS	X^2=0.653	df=1	P>0.05 NS	X^2=2.212	df=2	P>0.05 NS
II	Diabetic group	48	49	6	25	24	4	29	26	3
	Control group	42	52	7	7	11	-	37	44	7
	Value of Significance	X^2=0.632	df=2	P>0.05 NS	X^2=0.732	df=1	P>0.05 NS	X^2=0.643	df=2	P>0.05 NS
III	Diabetic group	32	61	10	13	33	7	20	29	4
	Control group	26	71	6	8	10	-	19	62	6
	Value of Significance	X^2=2.341	df=2	P>0.05 NS	X^2=1.325	df=1	P>0.05 NS	X^2=3.365	df=2	P>0.05 NS
IV	Diabetic group	61	40	2	23	29	-	39	12	2
	Control group	62	39	2	2	6	-	51	34	2
	Value of Significance	X^2=0.037	df=2	P>0.05 NS	X^2=2.873	df=1	P>0.05 NS	X^2=3.359	df=2	P>0.05 NS
V	Diabetic group	18	82	3	7	44	-	2	39	3
	Control group	21	78	4	3	15	-	19	64	4
	Value of Significance	X^2=0.531	df=2	P>0.05 NS	X^2=0.032	df=1	P>0.05 NS	X^2=0.018	df=2	P>0.05 NS
Total	Diabetic group	210	268	25	10	148	12	19	121	14
	Control group	195	287	21	38	44	-	159	244	21
	Value of Significance	X^2=1.533	df=2	P>0.05 NS	X^2=3.458	df=1	P>0.05 NS	X^2=6.358	df=2	P>0.05 Sig

P-Value Significance of Digital Pattern Frequency of Finger Tip Pattern Distribution

i.e. the control group.

The highest didtribution pattern for whorl, loop and the arch was found in the second, fourth and the fifth finger, although along with above said they were available with respect to fourth, fifth and third finger in the other group too, i.e. in the control group. 41% patients were found in case of experimental group and 52% was found in case of control group with respect to whorl spiral and in case of symmetrical whorl 41% constitutes for the experimental group and 57% for the control group present more towards with respect to fourth finger along with it loop whorl with two fold was revealed to be present with respect to first finger in case of experimental group which constitutes about 23% and 16% for the control group and in case of fifth finger for loop ulnar was found to be 80% for the experimental group and 76% for the control group, along with it loop radial was present more in case of second finger for experimental group for 8% and 7% for the control group. This contrast between the two groups i.e. for experimental as well as control group were revealed to be statistically significant.

In case of the experimental group i.e. for diabetic patient the rate of recurrence for whorl, arches and the loop were found to be 47.2%, 5.2% and 48% and with respect to contrast with the control group, in which it was found to be 37.6%, 4.35% and 57.7% respectively and individually. These difference among the different variables was found to be significant with $p < 0.05$, on the other hand these all were found to be insignificant when all the fingers were compared individually as single different entity and shown in Table 6.

2% of remnant design was revealed to be present in the thenar area in the experimental group patient only. The design of two loop was found to be present in the I4 region in both the groups i.e. the experimental group and the control group ie. For the experimental group it was found to be 8% and for the control group it was found to be 2%. In the I3 area loop design was mostly found in 53 percent cases of the experimental group and in the I4 area which constitutes about 50%.

It was noticed that c – line was not present in case of ulnar, radial and proximal varities. It was noticed that the design of c line proximal is found not to be present in case

of diabetic group i.e. the experimental group, on the other hand it was found to be significant in the other group i.e. the control group on the left side and constitute about only 10 percent. On the left side it was found that the c line was missing in the control group 12% as shown in fig.3, while it was seen to be available on both the sides in the control group i.e. on right side in 6% cases and on the left side in 14% of the cases. And in diabetic patients it is found that more radial tendency pattern was present as compared to the control group, but when seen in the ulnar group the ulnar tendency finding found to be turned

4. Discussion

The greek meaning of the word, dermatoglyphics is derma, which further means glyphae and skin, glyphae means cutting. Dermatoglyphics is verymuch remarkable field, which has the tendency and totally gets influenced by different genetic varities, as found in syndactyly, down's condition. Diabetes is in the other words is multifactorial illness which has it hereditary tendency. Hereditary features of dermatoglyphic acclimates to the framework of polygenic.[6]

In this current examination it is revealed that total finger ridge count was found to be more in case of the diabetic patient i.e. the experimental group when compared to the control group, another study done by Julian L et al reveals the same.[7] And the mean absolute finger ridge count is found to be more in male patients and less in case of female patient, our result is in relevance of the result given by Vera M et al.[8]

a-b number of ridge inclined was found to be not significant in case of the experimental group patient, our study this result is in favour of the result given by Ojha P et al.[9] which reveals that p<0.001 in their study. In case of the diabetic patient it was found that, there is rising of whorls along with arches and a reduction with respect to loops was not significant. The results of our study was found to be unsurprising with the consequences of Li Yanhua and Zia et al, they revealed increase in number of whorls along with arches along with lower in loop number in the selected patients.[10,11] It is found that the recurrence of the palmar design in case of both the groups is found to be insignificant statistically, that was in favour of the result given by Dam PK et al[12] our study revealed that there is decrease in pattern of recurrence in the I4 zone in case of male patient that are having diabetes, this observation was in favour of the results given by Zeigler et al[13] the design of c line looked for ulnar, proximal, radial classes. All of the above said three combinations tha are barring from the radial one was found and revealed to be lesser in the group of patients, those shows relevance with the results of examination of the study being conducted by Pathan FKJ et al.[14] It was found that on both the sides in case of diabetic patient the proximal variety was found to be not present on the other hand in case of the second group i.e. the control group it is present on the left side only.[15]

It was found that on the both sides in case of male and female patients 'atd' purposes of the patients were found to be more in or present study and it was found to have relevance with the results of Barta et al.[16] The angle 'tad' on the best right side fall under the range of 60 to 69 which constitutes about 46 percent out of all the cases in the diabetic patient, but in case of the second group i.e. the control group they fall in range of 50 to 59 i.e.46 percent on the left side. In case of diabetic females left 'tad' points was found to be significantly differentiated i.e. p>0.01 as compared to he normal or healthy females.

'tda' angle among the compared groups on the right side present with a contrast that is significant i.e.p<0.01 on the other hand bet the male as well as the female group, distinction present on the left side revealed to be insignificant in all the groups. So both the angle i.e. 'tda' and 'tad' that seen in current study were not examined by some other researcher. The findings of this investigation might be normally twisted by the dermatoglyphic irregularities which were related with ordinary people who were inclined to develop diabetes sometime in future.

5. Conclusion

The dermatoglyphic highlights of the current study might be utilized as an interesting diagnostic instrument to make a temporary conclusion and to distinguish the people who are in risk, yet it needs more broad investigations in an enormous number of patients.

6. Conflicts of Interest

All contributing authors declare no conflicts of interest.

7. Source of Funding

None.

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Morphology of Gall Bladder- A Cadaveric Study

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ABSTRACT

Aim: To study variations in external morphology of cadaveric gall bladder. Materials and

Methods: This study was undertaken on 30 cadaveric liver and gall bladder specimens in the Department of Anatomy at Tertiary Medical College of West Uttar Pradesh in terms of maximum length, maximum transverse diameter, thickness, shape, external variations and length of gall bladder below the inferior border of the liver using vernier caliper.

Results: Gall bladder had length ranging between 5.52 and 11.32 cm, transverse diameter between 2.78 and 5.57 cm, thickness at neck, body and fundus was not found uniform. The commonest shape observed in this study was pear shaped. The length of gall bladder below the inferior border of liver varied between 0.46 and 3.93 cm.

Conclusion: Since the incidence of gall bladder illness in our country is increasing day by day hence morphological knowledge is essential, not only from the point of biliary disease but also with respect to the various laprascopic, surgical and invasive techniques for example T-tube cholangiogram in the proper diagnosis and management of gall bladder and extrahepatic bile duct diseases. The morphological data may be useful to the surgeon's radiologists and anatomists.

Key words: Gall bladder, Morphometry

1 INTRODUCTION:

The gallbladder is a slate-blue, piriform sac, partly sunk in a fossa in the right hepatic lobe's inferior surface. It extends forward from a point near the right end of the porta hepatis to the inferior hepatic border. Its upper surface is attached to the liver by connective tissue; elsewhere it is completely covered by peritoneum continued from the hepatic surface. It is a blind ending diverticulum attached to the common bile duct by the cystic duct [1].

Gall bladder is 7–10 cm long, 3 cm broad at its widest and 30–50 ml in capacity[[1]. It is described as fundus, body and neck. The fundus is the expanded end which projects down, forward and to the right, extending beyond the inferior border of the liver to come in contact with the anterior abdominal wall behind the ninth right costal cartilage. The body is directed up, back and to the left; near the right end of the porta it is continuous with the gallbladder neck. The neck is narrow projecting forwards and then abruptly back and downwards, to become the cystic duct.

Though human beings are thought to be similar in their general anatomical phenotype, but when we come to investigate one particular region with more detail, it is surprising how frequently we meet one sort or another type of variations [2]. Understanding of these variants is important before laparoscopic procedures.

The present study will be of great help to surgeons and radiologists to understand the external morphology of the gall bladder.

2 MATERIALS AND METHODS:

This study was carried on 30 liver and gallbladder specimens obtained from 10% formalin fixed cadavers in the Department of Anatomy of Shri Ram Murti Smarak – Institute of Medical Sciences, Bareilly, Uttar Pradesh.

Cadavers with obvious abdominal surgery and crush injury to the abdominal organs were excluded from the study.

The parameters studied were the maximum length, maximum transverse diameter, thickness, shape, external variations of gall bladder, Level i.e. length of gall bladder below the inferior border of the liver.

The maximum length was measured from the porta hepatis to the mid-point of the fundusFigures 1 and 2 and the maximum transverse diameter Figures 3 and 4 was measured from the porta hepatisFigure 5 as well as from the

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inferior border of the liver Figure 6 by using vernier caliper in centimeters.

The shape and any variation in external appearance of gall bladder were noted. Part of the gall bladder i.e. fundus that lie below the inferior border of liver was noted.

The thickness of the gallbladder wall was measured by fine dissecting method. A longitudinal incision was made by sharp B-P blade through the peritoneal smooth surface of the gallbladder from fundus to neck and interior of the gallbladder was cleaned with jets of tap water. Then the thickness of wall of the gallbladder was measured in centimeters at the maximum transverse diameter of the fundus, body & neck region of the gallbladder with the help of vernier caliperFigures 7, 8 and 9. For taking measurements the non peritoneal surface was not chosen due to rough and irregular surface.

Maximum length:

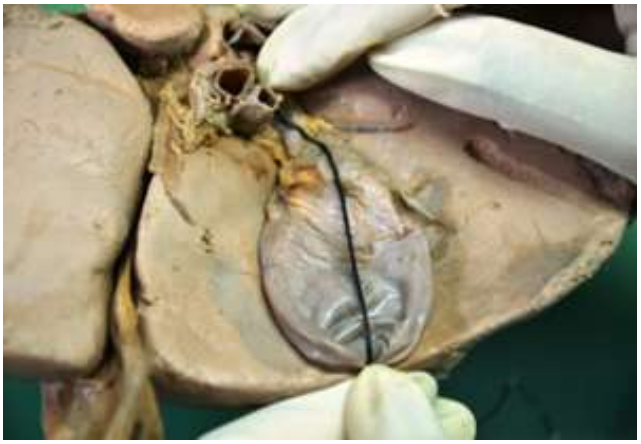


Figure 1.

Figure 2.

Maximum transverse diameter:
Thickness:

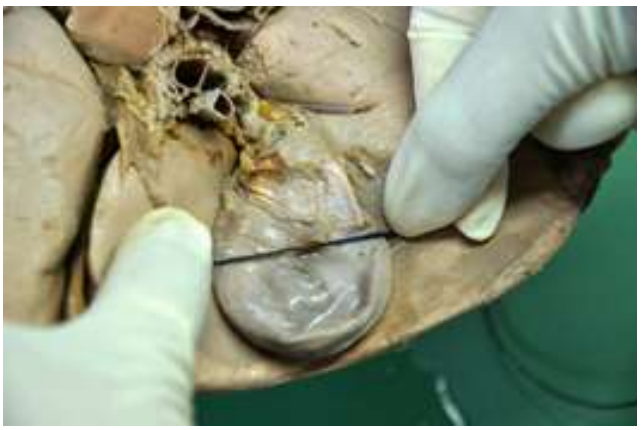


Figure 3.

Figure 4.

Figure 5.

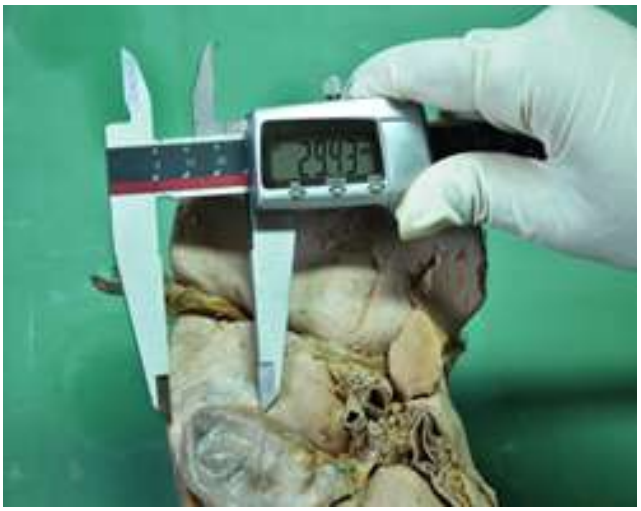


Figure 6.

Figure 7. Fundus

Figure 8. Body

Figure 9. Neck

3 RESULTS:

Maximum length of gall bladders Table 1:

Average length of gall bladder was found to be 8.25 cm. The smallest gall bladder was 5.52 cm in length and the largest had length 11.32 cm. 70 % (21/30) had length ranging between 7 and 10 cm.

Table 1. Length of gall bladders

Length in centimeters	No of specimens	Percentage (%)
< 7	6	20
7 – 10	21	70
> 10	3	10

Maximum transverse diameter of gall bladders Table 2:

Mean breadth of gall bladder was 4.30 cm. The shortest transverse diameter was 3.06 cm and largest 5.57 cm. 53.33% (16/30) had a maximum transverse diameter between 3 and 4 cm.

The distance of the maximum transverse diameter of gall bladder from the porta hepatis was found to be ranging between 2.46 and 7.06 cmFigure 5 and from the inferior border of the liver between 1.43 and 5.37 cm Figure 6.

Table 2. Transverse diameter of gall bladders

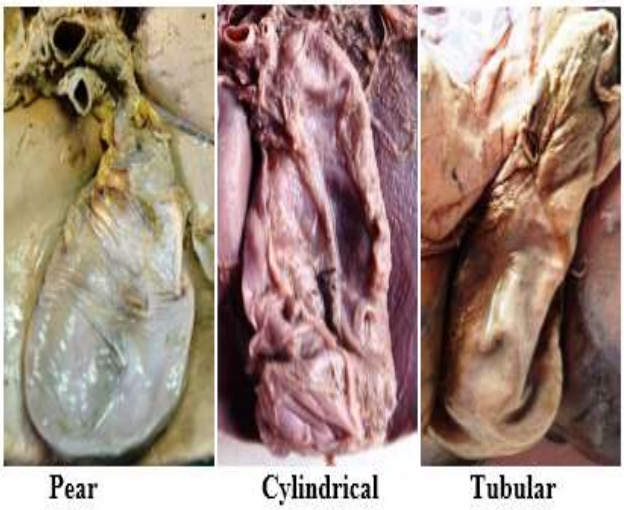
Transverse diameter in centimeters	No of specimens	Percentage (%)
< 3	1	3.33
3 – 4	16	53.33
> 4	13	43.33

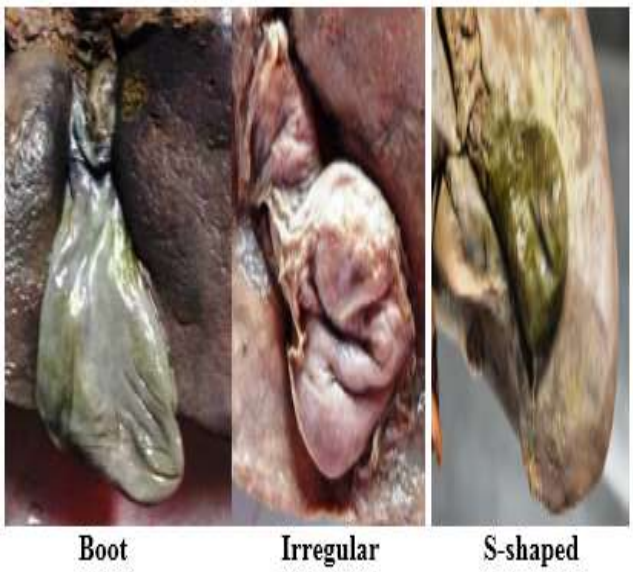
Shape of gall bladder:

The gall bladders were classified according to their shapes. Various shapes were observed. The commonest shape found was pear shaped (21/30, 70%). Their incidences are shown in theTable 3.

Table 3. Different shapes of gall bladders

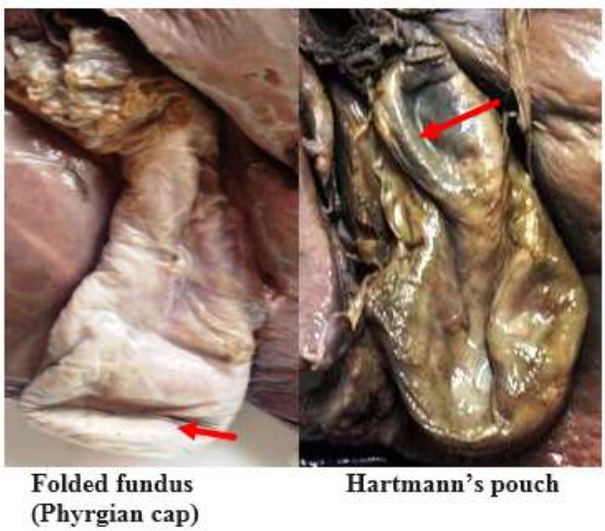
Shape	No of specimens	Percentage (%)
Pear shaped	21	70
Cylindrical	3	10
Tubular	2	6.66
Boot	1	3.33
Irregular	1	3.33
Retort	1	3.33
S-shaped	1	3.33





External appearance of gall bladder:

Foldings of neck and fundus (whether anteriorly or posteriorly) were observed. Folding of fundus was noted in 2 out of 30 specimens of GB. Hartmann's pouch was also observed in 1 specimen.



Length of gall bladder below inferior border of the liver:

21 gall bladders were crossing the inferior border of the liver and the length varied between 0.46 – 3.93cm Figure 10.

Thickness of gall bladder:

The thickness of gall bladder was found different at neck, body and fundus.

Figure 10.

Table 4. Thickness of gall bladders

	Thickness (mm)
Fundus	1.35 – 1.69
Body	1.30 – 1.75
Neck	0.46 – 0.95

4 DISCUSSION:

The gall bladder, liver and the biliary ductal system develop from the hepatic endodermal diverticulum of the foregut, at the beginning of the fourth week of development .This diverticulum rapidly proliferates into the septum transversum and divides into two parts – the cranial part develops the liver and the bile ducts while the caudal part gives rise to the gall bladder and the cystic duct. Any arrest or deviation from the normal embryological developmental process may result in some sort of malformation of the gallbladder and of the biliary system [3] .

Comparison of length and breadth with other studies has been shown inTable 5.

Table 5. Length and Transverse diameters of gall bladder as re-ported by other authors

S No.	Authors	Length of gall bladder	Transverse diameter of gall Bladder
1.	Chari RS & Shah SA [2]	7 – 10cm	2 – 5cm
2.	Turner MA et al [4]	10cm	3 – 5cm
3.	Vakili K & Pomfret EA [5]	7 – 10cm	4cm
4.	Rajguru J et al [6]	5 – 12cm	2.5 – 5cm
5.	Prakash AV et al [7]	7 – 10cm	2 – 5cm
6.	Present study	5.52 – 11.32cm	3.06 – 5.57cm

Size of gall bladder varies in different diseased conditions as well as in some physiological conditions too. It may be impossible sometimes to distinguish between various parts described. The size of gall bladder may increase after vagotomy, diabetes, pregnancy, sickle cell disease, after cystic duct or common bile duct obstruction [6].

Shapes of gall bladder vary and various authors have described various shapes as seen inTable 6. We found pear shaped gall bladder as most common (70%).

Table 6. Shapes of gall bladders

S.No	Authors	Shape
1.	Standring S [1]	Piriform
2.	Chari RS & Shah SA [2]	Pear
3.	Turner et al [4]	Elliptical
4.	Vakili K & Pomfret EA [5]	Piriform
5.	Rajguru J et al [6]	Pear (85%), Flask (5%), Cylindrical (3.33%), Hourglass, retort and irregular (1.67%)
6.	Prakash AV et al [7]	Pear (82.22%)
7.	Moore KL & Dalley AF [8]	Pear
8.	Present study	Pear (70%), Cylindrical (10%), Tubular (6.66%), Boot, Irregular, Retort and S – shaped (3.33%)

The gall bladder is relatively constant in its development and the two most significant variations are the folded fundus and variation at the neck of the gall bladder [6]. The folded fundus of the gall bladder, also called as the Phrygian cap, was reported in 3 – 7.5% of gall bladder by Lichtenstein M & Nicosia AJ [9].They proposed that it could due to a disproportion between the size of the gall bladder and that of the gallbladder bed, but without any pathological significance. Deutsch AA et al [10] and Gore RM et al [11] recorded folded fundus in very few percentage of gall bladder. Meilstrup JW et al [12] observed that gross bending of the gallbladder could occur posteriorly or anteriorly and lead to bizarre or unusual shapes when visualized by sonography and other imaging techniques. Futara G et al [13] observed that there was a significantly higher prevalence of kinking of the gallbladder and Hartmann's pouch in the females than in male subjects which could be related to the higher rate of gallstone formation and biliary tract diseases in females. In our study, we found folded fundus in 2 specimens (6.66%).

The length of gall bladder below the inferior border of the liver in our study was between 0. 46 – 3.93 cm. Prakash AV et al [7] reported between 0.4 – 2.5cm.This is the most susceptible part of gall bladder that can be damaged in laparoscopic procedures [1].

The thickness of the gall bladder at fundus, body and neck were 1.35-1.69mm, 1.30 – 1.75mm and 0.46 – 0.95mm

respectively. We couldn't find any literature regarding this parameter. Gallbladder diseases are diagnosed clinically and confirmed by various non invasive as well as invasive procedures and wall thickness is the most important indicator to diagnose such diseases [14]. In diseases such as cholecystitis, carcinoma and metastasis of gall bladder.

However congenital anomalies of gallbladder are rare and can be accompanied with other biliary and vascular malformations [15]. Due to these anatomical variations, complications seen were bleeding and biliary leaks leading morbidity [16]. The comparative study involving GB morphometry in cadavers and sonographic/ radiological findings should be undertaken.

5 CONCLUSION:

The occurrence of bizarre forms of anatomical variations of gall bladder and extra-hepatic biliary tree though are not common but can be of clinical importance, however comprehensive study of the morphological variations of the gall bladder and their incidence is relatively scarce. Most of the interventional procedures in this modern era are done laparoscopically and there is tremendous increase in number of laparoscopic cholecystectomies. So, thorough knowledge of possible variations in morphology of gall bladder is important. Awareness of these anomalies will decrease morbidity, and re-exploration in these patients. This article will be of utmost useful to the surgeons and radiologists to understand and identify possible variations of GB morphology.

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Original Research Article

Morphological and histological variations in livers and its embryological correlation

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ABSTRACT

Aim: To study the variations in gross morphology and any change in histological architecture in cadaveric liver specimens and correlate with development in intrauterine life.
Materials and Methods: The livers were obtained from the cadavers during dissection and museum in the department of Anatomy, MCI recognized private medical college in North India. The morphological and histological observations were documented.
Results: Morphological variations were observed and classified. Histologically all specimens appeared to be normal.
Conclusion: The knowledge of such variations is important to anatomists, morphologists and embryologists for developmental anomalies. This will be beneficial for the surgeons for planning surgery involving liver and radiologists for interpretation of CT scans and MRI images.

1. Introduction

The liver is wedged-shaped, largest of the abdominal viscera, occupying most of the right hypochondrium and epigastrium, and frequently extends into the left hypochondrium as far as the left lateral line. As the body grows from infancy to adulthood, the liver rapidly increases in size. The size of the liver also varies according to sex, age and body size. The capsule is no longer thought to play an important part in maintaining the integrity of the shape of the liver.[1]

The liver is responsible for a wide range of metabolic activities including homeostasis, nutrition, immune defences, blood detoxification and purification, synthesis of plasma proteins, production of bile and the metabolism of carbohydrates, fats and proteins. In man, the liver is essential for survival since there is no artificial organ or equipment to compensate for the absence of liver function.[1] It is an important site of haemopoiesis in the fetus.[1]

The complexity of liver function and its importance in body homeostasis has encouraged many anatomists to study the morphological features of the organ in considerable details. Despite recent technological advances in the evaluation of liver parenchyma using imaging techniques, such as computed tomography or nuclear magnetic resonance,[2] detailed studies of the macroscopic anatomy of cadaveric livers can still contribute to the identification of important anatomical variations. In many cases, such variations have enabled researches to understand specific responses to therapies applied in the treatment of liver disease.

The major fissures are the important landmarks for interpreting the lobar anatomy and locating the liver lesions. In the era of imaging and minimally invasive approaches, it is very important on the part of both the radiologists and operating surgeons to have a thorough knowledge of the anatomy and the commonly occurring variations of this organ. Anatomists witness most of the variations of the lobes and fissures of the liver. Although the segmental anatomy of the liver has been extensively researched, there

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are very few studies regarding the surface variations of the liver.

The aim of the present study was to investigate the type and frequency of anatomical variations and to find out any histological changes and correlate these with intrauterine development, in a collection of cadaveric livers.

2. Materials and Methods

Thirty nine (39) livers from adult human cadavers, fixed in 10% buffered formalin solution available in the department of Anatomy, MCI recognized private medical college in North India were studied. Age and gender of these specimens were not known. The specimens looked apparently normal. Histological sections from cornu and lingular process (if present) and different areas from the lobes in other specimens were taken and processed by H and E staining. These were observed for any variations in archi tecture and cellular structure.

3. Observations and Results

3.1. Morphological observations

Livers were examined on different occasions by two observers. The results obtained were compared and ratified. The distinct morphological characteristics observed were recorded on data sheets. On the basis of these descriptions, the organs were classified into ten groups (Table 1). The lingular process of left lobe (Type 8) was further defined according to shape (Table 2).

Table 1 shows different variants of liver. Type 1 is defined as the morphologically normal liver as classically described in the standard textbooks.[1,3], The present study showed an incidence of 28 specimens of type 1 (71.79%; Figure 1).

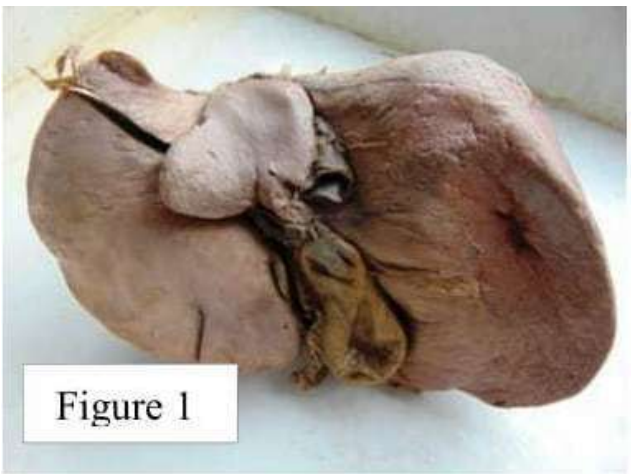

Fig. 1: Normal liver

Type 2 is liver with very small left lobe with incidence of 1 specimen (2.56%, Figure 2).

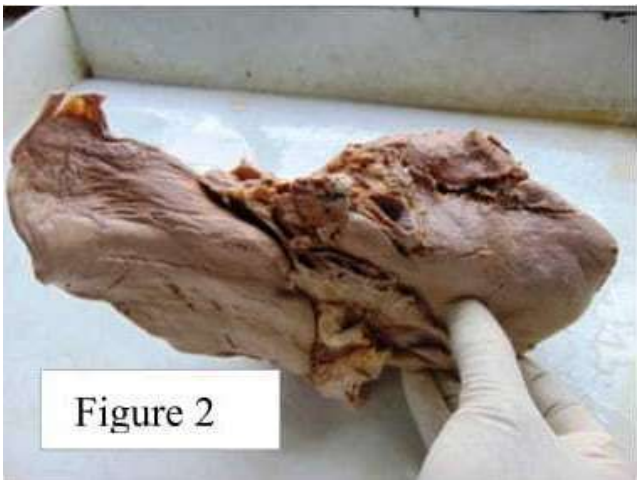

Fig. 2: Very small left lobe

Type 3 is defined as transverse "saddle-like" liver (1 specimen; 2.56%) as seen in Figure 3.

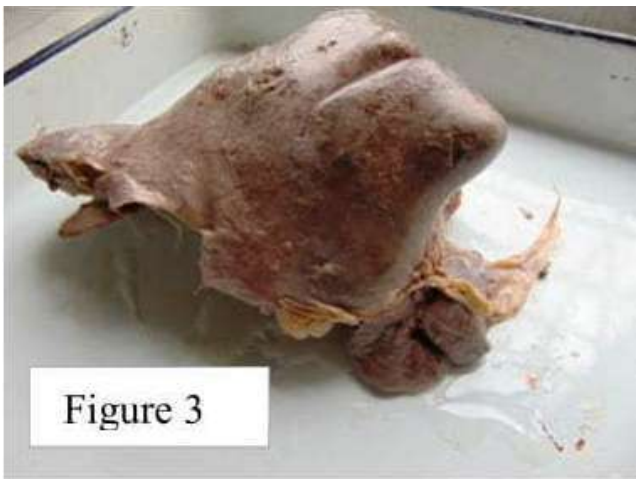

Fig. 3: Saddle-like liver

Types 4 (Figure 4), 5 (Figure 5) and 6 (Figure 6) are defined as livers with very deep renal impression, very deep costal impressions and diaphragmatic grooves respectively with incidence of 1 specimen each (2.56%).

Type 7 is defined as liver with enlarged left lobe (Figure 7). It was seen in 1 specimen (2.56%).

Type 8 is defined as liver with lingular process of left lobe (3 specimens; 7.69%). Lingular process is defined as tongue-like projection from the margin of liver.

Type 9 and 10 are defined as bicornuate (1 specimen; 2.56%, Figure 11) and unicornuate (1 specimen; 2.56%, Figure 12) left lobes of liver respectively. Cornu is defined as quadrilateral process projecting from the margin of the

Fig. 4: Very deep renal impressions

Fig. 5: Very deep costal impressions

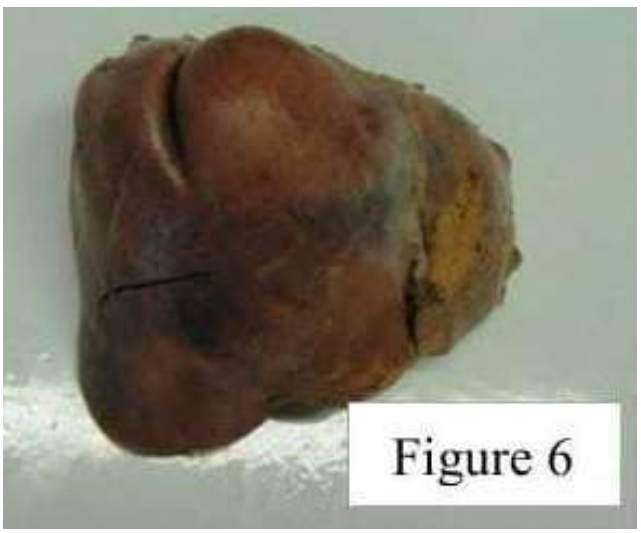

Fig. 6: Diaphragmatic grooves

liver.

Table 2 shows different shapes of lingular process of left lobe. They have been categorized into three types: apical (1 specimen, 2.56%; Figure 8), conical (1 specimen; 2.56%, Figure 9) and rounded (1 specimen; 2.56%, Figure 10).

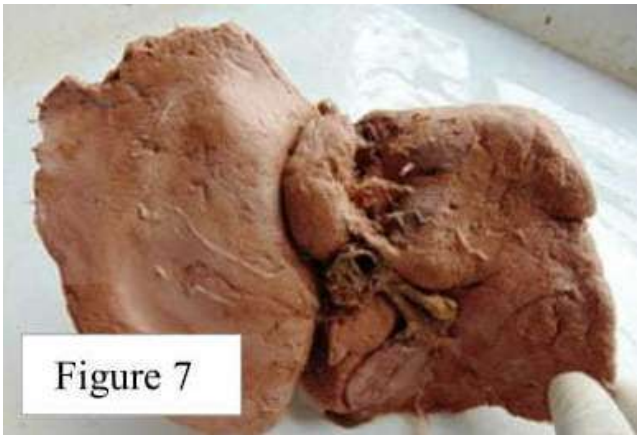

Fig. 7: Enlarged left lobe

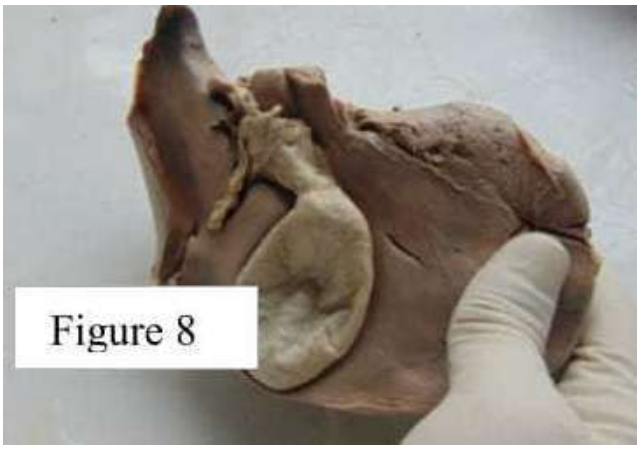

Fig. 8: Apical lingular process of left lobe

3.2. Histological observations

Sections for histological examination were taken from the cornu, lingula and different sites of the left and right lobes of all 39 specimens. All the histological sections taken from the liver specimens showed normal architecture. There was no change in cellular arrangement of cords and sinusoids were normal (Figures 13, 14, 15 and 16).

4. Discussion

Embryologically, the liver primodium appears in the middle of the 3^{rd} week as an outgrowth of the endodermal epithelium at the distal end of the foregut. This outgrowth,

Table 1: Different types of livers

Organ types	Characteristic features	Number	Frequency	Figure number
Type 1	Normal liver	28	71.79	1
Type 2	Very small left lobe	1	2.56	2
Type 3	Transverse "saddle-like" liver	1	2.56	3
Type 4	Very deep renal impression	1	2.56	4
Type 5	Very deep costal impressions	1	2.56	5
Type 6	Diaphragmatic grooves	1	2.56	6
Type 7	Enlarged left lobe	1	2.56	7
Type 8	Lingular process of left lobe	3	7.69	8 – 10
Type 9	Bicornuate left lobe	1	2.56	11
Type 10	Unicornuate left lobe	1	2.56	12

Table 2: Different types of lingular process of the left lobe

Type	Number	Frequency (%)	Figure number
Apical	1	2.56	8
Conical	1	2.56	9
Round	1	2.56	10

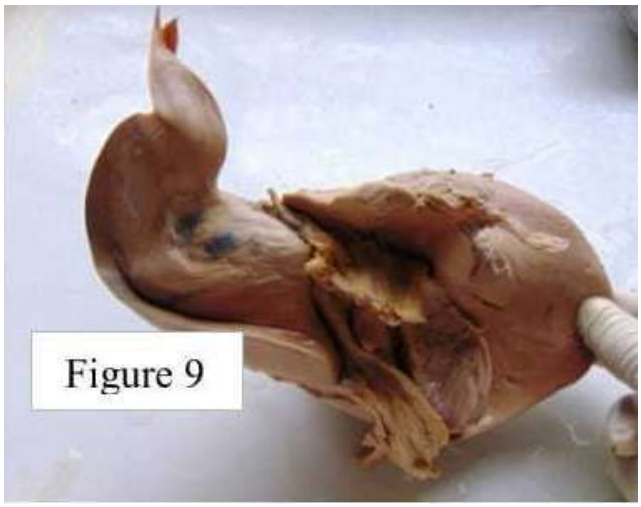

Fig. 9: Conical lingular process of left lobe

Fig. 10: Round lingular process of left lobe

Fig. 11: Bicornuate left lobe

Fig. 12: Unicornuate left lobe

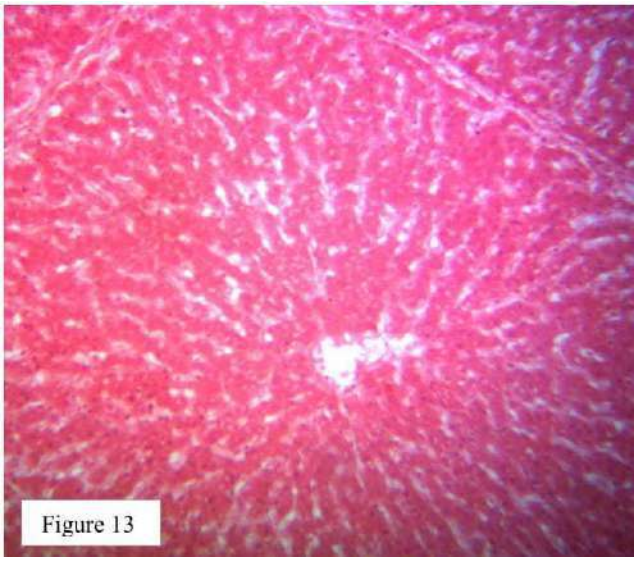

Fig. 13: Lingular process of left lobe of liver

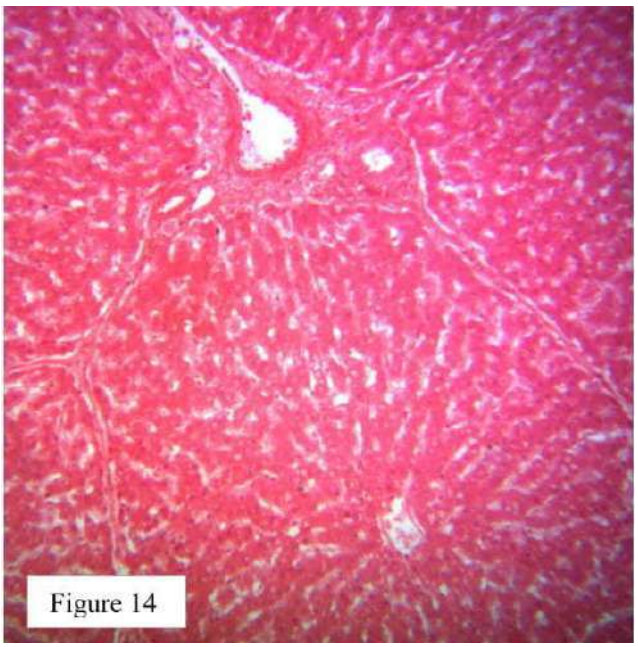

Fig. 14: Cornu of the left lobe of liver

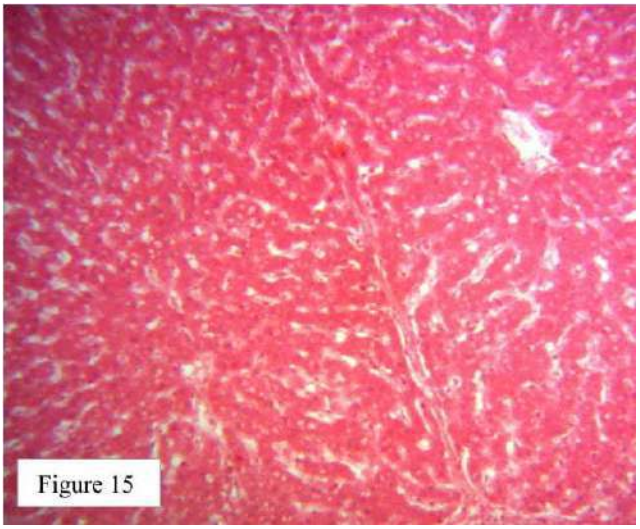

Fig. 15: Left lobe of liver

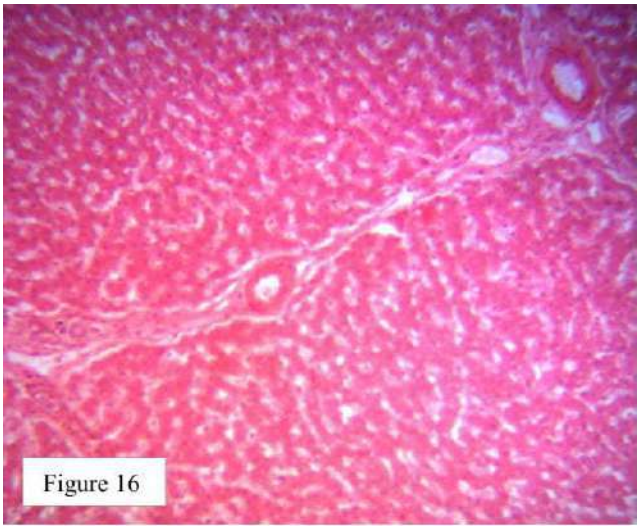

Fig. 16: Right lobe of liver

the hepatic diverticulum or liver bud, consists of rapidly profilerating cells that penetrate the septum transversum.[4]

The liver is reddish brown in colour, although this can vary depending upon the fat content. Obesity is the most common cause of excess fat in the liver (also known as steatosis): the liver assumes a more yellowish tinge as its fat content increases. The texture is usually soft to firm, depending upon the volume of blood and the fat content.[1]

The variations observed in the anatomy of the human liver have been classified as congenital or acquired. Congenital anomalies can be attributed to the following factors: a) separate lobes (considered to be a congenital variation by some anatomists); b) atrophy at some locations in the parenchyma; c) presence of only one lobe; d) presence of multiple lobes, typically involving numerous divisions (up to 16) of the right lobe; e) small lobes; f) peduncular lobes; g) lobes without division; and h) accessory lobes. Acquired changes in liver morphology are represented by the following characteristic features: i) linguiform lobes, ii) costal organ with very small left lobe, iii) deep renal impressions.[5]

Out of the 39 livers studied, 28 specimens (71.79%) were found to be normal. Morphological variations were observed in 11 specimens (28.20%).

On the basis of these variations, the livers were classified into ten groups. Six of these specimens, types 1 to

6, correspond to the morphological types (including the normal type) established by Netter[3] as described in Table 1. The remaining four liver specimens, types 7 to 10 reported inTable 1 of the present study have not been adequately described according to the classification of Netter[3] and were considered as new variant types 7, 8, 9 and 10.

Type 6 showed diaphragmatic grooves (Figure 6). This type of variant has been described previously by Nagato AC et al[2] and Yoshimitsu K et al.[6] These authors considered the diaphragmatic grooves to be accessory hepatic fissures caused by invaginations of the diaphragm. This can also be due to peritoneal fold or non union of segments in foetal life.

Type 7 showed enlarged left lobe (Figure 7). Historically, the liver has been considered to be divided into four lobes by the surface peritoneal and ligamentous attachments. The left lobe is the smaller of the two main lobes, although it is nearly as large as the right lobe in young children. It lies to the left of the falciform ligament with no subdivisions and is substantially thinner than the right lobe.[1] According to Gray and Williams,[7] the right lobe is typically larger and more bulky than the left. On this basis, one liver (2.56%) described as type 7 is considered as a morphological variation because the left lobe was very much larger than the right. Bezerra ASA et al[8] suggested that the reduction in size of the right hepatic lobe and the compensatory increase of the left and caudate lobes may result from pathological processes in patients with schistosomiasis.

Types 8, 9 and 10 of liver specimens with lingular processes and cornu of the left lobe may be due to excessive tissue formed at a localized site in the form of extentions or pressure from the surroundings organs during fetal life causing inhibition of formation of complete left lobe so these processes developed in the area of least resistance.

Histologically, all the specimens were normal according to the description in standard textbooks of histology.[9]

Though distinct morphological types of human liver can be identified in the literature, relatively few studies are available on this topic and detailed descriptions of the different types of anatomical variations are scarce. One reason for this may be associated with a particular difficulty encountered in the present study relating to the characterisation of cadaveric sources in terms of sex, age and previous diseases, all of which may impact on liver morphology.

Some apparent morphological changes detected during advanced imaging examinations may actually be pseudo–lesions resulting from perfusion defects, focal fatty infiltrations and other causes, and may not represent true parenchymatous lesions.[2]

This data suggests that there is a high incidence of anatomical variations in the human liver. No statistical data relating to the frequency of occurrence of livers displaying gross variations in morphological character could be found in the literature in order to serve as a basis for comparison with the studied samples.

5. Conclusion

Though many anatomical variations in the shape of the liver were encountered, histologically all specimens were normal hence the present study suggests that functionally these livers were normal. The possible explanation for gross anomalies could lie in its embryological development. Detailed descriptions of normal and variant liver morphologies can make a significant contribution to understanding the causes of the changes and is a prerequisite for the favourable outcome of a surgical procedure. It is useful for the imaging specialists and surgeons to avoid misinterpretation and misdiagnosis for appropriate planning of the surgical procedures.

6. Source of Funding

None.

7. Conflict of Interest

None.

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Original Article

Morpho-Histological Study of Placentae from Pregnancies Complicated by Anemia

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Abstract

Background: The placenta is an important organ that acts as a conduit for transporting substances from the mother to the fetus and vice versa. It performs many functions and is intimately related to both the mother and the fetus. Anemia is a leading disorder of pregnancy and is seen to effect >65% of pregnant women in India. It is also a known cause of intra-uterine growth retardation, preterm deliveries, low-birth-weight deliveries, etc. **Objective:** The aim is to study and compare the morphometric and histological changes seen in placentae from normal and anemic mothers. **Methods:** This study was done in the Department of Anatomy of Shri Ram Murti Smarak Institute of Medical Sciences and Research, Bareilly, Uttar Pradesh, India. One hundred and fifty placentae were collected, 75 each from normal and anemic mothers. A thorough morphometric and histological study of the placentae was done, and the results were recorded. **Results:** It was observed that the mean weight, diameter, circumference, and chorionic plate area of the placentae from anemic mothers was significantly reduced in comparison to the controls. Histological study showed that there was a significant increase in pathological changes such as syncytial knots, fibrinoid necrosis, calcification, and medial coat proliferation of blood vessels in samples obtained from placentae of anemic mothers in comparison to the controls. **Conclusion:** It was concluded from this study that maternal anemia has significant consequences on the developing placenta. These morphometric and microscopic changes in placental structure can in turn reduce its function, thus having an adverse effect on fetal outcome.

Keywords: Anemia, morphometry, placenta

Introduction

The placenta is an organ that connects the developing fetus to the uterine wall. As this complex structure is very closely associated with the fetus throughout gestation, its study provides us an accurate record of an infant's prenatal period.

Anemia is the most common nutritional deficiency disorder in the world. According to the WHO guidelines, a level of hemoglobin below 11 g/dl is an indication of maternal anemia. It is a hazardous, hematological disorder and, according to the WHO statistics, is seen in 65%–75% of pregnant women in our country. It contributes significantly to maternal morbidity and mortality.[1]

The placenta is a unique organ as it is both a conduit of oxygen to the fetus as well as an expender of oxygen to support its own metabolism and these two functions are perfectly balanced. In patients with anemia there is an underlying deficiency of oxygen-rich blood, and hence, the amount of available oxygen becomes a very critical factor for the development of the placenta, placental blood vessels, and the fetus.

When pregnancy is complicated by maternal anemia, many pathological changes are bound to occur, which can influence morphometry and histology of the placenta. A reduction in weight, circumference, diameter, area, and histological changes such as infarction, calcification, intervillous thrombosis, and fetal vessel hemolysis occurs and reduce the functional

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villous mass. Hypoxia that occurs as a result of prolonged anemia during pregnancy is associated with an increased risk of preterm delivery, intra-uterine growth retardation (IUGR), low-birth-weight baby, unfavorable APGAR scores and various other undesirable effects on the fetus.[2] Thus, placenta is a focus of increasing interest in modern obstetrics because significant pathological changes afflict the placenta often before affecting the fetus. Placental abnormalities can therefore be an "early warning system" for fetal problems. As most perinatal fetal deaths are related to insufficient oxygen supply in utero, the study of the placenta plays a pivotal role in predicting the outcome of future pregnancies and their management.

As anemia in pregnancy is known to have a detrimental effect on the placenta, the present study was undertaken to analyze the spectrum of changes that may occur when pregnancy is associated with this underlying disorder.

The purpose of this study was to evaluate the morphometric and histological changes seen in placentae from anemic mothers and to compare the findings with the control group.

Materials and Methods

This study was done in the Department of Anatomy of Shri Ram Murti Smarak Institute of Medical Sciences and Research, Bareilly, Uttar Pradesh, in association with the Department of Obstetrics and Gynaecology and the Department of Pathology after taking required ethical clearance from the institutional ethical committee. One hundred and fifty full-term placentae were randomly collected over a period of 1 year, from mothers who delivered either vaginally or by cesarean section. Relevant history was taken, and the results of hematological investigations were recorded.

The placentae were classified into the control and study group (anemic group). Under each group, 75 placentae were studied. Placentae from women with single, uncomplicated pregnancies of gestational age between 37 and 41 weeks were included in this study. Placentae from mothers with hemoglobin ≥11 g/dL were taken as control group, while those from mothers with hemoglobin ≤11 g/dL were taken as the study group. Placentae from women with associated obstetric or medical complications of pregnancy, i.e., gestational hypertension, fibroids, retroversion of uterus, cervical cancer, ovarian cysts, venous thromboembolism, etc., or with systemic disorders and chronic maternal illnesses were excluded from the study. Placentae obtained as a result of twin pregnancies were also excluded.

Morphometric and histological examination

The placenta was first inspected, and its various morphometric measurements were recorded. The following parameters of the placenta were then measured: weight, diameter, circumference, and chorionic plate area.

1. Weight was measured in grams by an electronic weighing scale
2. Diameter was measured by a digital vernier caliper. Both maximum and minimum diameters were measured in centimeters up to one decimal point
3. Circumference was measured in centimeters up to one decimal point by a thread which was wound around the entire circumference of the placenta and cut at the point of crossing after one round. The length of the cut thread was measured by stretching it between the two arms of the digital caliper.
4. From the diameter of the placenta, the mean chorionic plate area was also calculated by using the following formula:[3]

$$A = \frac{\pi dL.dS}{4}$$

Where A is area of an ellipse, dL is the largest diameter and dS is the smallest diameter.

For the histological study we obtained full-thickness tissue from the placenta and prepared it for routine H and E. In the light microscopic examination, the placental villi were quantitatively screened for syncytial knots, fibrinoid necrosis, cytotrophoblastic cellular proliferation, calcification, and endothelial changes in blood vessels. All the slides were first observed in low power (×10) and then the presence of the aforementioned parameters was recorded per low power field (per lpf). Three random and different areas of the slide were screened, and the range and mean of the values obtained per low power field was recorded. Histological photographs were taken with the help of an Olympus CX21i compound microscope, which had an attached camera.

A comparison between the control and study group was made by calculating the mean, median with standard deviation and *P*-value for each parameter by using *t*-test.

Results

Morphometric measurements

Table 1 shows the various morphometric measurements of the control and study group. It was observed that in the anemic group; the mean weight, minimum diameter, circumference, and chorionic plate area were reduced in comparison to the control group and this reduction was found to be statistically significant ($P \leq 0.05$). The maximum diameter of placentae from the anemic group was also reduced in comparison to the controls, but this reduction was statistically not significant.

Histological findings

Table 2 shows a comparison between various histological features observed in placentae from both the control and anemic group.

On light microscopic examination of placentae from anemic mothers, it was observed that syncytial knots [Figure 1], fibrinoid necrosis [Figure 2], areas of calcification and medial coat proliferation of blood vessels [Figure 3] were significantly increased in anemic groups in comparison to the controls.

Table 1: Morphometric parameters of placenta in control and study group

Morphometric parameter	Control ($n=75$)		Anameia ($n=75$)		*P*
	Range	Mean±SD	Range	Mean±SD	
Weight (g)	336-584	464.28±50.45	210-600	411.14±83.5	0.002
Maximum diameter (cm)	14.1-20.1	17.13±1.43	11.8-23.1	16.24±2.88	0.1061
Minimum diameter (cm)	13.1-18.1	15.76±1.3	10.4-20.8	14.52±2.81	0.0207
Circumference (cm)	48.2-68.7	57.54±5.45	23.1-64.2	47±8.58	0.001
Chorionic plate area (cm^2)	149.42-272.80	213.35±33.79	96.33-377.17	91.25±72.05	0.0001

SD: Standard deviation

Table 2: Histology by hematoxylin and eosin staining per lpf (low power field-×10)

Histological finding by H and E staining per lpf (×10)	Control ($n=75$)		Anameia ($n=75$)		*P*
	Range	Mean±SD	Range	Mean±SD	
Syncytial knots	10-15	12.2±1.49	6-21	13.88±4.23	0.03
Cytotrophoblastic proliferation	4-12	8.11±2.13	4-10	7.71±1.7	0.3883
Fibrinoid necrosis	3-9	6.85±2.25	7-17	10.82±2.13	0.0001
Calcification	2-9	5.71±2.35	9-24	14.11±4.6	0.0001
Medial coat proliferation of blood vessels	4-9	6.02±1.72	8-12	9.51±1.31	0.0001

SD: Standard deviation, H and E: Hematoxylin and eosin

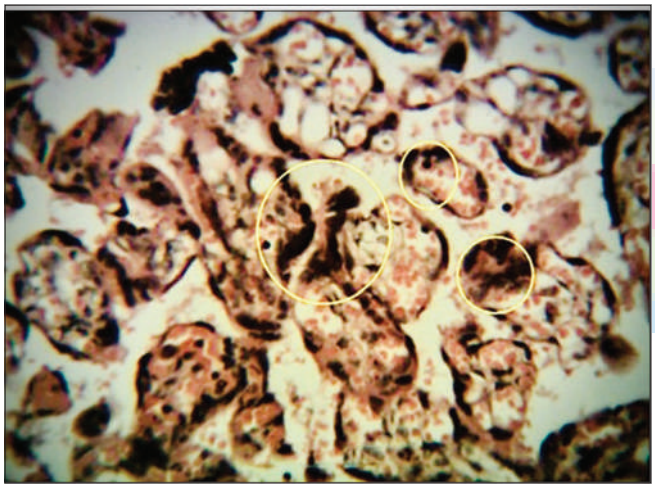

Figure 1: Showing syncytial knots in study group

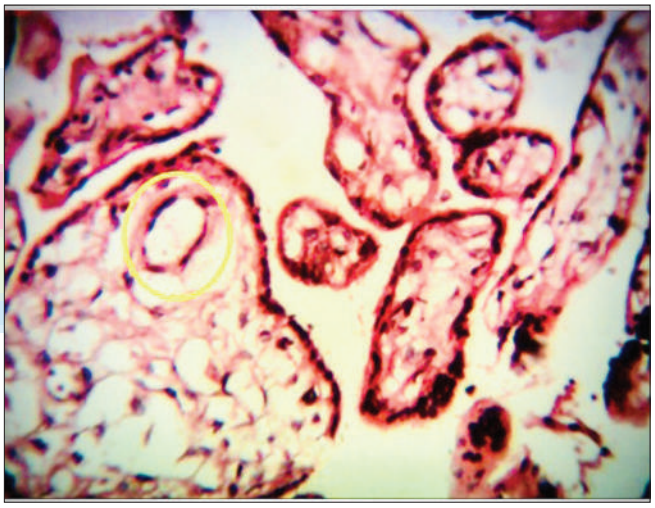

Figure 2: Showing fibrinoid necrosis seen in study group

Cytotrophoblastic cellular proliferation [Figure 4] was slightly reduced in the anemic group in comparison to the controls, but this reduction was not statistically significant.

Discussion

Anemic disorders of pregnancy are one of the leading causes of maternal and perinatal mortality and morbidity. The present study deals with changes in morphometry and histological structure of the placenta in mothers with anemia. A total of one hundred and fifty placentae were meticulously studied. It can be inferred from the results of the present study that the mean of all morphometric parameters of the placenta was reduced in the anemic group in comparison to the controls.

The mean chorionic plate area of anemic group was also reduced in comparison to the controls. This corresponds to a decreased diameter and circumference in the study group in comparison to the controls. It was seen that in mothers suffering from gestational anemia the placental size was smaller as compared to the placentae from normal, healthy mothers.

This overall reduction in the size of the placentae from mothers of the study group indicates that anemia has a detrimental effect on placental development, and it can be attributed to the lower oxygen-carrying capacity of the blood and the resulting hypoxia. Most authors like Rohini *et al*. reported that the mean weight of placentae from anemic mothers was 410 g.[4] This finding was similar to the findings of the present study. Mongia *et al*., who have studied placental morphometry in Indian women and other ethnicities, have also found similar results.[5] But some authors like Godfrey *et al*.[6] and Agboola,[7] who also studied placentae from anemic mothers, reported that anemia and iron deficiency

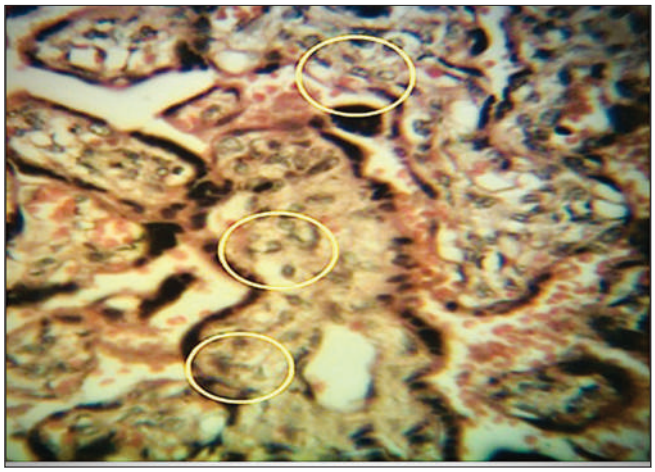

Figure 3: Showing medial coat proliferation of blood vessels in study group

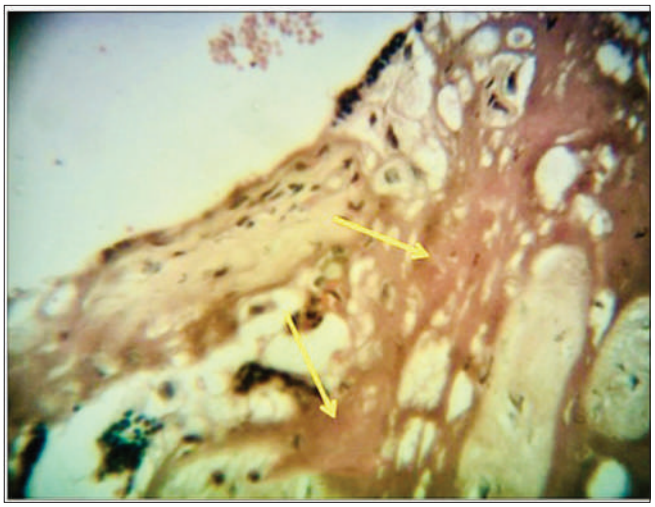

Figure 4: Showing cytotrophoblastic cellular proliferation in study group

during pregnancy were associated with large placental weight and size, and thus, they found a positive correlation between maternal anemia and placental weight. They also observed that placental hypertrophy appeared to be a uniform, proportional, physiological compensatory growth. This was in contrast to the findings of the present study, where placental weight was found to be significantly reduced in anemic group. A review of data published by a few other authors also reveals that hypoxia may initially cause hypertrophy of the placenta, but with the advancement in the pregnancy, i.e., toward term, placental growth retardation is observed.[8,9] This hypotrophy of the placenta may be dependent on the duration, time, and severity of anemia.[10]

One of the main functions of the placenta is that it acts as a barrier between the fetus and the mother by separating the fetal blood vessels from the maternal blood present in the intervillous spaces. The structure of this placental barrier can be observed under a light microscope. The barrier is selectively permeable and allows certain substances such as water, oxygen, hormones, and other nutritive molecules to pass from the maternal blood to the fetal blood vessels and excretory products to pass from the fetus to the mother. The components of the placental barrier from maternal to fetal side are:

a. Syncytiotrophoblast
b. Cytotrophoblast
c. Trophoblastic basement membrane
d. Connective tissue core of the villus derived from the fetus (extraembryonic mesoderm)
e. Basement membrane of fetal capillaries
f. Endothelium of fetal capillaries.[11]

With increasing gestational age, this barrier reduces in thickness and this appears to be a normal change seen with placental maturity. Closer to term, we also observed that the syncytiotrophoblast layer became thin and syncytial knots were increased. The cytotrophoblast layer also reduced and was seen as clumps and fragments. Increased deposition of fibrin was seen on the villus surface as well as in the tunica of the blood vessels. These changes are a sign of placental maturity and are seen in normal placentae, but their increased incidence in placentae from anemic mothers signifies that these changes in the placenta are not proportional to the gestational age.

On histology of placentae from anemic mothers, we observed that there was a significant increase in the presence of calcification, medial coat proliferation of blood vessels, syncytial knots, and fibrinoid necrosis in comparison to the controls. Areas showing fibrinoid necrosis were significantly increased, and fibrin deposit was seen even in the tunica of blood vessels. Fibrinoid necrosis of blood vessels leads to intervillous hemorrhage, which was also observed in few anemic cases but not in controls. Al-Hakeem *et al*.[12] studied changes in placentae from anemic mothers and found an increase in histomorphological abnormalities like thickening of the capillary basement membrane, cytotrophoblastic proliferation, syncytial knots, and fibrosis. Mehrotra *et al*.[13] and Biswas *et al*.[14] reported a similar increase in villous fibrosis and syncytial knots in placentae from anemic mothers. Increased syncytial knots, fibrinoid necrosis, and a reduction in cytotrophoblastic cellular proliferation are all effects of reduced perfusion and oxygen concentration. Tripathi and Sudele[15] and Soni and Nair[16] conducted a similar histopathological study on placentae from anemic mothers, and they found that the areas showing cytotrophoblastic cellular proliferation were significantly increased in the study group in comparison to the controls. This is contrary to our finding, but it is essential that gestational age and severity of anemia be considered before these values can be accurately compared. It is postulated that when the placenta develops in hypoxic conditions like anemia the villi show many changes, including an increase in angiogenesis and terminal capillaries.[17] These changes appear to be a compensatory mechanism to fulfill the needs of the developing fetus. Placental changes characterized by endothelial or vascular abnormalities like medial coat proliferation may present with increased permeability of the vessels, which can even lead to fetal anemia.[18]

These histological changes are also an indicator of placental maturity as the placentae from mothers who delivered postterm (beyond 42 weeks of gestation) usually present with a higher incidence of these features. An early appearance of signs of placental maturity can be a signal for induction of labor and spontaneous preterm delivery. This can be extremely dangerous for a yet under-developed fetus and can explain why anemia is a known and leading cause of preterm delivery, IUGR, and abnormal APGAR scores at birth.

Conclusion

From the various morphometric changes observed, it is concluded that placentae obtained from anemic mothers show a significant reduction in placental size. On histopathological analysis, these placentae also show an increase in signs of ischaemic damage to tissues along with maldeveloped terminal villi. These findings may account for impaired gas and nutrient transfer to and from the fetus in these disorders, thereby resulting in perinatal mortality and morbidity. This also helps us establish that IUGR, abnormal APGAR scores of the baby and preterm deliveries seen in anemic mothers can be caused due to microscopic changes in the structure of the placenta and fetal hypoperfusion. It is essential that the spectrum of placental changes and their effects on the fetus be studied further and evaluated qualitatively to establish such a correlation.

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Conflicts of interest

There are no conflicts of interest.

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ORIGINAL RESEARCH ARTICLE

Human Immunodeficiency Virus and Hepatitis B Virus Co-infection in a Tertiary Care Hospital From Rural Area

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Abstract:

Background:

The Hepatitis B virus (HBV) and Human immunodeficiency virus (HIV) are devastating viruses that share certain epidemiological characteristics such as risk population and transmission routes. Because of this, HIV positive individuals are at risk of co-infection with Hepatitis B virus. The reports show that co-infection by HIV/HBV causes increased morbidity and mortality as compared to HIV and HBV mono-infection.

Objectives:

The present study was undertaken to determine the prevalence of Hepatitis B virus co-infection in HIV positive patients.

Materials and Methods:

A total of 1000 clinically suspected HIV infected cases attending the Sexually transmitted disease (STD) clinic were selected. The blood samples were collected by taking all aseptic precautions. The serum samples were screened by Comb –AIDS test for HIV and confirmed as per National Aids Control Organization (NACO) guidelines and then HIV positive patients were screened for Hepatitis B surface antigen (HBsAg) marker by immunochromatographic test (Hepacard).

Results:

Out of 1000 clinically suspected cases, 348 (34.8%) were positive for HIV. Out of 348, 186(53.44%) were male and 162(46.55%) were females. Among a total of 348 HIV patients, six cases were found positive for HBsAg. Thus, HIV/HBV co-infection was detected in 1.72% cases in this study.

Conclusion:

The results indicate that the prevalence of co-infection in our area is comparatively lower as compared to other geographical areas.

Keywords:

HIV, Hepatitis B virus, Co-infection

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Introduction:

According to the Joint United Nations Programme on HIV/AIDS (UNAIDS), about 33 million people are infected with Human Immunodeficiency Virus (HIV) worldwide and majority of them live in Asia and Africa. India has the highest HIV/AIDS prevalence in the world with an estimated 5.7 million people living with HIV/AIDS.[1] Hepatitis B is a fatal infection of liver caused by Hepatitis B Virus (HBV). Both HIV and Hepatitis B are transmitted through sexual and percutaneous routes. Thus co-infection of HIV and Hepatitis B virus is common. Hepatitis B is reported to be 50 to 100 times more infectious than HIV.[2] Both HBV and HIV are noxious viruses that share certain epidemiological characteristics such as risk population and transmission routes. Because of this HIV positive individuals are at risk of co-infection with Hepatitis B virus.[3-5] The seroprevalence for HIV and HBV co-infection ranges from 6.3% to as high as 39%.[6-8] The reports show that co-infection by HIV/HBV causes increased morbidity and mortality as compared to HIV and HBV mono-infection. The interaction between HIV and HBV is an important issue which

suggests that HIV/HBV confection has negative impact on liver disease caused by these viruses.[9-10] HIV/HBV co-infected patients are at increased risk of developing cirrhosis, having higher levels of HBV replication, having lower rates of spontaneous resolution of HBV infection and having a higher risk of activation of previous infections.[9,11,12]

Whether HBV affects HIV progression has been a matter of much debate. However there are evidences that suggest that there is faster progression of HIV to AIDS defining illness in patients co-infected with HBV.[13-14]

Center for Disease Control (CDC) and prevention recommends all HIV infected patients should be screened for HBV and those susceptible should be vaccinated accordingly.[15-17]

There are very few studies done abroad as well as in India on prevalence of HBV co-infection in HIV infected patients. Therefore, the present study was undertaken to determine the prevalence of Hepatitis B virus infection in HIV positive patients at Tertiary Care Hospital in Latur District of Maharashtra, India.

Materials and Methods:

This study was conducted in Department of Microbiology, MIMSR Medical College, Latur District, Maharashtra, India from September 2010 to June 2014.

A total of 1000 clinically suspected HIV infected cases attending the Department of Skin and Venereal Diseases (VD) were selected. The blood samples were collected by taking aseptic precautions. Five ml of venous blood samples were collected from the patients. While collecting the blood samples the arm of subject was tied with tourniquet above the elbow joint to make the veins prominent. A vein was selected and cleaned with cotton swab dipped in spirit, and then a sterile 5 ml syringe with needle was used to pierce the vein and collect 5 ml of blood which was transferred aseptically in to a sterile dry plain bottle. The blood was allowed to clot for 30 minutes and centrifuged to get serum sample.

The serum samples were screened by Comb – AIDS test- a Dot immunoassay test that employs the same principle as Enzyme Immuno Assay (EIA) in which the immobilized antigen-antibody complex is visualized by means of color producing (chromogenic) reaction. The test was performed by adding and mixing two drops of sample to each of the wells. The Comb was placed and

sample was incubated at room temperature for 10 min. The comb was rocked in between during incubation. Four drops (0.2 ml) of colloidal gold signal reagent was dispensed into each of another set of unused micro-test wells. The comb was removed and blotted on absorbent material. The comb with the tip pointing down was rocked forward and backward in the wash solution for about 10 times, and then again the tips of the arm were blotted. · The comb then was placed into well containing colloidal gold signal reagent by incubating at room temperature for 10 min. After incubation the Comb was washed again and observed for chromogenic reaction. Presence of pink colored spot in the "test" and "control" area was reported positive for HIV and confirmed as per the Strategy IIB of NACO guidelines and then HIV positive patients were screened for HBsAg marker by immunochromatographic test (Hepacard), which is a one step immunoassay based on the antigen capture, or "sandwich" principle. The test was performed by adding two drops of human serum/plasma specimen into the sample well and allowed to react for 20 minutes. Formation of pink line in test as well as control area was considered as positive.

Table No. 01 : Surveys of prevalence of HBV/HIV co-infections in the world

Author	Publication year	Country	Prevalence of HBV/HIV co- infections (%)
Present study	2014	India	1.72
Okworiet al.[18]	2013	Nigeria	11
Ekanem et al. [19]	2013	----	12.1
Muhammad hamzaet al.[20]	2013	Nigeria	12.3
FarhangBabamahmmodiet al.[21]	2012	Iran	11.3
Kaur et al.[22]	2012	India	6.34
Ankuret al.[23]	2012	India	1.7
Suresh et al.[24]	2012	India	21
Kapembwa et al. [25]	2011	Zambia	9.9
Moore et al. [26]	2010	Malawi	6.7
Di Biscegliieet al.[27]	2010	South Africa	4.8
Hussain et al.[28]	2006	India	0.2
Okothet al.[29]	2006	Kenya	15
Deborah[30]	2005	---	8.7
Otedoet al.[31]	2004	Kenya	47
Ejeleet al.[32]	2004	Nigeria	9.7
Rouetet al.[33]	2004	Coted'sIvoire	09
Mustapha et al.[34]	2004	Gombe Nigeria	26.5
Kasoloet al.[35]	2003	Zambia	31.3
Ampofoet al.[36]	2002	Nigeria	15
Sudet al.[37]	2001	Nigeria	22.2
Treitingeret al.[38]	2000	Brazia	3.1
Dimitrakopolouset al.[39]	2000	Greek	67.4
Ramanammaet al.[40]	2000	India	14.3
Lodenyoet al.[41]	2000	South Africa	06

Results:

Out of 1000 clinically suspected cases of HIV, 348 (34.8%) were positive for HIV. Out of 348, 186 (53.44%) were male and 162 (46.55%) were females. Almost all HIV positive cases were from age group 20-50 years with a negligible number of cases from the age group below 20 years and age group above 50 years. Among the total of 348 HIV positive patients, six cases (1.72%) were found positive for HBsAg. Thus, HIV/HBV co-infection was detected in 1.72% cases.

Discussion:

Though the routes of transmission are same in HIV and HBV infections, the prevalence of co-infection varies from place to place. Different prevalence rates from different geographical areas have been reported in various earlier studies.[23,28,31,35,39] In the present study, a prevalence rate of co-infection was found to be 1.72%. Although this finding of a very low prevalence rate of HBV co-infection with HIV is consistent with studies by Ankur et al.[23] and Hussain et al.[28] and fairly correlates with the findings of these studies, it appears to be very low when compared with various other studies from other countries [31,35,39] and even from other studies from India[22,24,40] who report higher prevalence rates in their studies. The very low prevalence rate of co-infection may be attributed to the differences in the study groups and prevalence of HBsAgin the community in particular geographical area. A great variation in the pattern of HBV/HIV co-infection has been reported in different studies (Table no. 1) indicating that pattern of co-infection varies from place to place.

HIV has a substantial impact on the course and the outcome of HBV disease. The rate of HBV viral clearance is decreased in HIV infected patients after an acute HBV infection. The co-infected patients progress to liver disease more rapidly with a shortened period between acquisition of infection and end stage liver disease.[42,43] The studies show that HBV reactivation and replication are enhanced in co-infected patients.[44]

The effects of HBV infection on progression of HIV disease are less clear. The finding that some HBV products, such as HBV-x protein enhance HIV replication suggesting that HBV could have an impact in HIV progression.[45] However, these findings have not been supported by clinical studies.

Conclusion:

The findings of the present study indicate that the prevalence of co-infection in our area is comparatively lower as compared to other geographical areas suggesting that the prevalence rate of co-infection can change from country to country and even from region to region in same country.

Conflict of Interest: None to declare

Source of Funding: Nil

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ORIGINAL ARTICLE

OSPE in Biochemistry - An Assessment Tool for First M.B.B.S. Students as a Prelude to CBME in India

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Abstract:

Background and Introduction:
The study was undertaken with the anticipation of implementation of CBME in India**.**

Aims and Objectives:
Evaluate Objective Structured Practical Examination (OSPE) as a tool for effective assessment of practical skills in the subject of Biochemistry. To introduce the M.B.B.S. students to OSPE, evaluate the perception of students and teachers towards OSPE and compare OSPE with the conventional approach of practical examination taking into consideration the performance of students in both examinations.

Materials and Methods:
This cross-sectional study was conducted in the department of Biochemistry and included First M.B.B.S. students of the batch 2018-19. After prior sensitization to OSPE, First M.B.B.S. students were assessed by rotation around 10 stations. Later a conventional practical examination was also conducted on the same practical syllabus as OSPE. Students score in both examinations was compared and feedback was taken from the students as well as faculty to gain an insight into their perception about OSPE. The mean scores of the students in both the examinations were compared using student t test with the help of the Microsoft excel 2010 and Graph Pad prism 5 software.

Results and Discussion:
Out of the seventy-seven students who appeared for both OSPE and the conventional examination, twenty-six students scored ≥ 50% marks in OSPE as compared to seventy-five students in the conventional examination. Most of them agreed that OSPE was more focused on learning objective, encouraged learning, and analytical and interpretive thinking by the students, eliminated examiner bias and OSPE should be a part of their practical examination.

Conclusion:
OSPE is an objective and reliable tool for assessment in biochemistry, which helps to improve learning and evaluation of practical skills in biochemistry. With a proper and planned implementation, OSPE can be included in the evaluation system for the subject.

Keywords: OSPE, Biochemistry, CBME, assessment.

Introduction:

Competency based medical education (CBME) is an outcome-based practice of education where assessment plays a pivotal role in its successful pursuit. Since assessment is the driving force for learning, assessment in CBME should provide overall information about acquisition of skills by learner and facilitate learning as well[1,2].

Conventional methods of practical examination are based on viva taken at the end after the students complete the given practical. Thus, the practical is not

performed directly in front of the examiners. There is also examiner and experiment variability, and the students' communication skills which might affect the student's scores[3]. With the realization of the pitfalls in conventional assessment methods, Harden in 1975 introduced an objective structured examination for the assessment of clinical competencies (OSCE), which was later, modified to objective structured practical examination (OSPE) for practical skills. Structured examination can more easily control the examiner/ patient or experimental variables[4]. OSPE in Biochemistry can be used to assess various competencies like performance of simple bedside tests, interpretation of laboratory results, correlation of results with clinical conditions, correlation with theory component etc[5].

With this background, the study was undertaken to introduce M.B.B.S. students to OSPE and also to assess the perception of students and teachers towards OSPE.

Aims and Objectives:

1. To evaluate Objective Structured Practical Examination (OSPE) as a tool for effective assessment of practical skills in the subject of Biochemistry.
2. To introduce the First M.B.B.S. students to OSPE as a method of assessment.
3. To compare the performance of students in OSPE and conventional practical examination based on their scores in each exam.
4. To take an account of the perception and awareness of First M.B.B.S. students and teaching faculty towards OSPE as an assessment tool in Biochemistry.

Materials and Methods:

This cross-sectional study was conducted in the department of Biochemistry in a medical college of Rajasthan. The permission of Institutional Ethics Committee was taken. For the study 150 first year M.B.B.S. students were chosen. A written informed consent was also taken from the students. The students were primed about OSPE before the examination.

The syllabus for OSPE was displayed 15 days prior to conduction of OSPE. A conventional practical examination (CPE) based on same syllabus was also conducted the next week after OSPE.

For OSPE, students were rotated around ten stations. Out of these five were observed procedure stations and five were unobserved response stations. The stations were prepared to assess practical skills, analysis and interpretation of lab results, correlation of results with clinical conditions and demonstration of use of basic laboratory instruments like colorimeter and urinometer. Students were given a time of five minutes to attempt the questions at each station. Two rest stations were also given to students to finish any remaining writing work. For the assessment of OSPE, checklist was prepared beforehand with the mark distribution for each of the stations. At the end of OSPE a feedback was taken from the students. The questionnaire was prepared after extensive literature search and the questions were framed to include the cognitive, psychomotor and affective domains as well as assessment domain. A feedback was also taken from all the faculty members of the department.

Inclusion criteria for the study were students who appeared for both exams. Eighty-one students appeared for OSPE out of whom 4 did not appear for the conventional exam and hence were excluded from the study. The mean scores of the students in both the examinations were compared using student t test with the help of the Microsoft excel 2010 and GraphPad prism 5 software.

Results:

A total of 77 students appeared for both OSPE and the conventional examination. Out of these, 26 students scored $\geq$ 50% marks in OSPE as compared to 75 students in the conventional examination. Comparison of scores in OSPE and conventional exam revealed that students achieved more marks in conventional examination (mean score 29.27 $\pm$ 4.58) as compared to OSPE (mean score 15.74 $\pm$ 6.70) and the difference was statistically significant ($p < 0.001$).

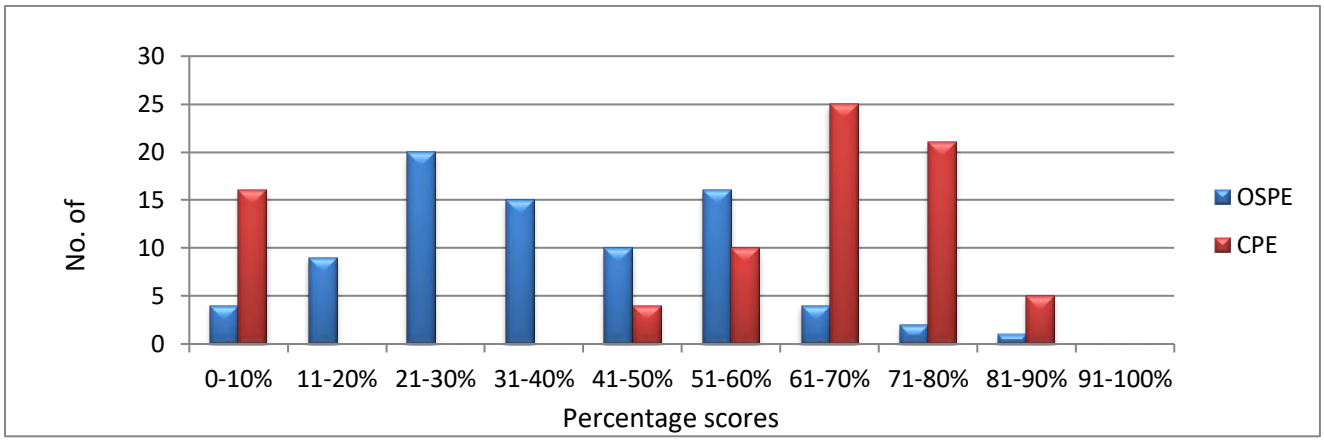

Figure 1: Frequency distribution diagram showing the marks obtained by the students in OSPE and conventional practical examination.

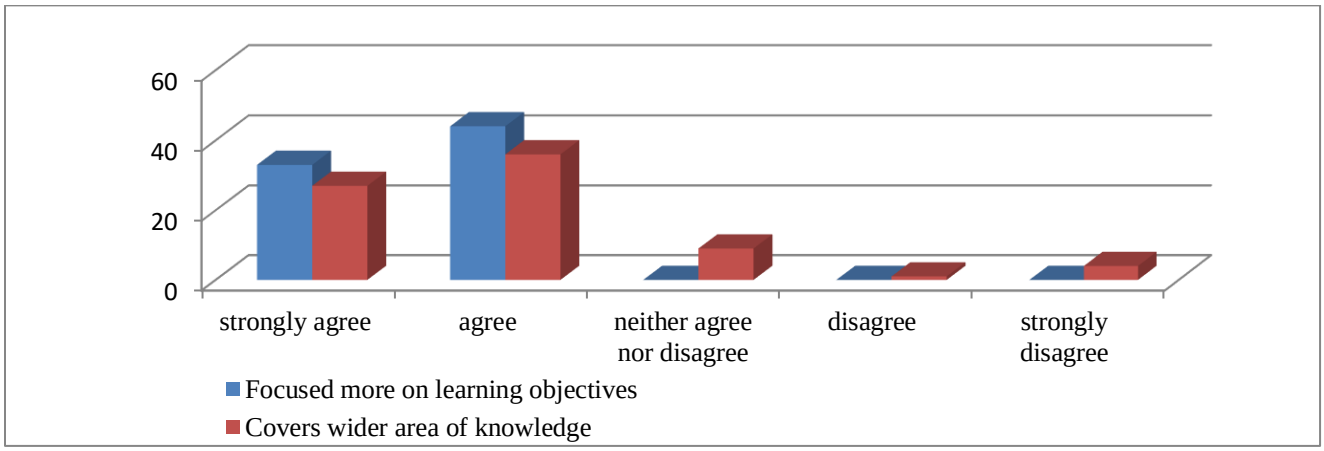

Figure 2: Student's Response for cognitive domain

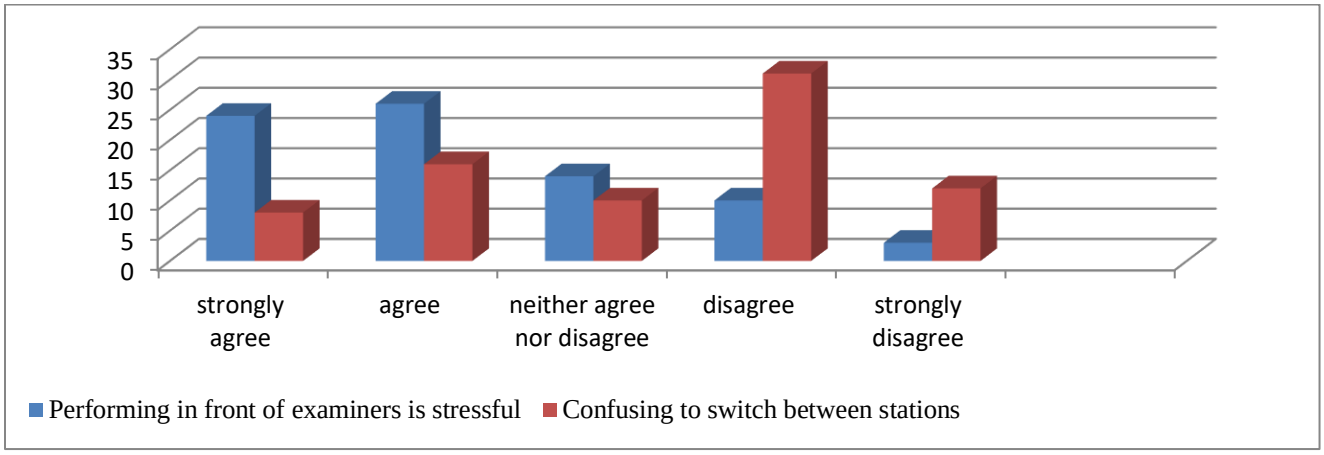

Figure 3: Response for psychomotor domain

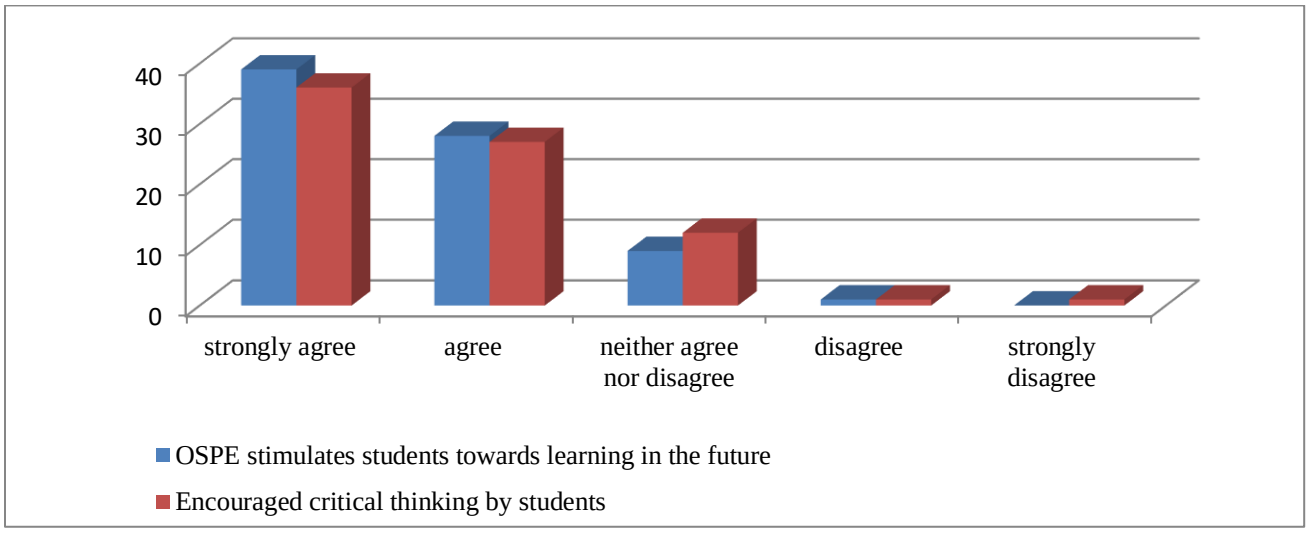

Figure 4: Response for Affective domain

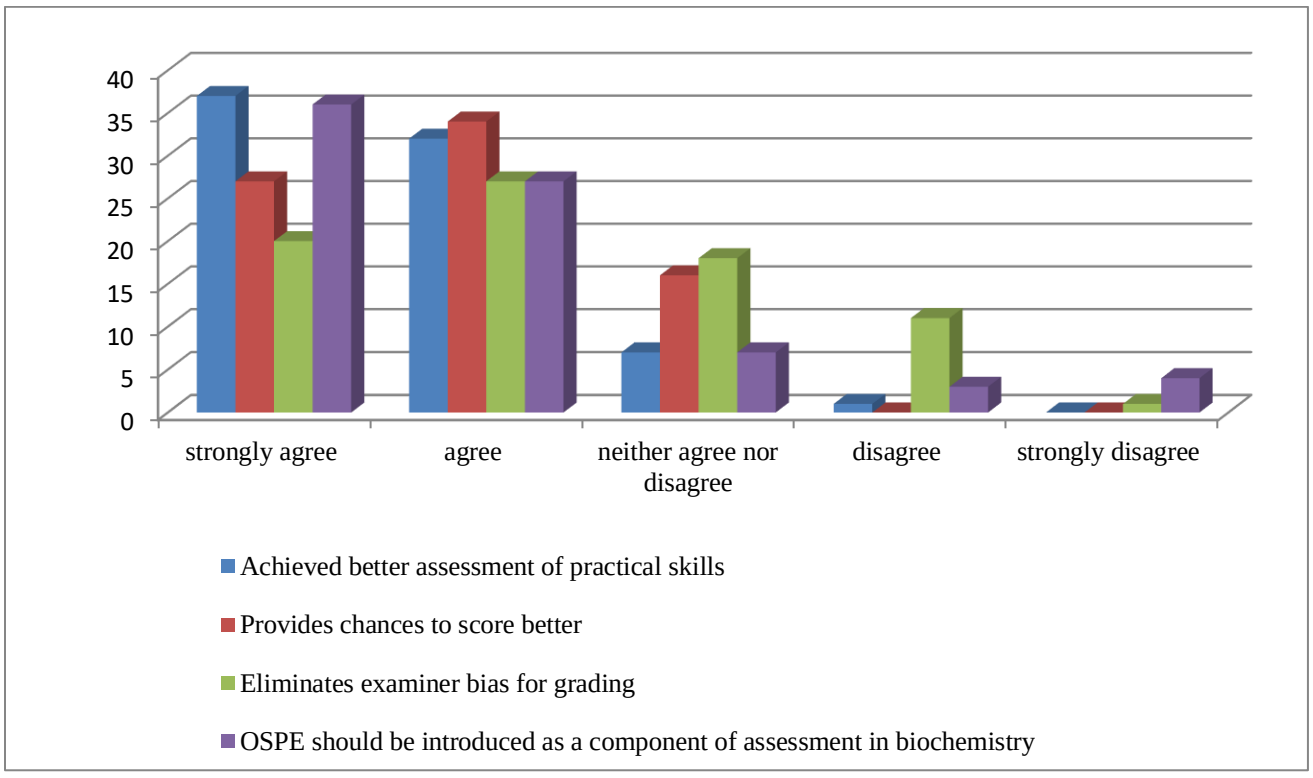

Figure 5: Response for Assessment domain

Table No 1: Student Feedback about OSPE

No.	Questions	strongly agree *n*	agree *n*	neither agree nor disagree *n*	disagree *n*	strongly disagree *n*
1.	Focused more on learning objectives	33	44	0	0	0
2.	Covers wider area of knowledge	27	36	9	1	4
3.	Performing in front of examiners is stressful	24	26	14	10	3
4.	Confusing to switch between stations	8	16	10	31	12
5.	OSPE stimulates students towards learning in the future	39	28	9	1	0
6.	Encouraged critical thinking by students	36	27	12	1	1
7.	Achieved better assessment of practical skills	37	32	7	1	0
8.	Provides chances to score better	27	34	16	0	0
9.	Eliminates examiner bias for grading	20	27	18	11	1
10.	OSPE should be introduced as a component of assessment in biochemistry	36	27	7	3	4

Table No 2: Faculty Feedback about OSPE

No.	Questions	strongly agree *n*	agree *n*	neither agree nor disagree *n*	disagree *n*	strongly disagree *n*
1.	Focused more on learning objectives	5	3	0	0	0
2.	Better assessment of practical skills	6	2	0	0	0
3.	Covers wider area of knowledge	2	5	1	0	0
4.	Provides chances to score better	4	1	1	2	0
5.	Eliminates examiner bias for grading	4	3	0	1	0
6.	Conducting OSPE requires a lot of preparation	5	2	0	1	0
7.	Conducting OSPE is time consuming	5	2	1	0	0
8.	Faculty training in MET is necessary for conducting OSPE	2	4	1	1	0
9.	Present faculty to student ratio is appropriate for implementing OSPE	0	2	0	2	4
10.	OSPE should be introduced as a component of assessment in Biochemistry	3	5	0	0	0

Student's feedback analysis (Table 1) revealed that most of them agreed OSPE was more focused on learning objective and also tested a wider area of knowledge in biochemistry. Most students agreed that switching stations was not confusing, but it was stressful to perform under the direct observation of examiners. They also agreed that OSPE encouraged learning and, analytical and interpretive thinking by the students. Majority of the students felt that OSPE eliminated examiner bias, which could affect scoring, and contrary to their scores in OSPE, most of the students felt that OSPE could help them achieve better score as compared to conventional practical examination. They were of the opinion that OSPE should be a part of their practical examination.

The feedback provided by faculty (Table 2) also revealed that OSPE focused more on learning objectives, with better chances to score by eliminating the examiner bias through the use of preapproved checklist. However, most of the faculty felt that conducting OSPE required more preparation than conventional practical examination, was time consuming and that the present student to teacher ratio was not adequate for OSPE. They also felt that training of faculty in medical education technology was necessary in implementation of newer methods of assessment but still agreed that OSPE should be a part of the practical examinations.

Discussion:

Until last academic session medical colleges in India have directed the training of medical graduates by applying traditional principles of medical education. Traditional curriculum focused more on the learning objectives rather than the outcome and hence conventional assessment methods concentrated mainly on the cognitive aspects with minuscule emphasis on the assessment of psychomotor skills or affective domain. This approach led to a deviation from achieving the goal of yielding first contact physicians for the community. Realization of this scenario ushered the implementation of competency based medical education (CBME) in India[6].

Utilization of a valid and reliable assessment tool to ascertain the achievement of desired competencies by medical students is the need of the hour. OSPE involves rotation of students around multiple stations for the assessment of all learning domains. OSPE helps to reduce the examiner or the experiment variability, by utilizing fixed set of questions, which are assessed using the same checklist by all the examiners. The examiner predefine marking scheme in OSPE and the feedback presented can help improve the teaching strategies as well as the learning process[4].

In the present study, the students' score for OSPE was significantly less than that for conventional pattern of examination. This could be due to the fact that students did not have any prior experience with OSPE. With conduction of repeated OSPE, sharing of checklist with students, their performance can improve. Also, in our study OSPE and the conventional examination were conducted a few days apart as time constraints made it impossible to conduct both on the same day. This could have affected the scores of students to some extent.

At the end of OSPE, feedback was taken from the students to gain an insight into the perception and attitude of students towards OSPE. Feedback plays an important role to ameliorate the standard of teaching – learning methods, assessment tools as well as the performance of the learners[7]. Students' feedback in the present study indicated that majority of them accepted OSPE as a more objective, fair and unbiased tool for assessment. This view has also been supported by other studies[8,9,10]. The students also felt that OSPE helped in assessment of all the three learning domains as opposed to the conventional practical examination.

Out of 77 students included in the study, 50 found that performing in front of the examiners was stressful which could have been due to lack of previous experience with OSPE, lack of knowledge of the procedure and the time restraints for performing it. However, 45 students agreed that there was no confusion while switching stations.

Sixty-seven students agreed that OSPE encouraged learning behavior and 63 students agreed that OSPE encouraged them to critical, analytical and interpretive thinking, which is required of a competent Indian medical graduate. Seventy-three students agreed that OSPE should be introduced as a component of assessment in Biochemistry.

Feedback from the faculty indicated that conducting an OSPE required a lot of prior preparation and was time consuming as opposed to conventional examination but agreed that OSPE should be a part of assessment in Biochemistry. Majority of the faculty agreed that faculty training in Medical Education Technology was necessary for conducting OSPE. This could be to understand the performance level at which assessment has to take place as well as in setting stations fit for the required domain of learning to be assessed. The guidelines put forth by the Medical Council of India (MCI) for Minimum Qualifications for Teachers in Medical Institutions has also made it mandatory for faculty at the post of Associate Professor and above to be trained in medical education technology[11]. Because OSPE involves use of multiple stations, most of our faculty agreed that the present faculty to student ratio was not adequate to implement OSPE. Also, OSPE should be introduced as one of the tools for evaluation in examinations.

Conclusion:

OSPE is an objective and reliable tool for assessment in biochemistry, which helps to improve learning and evaluation of practical skills in biochemistry. With a proper and planned implementation of OSPE, it can be included in the evaluation system for the subject.

Conflict of Interest - Nil
Sources of Support – Nil

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ROLE OF VITAMIN D AND RISK OF PROSTATE CANCER

Biochemistry

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ABSTRACT

Background: Vitamin D is a secosteroid hormone and well-known for its classical actions in the maintenance of calcium uptake and bone metabolism. Recently, numerous in vitro experiments demonstrated that 1,25-(OH)2D3, the active form of vitamin D, inhibited the growth and differentiation of human prostate cancer cells.
Aim: To estimate vitamin D level in prostate cancer patients along with increasing risk.
Material & Methods : 100 samples along with control were analysed by cobas e-411 for Vitamin D and PSA.
Results: we have found Higher risk of prostate cancer who having low vitamin D.
Conclusion: it's time to aware people for supplementation of Vitamin D, so we can prevent for the same.

KEYWORDS

Vitamin D, Prostate cancer, PSA, hypovitaminosis

INTRODUCTION:

Deficiency of vitamin D or hypovitaminosis D is widespread irrespective of age, gender, race and geography and has emerged as an important area of research Vitamin D deficiency is prevalent worldwide. This deficiency has many consequences which are still being explored, apart from the well-known skeletal complications. With the consequences of Vitamin D deficiency, namely, autoimmune diseases, cardiovascular diseases, cancer, and tuberculosis being explored. [1]. Vitamin D_3 deficiency continues to be an unrecognized epidemic in many populations around the world. Vitamin D is important for the absorption of calcium, and bone formation and maintenance [2] .The incidence of prostate cancer differs between countries due to coverage of prostate-specific antigen (PSA) screening [3]. patients with advanced-stage or metastatic cancer will ultimately progress to castration-resistant prostate cancer [4]. The mechanisms by which prostate cancer progresses to castration-resistant prostate cancer have been studied extensively [5]. Increasing evidence demonstrates that inflammation plays important roles in the pathogenesis of progression to castration-resistant prostate cancer [6]. A double-blinded clinical study found that vitamin D supplementation reduced prostate specific antigen (PSA) level and enhanced survival rate in patients with prostate cancer [7].

On the other hand, vitamin D receptor (VDR) polymorphisms were associated with the incidence of prostate cancer [7, 8]. Several epidemiological reports showed that men with vitamin D deficiency had a higher risk of prostate cancer compared to men with vitamin D sufficiency [9,10]. Nevertheless, the mechanisms through which vitamin D deficiency elevates the risk of prostate cancer remain unclear. The present study aimed to investigate whether there was an association among prostate cancer, vitamin D status in a hospital-based case-control study.

MATERIALS AND METHODS

A case control study done in Ananta institute of medical sciences and research centre, Rajsamand. During June 2016- November 2016. In the present study, total 50 newly diagnosed patients with prostate cancer were recruited as cases. Prostate cancer was confirmed by histopathology. 50 Controls were recruited from men undergoing physical examination. Vitamin D and PSA done by chemiluminescence immunoassay methodology. method on Cobas e-411 and chemistry (CRP) ,FBG, creatinine, uric acid, T.G., Total Cholesterol by Cobas Intigra 400^{+}. Serum samples of all cases and controls were collected at same season and stored at -20°C.

RESULTS

Biochemical characteristics were analyzed as shown in Table 1, no significant difference in Cr, UA, TG, TCH, fasting blood glucose was observed between cases and controls. As expected, serum T-PSA was significantly increased in patients with prostate cancer as compared with control subjects (Table 2).

Serum 25(OH)D concentration was analyzed in all subjects. As shown in Figure 1A, serum 25(OH)D in patients with prostate cancer was significantly lower than in controls.

Table 1

Parameters	Case(50)	Control (n=50)	P- value
FBG	70±1.2	69.12±.32	0.81 NS
Creatinine	0.87 ±.2	0.96±.31	0.734 NS
Uric acid	3.30±1.1	3.5±1.28	0.086 NS
Triglyceride	125.25±.25	128.35±3.25	0.45 NS
Total cholesterol	155.23±2.3	152.52±2.35	0.93 NS

No significant change

Table- 2

Parameters	case(n=50)	Control(n=50)	P- value
CRP	65.01±2.41	3.01±0.24	<0.0001*
Vitamin D	1.08±.56	8.10±2.16	<0.0001*
PSA	3.70±2.36	15.12±1.25	<0.001*

*Significant change

DISCUSSION

The present study analyzed the association among prostate cancer, vitamin D status. Our results showed that serum 25-(OH) D was reduced in patients with prostate cancer. By contrast, serum CRP, a marker of systemic inflammation, was elevated in patients with prostate cancer. These results provide evidence for the first time that low vitamin D status is associated with inflammation in patients with prostate cancer.

Chronic inflammation promotes metastases and progression to castration-resistant prostate cancer [11, 12]. CRP could predict tumor aggressiveness and potential treatment efficacy in patients with prostate cancer [13]. According to an early report, CRP is an independent prognostic factor for overall survival of patients with castration-resistant prostate cancer treated with docetaxel [14]. A recent study showed that elevated CRP level was associated with poor prognosis in prostate cancer patients treated with radiotherapy [15]. Our results showed that serum 25-(OH)D level was lower in patients with severe prostate cancer than in patients with mild and moderate prostate cancer. By contrast, serum CRP was higher in patients with prostate . These results suggest that low vitamin D status is associated with inflammation and the progression of prostate cancer.

Increasing evidence indicates that vitamin D has an anti-inflammatory activity [16]. These results suggest that inflammation may be a key mediator for prostate cancer progression in patients with low vitamin D status.

The present study has several limitations. First, the present study did not observe whether vitamin D deficiency and inflammation promotes metastasis and progression of prostate cancer. Thus, additional study is required to investigate whether prostatic inflammation promotes prostate cancer in patients with low vitamin D status.

In summary, the present study investigated the association among prostate cancer, vitamin D status and inflammation. Our results showed that serum 25-(OH) D was decreased in patients with prostate cancer. By contrast, serum CRP was increased in patients with prostate cancer.

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PREVALENCE OF HYPOTHYROID AND MENSTRUAL IRREGULARETIES WITH INFERTILITY IN UDAIPUR, RAJASTHAN, INDIA.

Biochemistry

KEYWORDS: hypothyroidism, Triiodothyronine (T3), Tetraiodothyronine (T4), menstrual disorder.

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ABSTRACT

It is important to predict the serum thyroid hormones level in females during infertility to prevent its occurrence later on. In this study, we studied serum thyroid hormones and menstrual irregularities during infertility. **Method :** A case control study was performed in 90 infertile patients with menstrual irregularities and 50 healthy matched women. Three biochemical parameters were measured in serum, hormones triiodothyronine (T3), tetraiodothyronine (T4) and serum thyroid stimulating hormone (TSH) by TOSOHAIA-360, immunoassay method. **Result :** Serum T3, T4 and TSH level were statistically highly significant in infertile women. Serum thyroid stimulating hormone level was found at higher side in infertile women. **Conclusion :** High incidence of hypothyroidism was found in infertile women and it shows a positive correlation with menstrual disorder.

Introduction : Mild or subclinical hypothyroidism is characterized by normal serum free thyroxin concentrations with elevated serum thyroid stimulating hormone concentrations.[1] The prevalence of hypothyroidism in the developed world is about 4-5% [1,2] The prevalence of subclinical hypothyroidism in the developed world is about 4-15% [3,4] In a developing and densely populated country like India, communicable diseases are priority health concerns due to their large contribution to the national disease burden[5]. In India, hypothyroidism was usually categorized under the cluster of iodine deficient disorders (IDDs), which were represented in terms of total goiter rates and urinary iodine concentrations, typicallyassessed in school-aged children[6,7,8]. Ever since India adopted the universal salt iodization program in 1983 [12] there has been a decline in goiter prevalence in several parts of the country, which were previously endemic [13-15]. In 2004, a WHO assessment of global iodine status classified India as having 'optimal' iodine nutrition2[6,7] with a majority of households (83.2% urban and 66.1% rural) now consuming adequate iodized salt[8,9] India is supposedly undergoing a transition from iodine deficiency to sufficiency state. A recent review of studies conducted in the post-iodization phase gives some indication of the corresponding change in the thyroid status of the Indian population[2]. Prevalence of hypothyroidism is 2-4% in women in the reproductive age group. Hypothyroidism can affect fertility due to anovulatory cycles, luteal phase defects, hyperprolactinemia, and sex hormone imbalance. Thyroid hormones are closely interacting through the women's reproductive hormones (estrogens and progesterone) to defend normal role of the ovaries along with maturation of egg (oocyte) .[2] Hormones are liable for maintain mood, reproduction , be asleep, sexual characteristics drive, and ability to switch stress, now to name a few function.[3] The above study undertaken shows a definite rise in serum thyroid hormones level and cases of infertility. Therefore, in this study, we examined serum thyroid hormone level in women during infertility with menstrual irregularities.

MATERIAL AND METHOD: This study was conducted in Annanta Institute of Medical Sciences, Udaipur (southern part of Rajasthan, Indian city) on patients of 2o-45 years of age of infertile women with irregular menstrual cycle, attending the out patients department of gynecology and obstetrics in collaboration with the department of biochemistry. 90 infertile women were included in this retrospective study with 50 healthy matched control women. Blood sample were collected by aseptic technique As per our clinical laboratory procedure, serum was separated from venous blood of fasting subjects and analysed within two hours of collection. The serum separated from the sample was analyzed for following parameters. Triiodothyronine (T3), tetraiodothyronine (T4), thyroid stimulating hormone (TSH) by cobas e-411 Immunoassay method . All results were expressed in mean±S.D. Difference between mean were calculated by student't' test. The level of significance was set as p< 0.05. Statistical analysis was performed using Graph Pad Prism version 5.00 for Windows, Graph Pad software, San Diego California USA, www.graphpad.com.

RESULTS: All women were in the age group of 20-45 years, Table 5 shows the menstrual disturbances with hypothyroidism in infertile women. Different type of menstrual disturbances like amenorrhea, oligomenorrhoea, menorrhagia and polymenorrhoea shown in table 5 , Out of 90 patients with irregular menstrual cycle only 15 had amenorrhea, of these only six (6) had hypothyroidism. Forty five (45) patients had oligomenorrhoea out of them only 16 had hypothyroidism. Twelve and thirteen (16, 14) patients had menorrhagia and polymenorrhoea, respectively. Out of them only 8 and 9 had hypothyroidism. Table 2 shows T3, T4 and TSH level in healthy control age matched patients. In control the mean value for T3, T4 and TSH were 1.35±0.32 ng/ml, 7.50±1.65 µg/dl and 2.12±1.03 µg/ml, respectively. Table 3 shows the serum T3, T4 and TSH level in infertile women, the values were found to be 0.90±0.34 ng/ml, 7.±1.68 µg/dl and 5.83±6.18 µIu/ml, respectively. On statistical analysis serum T3 and TSH level in these women were found to be statistically significant (table 4). P-value for serum T3 is found to be 0.05 and TSH p< 0.01 ,respectively. These were statistically highly significant. More than half of hypothyroid patients have menstrual irregularities and one third of sub fertile patients have thyroid disease.

TABLE 1

THYROID PROFILE IN DIFFERENT MENSTRUAL DISTURBANCES

Total case	hypothyroid	Percentage
90	35	38.88%

T3, T4 & TSH LEVEL IN NORMAL HEALTHY CONTROL GROUP WOMEN (n=50)

Hormones	Normal range	Mean ± Sd
T3 ng/ml	0.79-1.58	1.35± 0.32
T4 ug/dl	4.0-11.0	7.5±1.65
TSH uiu/ml	0.39-5.55	2.2±1.03

TABLE-3

T3 , T4 AND TSH LEVEL IN INFERTILE WOMEN WITH MENSTRUAL IRREGULARITIES (n=90)

Hormones	Normal range	Mean ± Sd
T3 ng/ml	0.21-2.4	0.90±0.34
T4 ug/dl	2.1-20.0	7.9±1.68
TSH uiu/ml	0.08-37.0	5.83± 6.18

TABLE-4

SERUM T3 , T4 AND TSH LEVEL IN NORMAL AND INFERTILE WOMEN WITH IRREGULAR MENSTRUAL CYCLE

Subject	T3ng/ml	T4 µg/dl	TSH µIU/m
Normal women n=50	1.35± 0.32	7.5± 1.65	2.12 ±1.03
Infertile women n= 90	0.90±0.34	7.9±1.68	5.83± 6.18

T3 <0.001; T4 >o.o5TSH< 0.01 Highly significant.

TABLE-5

MENSTRUAL DISTURBANCE WITH HYPOTHYROIDISM

No. of cases	Menstrual disturbances	Hypothyroidism	Percentage
15	Amenorrhea	6	40%
45	Oligomenorrhoea	16	35.55%
16	Menorrhogia	8	50%
14	Polymenorrhoea	9	64.28%

DISCUSSION: Infertility is defined as the failure of a couple to achieve a pregnancy despite one year regular unprotected sexual intercourse [9] . Although it has been proved that for normal sexual function , thyroid secretion of T3 , T4 need to approximately normal. Thyroid hormones have profound effects on reproduction and pregnancy. Thyroid dysfunction is implicated in a broad spectrum of reproductive disorders, ranging from abnormal sexual development to menstrual irregularities and infertility [9 . 14.] This study was demonstrated increased thyroid stimulating hormone level in infertile women. Serum thyroid level also affected by diet. We also found that menstrual pattern was abnormal in majority of infertile women. Our study is correlated with the study of Shalvev et al., (1994) [10]. Shalvev et al., studied the routine thyroid function test in infertile women and reported the low incidence of hypothyroidism in the pregnant patients is related to the close association between infertility and hypothyroidism 4 .. Usha R. Sharma reported hypothyroidism with menstrual irregularities. Our incidence of hypothyroidism is more probably because of case of infertility was not sub divided in to primary and secondary. In hypothyroidism, there is decreased synthesis of factors VII, VIII, IX, and XI and estrogen break through bleeding secondary to anovulation, which may explain the frequent, prolonged, and heavy menstruation [12] . Our study was also correlated with the study of Hassle et al., (1958), singh et al., (1990), and agarwal et al. (1994) [13,15]. Menon et al., (1995) studied menstrual dysfunction and thyroid disease and reported that there are contradictory reports regarding the types of menstrual disturbances seen in hypothyroidism and paucity of information in the Indian literature on the subject [10,13] . Our study has some limitations. It is a retrospective study which is inferior to prospective studies when the associations between different variables are to be ascertained. Our study is limited only to Women between 20 to 45 years in age. A wider range of age would have been more useful in gauging the distribution of the studied parameters in the population. A high incidence of hyperprolactinemia was found in infertile women and a positive correlation was found between hyperprolactinemia and hypothyroidism. [12,16]

CONCLUSION: The combination of analyzed serum thyroid hormone level and menstrual irregularities were important for infertility cases and useful for the prediction of infertility. So they can treated according to medically.

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Original Research Paper

EFFECT OF MUSHROOM DIET ON WEIGHT GAIN OF ALBINO RATS

Biochemistry

KEYWORDS: Oyster mushroom, *Pleurotus sajor-caju*, mycelium, protein

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ABSTRACT

Mushrooms are known for good quality of protein; therefore *Pleurotus sajor-caju* was selected to study the essential amino acid content and the effect of supplementation of *Pleurotus sajor-caju* on growth of albino rats. Rats were randomly assigned on diet containing mushroom fruiting and mushroom mycelium for a period of 30 days. On every 10th day, animals were weighed and their diet intake, remnant food and protein intake were measured. The result showed phenylalanine, methionine, tryptophan, threonine, isoleucine, lysine and histidine values of mycelium found significantly more than fruiting. In animal experiment values showed significant difference in body weight between control and experimental groups. Study concluded that the feeding of mushroom fruiting and mushroom mycelium diets helped to gain weight of albino rats because of then excellent nutritional composition.

INTRODUCTION

There has always been lack of harmony between the rapidly growing world population and the adequate supply of protein rich foods in the human diet. The mushrooms, yeast and algae are frequently mentioned as an alternative source for food. Mushrooms have been valued throughout the world as both food and medicine for thousands of years (Lindequist *et al.,* 2005; Wright 2004; and Tribe *et al.,* 1973).

Mushrooms are considered as a good source of protein, vitamins and minerals (Jiskani, 2001). *P. ostreatus* and *Pleurotus sajor-caju* are contain protein (27.4% and 26.9% respectively), carbohydrate (40.75%) and low lipid (5.4 % and 6.2 %) on dry weight basis (Dhonda *et al.*, 1996; Rai *et al.* 1988). Chang and Miles (1989) have suggested that the protein in mushroom, in general, is about twice that in asparagus and cabbage, and 4 and 12 times those in oranges and apples, respectively.

All the essential amino acids required by an adult are present in mushroom (Bisaria *et al.*, 1987). Lintgel *et al.* (1994) reported the digestibility of mushroom protein to be as high as 72-83 per cent. Quality of mushroom protein is far superior to the vegetable proteins and it is as good as or just inferior to animal protein because of presence of essential amino acids (Crisan and Sands, 1978; Bano and Rajarathnam, 1982; Chang and Miles, 1989). Quality of protein is nutritionally more important than its quantity. Requirement of protein is infact the requirement of amino acids. Human body is incapable of producing essential amino acids. Mushrooms are well recognized for their protein quality. Keeping this in view fruiting and mycelium of oyster mushroom were analyzed for its essential amino acids content and the diet supplemented with *Pleurotus sajor-caju* was selected to feed albino rats to know the growth effect.

MATERIAL AND METHODS

The present study was conducted during 2006-2007 in the Department of Home Science, Sant Gadge Baba Amravati University, Amravati. Oyster mushroom spp. *Pleurotus sajor-caju* was selected because it is grown commercially in central India and cost of cultivation is low. Fruiting of oyster mushrooms was cultivated by polybag technique and mycelium was grown on agar-agar media. Fruiting and mycelium of oyster mushroom were harvested from bags and media, respectively. Both were dried at 32^{0}C temperature in the incubator. Fruiting and mycelium were ground to form fine powder. Powders were stored in airtight container. Fruiting and mycelium of oyster mushroom were subjected to analyzed essential amino acids by paper chromatography method (Thimmaiah, 1999). Oyster Mushroom diets were prepared out of fruiting and pure mycelium. Oyster mushroom diets (as shown in table 1) were fed to albino rats to study the effect on weight of albino rats.

About thirty male albino rats were obtained from Department of Biochemistry, Rastra Sant Tukdoji Maharaj Nagpur University, Nagpur. The weight of rats was between 50 to 60 grams and age was between 40 to 45 days. Rats were randomly divided to in five groups. Each group had 6 rats. Control diet was fed to first group of rats and rest four groups were kept on experimental diets. At the beginning of the experiment, all rats were fed with standard diet (Swaminathan, 1999) for one week. The observations about diet provided and left over were recorded. The duration of feeding experiment was 30 days, on every 10th day rats were weighed. Their diet intake, remnant food and protein intake were measured. The composition of control and experimental diets is given in table 1. Control diet does not contain mushroom fruiting or mycelium. Diet 1 and 2 comprise control diet and 1 and 2g oyster mushroom fruiting (OMF) respectively. Diet 3 and 4 contain control diet and 1and 2g oyster mushroom mycelium (OMM) respectively. Water was given in adlibitum.

Table 1: Composition of control and experimental diets

S. No.	Ingredients (g)	Control diet	Experimental diets			
			Diet 1 1g OMF	Diet 2 2g OMF	Diet 3 1g OMM	Diet 4 2g OMM
1	Wheat flour	20.00	19.00	18.00	19.00	18.00
2	Roasted bengalgram dhal	58.00	58.00	58.00	58.00	58.00
3	Groundnut flour	10.00	10.00	10.00	10.00	10.00
4	Skimmilk powder	04.00	04.00	04.00	04.00	04.00
5	Casein	04.00	04.00	04.00	04.00	04.00

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6	Oil	04.00	04.00	04.00	04.00	04.00
7	Oyster Mushroom Fruiting	-	01.00	02.00	-	-
8	Oyster Mushroom Mycelium	-	-	-	01.00	02.00
9	Salt mixture	00.20	00.20	00.20	00.20	00.20
10	Vitamin mixture	00.50	00.50	00.50	00.50	00.50

RESULTS AND DISCUSSION

Oyster mushroom was analyzed to find out essential amino acids and estimated mean values are given in the table 2.

Table 2: Essential amino acids (% crude protein) in fruiting and mycelium of oyster mushroom

S. No.	Essential amino acids	Fruiting Mean ± SD	Mycelium Mean ± SD	't' value
1	Phenylalanine	4.00 ± 0.10	6.50 ± 0.10	10.00*
2	Valine	5.10 ± 0.10	4.30 ± 0.28	01.40
3	Methionine	2.20 ± 0.10	2.60 ± 0.37	02.00
4	Tryptophan	1.50 ± 0.10	2.10 ± 0.10	03.33*
5	Threonine	5.10 ± 0.10	7.50 ± 0.10	08.06*
6	Isoleucine	3.40 ± 0.10	4.20 ± 0.11	05.80*
7	Leucine	6.50 ± 0.10	5.20 ± 0.10	05.90*
8	Lysine	6.40 ± 0.10	7.00 ± 0.11	01.66
9	Histidine	2.10 ± 0.10	2.50 ± 0.01	00.86

* Significant at 0.05 level of probability

The fruiting and mycelium contained all essential amino acids but in varying amount. Fruiting contained 4.00 per cent and mycelium contained 6.50 per cent phenylalanine. It reveals that mycelium found to be better than fruiting in respect of phenylalanine which could be seen from the significant 't' value (10.00) at 5 per cent level of significance.

Valine present in fruiting and mycelium found to be 5.10 and 4.30 per cent, respectively. However, 't' value (1.40) reveals that there was no significant in the content of valine in fruiting and mycelium. Fruiting contained 2.20 per cent and mycelium 2.60 per cent methionine. This shows that both fruiting and mycelium were similar in methionine content, as could be seen from non significant difference between fruiting and mycelium at 5 per cent level of probability.

Fruiting and mycelium contained 1.50 per cent and 2.10 per cent tryptophan, respectively. Mycelium found to be better than fruiting in respect of tryptophan content as 't' value shows significant difference between fruiting and mycelium at 5 per cent level of significance.

Fruiting contained 5.10 per cent threonine and in mycelium it was found to be 7.50 per cent. It shows that mycelium found to be better source of threonine than fruiting as significant difference could be found between fruiting and mycelium at 5 per cent level of probability (t = 8.06).

Isoleucine present in fruiting was 3.40 and 4.20 per cent in mycelium. It indicates that the mycelium found to be better in isoleucine than fruiting, as 't' value (5.80) found to be significant at 5 per cent level of probability. Fruiting contained 6.50 per cent and mycelium contained 5.20 per cent leucine. Fruiting found to be better than mycelium in respect of leucine as significant difference could be noticed from the 't' value (5.90).

Fruiting contained 6.40 per cent lysine and mycelium contained 7 per cent lysine. Though mycelium showed high amount of lysine than fruiting but 't' value showed no significant difference between fruiting and mycelium and thus both are at par as far as lysine content is concerned.

Fruiting contained 2.10 per cent and mycelium contained 2.50 per cent histidine. Both fruiting and mycelium contained similar amount of histidine as no significant difference could be noticed (t = 0.86).

Animal experiment

The observed values of feeding experiment about total diet intake, total protein intake and the total gain in body weight on 10th, 20th and 30th day are given in tables 2, 3 and 4, respectively.

Table 2: Mean diet intake, protein intake, weight gain of albino rats on 10th day

S. No.	Diets	Protein g/100g diet	Actual diet intake (g) Mean ± SD	Actual protein intake (g)	Weight gain (g) Mean ± SD
1	Control	22.12	102.08 ± 2.91	22.67	22.50 ± 2.12
2	1g OMF	22.54	102.03 ± 1.67	22.99	22.58 ± 1.02
3	2g OMF	22.87	104.03 ± 2.95	23.79	27.24 ± 2.43
4	1g OMM	22.68	102.88 ± 2.50	23.33	24.50 ± 2.32
5	2g OMM	23.15	104.12 ± 4.02	24.10	29.18 ± 1.16

Data in table 2 indicates that the gain in body weight of rats kept on experimental diets was better than control diet. It was noted that the weight gain of rats fed on 2g OMF (27.24 ± 2.43) and 2g OMM (29.18 ± 1.16) was better than 1g OMF (22.58 ± 1.02) and 1g OMM (24.50 ± 2.32) diets. It was also observed that the gain in weight of rats fed on diet 1 and 2 comprise OMM was better than the diets 3 and 4 contains OMF. The results thus lead to the conclusion that higher the content of mushroom, better the weight gain. However, mushroom mycelium was found effective than the fruiting of oyster mushroom.

Table 3: Mean diet intake, protein intake, weight gain of albino rats 20th day

S. No.	Diets	Protein g/100g diet	Actual diet intake (g) Mean ± SD	Actual protein intake (g)	Weight gain (g) Mean ± SD
1	Control	22.21	110.12 ± 4.28	24.45	27.18 ± 3.51
2	1g OMF	22.54	112.02 ± 2.10	25.24	28.01 ± 2.51
3	2g OMF	22.87	118.16 ± 5.02	27.02	31.21 ± 1.15
4	1g OMM	22.68	112.78 ± 1.75	25.57	30.04 ± 1.52
5	2g OMM	23.15	115.21 ± 2.04	26.67	33.50 ± 2.64

Data in table 3 indicates that the highest weight gain of albino rat (33.50g) was observed in 2g OMM diet. Rats kept on control diet (27.18g) and 1g OMF diet (28.01g) showed low weight gain. The results showed that oyster mushroom mycelium was found better in increasing the body weight of albino rats and followed by OMF and OMM diets.

Table 4: Mean diet intake, protein intake, weight gain of albino rats on 30th day

S. No.	Diets	Protein g/100g diet	Actual diet intake (g) Mean ± SD	Actual protein intake (g)	Weight gain (g) Mean ± SD
1	Control	22.21	130.10 ± 2.32	28.89	29.01 ± 1.73
2	1g OMF	22.54	131.12 ± 3.98	29.55	28.50 ± 3.05
3	2g OMF	22.87	136.22 ± 3.23	31.15	33.48 ± 2.00
4	1g OMM	22.68	132.18 ± 2.05	29.97	31.50 ± 1.52
5	2g OMM	23.15	135.61 ± 4.01	31.39	36.11 ± 3.00

Perusal of data in table 4 reveal that the highest weight gain of albino rat (36.11g) was found in 2g OMM diet, relatively protein intake was 31.39g. One gram OMF supplemented rat group showed lower weight gain (28.50g) than control group (29.01g) but 2g OMF supplemented group showed better weight gain (33.48g) than 1g OMF fed group. The results thus lead to conclude that weight gain of rat fed on OMM diet was better than the OMF diet. As the amount of mushroom increases weight also increases. However, mushroom mycelium diet were found effective than the fruiting diet.

The data in respect of mean weight gain of albino rats on 10th day, 20th day and 30th day of control and experimental diets (1g and 2g OMF and OMM diets) have been presented in table 5 for comparison.

Table 5: Weight gain (g) of albino rats (control with 1g and 2g doses of fruiting and mycelium each)

S. No.	Days / Diets (n=6)	10th day	20th day	30th day	1st – 30th days
1	Control	22.50	27.18	29.01	78.69
2	1g OMF	22.58	28.01	28.50	79.09
3	2g OMF	27.24	31.21	33.48	91.93
4	1g OMM	24.50	30.04	31.50	86.04
5	2g OMM	29.18	33.50	36.11	98.79
	'F' Test	33.00*			

* Significant at 0.05 level of probability Two way ANOVA was applied for testing the significance of difference of means of control and experimental diets (1g and 2g OMF and OMM diets each) and data obtained have been presented in table 5.

Table 5 reveals that on 10th day the diet intake of albino rats were low, therefore, showed low weight gain. The plausible reason for low consumption of diet was albino rats were not accustomed to the diets. On 20th and 30th day, more weight gain was observed because of increased intake of diet and relative increase in protein intake. Overall weight gain pattern reflects that as diets comprising oyster mushroom increases body weight also increases. *In vivo* proteins are required for tissue development and oyster mushroom comprises good amount of protein. The 2g OMF and 2g OMM diets fed groups showed better weight as compared to 1g OMF and 1g OMM diets. Significant differences were found between weight gain of albino rats fed on different diets.

The quality of food protein depends upon its amino acid composition, especially that of essential amino acids. *In vivo* essential amino acids perform many functions but lysine, leucine, valine and histidine are especially required for growth and as such oyster mushroom comprise these four amino acids in good quantity as reported by Rai (1995).

Results show that the quality of protein depends on presence of all essential amino acids in food; as such oyster mushroom mycelium and fruiting contained all essential amino acids. The mean values of phenylalanine, tryptophan, threonine and isoleucine indicate that the content of these amino acid was definitely higher in mycelium than fruiting. Whereas, the fruiting of oyster mushroom definitely contained higher amount of leucine than the mycelium. The results of the animal experiment proved that the supplementation of oyster mushroom diets showed significant weight gain of albino rats. Thagumanaven and Maniekam (1980). Too observed weight gain in rats fed on *Pleurotus sajor-caju* due to its high digestibility. Similar result was also observed by Samajpati (1979).

CONCLUSION

Present investigation proved that the Oyster mushroom fruiting and mycelium contribute all essential amino acids. Phenylalanine, methionine, tryptophan, threonine, isoleucine, lysine and histidine values of mycelium found significantly more than fruiting. The supplementation of oyster mushroom helped to gain weight of albino rats because of its excellent nutritional composition.

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ORIGINAL RESEARCH PAPER

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ROLE OF NATURAL ANTIOXIDANT IN BREAST CANCER PATIENTS

Biochemistry

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ABSTRACT

Background: Breast cancer is a nonexistent entity for a majority of population till a near and dear one suffers from it.
Introduction: Breast cancer is now the most common cancer in most cities in India, and 2nd most common in the rural areas.
Material and Methods: This prospective study was carried out in Obstetrics and Gynecology, oncology and biochemistry department of Annanta institute of medical sciences, Udaipur ,India. 100 subjects with 100 controls were enrolled for the study.
Results: we have found decreased level of antioxidant in patients in comparison to control.
Conclusion: Awareness with supplementation of natural antioxidant is beneficial to prevent the risk of Brest cancer

KEYWORDS

Breast cancer, cancer, antioxidant vitamin C, vitamin E.

INTRODUCTION:

Breast cancer is now the most common cancer in most cities in India, and 2nd most common in the rural areas.[1] one fourth (or even approaching one thirds) of all female cancer cases are breast cancers. The most important reason being lack of awareness about breast cancer and screening of the same; more than 50% patients of breast cancer present in stages 3 and 4, and outcome is not as good as earlier stages, however aggressive the treatment may be. The western nations have achieved a steadily improving and good survival mainly because of screening of breast cancer**.** Out of every 100 breast cancer patients, 2% were in 20 to 30 years age group, 7% were in 30 to 40 and so on. 69% of the patients were above 50 years of age. Presently, 4% are in 20 to 30 yrs age group, 16% are in 30 to 40, 28% are in 40 to 50 age group. So, almost 48% patients are below 50.[2,3] An increasing numbers of patients are in the 25 to 40 years of age, and this definitely is a very disturbing trend. Of course, one particular reason for higher numbers of younger patients is our population pyramid, which is broad at the base and middle and narrow at top, which means that we have a huge population in the younger age group and much lesser in older age group. [4] In the year 2012, there were about 2,32,000 breast cancer cases reported in the US, whereas in India, 1,45,000 new cases were diagnosed. This implies that, though, because of India's population, the percentage of total women affected seems less, the breast cancer burden in India has almost reached about 2/3rds of that of the US and is steadily rising.[5,6]

Oxidative stress is a biochemical condition that occurs when intracellular antioxidants are unable to neutralize pro-oxidants such as reactive oxidant species (ROS). These ROS damage membranes, DNA, lipids, proteins, and carbohydrates, eventually causing cell injury and death. Vitamin C and vitamin E are natural antioxidant. They have many biological functions, antioxidant function, including enzyme activities. They also act on immune function and reduce the risk of breast cancer. [7]

Antioxidants counteract free radicals and prevent tissue and organ damage. Although antioxidants may play a role in the primary prevention of cancer by reducing the oxidative modification of DNA. Till date a very few studies have done in antioxidant and breast cancer relationship in this part of India. So we have planned this study.

MATERIALAND METHODS:

Study setting, study type: This prospective study was carried out in Obstetrics and Gynecology and department of Biochemistry in Annanta institute of medical sciences, Udaipur.

Study participants & study period: women admitted in gynecology and cancer department between March 2017 –September 2017 in the hospital were examined. Blood pressure was measured by mercury sphygmomanometer in reclining position in right brachial artery. Three readings were taken at 10 minutes interval. Participants having average systolic blood pressure ≥ 140 mm hg and/or diastolic blood pressure ≥ 90 mm Hg were included in the study.

EXCLUSION CRITERIA: Patients with history of hyperuricemia, liver diseases, diabetes, renal diseases, cardiovascular illness, and symptomatic infectious diseases , previous cancer history, were excluded.

Sample size and sampling: 100 subjects with 100 controls were enrolled for the study.

Data collection: After enrollment participants were grouped healthy control and patients with breast cancer. Informed consent was taken from all the participants. The history of all participants was taken. Blood samples of participants were taken from right or left cubital vein and collected in plain and citrate tubes.

Serum level of vitamin C was done by NATELSON method, and read at 520 nm by colorimeter.

Serum level of vitamin E was done by BAKER & FRANK method read at 520 nm.

STATISTICALANALYSIS:

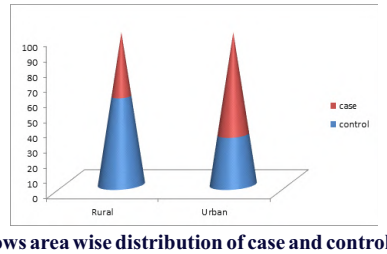
We used unpaired" test for comparing the mean level of uric acid, LDH, AST, ALT with maternal outcome. p value < 0.05 was considered statistically significant.

RESULTS:

In this study we have found a statically significant difference level of serum antioxidant in case and control. We have distributed them according to area, marital status, smoking habit and side of Breast having cancer. Then we have estimated serum Vitamin C and Vitamin E level in these groups.

Table-1 Area wise distribution among case and control

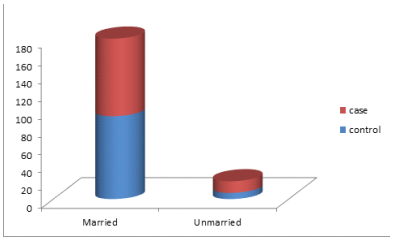
	Rural	Urban	Total
control	58	33	100
case	42	67	100



Figure; 1 shows area wise distribution of case and control

Table-2 Marital status of case and control

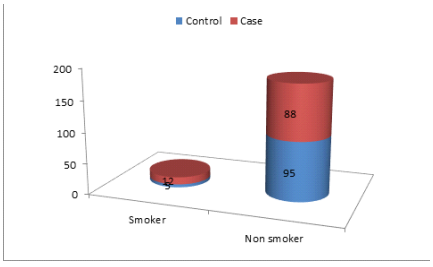
	Married	Unmarried	Total
control	93	07	100
case	87	13	100



Figure; 2 shows marital status of case and control

Table-3 Smoking status among case and control

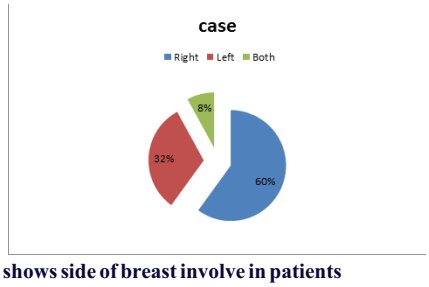
	Smoker	Non smoker	Total
Control	5	95	100
Case	12	88	100



Figure; 3 shows distribution of case and control according to history of smoking habit.

Table-4 Side of breast involve in patients

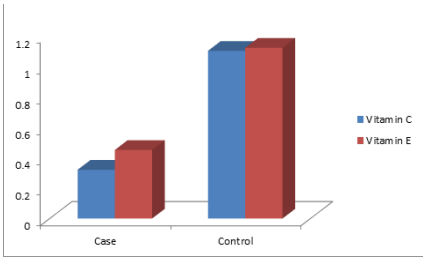
Side involved	case
Right	60
Left	32
Both	08
Total	100



Figure; 4 shows side of breast involve in patients

Table-5 Antioxidant level in case and control

Antioxidant	Case	Control	P-value
Vitamin C	0.32± 0.12	1.10±0.02	<0.0001
Vitamin E	0.45±0.13	1.12 ±0.11	<0.0001



Figure; 5 Shows level of serum antioxidant in case and control

DISCUSSION:

we have determined the level of natural antioxidants in patients and control and then compared it. We have found a strong association between case and control in serum antioxidant level. We have found lower level of vitamin C and E in cases in comparison to control.

In Table 1 we have found distribution of case and control according to their area, main difference in ratio is their lack of awareness of breast cancer in these patients. Table-2 shows marital status of patients. Breast cancer not only affects patients health even it also affect their personal relationship.

Table-3 shows smoking status of patients, Tobacco smoke contains thousands of chemicals, many of which are known to be mammary carcinogens. Although not initially thought to be a tobacco-related cancer, over the last several decades evidence has been accumulating on the role of both active smoking and secondhand smoking in the etiology of breast cancer.[8] Table-4 shows side of Brest in patients.

Table -5 shows level of antioxidant in case and control group. Cancer cells operate under a high level of oxidative stress, due to high baseline levels of reactive oxygen species, oncogenic transformation, and metabolic reprogramming.[9] Oxidative stress occurs due to imbalance between the production of free radicals [superoxide anion (O2 -), hydrogen peroxide (H2O2), hydroxyl radical (OH-), nitric oxide (NO), and more] and their elimination by antioxidant defense mechanisms [superoxide dismutase (SOD), catalase (CAT), glutathione peroxidase (GPx), among others], which induces cell damage caused by lipid peroxidation generating derangement and loss of function and integrity of the cell membrane, as well as DNA damage, promoting genomic instability and cell proliferation, thereby increasing the somatic mutations and neoplastic transformation.[10,11.]

Ascorbic acid (vitamin C) has been widely used in the treatment and prevention of cancer; nevertheless, the clinical results are still inconclusive. At low concentrations, it has an antioxidant role, preventing oxidation, which induces apoptosis. However, its high content can increase the production of ATP (generated by mitochondria) inducing apoptosis in tumor cell lines, via a pro-oxidant mechanism.[11] Studies show dose-dependent antineoplastic activity with influence on apoptosis, cell cycle, and cell signaling, increasing the cytotoxicity of the antineoplastic agent in cell lines of breast cancer treated with mitoxantrone and ascorbic acid.[12,13,14]

It has been proposed that the dietary supplementation of vitamin E, a lipid-soluble antioxidant, may reduce a woman's risk of developing breast cancer.[15,16] In animal models, vitamin E has decreased the incidence of carcinogen-induced mammary tumors. Intake and serum levels of vitamin E and their relation to breast cancer have been evaluated in epidemiologic studies.[17] Results of epidemiologic studies, however, have been conflicting. In this , we examine the evidence that is available pertaining to the relationship between vitamin E and breast cancer. Although epidemiologic study results have been inconsistent, further study of this nontoxic vitamin is warranted. Particular attention should be paid to the interactions of other antioxidants with vitamin E and to the duration and timing (pre- vs. postmenopausal) of vitamin E use in determining its preventive utility in breast cancer .[18,19]

CONCLUSION:

awareness with supplementation of natural antioxidant are beneficial to prevent the risk of breast cancer.

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Study of Level of various Infertility hormones like FSH, LH, Testosterone, Thyroid hormone and Prolactin in obese hyperglycemic and non-obese normoglycemic women of polycystic ovarian syndrome (PCOD) in southern Rajasthan, India

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Abstract: The polycystic ovary syndrome (PCOS) is a mostly hyper androgenic disorder and is possibly the most common endocrinopathy of premenopausal women. The primary defect in polycystic ovary syndrome (PCOS) appears to be an exaggerated androgen synthesis (testosterone) (secretion by the ovaries and the adrenal glands) and hyperglycemia or insulin resistance. The objective of the study is to study the level of various Infertility hormones like FSH, LH, Progesterone, Estradiol, Testosterone, Insulin, HOMA-IR, Thyroid hormone (T3,T4,TSH)& Prolactin and in obese hyperglycemic and non-obese normoglycemic women of Polycystic ovarian syndrome(PCOD). This study includes total 500 female participants of age Group between 18-40 year of age**.** They were divided in to two group. Group 1(n=300) includes women having PCOD and Group 2(n=200) is control Group. Fasting Blood samples were obtained from all participants to measure Blood sugar, Lipid Profile, Testosterone, Progesterone, Estradiol FSH, LH, Insulin, HOMA-IR, Thyroid hormone(T3,T4,TSH) and Prolactin. History of PCOD women also had taken with Age, Menstrual cycle, hirsutism, acne, BMI, Waiste Hip ratio & Veg or Occasional Non-veg food diets. The Mean level of Fasting Blood sugar, S. cholesterol, S.Triglyceride, S. Insulin, S. Testosterone, S. Estradiol ,S.FSH ,and S.LH is found to be higher in both obese hyperglycemic & non-obese normoglycemic PCOD group (Except: S. Progesterone) as compared to control group and difference among them found to be statically significant. In PCOD women were also finds symptoms of oligomenorrhoea or anovulatory menstrual cycle, histustim with different F-G score, obesity in different ratio. From our study I would like to conclude that Obesity is a common finding in PCOS and aggravates many of its reproductive and metabolic features. The relationship between PCOS and obesity is complex, not well understood, and most likely involves interaction of genetic and environmental factors. Insulin resistance and weight gain are two contributing factors to PCOS. Insulin resistance typically causes the body to produce more insulin than normal (hyperinsulinemia). Higher levels of insulin can then cause ovaries to produce too much testosterone which can impair normal ovulation from occurring. Hyperandrogenism caused other secondary characteristics like Virilization, hirsutism (hairs on body), acne, obesity etc. These symptoms differ according to age of PCOD women, early age hyperandrogenism which further leads to metabolic syndrome with insulin resistance in later age.
Keywords: PCOD, Testosterone, Insuline, FSH, LH ,Prolactin, Progesterone, Estradiol, Thyroid hormone

INTRODUCTION

In polycystic ovary Syndrome (PCOS), increased androgen production results in high levels of luteinizing hormone (LH) and low levels of follicle-stimulating hormone (FSH), so that follicles are prevented from producing a mature egg. Without egg

production, the follicles swell with fluid and form into cysts. Every time an egg is trapped within the follicle, another cyst forms and the ovary swells, sometimes reaching the size of a grapefruit. Without ovulation, progesterone is no longer produced, whereas estrogen levels remain normal [1].

Factors that cause PCOS are insulin resistance & obesity, Genetic tendency, bad dietary habbits, weakened immune system, accumulation of toxins etc. In PCOS while diabetes mellitus and impaired glucose tolerance are easily diagnosed, the diagnosis of and concern for insulin resistance as a precursor disorder is underappreciated [2, 3].

Polycystic ovarian syndrome (PCOS) is a highly prevalent hormonal and metabolic disorder among reproductive aged women worldwide. Women with polycystic ovarian syndrome (PCOS) have widely varying phenotypes and seek medical care for differing reasons. In addition to concern for menstrual cycle function, ovulation, hirsutism and acne, many polycystic ovarian syndrome (PCOS) women have abnormal glucose metabolism.

MATERIAL & METHOD

This prospective study was conducted at Department of Biochemistry and Department of Obstetrics & Gynaecology, RNT Medical college and associated group of hospital, Udaipur, Rajasthan, India from June 2012-Dec 2013.

A total of 500 subjects of age group between 18-40 years belonging to both normal & polycystic ovary syndrome will be classified as:

Group-1:300 women with PCOD (Cases) of polycystic ovary disease will be taken.
Group-2:200 normal women will be taken as control for these parameters.

All PCOD women & controls were underwent a complete history and physical examination. Women with PCOD should be interviewed of their name, address, age, socio-economic status, and menstrual history, age of menarche, education level and family history of PCOD. All women were gone through gynaecological ultrasonography to determine their uterus and ovary condition.

Inclusion criteria

Women with PCOD are attending outdoor OPD of the hospital, first time diagnosed PCOD ,Diagnosed polycystic ovarian syndrome, age ranging from 18-40 years.Women with PCOD Willing to have physical examinations like Weight, Height, BMI, W/H ratio, Blood Pressure, Hirsutism, Acne, Dark patches, Virilization, Ultra sonography etc.

Polycystic ovary syndrome (PCOS) associated with Diabetes, obesity, cardiovascular disorders, Irregular menstrual disorder and anovulation, Hirsutism & Acne symptoms.

Exclusion criteria

Women with diagnosed adrenal hyperplasia, androgen secreting neoplasm, other pituitary (acromegaly) and adrenal disorders like Cushing syndrome, Virilizing adrenal or ovarian neoplasm**,** hyperProlactinemia and other infertility cause **,**Thyroid hormone related infertility, Women having history of smoking, taking alcohol or tobacco chewing**,** Any other type of gynaecologic complications except related with Polycystic ovary syndrome (PCOS) will be excluded from the study.

Fasting 10 ml venous blood samples were obtained from all participants and collected it in to fluoride and plain vaccutainer. A Uniq ID number was given to each sample to hidden the identity of participants. All samples were centrifugated at 3000 RPM at clinical biochemistry laboratory for a period of 10 minutes to obtain a Plasma and serum.

Blood Glucose (FBS) measured by GOD POD method and lipid profile (S.Cholesterol, Triglyceride, HDL, VLDL, LDL) measured by enzymatic colorimetric method from all samples.

Various Endocrinal Hormones like, Testosterone, LH, FSH, Estradiol, and Progesterone was measured by enzyme linked immune assay (ELISA) method based on electrochemilumnescence from all samples. Thyroid hormone and Prolactin was done only for case group (exlusion criteria).

After assessing all the values, Mean, Standard deviation of all subjects & parameters were analysed. Statistical analysis was performed with SPSS software. Comparison between cases and with control is done by independent student's t test. By using' values now P value is less than 0.05 (P value < 0.05), it is significant. Comparison of the categorical variables (among category comparison) was done by using Chi-Square test.

RESULTS & DISCUSSION

The present study has been conducted on 300 PCOD women attending in OPD of R.N.T. medical college & associated group of hospitals, Udaipur and Geetanjali medical college & hospital, Udaipur. The results have been compared with 200 age and matched health women. All subjects were taken in the age group of fertile age 18-40 years.

Clinical data of all groups were collected via a questionnaire supplemented with an interview & were subjected to:

1. Verbal consent has been taken from patient after explaining the aim of the study.
2. **History**
   - Marital status or single
   - Education - awareness about PCOD & its consequences.
   - Socioeconomic status- life style & diet (veg/non-veg/fastfood/junk food) behaviour of subjects
   - Menstrual history- to determine the period of cycle relate with PCOD symptoms
   - Past history-to know the no of children and any type of history of Diabetes, Hypertension
   - Family history- family history of poly cystic ovary disease.
   - Hirsutism- to examine for excessive male hair pattern in females.

3. **General Examination**
   - Blood pressure (systolic and Diastolic) – measured in semi recumbent position. Two blood pressure recording 4 hours apart have been obtained.
   - Body mass index (BMI) – equals to weight in kilograms devided by th square of the height in meters.

     BMI = (Weight in KG) / (Height in meters)^2

   - Abdominal examination – to determine any metabolic syndrome and inflammation.
   - Hirsuism examination (F-G score) - When evaluating a woman with hirsutism, the Ferriman–Gallwey (FG) score is a simple and commonly used method to quantify hair growth. This method evaluates nine androgen sensitive sites and grades them from 0 to 4. Scores between 8 and 15 are usually considered to be mild hirsutism, whereas scores greater than 25 indicate severe hirsutism. Some limitations of this scoring system include: (a) the variation in hair growth between different ethnic groups; (b) failure to account for regional hirsutism; and (c) the fact that many women may have treated their excessive hair growth with cosmetic measures, such as chemical depilatories, electrolysis, laser therapy, etc.

Ferriman-Gallway (F-G) score

This is the established and most prevalent system of measuring hirsutism. It was introduced in 1961. The scorecard of every body part analyzed began from 0 (zero terminal hairs) to 4 (massive terminal hair growth or frankly hirsute) and the numbers are added up to a maximum count of 36. The survey also suggested that hair production over the forearm and lower leg were less androgen receptive. This was an important finding since androgen is the main hormone that determines terminal hair production and its dysfunction is one of the main causes of hirsutism. Excluding the other nine body parts, 4.3% of patients evaluated registered a count of greater than 7. Hence, the experts conducting the study concluded that a score of 8 or more suggests hirsutism. Later there have been various modifications of the method. Some have been based on the analysis of hair production preferentially in the sideburn region, lower jaw, and upper neck, or perineal region and this has led to new measurement processes. Based on this score pattern and other clinical tests, hirsutism can be evaluated as mild, moderate or severe. DM Ferriman, JD Gallwey[4].

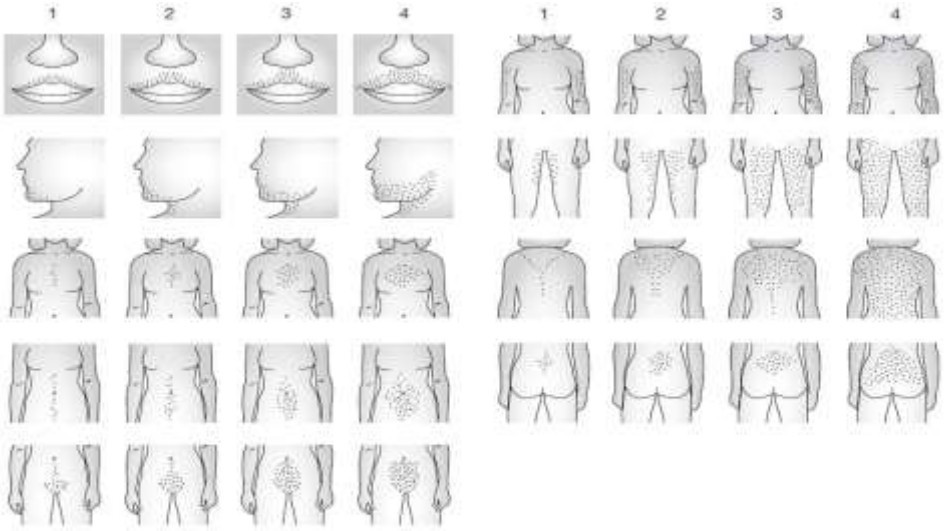


Figure 2 The modified Ferriman–Gallwey scoring system for hirsutism. Each of the nine body areas is rated from 0 (absence of terminal hairs) to 4 (extensive terminal hair growth) and the numbers in each area are added to obtain the total score. A score ≥6–8 generally defines hirsutism. Permission obtained from Humana Press © Azziz R *et al.* (2006) *Androgen Excess Disorders in Women: Polycystic Ovary Syndrome and Other Disorders*, edn 2. Totowa, NJ: Human Press.

Fig: The Modified Ferriman- Gallway scoring system [4]

Gynecological Ultrasonography

To determine condition of uterus and ovary whether normal or immature follicles as a form of poly cyst, their numbers, size and volume, specifically looking for small ovarian follicles. These are believed to be the result of disturbed ovarian function with failed ovulation, reflected by the infrequent or absent menstruation that is typical of the condition. In a normal menstrual cycle, one egg is released from a dominant follicle - essentially a cyst that bursts to release the egg. After ovulation the follicle remnant is transformed into a progesterone-producing corpus luteum, which shrinks and disappears after approximately 12–14 days.

Table−1: Age wise distribution of participants

			GROUP		Total
			Control	Cases	
AGE (in years)	<20	Count	25	38	63
		% within GROUP	12.5%	12.7%	12.6%
	21-30	Count	158	185	343
		% within GROUP	79.0%	61.7%	68.6%
	31-40	Count	17	77	94
		% within GROUP	8.5%	25.7%	18.8%
Total		Count	200	300	500
		% within GROUP	100.0%	100.0%	100.0%

Table−2: Comparison of weight between case and control group

			GROUP		Total
			Control	Cases	
WEIGHT	<55 KG	Count	189	130	319
		% within GROUP	94.5%	43.3%	63.8%
	56-65 KG	Count	11	121	132
		% within GROUP	5.5%	40.3%	26.4%
	66-86 KG	Count	0	49	49
		% within GROUP	0.0%	16.3%	9.8%
Total		Count	200	300	500
		% within GROUP	100.0%	100.0%	100.0%

Table-3: Comparison of waste hip(W/H) ratio between case and control group

			GROUP		Total
			Control	Cases	
W/H RATIO	<0.85	Count	191	94	285
		% within GROUP	95.5%	31.3%	57.0%
	0.86-0.95	Count	9	172	181
		% within GROUP	4.5%	57.3%	36.2%
	>0.95	Count	0	34	34
		% within GROUP	0.0%	11.3%	6.8%
Total		Count	200	300	500
		% within GROUP	100.0%	100.0%	100.0%

Table-4: Comparison of BMI between case and control group

			GROUP		**Total**
			Control	**Cases**	
BMI	<25	Count	200	244	444
		% within GROUP	100.0%	81.3%	88.8%
	26-30	Count	0	41	41
		% within GROUP	0.0%	13.7%	8.2%
	>30	Count	0	15	15
		% within GROUP	0.0%	5.0%	3.0%
Total		Count	200	300	500
		% within GROUP	100.0%	100.0%	100.0%

Table-4A: Distribution of obese participants based on BMI

			GROUP		**Total**
			Control	Cases	
OBESE	CLI. OB.	Count	0	16	16
		% within GROUP	0.0%	5.3%	3.2%
	MOR.OB.	Count	0	3	3
		% within GROUP	0.0%	1.0%	0.6%
	NO	Count	200	240	440
		% within GROUP	100.0%	80.0%	88.0%
	OBESE	Count	0	41	41
		% within GROUP	0.0%	13.7%	8.2%
Total		Count	200	300	500
		% within GROUP	100.0%	100.0%	100.0%

Table-5: Comparison of Marital status between case and control group

			GROUP		**Total**
			Control	Cases	
M.STATUS	M	Count	57	122	179
		% within GROUP	28.5%	40.7%	35.8%
	M*	Count	43	65	108
		% within GROUP	21.5%	21.7%	21.6%
	M**	Count	16	10	26
		% within GROUP	8.0%	3.3%	5.2%
	M***	Count	2	3	5
		% within GROUP	1.0%	1.0%	1.0%
	S	Count	82	100	182
		% within GROUP	41.0%	33.3%	36.4%
Total		Count	200	300	500
		% within GROUP	100.0%	100.0%	100.0%

(M: Married,M*: Married having one child,M**: Married having two child,M***: Married having three child)

Table−6: Comparison based on menstrual cycle history between case and control group

			GROUP		Total
			Control	Cases	
M.H./CYCLE	<5	Count	0	22	22
		% within GROUP	0.0%	7.3%	4.4%
	5-9	Count	0	277	277
		% within GROUP	0.0%	92.3%	55.4%
	>=10	Count	200	1	201
		% within GROUP	100.0%	0.3%	40.2%
Total		Count	200	300	500
		% within GROUP	100.0%	100.0%	100.0%

Table−7: Showing Hirsutism status of Case group

TOTAL COUNTS	HIRSUTISM		NON HIRSUTISM	
	Counts	valid %	Counts	valid %
Cases (300)	160	53%	140	47%

Table−8: Comparison of various biochemical parameters between case and control group

parameter	Group	N	Mean ± SD	p-value
FBS(mg/dl)	Case	300	106.7 ± 19.4	<0.001
	Control	200	96.12± 17.03	
S.choletsterol(mg/dl)	Case	300	189.1± 45.47	<0.001
	Control	200	157.49± 23.80	
S.Triglyceride(mg/dl)	Case	300	160.69 ± 36.98	0.025
	Control	200	154.62 ± 23.42	
S.HDL(mg/dl)	Case	300	40.24 ± 6.30	0.006
	Control	200	38.66± 6.25	
S.LDL(mg/dl)	Case	300	116.95± 42	<0.001
	Control	200	87.98 ± 22.27	
S.VLDL(mg/dl)	Case	300	32.0 ± 7.32	0.032
	Control	200	30.84 ± 4.72	

Table−9: Comparison of level of various endocrinal hormonal status between case and control group

parameter	Group	N	Mean SD	p-value
S.LH(µIU/ml)	Case	300	147.12 ± 39.13	<0.001
	Control	200	90.86 ± 43.62	
S.FSH(µIU/ml)	Case	300	76.42 ± 45.67	<0.001
	Control	200	22.22 ± 17.11	
S. Testosterone(ng/ml)	Case	300	13.82 ± 6.38	<0.001
	Control	200	2.67 ± 1.48	
S.Estradiol(pg/ml)	Case	300	235.3±90.29	<0.001
	Control	200	60.9±19.69	
S. Progesteron(ng/ml)	Case	300	2.58±3.13	0.001
	Control	200	1.72±2.26	
S. Insulin(U/ML)	Case	300	15.52 ± 6.29	<0.001
	Control	200	7.44± 2.04	
HOMA IR	Case	300	75.45± 41.15	<0.001
	Control	200	31.83± 10.69	

Table-10: Results of thyroid hormone and prolactin in case group

Parameter	Number(n)	Result(Mean±SD)
S.TSH(µIU/ml)	300	1.22±6.8
S.T3(nmol/l)	300	2.18±0.57
S.T4(nmol/l)	300	134.06±30.53
S.Prolactin(µIU/Ml)	300	228.08±11.5

Table-11: Comparison between 'vegeterian diets with fastfood(FF) eaters & nonvegetarian diets with fast food eaters' in hyperglycemic cases (Total: 74 / 300 Cases)

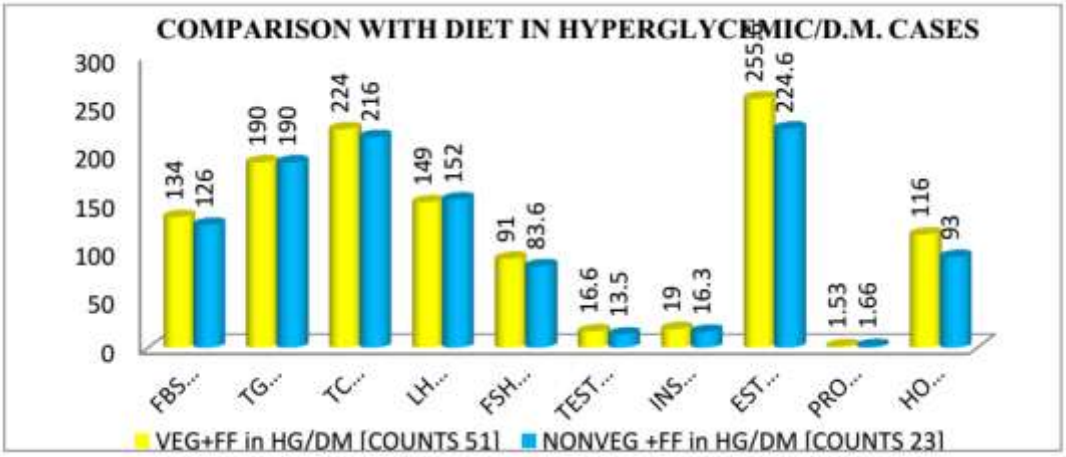
S.NO.	COUNTS	51	23
	PARAMETERS	Veg + FF in HG/DM Mean	Nonveg + FF in HG/DM Mean
1.	Fasting Blood sugar (mg/dl)	134	126
2.	UREA (mg/dl)	25	24.7
3.	CREATININE (mg/dl)	0.6	0.57
4.	TG (mg/dl)	190	190
5.	TC (mg/dl)	224	216
6.	HDL (mg/dl)	39	38
7.	LDL (mg/dl)	148	140
8.	VLDL (mg/dl)	38	38
9.	LH (µIU/ml)	149	152
10.	FSH (µIU/ml)	91	83.6
11.	TESTOSTERONE(ng/ml)	16.6	13.5
12.	INSULIN(U/ml)	19	16.3
13.	ESTROGEN (pg/ml)	255.6	224.6
14.	PROGESTERONE(ng/ml)	1.53	1.66
15.	HOMA-IR	116	93

Table-12: Hyperglycemic /Diabetes mellitus case with obesity and without obesity (Total: 74 / 300 Cases)

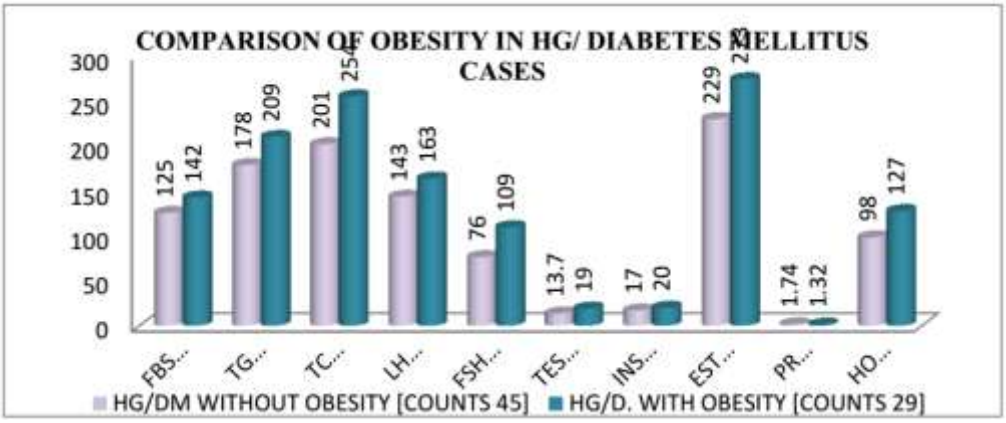
S.NO.	COUNTS	45	29
	PARAMETERS	HG/DM WITHOUT OBESITY Mean	HG/DM WITH OBESITY Mean
1.	Fasting Blood sugar (mg/dl)	125	142
2.	UREA(mg/dl)	24	26
3.	CREATININE(mg/dl)	0.58	0.62
4.	TG (mg/dl)	178	209
5.	TC (mg/dl)	201	254
6.	HDL (mg/dl)	41	37
7.	LDL (mg/dl)	126	176
8.	VLDL (mg/dl)	35	42
9.	LH (µIU/ml)	143	163
10.	FSH (µIU/ml)	76	109
11.	TESTOSTERONE(ng/ml)	13.7	19
12.	INSULIN (U/ml)	17	20
13.	ESTROGEN (pg/ml)	229	273
14.	PROGESTERONE(ng/ml)	1.74	1.32
15.	HOMA-IR	98	127

Table–13: Comparison of different groups of 'oligomennrohea (o/m), o/m with & without Hirsutism' among case (TOTAL: 268/300 CASES)

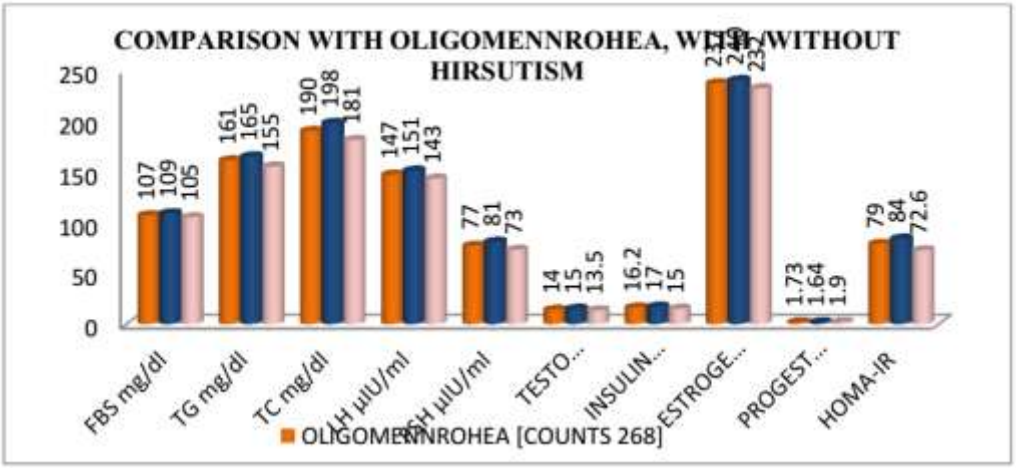
S.NO.	COUNTS	268	148	120
	PARAMETERS	OLIGOMENNROHEA (OM) Mean	OM WITH HIRSUTISM Mean	OM WITHOUT HIRSUTISM Mean
1.	Fasting Blood sugar(mg/dl)	107	109	105
2.	UREA (mg/dl)	25	25	25
3.	CREATININE(mg/dl)	0.58	0.57	0.59
4.	TG (mg/dl)	161	165	155
5.	TC (mg/dl)	190	198	181
6.	HDL (mg/dl)	40	40	41
7.	LDL (mg/dl)	118	125	109
8.	VLDL (mg/dl)	32	33	31
9.	LH (µIU/ml)	147	151	143
10.	FSH (µIU/ml)	77	81	73
11.	TESTOSTERONE(ng/ml)	14	15	13.5
12.	INSULIN (U/ml)	16.2	17	15
13.	ESTROGEN (pg/ml)	237	240	232
14.	PROGESTERONE (ng/ml)	1.73	1.64	1.9
15.	HOMA-IR	79	84	72.6



Graph-1: Graphical presentation of Comparison between 'vegeterian diets with fastfood(FF) eaters & nonvegetarian diets with fast food eaters' in hyperglycemic cases (table 11)



Graph-2: Graphical presentation of Hyperglycemic /Diabetes mellitus case with obesity and without obesity. Table-12



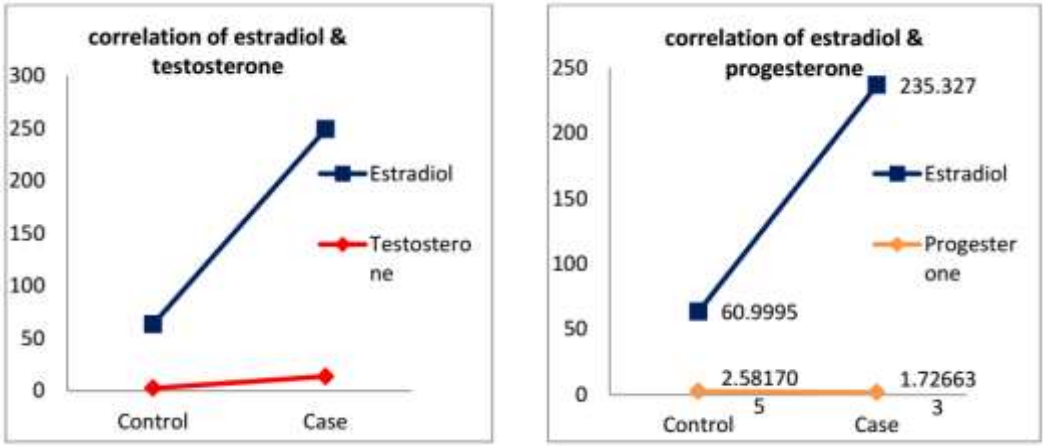
Graph-3: Comparison of different groups of 'oligomennrohea (o/m), o/m with & without Hirsutism' among case (TOTAL: 268/300 CASES) (Table-13)

Table−14: Comparison of different type of 'obesity' among cases (one way anova)

S.NO.	COUNTS	240		41		16		3		Df2 (welch) / Anova	P VALUE
	PARAMETERS	Non Obese Mean	SD	Obese Mean	SD	Clinical Ob. Mean	SD	Morbid Ob. Mean	SD		
1.	FBS(mg/dl)	103.3	15.10	115.1	23.52	134.5	35.35	108.3	10.40	8.87	**0.014**
2.	UREA (mg/dl)	24.8	5.56	25.5	6.16	26.4	7.0	26.3	0.57	0.557	0.644
3.	CREATININE (mg/dl)	0.58	0.21	0.55	0.25	0.61	0.33	0.5	0.05	0.14	0.932
4.	TG (mg/dl)	153.3	29.96	177.7	40.34	214.5	49.0	225	70.0	8.58	**0.002**
5.	TC (mg/dl)	176.9	36.64	222.6	36.98	270.6	47.22	270	28.93	49.88	**<0.001**
6.	HDL(mg/dl)	40.77	6.15	38.31	6.49	37.1	5.11	40.6	14.15	8.70	0.075
7.	LDL(mg/dl)	105.7	34.27	148.4	33.3	190.9	45.68	184.3	18.34	47.50	**<0.001**
8.	VLDL (mg/dl)	30.6	5.98	34.9	7.74	42.5	10.29	45	14.0	8.58	**0.004**
9.	LH(µIU/ml)	145.6	38.0	147.9	47.9	165.1	25.88	158.3	41.63	1.33	0.264
10.	FSH(µIU/ml)	74.1	42.67	79	56.98	95.9	49.10	120.6	67.0	8.65	0.332
11.	INSULIN (U/ml)	15.9	6.0	15.18	5.86	20	8.74	17.03	7.95	3.56	**0.015**
12.	TESTOSTERONE (ng/ml)	13.6	6.0	13.55	6.17	18.23	10.0	16.96	7.46	8.68	0.304
13.	ESTROGEN(pg/ml)	234.5	87.62	224.2	89.46	298	104.8	151	118.0	3.77	**0.011**
14.	PROGESTERONE (ng/ml)	1.63	2.11	1.77	2.11	1.81	3.0	6.3	6.13	8.61	**0.006**

- Comparison of the fasting basal sugar (FBS) between the two groups shows that FBS is higher (mean value = 106.7 ± 19.49) in Cases group than Controls (mean value = 96.1 ± 17.0.(Table 8)
- Comparison of the Triglyceride (TG) between two groups shows that TG is higher (mean value = 160.6 ± 36.98) than Controls (mean value = 154.6 ± 23.42). Comparison of Total Cholesterol (TC) between two groups shows that TC is higher (mean value = 189.1 ± 45.47) in Cases than Controls.(Table 8)
- Comparison of the luteinizing hormone (LH) between two groups shows that LH is higher (mean value 147 ± 39) in Cases than Controls (mean value = 90.8 ± 43.6). (Table 9)
- Comparison of the follicular stimulating hormone (FSH) between two groups shows that FSH is higher (mean value 76.4 ± 45.6) in Cases than Controls (mean value = 22.2 ± 17.1). (Table 9)
- Testosterone is higher (mean value 13 ± 6.3) in Cases than Controls (mean value = 2.67 ± 1.4). (Table 9)

- Insulin hormone is higher (mean value 15.5 ± 6.2) in Cases than Controls (mean value = 7.4 ± 2.0). (Table 9)
- Estradiol is higher (mean value 235 ± 90.2) in Cases than Controls (mean value = 60.9 ± 19.6). (Table 9)
- Progesterone is higher (mean value 2.58 ± 3.1) in Controls than Cases (mean value = 1.72 ± 2.2). (Table 9)



Graph−4 & 5: correlation of estradiol & testosterone; correlation of Estradiol & progesterone

Comparison of various parameters in different group's categories among hyperglycemic/ diabetes mellitus cases

- In study there is comparison between vegetarian diets with fast food eaters and Nonvegetarian diets with fast food eaters in hyperglycaemic 74 cases out of 300 PCOD women cases. All parameters are higher in veg with FF eaters. Progesterone ng/ml mean values are 1.53 & 1.66 (lower in veg eaters) in hyperglyemic/DM women.(Table 11 & graph 1)
- In study there is comparison between Without Obesity &With Obesity in hyperglycaemic/DM 74 cases out of 300 PCOD women cases. All parameters are higher in Hyperglyemic /DM with obesity group. Progesterone ng/ml mean values are 1.74 & 1.32 (lower in Hyperglyemic /DM with obesity group) in women. (Table 12 & graph 2)**.**
- In study there is comparison among different groups of Oligomennrohea (O/M), O/M with Hirsutism & O/M without Hirsutism in 268 cases out of 300 PCOD women cases. All parameters are higher in O/M with Hirsutism group compare to O/M without Hirsutism group. Progesterone ng/ml mean values are 1.73, 1.64 & 1.9 (lower in O/M with Hirsutism group) in women (Table 13 & graph 3)**.**

Dunaif *et al*. said that in teenagers, abnormalities in glucose metabolism manifest prior to dyslipidemia, suggesting that assessment of glucose metabolism is even more important in younger women. DM is diagnosed by an 8 h fasting plasma glucose ≥ 126 mg/dL, 2 h glucose value ≥ 200 mg/dL after oral glucose tolerance test (OGTT) or random glucose ≥ 200 mg/dL with symptoms of DM confirmed by either fasting plasma glucose or OGTT. The prevalence of IGT in obese adolescents is surprisingly as high as 15%. It's interesting that despite all the research into PCOS, the exact relationship between the condition and weight gain (or loss) is unclear. But being overweight, and especially increased abdominal fat, seems to be a strong predictor of having other hormonal problems – such as raised male hormones and tendencies to having diabetes [5, 6].

Dahlgren E. *et al.* study, women with PCOS present a more atherogenic lipid profile with elevations of serum triglycerides (TG) and reductions of serum high density lipoprotein (HDL) cholesterol concentrations and are at a greater risk of cardiovascular diseases compared with age-matched control subjects. These clustering risk factors associated with PCOS emphasize the importance of studies to distinguish between metabolic and hormonal alterations which are related to PCOS or to obesity [7, 8].

Mckenna *et al.* Moghetti *et al***.** & Hammami *et al*., Most studies have shown hypersecretion of adrenal hormones in PCOS subjects compared with healthy women, but the mechanism of this hypersecretion is not well understood. Possible explanations include hypersensitivity of the adrenal gland to adrenocorticotrophic hormone (ACTH) stimulation, conjugated hypersecretion from the ovary and the adrenals, dysregulation of steroid synthesis enzymes

such as 11β-hydroxysteroid dehydrogenase (11β-HSD) and hyperstimulation of cytochrome *P*450c-17α activity in the adrenal glands as a result of hyperinsulinaemia in these patients[9-14,15].

Acien P *et al.* & Jayagopal V *et al.* studies show that obese (compared to lean) PCOS women tend to have a higher degree of IR. Correlation between hyperandrogenism and IR is significant in many studies but not as significant as the link between insulin abnormalities and obesity. PCOS women demonstrate greater variation in insulin parameters compared to controls, independent of weight. Some human data shows a high degree of correlation between hyperandrogenism and IR. The relationship between hyperandrogenism and IR seem to differ between PCOS and non-PCOS women [16-19].

Unfer *et al.* & Gluck *et al.* studies said that the ratio of LH (Luteinizing hormone) to FSH (Follicle stimulating hormone) is greater than 1:1 (sometimes more than 3:1), as tested on Day 3 of the menstrual cycle. The pattern is not very specific and was present in less than 50% in one study [20,21].

Knochenhaur ES *et al.* Asuncion M *et al.* studies show women presenting with menstrual dysfunction and hirsutism, 86% (and 68% of women with hirsutism but apparent eumenorrhea) had PCOS. Alternatively, in this populational study only 8% of patients with menstrual dysfunction alone (i.e. without hirsutism) had PCOS, raising questions regarding the high proportion of PCOS suggested affecting women with oligoovulatory infertility. Prevalence rate of reported menstrual dysfunction in our population was 22.8%. The incidence of oligomenorrhea (14.6%; 28 of 192) in the studied population may be overestimated because of the definition we used, i.e. less than 8 cycle/yr; this definition was also used in the recent study by Knochenhauer *et al*. H/A was confirmed in 6.77% of the examined women with oligomenorrhea or oligomenorrhea and hirsutism [21].

Hull MG *et al.* population, 74% of women with hirsutism were estimated to suffer from PCOS, and 76% (20.1 of 26.5) of women diagnosed with PCOS demonstrated hirsutism, consistent with our findings in studies of women seeking care for hirsutism [22].

The study demonstrates that there is a relationship between the degree of hormonal abnormality and the menstrual irregularities and hirsutism in women with PCOS suggesting that there may be a progressive nature to the syndrome.

One of the important etiologic factors in acne is an increase in sebaceous gland activity, which is androgen dependent. Acne is a common manifestation of hyperandrogenemia. Therefore, acne may not only cause cosmetic concern but may also be a sign of underlying disease. In females, the most common cause of hyperandrogenemia is polycystic ovary syndrome (PCOS).

CONCLUSION

Obesity is a common finding in PCOS and aggravates many of its reproductive and metabolic features. The relationship between PCOS and obesity is complex, not well understood, and most likely involves interaction of genetic and environmental factors. Insulin resistance and weight gain are two contributing factors to PCOS. Insulin resistance typically causes the body to produce more insulin than normal (hyperinsulinemia). Higher levels of insulin can then cause ovaries to produce too much testosterone which can impair normal ovulation from occurring and further leads to metabolic syndrome in PCOD women with symptoms of Hirsutism, Oligomennrohea and acne.

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Biochemistry

A Correlation Study between Polycystic Ovarian Syndrome (PCOD) and Its Related Endocrinal Hormones in Udaipur, Rajasthan, India

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Abstract **Original Research Article**

Background: Polycystic ovary syndrome (PCOS) is a complex endocrine disorder affecting 5–10 % of women of reproductive age. It generally manifests with oligo/anovulatory cycles, hirsutism and polycystic ovaries, together with a considerable prevalence of insulin resistance. ***Objectives:*** The objective of the study is to establish correlation among testosterone, insulin, FSH, LH and lipid profile among the women with polycystic ovary syndrome (PCOS), in order to evaluate their diagnostic and prognostic significance**.** ***Methodology:*** This study includes total 300 female participants of age Group between 18-40 year of age**.** They were divided in to two groups. Group 1(n=150) includes women having PCOD and Group 2(n=150) is control Group. Fasting Blood samples were obtained from all participants to measure Blood sugar, Lipid Profile insulin, HOMA-IR, Testosteron, FSH, LH and Prolactine**.** ***Result:*** The Mean level of S.Testosteron, S.FSH, S.LH, S.Prolactine and HOMA-IR Fasting Blood sugar, S.cholesterol, S, and Triglyceride S.Insulin is found to be Lower Control Group as compared to PCOD group and difference among them found to be statically significant. ***Conclusion:*** From our study I would like to conclude that a PCOS, as a syndrome, has got multiple components including reproductive, metabolic and hormonal, with long-term health concerns that cross the life span. Moreover, PCOS patients have a higher risk of metabolic and cardiovascular diseases and their related morbidity, if compared to the general population.

Key words: PCOD, Insulin, HOMA-IR, Testosteron, FSH, LH, Prolactine.

INTRODUCTION

Polycystic ovary syndrome (PCOS) is the most common endocrine disorder in women and major cause of anovulatory infertility. PCOS patients can present a wide range of signs and symptoms, which make difficult the precise grading of the condition. Diagnosis of PCOS is currently based on the criteria of the ESRHE/ASRM Rotterdam consensus meeting in 2003 [1], which broadened the previous NIH classification of 1990 [2]. It based on at least two of the following features: oligo-anovulation, hyperandrogenism and polycystic ovaries by ultrasound [1]. In 2006, the Androgen Excess Society (AES) set up a committee of experts to review all the data published on PCOS for the purpose of simplifying diagnosis [3]. The AES criteria require clinical and/or biochemical hyperandrogenism simultaneously with oligo/anovulation and ultrasonographic evidence of polycystic ovaries.

There is increasing evidence suggesting that PCOS affects the whole life of a woman, can begin in utero in genetically predisposed subjects, it manifests clinically at puberty, continues during the reproductive years. It can also expose patients to increased risk of cardiovascular disease, hypertension, diabetes and other metabolic complications, especially after menopause [4]. During the fertile period it may cause anovulatory infertility and could be associated with increased prevalence of gestational complications, such as miscarriage, gestational diabetes and preeclampsia [5]. Early diagnosis is therefore crucial by enabling close follow-up and in an attempt to reduce the risk of such complications.

Therefore, the present investigations will be carried out to assess testosterone, LH, FSH & insulin hormones level, HOMA-IR level. Subsequently regular assessing of sugar glucose, lipid profile and differential diagnosis of prolactin (PRL) in clinical biochemistry laboratory is important to monitor & study the effect of these parameters among normal and polycystic ovary Syndrome (PCOS) women & its adverse consequences.

MATERIAL & METHOD

This prospective study was conducted at Department of Biochemistry and Department of

Obstetrics & Gynaecology, Geetanjali Medical College & Hospital, Udaipur, Rajasthan, India from June 2012-Dec 2013. A total of 300 subjects of age group between 18-40 years belonging to both normal & polycystic ovary syndrome will be classified as:

Group-1:150 women with PCOD (Cases) of polycystic ovary disease will be taken.
Group-2:150 normal women will be taken as control for these parameters.

All PCOD women & controls were underwent a complete history and physical examination. Women with PCOD should be interviewed of their name, address, age, socio-economic status, and menstrual history, age of menarche, education level and family history of PCOD. All women were gone through gynaecological ultrasonography to determine their uterus and ovaried condition.

Inclusion Criteria

Women with PCOD are attending outdoor OPD of the hospital, first time diagnosed PCOD, Diagnosed polycystic ovarian syndrome, age ranging from 18-40 years.

Women with PCOD Willing to have physical examinations like Weight, Height, BMI, W/H ratio, Blood Pressure, Hirsutism, Acne, Dark patches, Virilization, Ultra sonography etc.

Polycystic ovary syndrome (PCOS) associated with Diabetes,obesity, Cardiovascular disorders. Irregular menstrual disorder and anovulation, Hirsutism & Acne symptoms.

Exclusion Criteria

Women with diagnosed adrenal hyperplasia, androgen secreting neoplasm, other pituitary (acromegaly) and adrenal disorders like Cushing syndrome, Virilizing adrenal or ovarian neoplasm**,** hyperprolactinemia and other infertility cause, Thyroid hormone related infertility, Women having history of smoking, taking alcohol or tobacco chewing**,** Any other type of gynaecologic complications except related with Polycystic ovary syndrome (PCOS) will be excluded from the study.

Fasting 10 ml venous blood samples were obtained from all participants and collected it in to fluoride and plain vaccutainer. An Uniq ID number was given to each sample to hidden the identity of participants. All samples were centrifugated at 3000 RPM for a period of 10 minutes to obtain a Plasma and serum.

Blood Glucose (FBS) measured by GOD POD method and lipid profile (S. Cholesterol, Triglyceride, HDL, VLDL, LDL) measured by enzymatic colorimetric method from all samples.

Fasting Insulin level estimation was done by enzyme linked immune assay (ELISA) method based electrochemilumnescence and HOMA-IR will be estimated by calculation (fasting sugar×fasting insulin/22.5).

Various Endocrinal Hormones like testosterone, LH, FSH, Insulin and Prolactine was measured by enzyme linked immune assay (ELISA) method based on electrochemilumnescence from all samples.

After assessing all the values, Mean, Standard deviation of all subjects & parameters were analysed. Statistical analysis was performed with SPSS software. Comparison between cases and with control is done by independent student's t test. By using't' values now P value is less than 0.05 (P value < 0.05), it is significant. Comparison of the categorical variables (among category comparison) was done by using Chi-Square test.

RESULTS & DISCUSSION

Infertility, hirsutism, and oligomenorrhea were more common among the subjects with PCOS, but there was a considerable spontaneous restitution of cyclic regularity with time. Women with PCOS were more often hysterectomized and entered menopause later compared with referents. The hormone data show a typical profile for PCOS. Compared with referents women with PCOS showed marked increase in prevalence of central obesity, higher basal serum insulin concentrations, and a higher prevalence of diabetes mellitus and hypertension [65].

Table-1: Age wise distribution of participants

Group	Number(n)	Mean Age(Yr)
Group 1(PCOD)	150	26.30 ± 5.0
Group 2(Control)	150	24.50 ± 4.13

Table-2: Location wise distribution of participants

Location	Group 1(PCOD)	Group 2(Control)
Rural	57(38%)	36(36%)
Urban	93(62%)	64(64%)
Total	150(100%)	150(100%)

Table-3: Comparison of weight between case and control group

Group	Number(n)	Mean wt (kg)
Group 1(PCOD)	150	58.91 ± 5.24
Group 2(Control)	150	48.36 ± 5.8

Table-4: Comparison of waste hip(W/H) ratio between case and control group

Group	Number(n)	Mean W/H ratio
Group 1(PCOD)	150	0.84 ± 0.13
Group 2(Control)	150	0.79 ± 0.05

Table-5: Comparison of BMI between case and control group

Group	Number(n)	Mean BMI
Group 1(PCOD)	150	23.70 ± 2.73
Group 2(Control)	150	18.72 ± 2.41

Table-6: Comparison of Marital status between case and control group

Group	Number(n)	Married	single
Group 1(PCOD)	150	100(66.7%)	50(33.3%)
Group 2(Control)	150	59 (39%)	91(61%)

Table-7: Comparison based on menstrual cycle history between case and control group

			GROUP		Total
			Control	Cases	
M.H./CYCLE	<5	Count	0	11	11
		% within GROUP	0.0%	16.5%	3.66%
	5-9	Count	0	138	138
		% within GROUP	0.0%	92.3%	46%
	>=10	Count	150	1	151
		% within GROUP	100.0%	0.6%	50.33%
Total		Count	150	150	300
		% within GROUP	100.0%	100.0%	100.0%

Table-8: Showing valid Hirsutism status of Case group

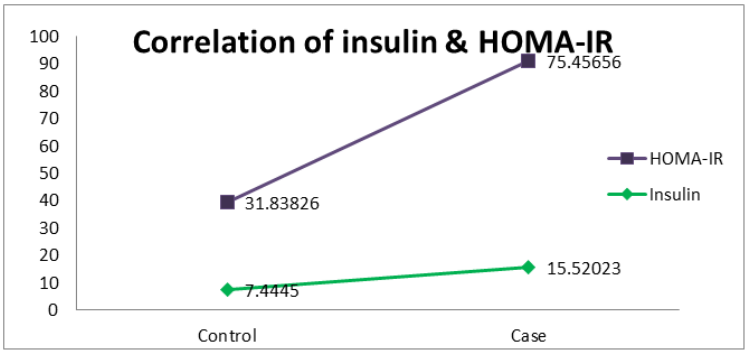
TOTAL COUNTS	HIRSUTISM		NON HIRSUTISM	
	Counts	valid %	Counts	valid %
Cases (150)	80	53%	70	46%

Table-9: Comparison of various biochemical parameters between case and control group

parameter	Group	N	Mean SD	p-value
FBS(mg/dl)	Case	300	106.7 ± 19.4	<0.001
	Control	200	96.12 ± 17.03	
S.choletsterol(mg/dl)	Case	300	189.1 ± 45.47	<0.001
	Control	200	157.49 ± 23.80	
S.Triglyceride(mg/dl)	Case	300	160.69± 36.98	0.025
	Control	200	154.62 ± 23.42	
S.HDL(mg/dl)	Case	300	40.24 ± 6.30	0.006
	Control	200	38.66 ± 6.25	
S.LDL(mg/dl)	Case	300	116.95 ± 42	<0.001
	Control	200	87.98 ± 22.27	
S.VLDL(mg/dl)	Case	300	32.0± 7.32	0.032
	Control	200	30.84 ± 4.72	

Table-10: Comparison of level of various endocrinal hormonal statuses between case and control group

parameter	Group	N	Mean SD	p-value
S.LH(µIU/ml)	Case	150	147.12± 39.13	<0.001
	Control	150	90.86 ± 43.62	
S.FSH(µIU/ml)	Case	150	76.42 ± 45.67	<0.001
	Control	150	22.22 ± 17.11	
S. Testosteron(ng/ml)	Case	150	13.82 ± 6.38	<0.001
	Control	150	2.67 ± 1.48	
S. Insulin(U/ML)	Case	150	15.52 ± 6.29	<0.001
	Control	150	7.44 ± 2.04	
HOMA-IR	Case	150	75.45± 41.15	<0.001
	Control	150	31.83 ± 10.69	



Graph-1: Showing Correlation of insulin & HOMA-IR between case and control group

- Comparison of the fasting basal sugar (FBS) between the two groups shows that FBS is higher (mean value = 106.7 ± 19.49) in Cases group than Controls (mean value = 96.1 ± 17.0 (Table 9).
- Comparison of the Triglyceride (TG) between two groups shows that TG is higher (mean value = 160.6 ± 36.98) than Controls (mean value = 154.6 ± 23.42). Comparison of Total Cholesterol (TC) between two groups shows that TC is higher (mean value = 189.1 ± 45.47) in Cases than Controls (Table 9).
- Comparison of the luteinizing hormone (LH) between two groups shows that LH is higher (mean value 147 ± 39) in Cases than Controls (mean value = 90.8 ± 43.6) (Table 10).
- Comparison of the follicular stimulating hormone (FSH) between two groups shows that FSH is higher (mean value 76.4 ± 45.6) in Cases than Controls (mean value = 22.2 ± 17.1) (Table 10).
- Testosterone is higher (mean value 13 ± 6.3) in Cases than Controls (mean value = 2.67 ± 1.4) (Table 10).
- Insulin hormone is higher (mean value 15.5 ± 6.2) in Cases than Controls (mean value = 7.4 ± 2.0) (Table 10).
- HOMA-IR is higher (mean value 75 ± 41.1) in Cases than Controls (mean value = 31.8 ± 10.6) (Table 10).

Although the exact cause of PCOS is unknown, it is understood to be a multifactorial condition with a genetic component. Approximately 20–40% of first-degree female relatives of women with PCOS go on to develop PCOS themselves, compared to estimated 4–6% prevalence in the general population [6]. Many women with PCOS have female relatives with PCOS, even if it was never diagnosed as with type 2 diabetes, it is likely that numerous genes each make a small contribution to the etiology of PCOS; and recent genome-wide association studies have identified candidate genes [7-9]. Any underlying genetic predisposition is likely complicated by epigenetic and environmental factors such as an unhealthy diet and lack of physical activity.

Clinically, PCOS may manifest as a mild menstrual disorder or a severe disturbance of reproductive and metabolic functions [10]. Most visible signs are caused by excessive production of insulin or androgens. Hirsutism (excess hair growth on the face and body) is present in ~ 70% of women with PCOS and is considered to be a good marker for hyperandrogenism but should be evaluated biochemically.

CONCLUSION

From our study I would like to conclude that a PCOS, as a syndrome, has got multiple components including reproductive, metabolic and hormonal, with long-term health concerns that cross the life span. Moreover, PCOS patients have a higher risk of metabolic and cardiovascular diseases and their related morbidity, if compared to the general population.

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ORIGINAL RESEARCH ARTICLE

Impact of Conducting Part Completion Tests (Written) on Outcome of Terminal Examination in Biochemistry Subject

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Abstract:

Introduction:

According to Medical Council of India guidelines, regular periodical examinations shall be conducted throughout the course. The question of number of examinations is left to the institution. However it is seen that maximum medical institutes in India conduct at least two internal assessment (terminal) examinations but doesn't conduct part completion test.

Objectives:

To observe the effectiveness of conducting part completion tests for improvement of academic performance in terminal examination and also to take feedback from faculties and students.

Methods:

Permission was taken from Institutional Ethical Committee. Five part completion test and one terminal examination were conducted. 122 First MBBS students were enrolled. Groups were divided according to number of students appeared in part completion tests and terminal examination. Feedback was taken using Likert's Scale.

Results:

There were zero students in group I, 6 in group II, 28 in Group III, 69 in group IV and 19 in group V. There was increase in percentage of marks from group II to III (8%), group III to IV (15%) and group IV to V (24%). There was significant difference in marks among different group (F= 3.76; p <

0.01). Comparison of average marks shows highly significant value (Coefficient of Correlation, r = 0.965916).

Conclusion:

Those students who have given more number of part completion tests scored well in terminal examination.Faculties and students have agreed that these part completion tests are necessary, will give better outcome on performance of terminal examination, and part completion test should be incorporated in curriculum.

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Introduction:

Biochemistry is one of the basic subjects of medical sciences. A well designed curriculum, teaching and learning activities and assessment methods are essential for better academic performance of the students[1- 3]. Medical Council of India (MCI) has placed a lot of emphasis on internal assessment examination. According to MCI guidelines, internal assessment shall be on day to day assessment including assignments, preparation for seminar, clinical case presentation, preparation of clinical case for discussion, clinical case study/problem solving exercise, participation in project for health care in the community, proficiency in carrying out a practical or a skill in small

research project, multiple choice questions after completion of a system/teaching etc. Regular periodical examinations shall be conducted throughout the course. The question of number of examinations is left to the institution[4]. There shall be no less than two internal assessment examination in each non clinical department[5]. However it is seen that maximum medical institute in India conduct at least two internal assessment examinations (terminal or semester examination) but doesn't conduct part completion test.

Part completion test is a type of formative assessment. It is conducted upon completion of small portion of syllabus. The terminal examination is conducted at completion of every term and is a mirror image of summative examination and is considered as a rehearsal for that.

Aims and Objectives:

Aim:

To observe the effectiveness of conducting part completion tests in Biochemistry for improvement of academic performance in terminal examination.

Objectives:

To see the difference in performance of students who have given one or more part completion test with the result of their terminal examination.

To take perception of the students that whether conducting part completion tests has benefited them to perform well in terminal examination and to get feedback from faculties of Biochemistry department regarding the feasibility of conducting part completion tests.

Methodology:

This study was carried out at Department of Biochemistry, Ananta Institute of Medical Sciences and Research Centre, Rajsamand, Rajasthan State. The project was of six months commencing from the month of October 2018 and was a prospective longitudinal study. This project was approved by Institutional Ethical Committee. A total of 122 students of M.B.B.S. Batch: 2018 - 2019 was included in this study after obtaining their voluntary written informed consent. Twenty Eight (28) students were not allowed to appear in the terminal examination due to shortage of attendance. Eight faculties of biochemistry department were also included in this study. The study included 5 part completion tests of 20 marks each and one terminal examination of 50 marks

(Written pattern). The pattern of part completion test was kept similar to that of terminal examination.

Inclusion Criteria:

Those students who have appeared for terminal examination.

Exclusion Criteria:

Students who have not appeared in terminal examination.

Students who have not appeared in at least one part completion test examination.

Hence the study comprised of following groups for comparative analysis:

Group I: Students appeared in one part completion test and terminal examination. (n = 0)

Group II: Students appeared in two part completion tests and terminal examination. (n = 6)

Group III: Students appeared in three part completion tests and terminal examination. (n = 28)

Group IV: Students appeared in four part completion tests and terminal examination. (n = 69)

Group V: Students appeared in five part completion tests and terminal examination. (n = 19)

Feedback from faculties of Biochemistry department regarding feasibility of part completion test was taken. Faculty has to answer the questions for rating from 1 to 5 (1 = minimum and 5 = maximum: Likert Scale). Average Score and Interpretation was drawn after the feedback.

Q.1. Is all these part completion tests necessary ?

Q.2. Will be there any better outcome of these part completion tests in terms of performance in terminal examination.

Q.3. Would you think these part completion tests disturbing day to day teaching activities of students

Q.4. Would you think that these part completion tests are having impact on attendance of student

Q.5. Would you think this part completion tests to be incorporated as a part of curriculum.

Perception in terms of feedback from student of M.B.B.S. Batch 2018 - 19 regarding part completion tests was taken. Students have to answer the questions for rating from 1 to 5 (1 = minimum and 5 = maximum: Likert Scale). Average Score and Interpretation was drawn after the perception.

Q.1. Do you think that these part completion tests necessary?

Q.2. Will is there any better outcome of these part completion tests in terms of your performance in terminal examination.

Q.3. Would you think these part completion test disturbing your day to day teaching activities

Q.4. Would you think that these part completion tests are having impact on your attendance

Q.5. Would you think this part completion tests to be incorporated as a part of curriculum.

Statistical Analysis:

Data was analysed in terms of either increase or decrease in percentage of marks among the groups. Statistical analysis was done on SPSS statistical software. $P < 0.05$ was considered statistically significant. Coefficient correlation and ANOVA was applied to see the statistical difference among groups.

Results:

A total of 122 students out of 150 were enrolled in this study after applying inclusion and exclusion criteria. There were zero students in group I, 6 in group II, 28 in Group III, 69 in group IV and 19 in group V. There was increase in percentage of marks from group II to III (8%), group III to IV (15%) and group IV to V (24%). (Table 1) By applying ANOVA, it was seen that there was significant difference in marks among different groups ($F= 3.76$; $p < 0.01$), although there was no significant difference between groups. (Table 1) Comparison of average marks between marks of part completion test and terminal examination shows highly significant value (Coefficient of Correlation, $r = 0.965916$) (Table 1). Hence we can see that those students who have given more number of part completion tests scored well in terminal examination.

Table 1 : Comparison between groups for terminal examination marks.

	Group II (n=6)	Group III (n=28)	Group IV (n=69)	Group V (n=19)
Increase in percentage of marks	--	8 %	15 %	24 %
ANOVA	F= 3.76; p < 0.01 (statistically significant among groups) Average marks of different groups in terminal examination			
Coefficient of Correlation	r = 0.965916 (highly significant) Comparison of average marks of Part Completion test and Terminal Examination			

P < 0.05 was considered statistically significant. Note: Results are not generalized

Figure No.1 shows perception from students for part completion test. Students have agreed that these part completion tests are necessary and will give better outcome on performance of terminal examination and also will have impact on attendance. They also agree that part completion test should be incorporated in curriculum. Students also agreed that these part completion tests are disturbing day to day teaching activity.

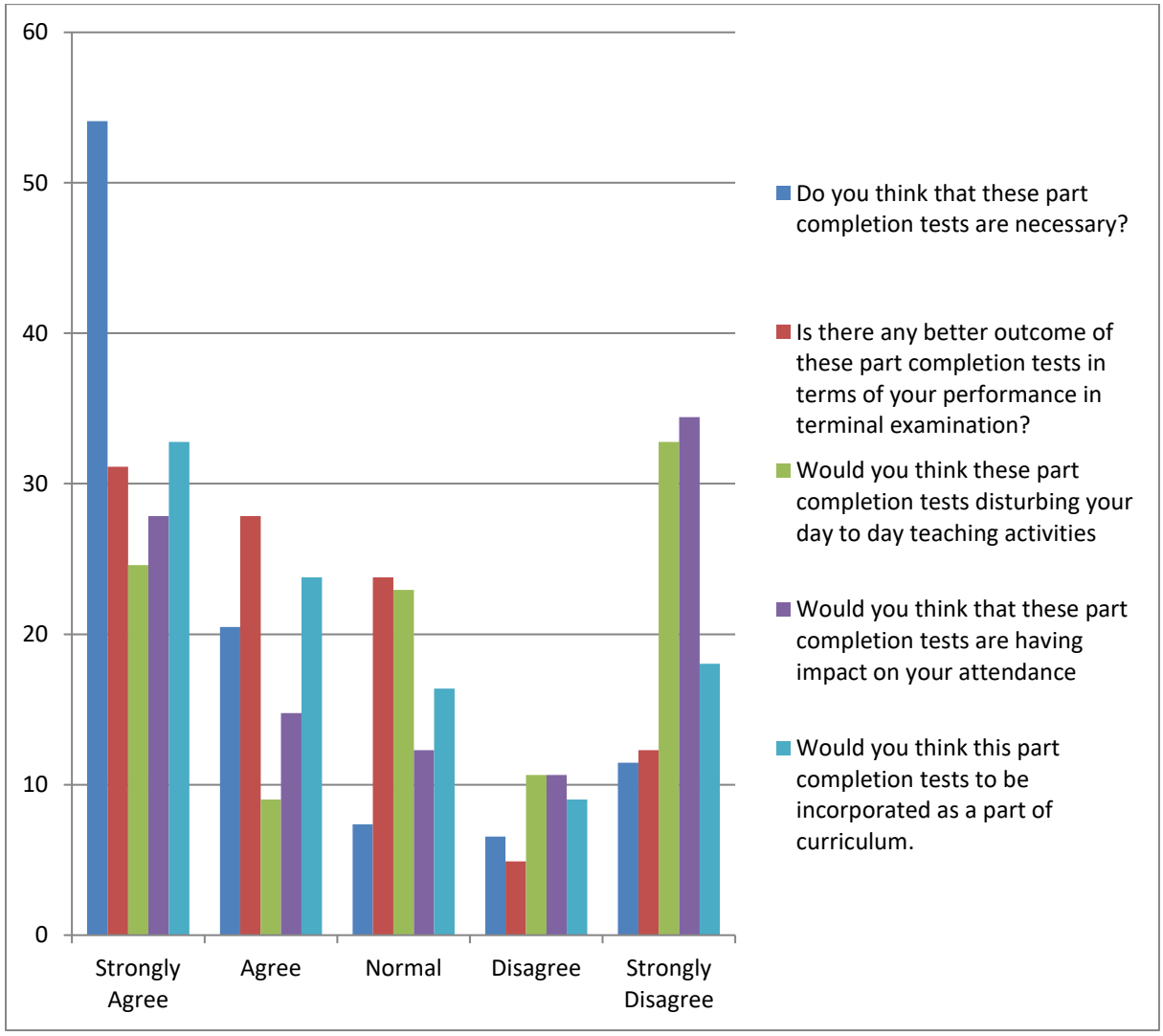

Figure No. 1

Perception from Students (n = 122) by Likert's Scale

Figure No. 2 shows perception from faculties for part completion test. Faculties have agreed that these part completion tests are necessary and will give better outcome on performance of terminal examination and also will have impact on attendance. They also agree that part completion test should be incorporated in curriculum. However faculties disagreed that these part completion tests are disturbing day to day teaching activity.

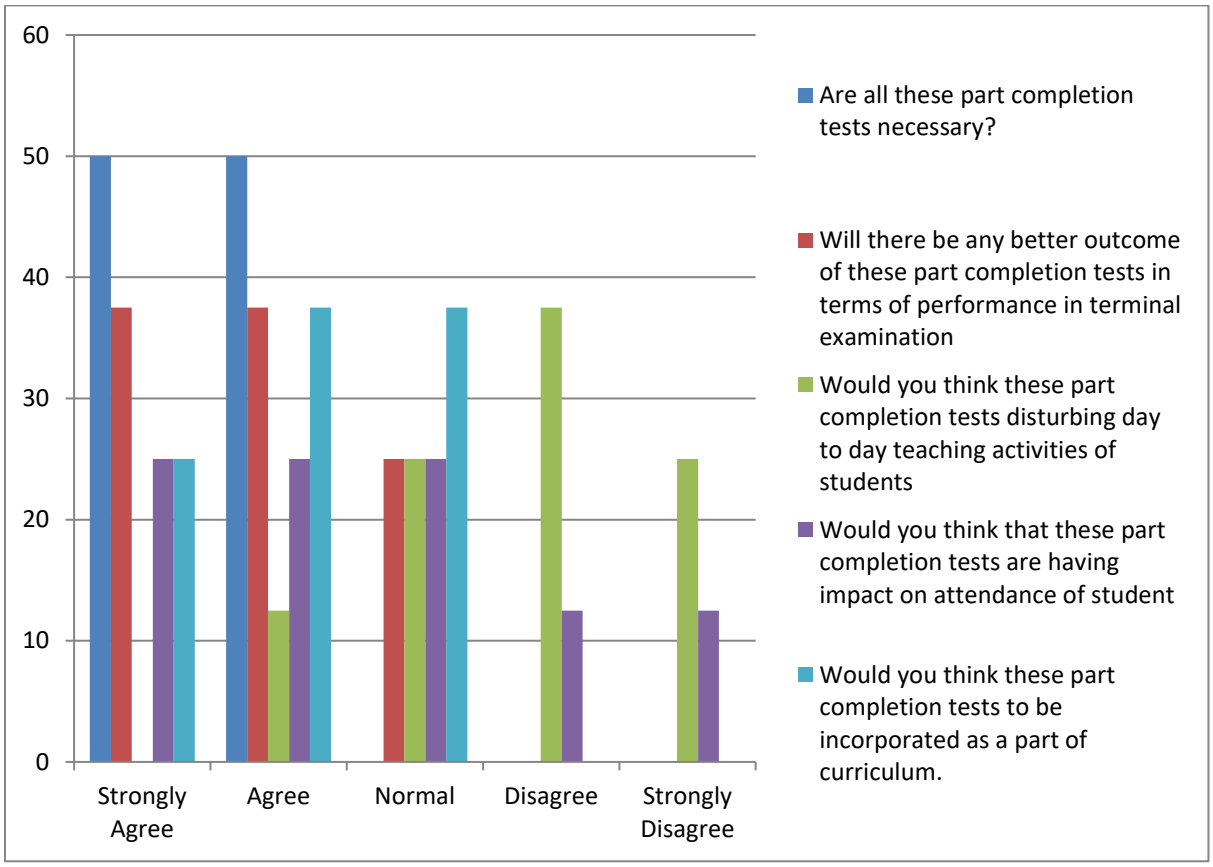

Figure No. 2

Feedback from faculties (n = 8) by Likert's Scale[6]

Discussion:

Assessment is driving force for student in learning. Continuous assessment plays a vital role in influencing the summative exam performance. Santra et al[7] found a strong correlation between internal assessment marks and professional exam marks. Karpicke and Roediger[8] showed that repeated testing produced a large positive effect on long term retention, while repeated studying has

no effect. It is universally accepted fact that students are under severe stress and anxiety during professional exams as compared to day to day exams. Studies have proven that exam anxiety interfere with academic performance[9].

So under these all observations, it was interesting to know whether conducting part completion tests will have better outcome in form of performance in terminal examinations. Hence in order to improve the internal assessment marks, we have conducted this study to see the effect of written test in day to day assessment, presuming that this practice might help students to perform better in terminal exams and henceforth in summative exams as well.

In our study, we have found that, those students who have given more number of part completion tests scored well in terminal examination as compared to those who have given less.

Faculties and students have agreed that these part completion tests are necessary and will give better outcome on performance of terminal examination and also will have impact on attendance. They also agree that part completion test should be incorporated in curriculum. However students agreed and faculties do not agree that these part completion tests are disturbing day to day teaching activity.

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Biochemistry

A Correlation Study between Polycystic Ovarian Syndrome (PCOD) and Its Related Endocrinal Hormones in Udaipur, Rajasthan, India

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Abstract **Original Research Article**

Background: Polycystic ovary syndrome (PCOS) is a complex endocrine disorder affecting 5–10 % of women of reproductive age. It generally manifests with oligo/anovulatory cycles, hirsutism and polycystic ovaries, together with a considerable prevalence of insulin resistance. ***Objectives:*** The objective of the study is to establish correlation among testosterone, insulin, FSH, LH and lipid profile among the women with polycystic ovary syndrome (PCOS), in order to evaluate their diagnostic and prognostic significance**.** ***Methodology:*** This study includes total 300 female participants of age Group between 18-40 year of age**.** They were divided in to two groups. Group 1(n=150) includes women having PCOD and Group 2(n=150) is control Group. Fasting Blood samples were obtained from all participants to measure Blood sugar, Lipid Profile insulin, HOMA-IR, Testosteron, FSH, LH and Prolactine**.** ***Result:*** The Mean level of S.Testosteron, S.FSH, S.LH, S.Prolactine and HOMA-IR Fasting Blood sugar, S.cholesterol, S, and Triglyceride S.Insulin is found to be Lower Control Group as compared to PCOD group and difference among them found to be statically significant. ***Conclusion:*** From our study I would like to conclude that a PCOS, as a syndrome, has got multiple components including reproductive, metabolic and hormonal, with long-term health concerns that cross the life span. Moreover, PCOS patients have a higher risk of metabolic and cardiovascular diseases and their related morbidity, if compared to the general population.

Key words: PCOD, Insulin, HOMA-IR, Testosteron, FSH, LH, Prolactine.

INTRODUCTION

Polycystic ovary syndrome (PCOS) is the most common endocrine disorder in women and major cause of anovulatory infertility. PCOS patients can present a wide range of signs and symptoms, which make difficult the precise grading of the condition. Diagnosis of PCOS is currently based on the criteria of the ESRHE/ASRM Rotterdam consensus meeting in 2003 [1], which broadened the previous NIH classification of 1990 [2]. It based on at least two of the following features: oligo-anovulation, hyperandrogenism and polycystic ovaries by ultrasound [1]. In 2006, the Androgen Excess Society (AES) set up a committee of experts to review all the data published on PCOS for the purpose of simplifying diagnosis [3]. The AES criteria require clinical and/or biochemical hyperandrogenism simultaneously with oligo/anovulation and ultrasonographic evidence of polycystic ovaries.

There is increasing evidence suggesting that PCOS affects the whole life of a woman, can begin in utero in genetically predisposed subjects, it manifests clinically at puberty, continues during the reproductive years. It can also expose patients to increased risk of cardiovascular disease, hypertension, diabetes and other metabolic complications, especially after menopause [4]. During the fertile period it may cause anovulatory infertility and could be associated with increased prevalence of gestational complications, such as miscarriage, gestational diabetes and preeclampsia [5]. Early diagnosis is therefore crucial by enabling close follow-up and in an attempt to reduce the risk of such complications.

Therefore, the present investigations will be carried out to assess testosterone, LH, FSH & insulin hormones level, HOMA-IR level. Subsequently regular assessing of sugar glucose, lipid profile and differential diagnosis of prolactin (PRL) in clinical biochemistry laboratory is important to monitor & study the effect of these parameters among normal and polycystic ovary Syndrome (PCOS) women & its adverse consequences.

MATERIAL & METHOD

This prospective study was conducted at Department of Biochemistry and Department of

Obstetrics & Gynaecology, Geetanjali Medical College & Hospital, Udaipur, Rajasthan, India from June 2012-Dec 2013. A total of 300 subjects of age group between 18-40 years belonging to both normal & polycystic ovary syndrome will be classified as:

Group-1:150 women with PCOD (Cases) of polycystic ovary disease will be taken.
Group-2:150 normal women will be taken as control for these parameters.

All PCOD women & controls were underwent a complete history and physical examination. Women with PCOD should be interviewed of their name, address, age, socio-economic status, and menstrual history, age of menarche, education level and family history of PCOD. All women were gone through gynaecological ultrasonography to determine their uterus and ovaried condition.

Inclusion Criteria

Women with PCOD are attending outdoor OPD of the hospital, first time diagnosed PCOD, Diagnosed polycystic ovarian syndrome, age ranging from 18-40 years.

Women with PCOD Willing to have physical examinations like Weight, Height, BMI, W/H ratio, Blood Pressure, Hirsutism, Acne, Dark patches, Virilization, Ultra sonography etc.

Polycystic ovary syndrome (PCOS) associated with Diabetes,obesity, Cardiovascular disorders. Irregular menstrual disorder and anovulation, Hirsutism & Acne symptoms.

Exclusion Criteria

Women with diagnosed adrenal hyperplasia, androgen secreting neoplasm, other pituitary (acromegaly) and adrenal disorders like Cushing syndrome, Virilizing adrenal or ovarian neoplasm**,** hyperprolactinemia and other infertility cause, Thyroid hormone related infertility, Women having history of smoking, taking alcohol or tobacco chewing**,** Any other type of gynaecologic complications except related with Polycystic ovary syndrome (PCOS) will be excluded from the study.

Fasting 10 ml venous blood samples were obtained from all participants and collected it in to fluoride and plain vaccutainer. An Uniq ID number was given to each sample to hidden the identity of participants. All samples were centrifugated at 3000 RPM for a period of 10 minutes to obtain a Plasma and serum.

Blood Glucose (FBS) measured by GOD POD method and lipid profile (S. Cholesterol, Triglyceride, HDL, VLDL, LDL) measured by enzymatic colorimetric method from all samples.

Fasting Insulin level estimation was done by enzyme linked immune assay (ELISA) method based electrochemilumnescence and HOMA-IR will be estimated by calculation (fasting sugar×fasting insulin/22.5).

Various Endocrinal Hormones like testosterone, LH, FSH, Insulin and Prolactine was measured by enzyme linked immune assay (ELISA) method based on electrochemilumnescence from all samples.

After assessing all the values, Mean, Standard deviation of all subjects & parameters were analysed. Statistical analysis was performed with SPSS software. Comparison between cases and with control is done by independent student's t test. By using't' values now P value is less than 0.05 (P value < 0.05), it is significant. Comparison of the categorical variables (among category comparison) was done by using Chi-Square test.

RESULTS & DISCUSSION

Infertility, hirsutism, and oligomenorrhea were more common among the subjects with PCOS, but there was a considerable spontaneous restitution of cyclic regularity with time. Women with PCOS were more often hysterectomized and entered menopause later compared with referents. The hormone data show a typical profile for PCOS. Compared with referents women with PCOS showed marked increase in prevalence of central obesity, higher basal serum insulin concentrations, and a higher prevalence of diabetes mellitus and hypertension [65].

Table-1: Age wise distribution of participants

Group	Number(n)	Mean Age(Yr)
Group 1(PCOD)	150	26.30 ± 5.0
Group 2(Control)	150	24.50 ± 4.13

Table-2: Location wise distribution of participants

Location	Group 1(PCOD)	Group 2(Control)
Rural	57(38%)	36(36%)
Urban	93(62%)	64(64%)
Total	150(100%)	150(100%)

Table-3: Comparison of weight between case and control group

Group	Number(n)	Mean wt (kg)
Group 1(PCOD)	150	58.91 ± 5.24
Group 2(Control)	150	48.36 ± 5.8

Table-4: Comparison of waste hip(W/H) ratio between case and control group

Group	Number(n)	Mean W/H ratio
Group 1(PCOD)	150	0.84 ± 0.13
Group 2(Control)	150	0.79 ± 0.05

Table-5: Comparison of BMI between case and control group

Group	Number(n)	Mean BMI
Group 1(PCOD)	150	23.70 ± 2.73
Group 2(Control)	150	18.72 ± 2.41

Table-6: Comparison of Marital status between case and control group

Group	Number(n)	Married	single
Group 1(PCOD)	150	100(66.7%)	50(33.3%)
Group 2(Control)	150	59 (39%)	91(61%)

Table-7: Comparison based on menstrual cycle history between case and control group

			GROUP		Total
			Control	Cases	
M.H./CYCLE	<5	Count	0	11	11
		% within GROUP	0.0%	16.5%	3.66%
	5-9	Count	0	138	138
		% within GROUP	0.0%	92.3%	46%
	>=10	Count	150	1	151
		% within GROUP	100.0%	0.6%	50.33%
Total		Count	150	150	300
		% within GROUP	100.0%	100.0%	100.0%

Table-8: Showing valid Hirsutism status of Case group

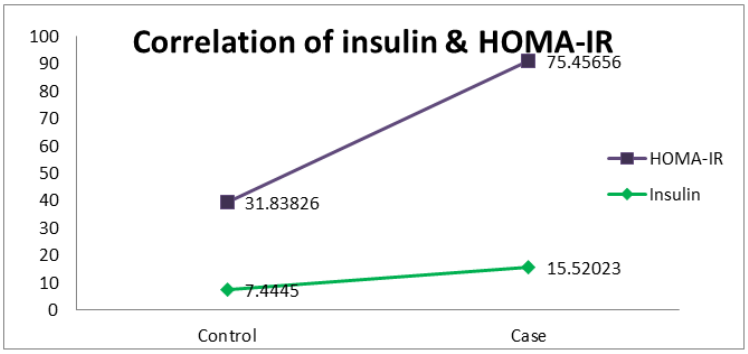
TOTAL COUNTS	HIRSUTISM		NON HIRSUTISM	
	Counts	valid %	Counts	valid %
Cases (150)	80	53%	70	46%

Table-9: Comparison of various biochemical parameters between case and control group

parameter	Group	N	Mean SD	p-value
FBS(mg/dl)	Case	300	106.7 ± 19.4	<0.001
	Control	200	96.12 ± 17.03	
S.choletsterol(mg/dl)	Case	300	189.1 ± 45.47	<0.001
	Control	200	157.49 ± 23.80	
S.Triglyceride(mg/dl)	Case	300	160.69± 36.98	0.025
	Control	200	154.62 ± 23.42	
S.HDL(mg/dl)	Case	300	40.24 ± 6.30	0.006
	Control	200	38.66 ± 6.25	
S.LDL(mg/dl)	Case	300	116.95 ± 42	<0.001
	Control	200	87.98 ± 22.27	
S.VLDL(mg/dl)	Case	300	32.0± 7.32	0.032
	Control	200	30.84 ± 4.72	

Table-10: Comparison of level of various endocrinal hormonal statuses between case and control group

parameter	Group	N	Mean SD	p-value
S.LH(µIU/ml)	Case	150	147.12± 39.13	<0.001
	Control	150	90.86 ± 43.62	
S.FSH(µIU/ml)	Case	150	76.42 ± 45.67	<0.001
	Control	150	22.22 ± 17.11	
S. Testosteron(ng/ml)	Case	150	13.82 ± 6.38	<0.001
	Control	150	2.67 ± 1.48	
S. Insulin(U/ML)	Case	150	15.52 ± 6.29	<0.001
	Control	150	7.44 ± 2.04	
HOMA-IR	Case	150	75.45± 41.15	<0.001
	Control	150	31.83 ± 10.69	



Graph-1: Showing Correlation of insulin & HOMA-IR between case and control group

- Comparison of the fasting basal sugar (FBS) between the two groups shows that FBS is higher (mean value = 106.7 ± 19.49) in Cases group than Controls (mean value = 96.1 ± 17.0 (Table 9).
- Comparison of the Triglyceride (TG) between two groups shows that TG is higher (mean value = 160.6 ± 36.98) than Controls (mean value = 154.6 ± 23.42). Comparison of Total Cholesterol (TC) between two groups shows that TC is higher (mean value = 189.1 ± 45.47) in Cases than Controls (Table 9).
- Comparison of the luteinizing hormone (LH) between two groups shows that LH is higher (mean value 147 ± 39) in Cases than Controls (mean value = 90.8 ± 43.6) (Table 10).
- Comparison of the follicular stimulating hormone (FSH) between two groups shows that FSH is higher (mean value 76.4 ± 45.6) in Cases than Controls (mean value = 22.2 ± 17.1) (Table 10).
- Testosterone is higher (mean value 13 ± 6.3) in Cases than Controls (mean value = 2.67 ± 1.4) (Table 10).
- Insulin hormone is higher (mean value 15.5 ± 6.2) in Cases than Controls (mean value = 7.4 ± 2.0) (Table 10).
- HOMA-IR is higher (mean value 75 ± 41.1) in Cases than Controls (mean value = 31.8 ± 10.6) (Table 10).

Although the exact cause of PCOS is unknown, it is understood to be a multifactorial condition with a genetic component. Approximately 20–40% of first-degree female relatives of women with PCOS go on to develop PCOS themselves, compared to estimated 4–6% prevalence in the general population [6]. Many women with PCOS have female relatives with PCOS, even if it was never diagnosed as with type 2 diabetes, it is likely that numerous genes each make a small contribution to the etiology of PCOS; and recent genome-wide association studies have identified candidate genes [7-9]. Any underlying genetic predisposition is likely complicated by epigenetic and environmental factors such as an unhealthy diet and lack of physical activity.

Clinically, PCOS may manifest as a mild menstrual disorder or a severe disturbance of reproductive and metabolic functions [10]. Most visible signs are caused by excessive production of insulin or androgens. Hirsutism (excess hair growth on the face and body) is present in ~ 70% of women with PCOS and is considered to be a good marker for hyperandrogenism but should be evaluated biochemically.

CONCLUSION

From our study I would like to conclude that a PCOS, as a syndrome, has got multiple components including reproductive, metabolic and hormonal, with long-term health concerns that cross the life span. Moreover, PCOS patients have a higher risk of metabolic and cardiovascular diseases and their related morbidity, if compared to the general population.

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IRON DEFICIENCY ANEMIA AND ITS ASSOCIATION WITH THYROID DYSFUNCTION IN SCHOOL GOING ADOLESCENT GIRLS OF SCHEDULED TRIBES IN UDAIPUR

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ABSTRACT

Background: Scheduled Tribe people being about 8% of the total population in India and 13 per cent of total population of Rajasthan form a distinct group compared to other populations and is the most underprivileged section of society. The people especially women and adolescent girls are at a higher risk of under-nutrition and micronutrient deficiency leading to iron deficiency anemia. A depleted iron status may largely affect the thyroid function of tribal females and this still remains unexplored. **Materials and Methods**: The present study conducted in adolescent school going girls of local tribal community. Their blood samples were tested for various parameters like hemoglobin, serum iron, iron binding capacity and Throtropin stimulating hormone (TSH). **Results**: The investigation hereby reports anemia in 79.5% of girls. Among anaemic 47.05% were mildly anaemic and 22.5% were moderately anaemic and 9.8% of the total girls were found to suffer from severe anemia. A significant reduction in iron status confirmed anemic conditions due to iron deficiency. Significantly increased TSH levels were observed in moderate and severely anemic girls.**Conclusion:** A reduced iron status may result in clinical or subclinical hypothyroidism in adolescent girls.

Keywords: Anemia, Scheduled tribes, adolescent girls, hypothyroidism

INTRODUCTION:

The prevalence of anaemia in developing countries is relatively high ranging from 33 percent to 75 percent **(1)**. In India, anemia is classified as a major public health problem as 52% of non pregnant women of reproductive age are estimated to suffer from this condition **(2)**. Various studies conducted in India further confirm the high prevalence of anemia among adolescent girls and women due to micronutrient deficiency and anaemia trends remain strongly correlated with iron-deficiency **(3-6)**. The low dietary intake of iron and folic acid coupled with poor bio-availability of iron is the major factor responsible for very high prevalence of anemia in the country **(7)**.

Scheduled Tribe people constitute about 8% of the total population in India and 13 per cent of total population of Rajasthan, with varying proportions in different states. They live in unique physical, socio-economic and cultural environment, isolated from general population. They form a distinct group compared to other populations and is the most underprivileged section of society **(8)**. The tribal population is at a higher risk of under-nutrition,

because of the socio-cultural, socio-economic and environmental factors influencing the food intake and health seeking behaviour. Iron-deficiency anemia is widespread yet the most neglected micronutrient deficiency disorder among children, adolescence girls, and pregnant women of scheduled tribes **(9-11)**.

Many studies suggest that hypothyroidism should be suspected in patients who have anemia with an unknown aetiology. It has been shown in various studies that for adequate functioning of thyroid hormone various minerals and trace elements are considered to be important. Iron is one of such element that is required in metabolism of thyroid hormone **(12)** as it acts as a co-factor in catalyzing the activity of some important biological enzymes including thyroid peroxidase TPO **(13)**. TPO, a membrane bound enzyme is reported to be responsible for the oxidation of iodide and binding of iodine to tyrosin residue of thyroglobulin **(14)**. A lower iron status may decrease the efficiency of TPO and thereby affect the overall thyroid hormone metabolism **(15)**.

The female population of tribal community is likely at increased risk for iron deficiency, since there is a high prevalence of anemia. The effects of depletion of iron status may largely affect the thyroid function of tribal females and this still remains unexplored. The main goal of this study is to better understand the relationship between iron status, as measured by hemoglobin, serum Iron, total iron binding capacity (TIBC) and thyrotropin stimulating hormone in adolescent females attending schools. Thus the study was conducted to find out the proportion of hypothyroidism in both anemic and non-anemic school going girls of age group 12-18 years of tribal area of Southern Rajasthan specifically Udaipur. Our study aims to determine the association between iron deficiency anemia and hypothyroidism, if any.

MATERIALS AND METHODS:

Study area : Unfortunately, prevalence of anemia and its effect on thyroid function in adolescent school going girls of tribal community has been the least explored area of research, particularly in Southern Rajasthan. This community-based study was undertaken to assess the iron deficiency anemia and its correlation with hypothyroidism in adolescent school going girls of local tribal community residing in Udaipur district.

Informed oral consent was obtained from the children's teachers and families. Ethical approval for the study was obtained from the Institutional Ethical Committees of Geetanjali University, Udaipur. In the first step, subjects who fulfilled all of the inclusion criteria were chosen for the study. A total of 102 girls of tribal community (with or without iron-deficiency) were enrolled from 8th standard to 12th standard.

Inclusion criteria: Adolescent school girls, aged 12-18years, unmarried, not on hormonal therapy, no history of anemia or hypothyroidism, with no history of any autoimmune disease, not taking any vitamin or iron supplementation were included.

Exclusion criteria: Male participants, females above 18 years, married,, females on hormonal therapy, or on vitamin or iron supplementation, with a history of anemia, hypothyroidism or any other chronic or autoimmune disease were excluded.

Biochemical analyses: 5 ml fasting venous blood samples were drawn from the arm. Blood was collected in two different test tubes; 2 ml were placed in the EDTA tube for measurement of hemoglobin and 3 ml in another tube for determination of serum iron, TIBC, thyrotropin stimulating hormone (TSH). Anemia was diagnosed according to WHO guidelines **(16)** (Demaeyer, 1985) (Table 1). The quantitative measurement of serum iron, and total iron binding capacity (TIBC) was performed. Transferrin saturation was calculated as follows: (serum iron/TIBC) ×100. The quantitative measurement of thyroid stimulating hormone (TSH) was done using chemiluminescence immunoassay.

Data analysis: The master chart was prepared by using the EXCEL 2007 software. Mean values and standard deviations were presented. The data which were obtained were analyzed statistically by using online student t-test calculator. P value less than 0.005 was considered as a

RESULTS:

1. Prevalence of anaemia according to the severity of anaemia:

In the present study, of the 102 adolescent girls, 21 (20.5 %) girls were having normal Hb (>12gms/dl) and 81 (79.5%) were anaemic. Among anaemic 48 (47.05%), were mild anaemic and 23 (22.5%) of the girls were moderately anaemic having mean Hb. 10 (9.8%) of the total girls were found to suffer from severe anemia Table 2.

2. Iron status of anemic and non anemic girls

There was significant reduction in serum iron level in moderately and severely anemic girls as compared to that of non anemic girls. No significant correlation was observed in mildly anemic girls. Further, a signicant increase in all anemic females was observed as compared to girls having normal hemoglobin levels. Transnerrin saturation percentage less than 16% depicts iron deficiency, moderately and severely anemic girls were found to have severe iron deficiency (Table 3).

3. Correlation of iron deficiency and TSH

Significantly increased TSH levels were observed in moderate and severely anemic girls. There was not significant increase in mild anemic girls (Table 3).

DISCUSSION

This is the first study report prevalence of anemia and its correlation with thyroid dysfunction in adolescent school going girls of local tribal community of Udaipur. In females, adolescence marks the beginning of the menstrual cycle or reproduction. Adolescents gain 30% of their adult weight and more than 20% of their adult height between 10-19 years, which is mentioned as growth spurt **(17)**. Adolescent girls are at a high risk for anaemia as there is increased iron requirement because of growth and menstrual loss. Malnutrition and inadequate nutrition during adolescence may result in serious consequences throughout the reproductive years of life and beyond **(18)**.

The data from the District Nutrition Project (Indian Council of Medical Research) in 16 districts of 11 states of India including Rajasthan, on the prevalence of anemia in non-pregnant adolescent girls (11-18 years) in year 2002, also demonstrated anemia as high as 90.1% out of which 7.1% of the girls were reported to suffer from severe anemia i.e. Hemoglobin <7 g/dl **(19)**. It has been further reported by Indian Institute for Population Sciences and Ministry of Health and Family Welfare in 2006, that in India, 98 percent of adolescent girls have any anemia. Twenty two percent of them are mildly anemic, 49 percent are moderately anemic and 27 percent are suffering from severe anemia. Severely anemic adolescent girls are highest among Scheduled Tribes as compared to other castes vide DLHS, 2002-2004 **(20)**.

According to Vyas and Choudhary (2005) 93.7 per cent school children were reported to suffer from different forms of anaemia confirming high prevalence of anaemia in the tribal school children of Udaipur region **(8)**. Our study conducted during 2014-15, in adolescent school going girls of local tribal community hereby reports anemias, in the studied group of girls upto 79.5%. 47.05% of girls were having mild anemia, 22.5% were moderately anemic and 9.8% were severely anemic. A very high prevalence of anaemia in our study could be attributed to lower socio-economic status and nutritional deficiencies found in adolescent girls of tribal population, as similar results were reported in adolescent girls of certain slum areas **(21)**. Respective transfrrin saturation percentages were also observed below the normal levels depicting lower iron status.

Studies have shown that anemia is an indicator of poor nutrition and poor health, with major consequences on the human health as well as on the social and economic development.

According to the WHO, if the prevalence of anemia at the community levels is more than 40%, it should be considered as a problem of high magnitude **(22)** The present study thus brings out the fact that the problem of anemia is related to a wider population than the traditionally considered groups of the non pregnant adolescent females. Our study further confirmed that the anemia in studied population is

due to reduction in iron status. Significant changes in TIBC and Serum iron confirmed that anemic condition in these females is due to iron deficiency.

None of studies have yet reported the relationship between anemia and thyroid dysfunction in adolescent girls in India till date. Though such kind of relationship has been demonstrated by Eftekhari and coworkers in iron-deficient adolescent Iranian girls **(23-24)**. Normal thyroid status is dependent on the presence of many trace elements e.g., iron, iodine, selenium, and zinc for both the synthesis and metabolism of thyroid hormones **(12, 25)**. Iron is very intricately connected to thyroid hormone metabolism. Therefore, estimation of serum iron and total iron binding is of great significance in thyroid dysfunction. Our study clearly addressed the association of iron status with hypothyroidism by estimating Hb level, serum iron, TIBC, trasferrin saturation and serum TSH levels. The estimation of serum TSH the is single best screening parameter for hypothyroidism therefore only serum TSH was measured which is increased in primary hypothyroidism **(26)**.

Our study demonstrates that TSH levels were significantly higher in all the girls of tribal community having moderate and severe anemia as compared to non anemic girls. Our results are in accordance with other studies which demonstrated increased levels of TSH and low levels of thyroid hormones in associated with reduced body iron status **(25)**. It has also been suggested in one of the study conducted in Nepalese children that anemic and iron deficient subjects have high risk of hypothyroidism as they are reported to have higher TSH than non-anemic subjects **(27)**. Similarly, a development of secondary and subclinical hyperthyroidism in a significant portion of patients with iron deficiency anemia has been reported in a clinical study conducted in adults with iron deficiency anemia **(28)**.

The present study is the first report to associate iron deficiency anemia with hypothyroidism in adolescent school going girls of local tribal community in Udaipur. The study do have limitation of small sample size, less number of parameters tested and the data of non school going girls of same age group. It is suggested that routine monitoring of thyroid function test and iron deficiency anemia in adolescent girls along with appropriate iron supplementations may reduce adverse pregnancy outcomes and mother mortality in their later life.

CONCLUSION

A considerable proportion of adolescent school going tribal girls had iron deficiency anemia. Nearly two-third girls were anaemic (Hb < 12 g/dl); anaemia was significantly more in girls belonging to bigger family size. All severely anemic girls were found to have thyroid dysfunction. Thus, there is a need for closely monitored implementation of intervention strategies and methodologies for tribal areas, as per the local socio-cultural context. An effort would be required to promote consumption of iron rich foods for long-term gains in iron status of the adolescent tribal girls. Various Interventions for anemic adolescent tribal girls may raise their iron stores and sustain their hemoglobin at normal levels. This will not only improve their physical and mental capacity, but also subsequently help in reducing the incidence of low birth weight of infants and maternal mortality rates. The results further indicated a need for longitudinal studies with larger sample size to be undertaken in different parts of the Southern Rajasthan to assess the magnitude of iron deficiency anemia and associated thyroid dysfunctions amongst school going adolescent girls of tribal community.

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LIST OF TABLES

"Table 1: Classification of anaemia according to severity proposed by WHO"

S.No	Degree of anemia	Cut-off points of Hb(gm/dl)
1	Normal (non anemic)	≥ 12.00
2	Mild Anaemia	10.00 – <12
3	Moderate Anaemia	7.00 – <10.00
4	Severe Anaemia	< 7.00

"Table 2: Prevalence of different grades of anaemia in adolescent school going girls of tribal community"

Haemoglobin levels(g/dl)	Grade of anaemia	Hb gm%	% (n=102)
< 7	Severe Anaemia	6.4±0.9	9.8 (10)
7 - 10	Moderate anaemia	9.44±0.46	22.5(23)
10 - 12	Mild anaemia	10.78±1.12	47.05(48)
> 12	Normal	12.8± 0.69	20.5(21)

Values in parenthesis denote the number of girls

"Table 3: Correlation of Thyroid Stimulating hormone with degree of anemia and iron status"

Groups ☛ / Parameters ☟	Normal	Mild Anaemia	Moderate anaemia	Severe anaemia
Hb	> 12	10.78±1.12	9.44±0.46	6.4±0.53
TIBC	315.48±11.5	407.26±9.87*	442.86±10.2*	499.5±14.9*
Serum iron	68.34±4.3	64.93±7.6	56.46±5.5*	23.07±8.22*
Transferrin saturation (%)	21.6	15.94	12.7	4.62
TSH	2.01± 1.82	2.91±1.9	17.56±4.1*	23.39±3.3*

* denotes p value less than 0.005 as compared with non anemic group.

ORIGINAL RESEARCH PAPER

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ROLE OF VITAMIN D AND RISK OF PROSTATE CANCER

Biochemistry

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ABSTRACT

Background: Vitamin D is a secosteroid hormone and well-known for its classical actions in the maintenance of calcium uptake and bone metabolism. Recently, numerous in vitro experiments demonstrated that 1,25-(OH)2D3, the active form of vitamin D, inhibited the growth and differentiation of human prostate cancer cells.
Aim: To estimate vitamin D level in prostate cancer patients along with increasing risk.
Material & Methods : 100 samples along with control were analysed by cobas e-411 for Vitamin D and PSA.
Results: we have found Higher risk of prostate cancer who having low vitamin D.
Conclusion: it's time to aware people for supplementation of Vitamin D, so we can prevent for the same.

KEYWORDS

Vitamin D, Prostate cancer, PSA, hypovitaminosis

INTRODUCTION:

Deficiency of vitamin D or hypovitaminosis D is widespread irrespective of age, gender, race and geography and has emerged as an important area of research Vitamin D deficiency is prevalent worldwide. This deficiency has many consequences which are still being explored, apart from the well-known skeletal complications. With the consequences of Vitamin D deficiency, namely, autoimmune diseases, cardiovascular diseases, cancer, and tuberculosis being explored. [1]. Vitamin D_3 deficiency continues to be an unrecognized epidemic in many populations around the world. Vitamin D is important for the absorption of calcium, and bone formation and maintenance [2] .The incidence of prostate cancer differs between countries due to coverage of prostate-specific antigen (PSA) screening [3]. patients with advanced-stage or metastatic cancer will ultimately progress to castration-resistant prostate cancer [4]. The mechanisms by which prostate cancer progresses to castration-resistant prostate cancer have been studied extensively [5]. Increasing evidence demonstrates that inflammation plays important roles in the pathogenesis of progression to castration-resistant prostate cancer [6]. A double-blinded clinical study found that vitamin D supplementation reduced prostate specific antigen (PSA) level and enhanced survival rate in patients with prostate cancer [7].

On the other hand, vitamin D receptor (VDR) polymorphisms were associated with the incidence of prostate cancer [7, 8]. Several epidemiological reports showed that men with vitamin D deficiency had a higher risk of prostate cancer compared to men with vitamin D sufficiency [9,10]. Nevertheless, the mechanisms through which vitamin D deficiency elevates the risk of prostate cancer remain unclear. The present study aimed to investigate whether there was an association among prostate cancer, vitamin D status in a hospital-based case-control study.

MATERIALS AND METHODS

A case control study done in Ananta institute of medical sciences and research centre, Rajsamand. During June 2016- November 2016. In the present study, total 50 newly diagnosed patients with prostate cancer were recruited as cases. Prostate cancer was confirmed by histopathology. 50 Controls were recruited from men undergoing physical examination. Vitamin D and PSA done by chemiluminescence immunoassay methodology. method on Cobas e-411 and chemistry (CRP) ,FBG, creatinine, uric acid, T.G., Total Cholesterol by Cobas Intigra 400^{+}. Serum samples of all cases and controls were collected at same season and stored at -20°C.

RESULTS

Biochemical characteristics were analyzed as shown in Table 1, no significant difference in Cr, UA, TG, TCH, fasting blood glucose was observed between cases and controls. As expected, serum T-PSA was significantly increased in patients with prostate cancer as compared with control subjects (Table 2).

Serum 25(OH)D concentration was analyzed in all subjects. As shown in Figure 1A, serum 25(OH)D in patients with prostate cancer was significantly lower than in controls.

Table 1

Parameters	Case(50)	Control (n=50)	P- value
FBG	70±1.2	69.12±.32	0.81 NS
Creatinine	0.87 ±.2	0.96±.31	0.734 NS
Uric acid	3.30±1.1	3.5±1.28	0.086 NS
Triglyceride	125.25±.25	128.35±3.25	0.45 NS
Total cholesterol	155.23±2.3	152.52±2.35	0.93 NS

No significant change

Table- 2

Parameters	case(n=50)	Control(n=50)	P- value
CRP	65.01±2.41	3.01±0.24	<0.0001*
Vitamin D	1.08±.56	8.10±2.16	<0.0001*
PSA	3.70±2.36	15.12±1.25	<0.001*

*Significant change

DISCUSSION

The present study analyzed the association among prostate cancer, vitamin D status. Our results showed that serum 25-(OH) D was reduced in patients with prostate cancer. By contrast, serum CRP, a marker of systemic inflammation, was elevated in patients with prostate cancer. These results provide evidence for the first time that low vitamin D status is associated with inflammation in patients with prostate cancer.

Chronic inflammation promotes metastases and progression to castration-resistant prostate cancer [11, 12]. CRP could predict tumor aggressiveness and potential treatment efficacy in patients with prostate cancer [13]. According to an early report, CRP is an independent prognostic factor for overall survival of patients with castration-resistant prostate cancer treated with docetaxel [14]. A recent study showed that elevated CRP level was associated with poor prognosis in prostate cancer patients treated with radiotherapy [15]. Our results showed that serum 25-(OH)D level was lower in patients with severe prostate cancer than in patients with mild and moderate prostate cancer. By contrast, serum CRP was higher in patients with prostate . These results suggest that low vitamin D status is associated with inflammation and the progression of prostate cancer.

Increasing evidence indicates that vitamin D has an anti-inflammatory activity [16]. These results suggest that inflammation may be a key mediator for prostate cancer progression in patients with low vitamin D status.

The present study has several limitations. First, the present study did not observe whether vitamin D deficiency and inflammation promotes metastasis and progression of prostate cancer. Thus, additional study is required to investigate whether prostatic inflammation promotes prostate cancer in patients with low vitamin D status.

In summary, the present study investigated the association among prostate cancer, vitamin D status and inflammation. Our results showed that serum 25-(OH) D was decreased in patients with prostate cancer. By contrast, serum CRP was increased in patients with prostate cancer.

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Original Research Paper

EFFECT OF MUSHROOM DIET ON WEIGHT GAIN OF ALBINO RATS

Biochemistry

KEYWORDS: Oyster mushroom, *Pleurotus sajor-caju*, mycelium, protein

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ABSTRACT

Mushrooms are known for good quality of protein; therefore *Pleurotus sajor-caju* was selected to study the essential amino acid content and the effect of supplementation of *Pleurotus sajor-caju* on growth of albino rats. Rats were randomly assigned on diet containing mushroom fruiting and mushroom mycelium for a period of 30 days. On every 10th day, animals were weighed and their diet intake, remnant food and protein intake were measured. The result showed phenylalanine, methionine, tryptophan, threonine, isoleucine, lysine and histidine values of mycelium found significantly more than fruiting. In animal experiment values showed significant difference in body weight between control and experimental groups. Study concluded that the feeding of mushroom fruiting and mushroom mycelium diets helped to gain weight of albino rats because of then excellent nutritional composition.

INTRODUCTION

There has always been lack of harmony between the rapidly growing world population and the adequate supply of protein rich foods in the human diet. The mushrooms, yeast and algae are frequently mentioned as an alternative source for food. Mushrooms have been valued throughout the world as both food and medicine for thousands of years (Lindequist *et al.,* 2005; Wright 2004; and Tribe *et al.,* 1973).

Mushrooms are considered as a good source of protein, vitamins and minerals (Jiskani, 2001). *P. ostreatus* and *Pleurotus sajor-caju* are contain protein (27.4% and 26.9% respectively), carbohydrate (40.75%) and low lipid (5.4 % and 6.2 %) on dry weight basis (Dhonda *et al.*, 1996; Rai *et al.* 1988). Chang and Miles (1989) have suggested that the protein in mushroom, in general, is about twice that in asparagus and cabbage, and 4 and 12 times those in oranges and apples, respectively.

All the essential amino acids required by an adult are present in mushroom (Bisaria *et al.*, 1987). Lintgel *et al.* (1994) reported the digestibility of mushroom protein to be as high as 72-83 per cent. Quality of mushroom protein is far superior to the vegetable proteins and it is as good as or just inferior to animal protein because of presence of essential amino acids (Crisan and Sands, 1978; Bano and Rajarathnam, 1982; Chang and Miles, 1989). Quality of protein is nutritionally more important than its quantity. Requirement of protein is infact the requirement of amino acids. Human body is incapable of producing essential amino acids. Mushrooms are well recognized for their protein quality. Keeping this in view fruiting and mycelium of oyster mushroom were analyzed for its essential amino acids content and the diet supplemented with *Pleurotus sajor-caju* was selected to feed albino rats to know the growth effect.

MATERIAL AND METHODS

The present study was conducted during 2006-2007 in the Department of Home Science, Sant Gadge Baba Amravati University, Amravati. Oyster mushroom spp. *Pleurotus sajor-caju* was selected because it is grown commercially in central India and cost of cultivation is low. Fruiting of oyster mushrooms was cultivated by polybag technique and mycelium was grown on agar-agar media. Fruiting and mycelium of oyster mushroom were harvested from bags and media, respectively. Both were dried at 32^{0}C temperature in the incubator. Fruiting and mycelium were ground to form fine powder. Powders were stored in airtight container. Fruiting and mycelium of oyster mushroom were subjected to analyzed essential amino acids by paper chromatography method (Thimmaiah, 1999). Oyster Mushroom diets were prepared out of fruiting and pure mycelium. Oyster mushroom diets (as shown in table 1) were fed to albino rats to study the effect on weight of albino rats.

About thirty male albino rats were obtained from Department of Biochemistry, Rastra Sant Tukdoji Maharaj Nagpur University, Nagpur. The weight of rats was between 50 to 60 grams and age was between 40 to 45 days. Rats were randomly divided to in five groups. Each group had 6 rats. Control diet was fed to first group of rats and rest four groups were kept on experimental diets. At the beginning of the experiment, all rats were fed with standard diet (Swaminathan, 1999) for one week. The observations about diet provided and left over were recorded. The duration of feeding experiment was 30 days, on every 10th day rats were weighed. Their diet intake, remnant food and protein intake were measured. The composition of control and experimental diets is given in table 1. Control diet does not contain mushroom fruiting or mycelium. Diet 1 and 2 comprise control diet and 1 and 2g oyster mushroom fruiting (OMF) respectively. Diet 3 and 4 contain control diet and 1and 2g oyster mushroom mycelium (OMM) respectively. Water was given in adlibitum.

Table 1: Composition of control and experimental diets

S. No.	Ingredients (g)	Control diet	Experimental diets			
			Diet 1 1g OMF	Diet 2 2g OMF	Diet 3 1g OMM	Diet 4 2g OMM
1	Wheat flour	20.00	19.00	18.00	19.00	18.00
2	Roasted bengalgram dhal	58.00	58.00	58.00	58.00	58.00
3	Groundnut flour	10.00	10.00	10.00	10.00	10.00
4	Skimmilk powder	04.00	04.00	04.00	04.00	04.00
5	Casein	04.00	04.00	04.00	04.00	04.00

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6	Oil	04.00	04.00	04.00	04.00	04.00
7	Oyster Mushroom Fruiting	-	01.00	02.00	-	-
8	Oyster Mushroom Mycelium	-	-	-	01.00	02.00
9	Salt mixture	00.20	00.20	00.20	00.20	00.20
10	Vitamin mixture	00.50	00.50	00.50	00.50	00.50

RESULTS AND DISCUSSION

Oyster mushroom was analyzed to find out essential amino acids and estimated mean values are given in the table 2.

Table 2: Essential amino acids (% crude protein) in fruiting and mycelium of oyster mushroom

S. No.	Essential amino acids	Fruiting Mean ± SD	Mycelium Mean ± SD	't' value
1	Phenylalanine	4.00 ± 0.10	6.50 ± 0.10	10.00*
2	Valine	5.10 ± 0.10	4.30 ± 0.28	01.40
3	Methionine	2.20 ± 0.10	2.60 ± 0.37	02.00
4	Tryptophan	1.50 ± 0.10	2.10 ± 0.10	03.33*
5	Threonine	5.10 ± 0.10	7.50 ± 0.10	08.06*
6	Isoleucine	3.40 ± 0.10	4.20 ± 0.11	05.80*
7	Leucine	6.50 ± 0.10	5.20 ± 0.10	05.90*
8	Lysine	6.40 ± 0.10	7.00 ± 0.11	01.66
9	Histidine	2.10 ± 0.10	2.50 ± 0.01	00.86

* Significant at 0.05 level of probability

The fruiting and mycelium contained all essential amino acids but in varying amount. Fruiting contained 4.00 per cent and mycelium contained 6.50 per cent phenylalanine. It reveals that mycelium found to be better than fruiting in respect of phenylalanine which could be seen from the significant 't' value (10.00) at 5 per cent level of significance.

Valine present in fruiting and mycelium found to be 5.10 and 4.30 per cent, respectively. However, 't' value (1.40) reveals that there was no significant in the content of valine in fruiting and mycelium. Fruiting contained 2.20 per cent and mycelium 2.60 per cent methionine. This shows that both fruiting and mycelium were similar in methionine content, as could be seen from non significant difference between fruiting and mycelium at 5 per cent level of probability.

Fruiting and mycelium contained 1.50 per cent and 2.10 per cent tryptophan, respectively. Mycelium found to be better than fruiting in respect of tryptophan content as 't' value shows significant difference between fruiting and mycelium at 5 per cent level of significance.

Fruiting contained 5.10 per cent threonine and in mycelium it was found to be 7.50 per cent. It shows that mycelium found to be better source of threonine than fruiting as significant difference could be found between fruiting and mycelium at 5 per cent level of probability (t = 8.06).

Isoleucine present in fruiting was 3.40 and 4.20 per cent in mycelium. It indicates that the mycelium found to be better in isoleucine than fruiting, as 't' value (5.80) found to be significant at 5 per cent level of probability. Fruiting contained 6.50 per cent and mycelium contained 5.20 per cent leucine. Fruiting found to be better than mycelium in respect of leucine as significant difference could be noticed from the 't' value (5.90).

Fruiting contained 6.40 per cent lysine and mycelium contained 7 per cent lysine. Though mycelium showed high amount of lysine than fruiting but 't' value showed no significant difference between fruiting and mycelium and thus both are at par as far as lysine content is concerned.

Fruiting contained 2.10 per cent and mycelium contained 2.50 per cent histidine. Both fruiting and mycelium contained similar amount of histidine as no significant difference could be noticed (t = 0.86).

Animal experiment

The observed values of feeding experiment about total diet intake, total protein intake and the total gain in body weight on 10th, 20th and 30th day are given in tables 2, 3 and 4, respectively.

Table 2: Mean diet intake, protein intake, weight gain of albino rats on 10th day

S. No.	Diets	Protein g/100g diet	Actual diet intake (g) Mean ± SD	Actual protein intake (g)	Weight gain (g) Mean ± SD
1	Control	22.12	102.08 ± 2.91	22.67	22.50 ± 2.12
2	1g OMF	22.54	102.03 ± 1.67	22.99	22.58 ± 1.02
3	2g OMF	22.87	104.03 ± 2.95	23.79	27.24 ± 2.43
4	1g OMM	22.68	102.88 ± 2.50	23.33	24.50 ± 2.32
5	2g OMM	23.15	104.12 ± 4.02	24.10	29.18 ± 1.16

Data in table 2 indicates that the gain in body weight of rats kept on experimental diets was better than control diet. It was noted that the weight gain of rats fed on 2g OMF (27.24 ± 2.43) and 2g OMM (29.18 ± 1.16) was better than 1g OMF (22.58 ± 1.02) and 1g OMM (24.50 ± 2.32) diets. It was also observed that the gain in weight of rats fed on diet 1 and 2 comprise OMM was better than the diets 3 and 4 contains OMF. The results thus lead to the conclusion that higher the content of mushroom, better the weight gain. However, mushroom mycelium was found effective than the fruiting of oyster mushroom.

Table 3: Mean diet intake, protein intake, weight gain of albino rats 20th day

S. No.	Diets	Protein g/100g diet	Actual diet intake (g) Mean ± SD	Actual protein intake (g)	Weight gain (g) Mean ± SD
1	Control	22.21	110.12 ± 4.28	24.45	27.18 ± 3.51
2	1g OMF	22.54	112.02 ± 2.10	25.24	28.01 ± 2.51
3	2g OMF	22.87	118.16 ± 5.02	27.02	31.21 ± 1.15
4	1g OMM	22.68	112.78 ± 1.75	25.57	30.04 ± 1.52
5	2g OMM	23.15	115.21 ± 2.04	26.67	33.50 ± 2.64

Data in table 3 indicates that the highest weight gain of albino rat (33.50g) was observed in 2g OMM diet. Rats kept on control diet (27.18g) and 1g OMF diet (28.01g) showed low weight gain. The results showed that oyster mushroom mycelium was found better in increasing the body weight of albino rats and followed by OMF and OMM diets.

Table 4: Mean diet intake, protein intake, weight gain of albino rats on 30th day

S. No.	Diets	Protein g/100g diet	Actual diet intake (g) Mean ± SD	Actual protein intake (g)	Weight gain (g) Mean ± SD
1	Control	22.21	130.10 ± 2.32	28.89	29.01 ± 1.73
2	1g OMF	22.54	131.12 ± 3.98	29.55	28.50 ± 3.05
3	2g OMF	22.87	136.22 ± 3.23	31.15	33.48 ± 2.00
4	1g OMM	22.68	132.18 ± 2.05	29.97	31.50 ± 1.52
5	2g OMM	23.15	135.61 ± 4.01	31.39	36.11 ± 3.00

Perusal of data in table 4 reveal that the highest weight gain of albino rat (36.11g) was found in 2g OMM diet, relatively protein intake was 31.39g. One gram OMF supplemented rat group showed lower weight gain (28.50g) than control group (29.01g) but 2g OMF supplemented group showed better weight gain (33.48g) than 1g OMF fed group. The results thus lead to conclude that weight gain of rat fed on OMM diet was better than the OMF diet. As the amount of mushroom increases weight also increases. However, mushroom mycelium diet were found effective than the fruiting diet.

The data in respect of mean weight gain of albino rats on 10th day, 20th day and 30th day of control and experimental diets (1g and 2g OMF and OMM diets) have been presented in table 5 for comparison.

Table 5: Weight gain (g) of albino rats (control with 1g and 2g doses of fruiting and mycelium each)

S. No.	Days / Diets (n=6)	10th day	20th day	30th day	1st – 30th days
1	Control	22.50	27.18	29.01	78.69
2	1g OMF	22.58	28.01	28.50	79.09
3	2g OMF	27.24	31.21	33.48	91.93
4	1g OMM	24.50	30.04	31.50	86.04
5	2g OMM	29.18	33.50	36.11	98.79
	'F' Test	33.00*			

* Significant at 0.05 level of probability Two way ANOVA was applied for testing the significance of difference of means of control and experimental diets (1g and 2g OMF and OMM diets each) and data obtained have been presented in table 5.

Table 5 reveals that on 10th day the diet intake of albino rats were low, therefore, showed low weight gain. The plausible reason for low consumption of diet was albino rats were not accustomed to the diets. On 20th and 30th day, more weight gain was observed because of increased intake of diet and relative increase in protein intake. Overall weight gain pattern reflects that as diets comprising oyster mushroom increases body weight also increases. *In vivo* proteins are required for tissue development and oyster mushroom comprises good amount of protein. The 2g OMF and 2g OMM diets fed groups showed better weight as compared to 1g OMF and 1g OMM diets. Significant differences were found between weight gain of albino rats fed on different diets.

The quality of food protein depends upon its amino acid composition, especially that of essential amino acids. *In vivo* essential amino acids perform many functions but lysine, leucine, valine and histidine are especially required for growth and as such oyster mushroom comprise these four amino acids in good quantity as reported by Rai (1995).

Results show that the quality of protein depends on presence of all essential amino acids in food; as such oyster mushroom mycelium and fruiting contained all essential amino acids. The mean values of phenylalanine, tryptophan, threonine and isoleucine indicate that the content of these amino acid was definitely higher in mycelium than fruiting. Whereas, the fruiting of oyster mushroom definitely contained higher amount of leucine than the mycelium. The results of the animal experiment proved that the supplementation of oyster mushroom diets showed significant weight gain of albino rats. Thagumanaven and Maniekam (1980). Too observed weight gain in rats fed on *Pleurotus sajor-caju* due to its high digestibility. Similar result was also observed by Samajpati (1979).

CONCLUSION

Present investigation proved that the Oyster mushroom fruiting and mycelium contribute all essential amino acids. Phenylalanine, methionine, tryptophan, threonine, isoleucine, lysine and histidine values of mycelium found significantly more than fruiting. The supplementation of oyster mushroom helped to gain weight of albino rats because of its excellent nutritional composition.

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Biochemistry

A Correlation Study between Polycystic Ovarian Syndrome (PCOD) and Its Related Endocrinal Hormones in Udaipur, Rajasthan, India

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Abstract **Original Research Article**

Background: Polycystic ovary syndrome (PCOS) is a complex endocrine disorder affecting 5–10 % of women of reproductive age. It generally manifests with oligo/anovulatory cycles, hirsutism and polycystic ovaries, together with a considerable prevalence of insulin resistance. ***Objectives:*** The objective of the study is to establish correlation among testosterone, insulin, FSH, LH and lipid profile among the women with polycystic ovary syndrome (PCOS), in order to evaluate their diagnostic and prognostic significance**.** ***Methodology:*** This study includes total 300 female participants of age Group between 18-40 year of age**.** They were divided in to two groups. Group 1(n=150) includes women having PCOD and Group 2(n=150) is control Group. Fasting Blood samples were obtained from all participants to measure Blood sugar, Lipid Profile insulin, HOMA-IR, Testosteron, FSH, LH and Prolactine**.** ***Result:*** The Mean level of S.Testosteron, S.FSH, S.LH, S.Prolactine and HOMA-IR Fasting Blood sugar, S.cholesterol, S, and Triglyceride S.Insulin is found to be Lower Control Group as compared to PCOD group and difference among them found to be statically significant. ***Conclusion:*** From our study I would like to conclude that a PCOS, as a syndrome, has got multiple components including reproductive, metabolic and hormonal, with long-term health concerns that cross the life span. Moreover, PCOS patients have a higher risk of metabolic and cardiovascular diseases and their related morbidity, if compared to the general population.

Key words: PCOD, Insulin, HOMA-IR, Testosteron, FSH, LH, Prolactine.

INTRODUCTION

Polycystic ovary syndrome (PCOS) is the most common endocrine disorder in women and major cause of anovulatory infertility. PCOS patients can present a wide range of signs and symptoms, which make difficult the precise grading of the condition. Diagnosis of PCOS is currently based on the criteria of the ESRHE/ASRM Rotterdam consensus meeting in 2003 [1], which broadened the previous NIH classification of 1990 [2]. It based on at least two of the following features: oligo-anovulation, hyperandrogenism and polycystic ovaries by ultrasound [1]. In 2006, the Androgen Excess Society (AES) set up a committee of experts to review all the data published on PCOS for the purpose of simplifying diagnosis [3]. The AES criteria require clinical and/or biochemical hyperandrogenism simultaneously with oligo/anovulation and ultrasonographic evidence of polycystic ovaries.

There is increasing evidence suggesting that PCOS affects the whole life of a woman, can begin in utero in genetically predisposed subjects, it manifests clinically at puberty, continues during the reproductive years. It can also expose patients to increased risk of cardiovascular disease, hypertension, diabetes and other metabolic complications, especially after menopause [4]. During the fertile period it may cause anovulatory infertility and could be associated with increased prevalence of gestational complications, such as miscarriage, gestational diabetes and preeclampsia [5]. Early diagnosis is therefore crucial by enabling close follow-up and in an attempt to reduce the risk of such complications.

Therefore, the present investigations will be carried out to assess testosterone, LH, FSH & insulin hormones level, HOMA-IR level. Subsequently regular assessing of sugar glucose, lipid profile and differential diagnosis of prolactin (PRL) in clinical biochemistry laboratory is important to monitor & study the effect of these parameters among normal and polycystic ovary Syndrome (PCOS) women & its adverse consequences.

MATERIAL & METHOD

This prospective study was conducted at Department of Biochemistry and Department of

Obstetrics & Gynaecology, Geetanjali Medical College & Hospital, Udaipur, Rajasthan, India from June 2012-Dec 2013. A total of 300 subjects of age group between 18-40 years belonging to both normal & polycystic ovary syndrome will be classified as:

Group-1:150 women with PCOD (Cases) of polycystic ovary disease will be taken.
Group-2:150 normal women will be taken as control for these parameters.

All PCOD women & controls were underwent a complete history and physical examination. Women with PCOD should be interviewed of their name, address, age, socio-economic status, and menstrual history, age of menarche, education level and family history of PCOD. All women were gone through gynaecological ultrasonography to determine their uterus and ovaried condition.

Inclusion Criteria

Women with PCOD are attending outdoor OPD of the hospital, first time diagnosed PCOD, Diagnosed polycystic ovarian syndrome, age ranging from 18-40 years.

Women with PCOD Willing to have physical examinations like Weight, Height, BMI, W/H ratio, Blood Pressure, Hirsutism, Acne, Dark patches, Virilization, Ultra sonography etc.

Polycystic ovary syndrome (PCOS) associated with Diabetes,obesity, Cardiovascular disorders. Irregular menstrual disorder and anovulation, Hirsutism & Acne symptoms.

Exclusion Criteria

Women with diagnosed adrenal hyperplasia, androgen secreting neoplasm, other pituitary (acromegaly) and adrenal disorders like Cushing syndrome, Virilizing adrenal or ovarian neoplasm**,** hyperprolactinemia and other infertility cause, Thyroid hormone related infertility, Women having history of smoking, taking alcohol or tobacco chewing**,** Any other type of gynaecologic complications except related with Polycystic ovary syndrome (PCOS) will be excluded from the study.

Fasting 10 ml venous blood samples were obtained from all participants and collected it in to fluoride and plain vaccutainer. An Uniq ID number was given to each sample to hidden the identity of participants. All samples were centrifugated at 3000 RPM for a period of 10 minutes to obtain a Plasma and serum.

Blood Glucose (FBS) measured by GOD POD method and lipid profile (S. Cholesterol, Triglyceride, HDL, VLDL, LDL) measured by enzymatic colorimetric method from all samples.

Fasting Insulin level estimation was done by enzyme linked immune assay (ELISA) method based electrochemilumnescence and HOMA-IR will be estimated by calculation (fasting sugar×fasting insulin/22.5).

Various Endocrinal Hormones like testosterone, LH, FSH, Insulin and Prolactine was measured by enzyme linked immune assay (ELISA) method based on electrochemilumnescence from all samples.

After assessing all the values, Mean, Standard deviation of all subjects & parameters were analysed. Statistical analysis was performed with SPSS software. Comparison between cases and with control is done by independent student's t test. By using't' values now P value is less than 0.05 (P value < 0.05), it is significant. Comparison of the categorical variables (among category comparison) was done by using Chi-Square test.

RESULTS & DISCUSSION

Infertility, hirsutism, and oligomenorrhea were more common among the subjects with PCOS, but there was a considerable spontaneous restitution of cyclic regularity with time. Women with PCOS were more often hysterectomized and entered menopause later compared with referents. The hormone data show a typical profile for PCOS. Compared with referents women with PCOS showed marked increase in prevalence of central obesity, higher basal serum insulin concentrations, and a higher prevalence of diabetes mellitus and hypertension [65].

Table-1: Age wise distribution of participants

Group	Number(n)	Mean Age(Yr)
Group 1(PCOD)	150	26.30 ± 5.0
Group 2(Control)	150	24.50 ± 4.13

Table-2: Location wise distribution of participants

Location	Group 1(PCOD)	Group 2(Control)
Rural	57(38%)	36(36%)
Urban	93(62%)	64(64%)
Total	150(100%)	150(100%)

Table-3: Comparison of weight between case and control group

Group	Number(n)	Mean wt (kg)
Group 1(PCOD)	150	58.91 ± 5.24
Group 2(Control)	150	48.36 ± 5.8

Table-4: Comparison of waste hip(W/H) ratio between case and control group

Group	Number(n)	Mean W/H ratio
Group 1(PCOD)	150	0.84 ± 0.13
Group 2(Control)	150	0.79 ± 0.05

Table-5: Comparison of BMI between case and control group

Group	Number(n)	Mean BMI
Group 1(PCOD)	150	23.70 ± 2.73
Group 2(Control)	150	18.72 ± 2.41

Table-6: Comparison of Marital status between case and control group

Group	Number(n)	Married	single
Group 1(PCOD)	150	100(66.7%)	50(33.3%)
Group 2(Control)	150	59 (39%)	91(61%)

Table-7: Comparison based on menstrual cycle history between case and control group

			GROUP		Total
			Control	Cases	
M.H./CYCLE	<5	Count	0	11	11
		% within GROUP	0.0%	16.5%	3.66%
	5-9	Count	0	138	138
		% within GROUP	0.0%	92.3%	46%
	>=10	Count	150	1	151
		% within GROUP	100.0%	0.6%	50.33%
Total		Count	150	150	300
		% within GROUP	100.0%	100.0%	100.0%

Table-8: Showing valid Hirsutism status of Case group

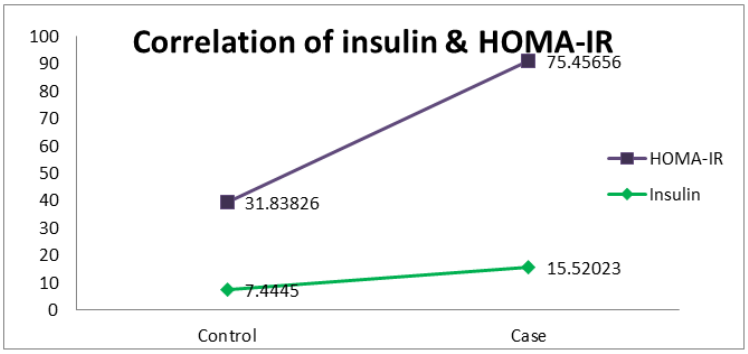
TOTAL COUNTS	HIRSUTISM		NON HIRSUTISM	
	Counts	valid %	Counts	valid %
Cases (150)	80	53%	70	46%

Table-9: Comparison of various biochemical parameters between case and control group

parameter	Group	N	Mean SD	p-value
FBS(mg/dl)	Case	300	106.7 ± 19.4	<0.001
	Control	200	96.12 ± 17.03	
S.choletsterol(mg/dl)	Case	300	189.1 ± 45.47	<0.001
	Control	200	157.49 ± 23.80	
S.Triglyceride(mg/dl)	Case	300	160.69± 36.98	0.025
	Control	200	154.62 ± 23.42	
S.HDL(mg/dl)	Case	300	40.24 ± 6.30	0.006
	Control	200	38.66 ± 6.25	
S.LDL(mg/dl)	Case	300	116.95 ± 42	<0.001
	Control	200	87.98 ± 22.27	
S.VLDL(mg/dl)	Case	300	32.0± 7.32	0.032
	Control	200	30.84 ± 4.72	

Table-10: Comparison of level of various endocrinal hormonal statuses between case and control group

parameter	Group	N	Mean SD	p-value
S.LH(µIU/ml)	Case	150	147.12± 39.13	<0.001
	Control	150	90.86 ± 43.62	
S.FSH(µIU/ml)	Case	150	76.42 ± 45.67	<0.001
	Control	150	22.22 ± 17.11	
S. Testosteron(ng/ml)	Case	150	13.82 ± 6.38	<0.001
	Control	150	2.67 ± 1.48	
S. Insulin(U/ML)	Case	150	15.52 ± 6.29	<0.001
	Control	150	7.44 ± 2.04	
HOMA-IR	Case	150	75.45± 41.15	<0.001
	Control	150	31.83 ± 10.69	



Graph-1: Showing Correlation of insulin & HOMA-IR between case and control group

- Comparison of the fasting basal sugar (FBS) between the two groups shows that FBS is higher (mean value = 106.7 ± 19.49) in Cases group than Controls (mean value = 96.1 ± 17.0 (Table 9).
- Comparison of the Triglyceride (TG) between two groups shows that TG is higher (mean value = 160.6 ± 36.98) than Controls (mean value = 154.6 ± 23.42). Comparison of Total Cholesterol (TC) between two groups shows that TC is higher (mean value = 189.1 ± 45.47) in Cases than Controls (Table 9).
- Comparison of the luteinizing hormone (LH) between two groups shows that LH is higher (mean value 147 ± 39) in Cases than Controls (mean value = 90.8 ± 43.6) (Table 10).
- Comparison of the follicular stimulating hormone (FSH) between two groups shows that FSH is higher (mean value 76.4 ± 45.6) in Cases than Controls (mean value = 22.2 ± 17.1) (Table 10).
- Testosterone is higher (mean value 13 ± 6.3) in Cases than Controls (mean value = 2.67 ± 1.4) (Table 10).
- Insulin hormone is higher (mean value 15.5 ± 6.2) in Cases than Controls (mean value = 7.4 ± 2.0) (Table 10).
- HOMA-IR is higher (mean value 75 ± 41.1) in Cases than Controls (mean value = 31.8 ± 10.6) (Table 10).

Although the exact cause of PCOS is unknown, it is understood to be a multifactorial condition with a genetic component. Approximately 20–40% of first-degree female relatives of women with PCOS go on to develop PCOS themselves, compared to estimated 4–6% prevalence in the general population [6]. Many women with PCOS have female relatives with PCOS, even if it was never diagnosed as with type 2 diabetes, it is likely that numerous genes each make a small contribution to the etiology of PCOS; and recent genome-wide association studies have identified candidate genes [7-9]. Any underlying genetic predisposition is likely complicated by epigenetic and environmental factors such as an unhealthy diet and lack of physical activity.

Clinically, PCOS may manifest as a mild menstrual disorder or a severe disturbance of reproductive and metabolic functions [10]. Most visible signs are caused by excessive production of insulin or androgens. Hirsutism (excess hair growth on the face and body) is present in ~ 70% of women with PCOS and is considered to be a good marker for hyperandrogenism but should be evaluated biochemically.

CONCLUSION

From our study I would like to conclude that a PCOS, as a syndrome, has got multiple components including reproductive, metabolic and hormonal, with long-term health concerns that cross the life span. Moreover, PCOS patients have a higher risk of metabolic and cardiovascular diseases and their related morbidity, if compared to the general population.

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Original Research Article

Coverage evaluation of vaccines using 30×7 cluster survey in rural area of Dhule, Maharashtra

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ABSTRACT

Background: Infectious diseases are a major cause of morbidity and mortality in children. One of the most cost-effective and easy methods for child survival is immunization. The objective of study was to assess the immunization coverage in the rural area of Dhule.
Methods: A community based cross-sectional study was conducted by using WHO 30x7 cluster sampling technique in Primary Health Centre, Kheda catchment villages among children aged 12-23 months on the day of survey. The total sample size was found out to be 210. Identification of clusters was done as per WHO manual on 30×7 cluster survey. Interviews were conducted as per a structured interview format in households with eligible children. Data feeding was done in MS Excel sheet.
Results: Full immunization coverage (FIC) was found out to be 58.6%. Drop-out rate was calculated to be 22.95%. The main reason for not completing the immunization was unaware to return for subsequent vaccine doses.
Conclusions: Coverage evaluation of vaccines was found out to be 58.6%. Drop-out rate is high.

Keywords: Immunization, Cluster sample, Coverage evaluation, Drop-outs

INTRODUCTION

Infectious diseases are a major cause of morbidity and mortality in children.[1] Globally, 3 million children die each year of vaccine preventable diseases. Most of these children reside in developing countries.[2] One of the most cost-effective and easy methods for child survival is immunization.[3] Though all efforts are put in, by the governmental and non-governmental agencies, there are pockets of low coverage areas.[1]

Based on DLHS-4 study conducted by the Government of India and published in 2012-13, in rural area of Maharashtra, the percentage of children aged 12-23 months who were fully immunized was 67%.[4] Further, partially immunized and unimmunized children are more susceptible to childhood infectious diseases.[5]

The present study was planned to evaluate the coverage of vaccines using WHO 30×7 cluster sampling technique in the catchment villages of primary health center, Kheda in district Dhule, Maharashtra. The objective of the study was to assess the immunization coverage in the rural area of Dhule.

METHODS

The Catchment villages of primary health centre, Kheda, Dhule, Maharashtra were the survey setting while, coverage evaluation by WHO 30x7 cluster survey was the survey design for the study.

The standard WHO 30x7 cluster survey method was used to evaluate the immunization coverage.[6] This is a cluster sampling technique. Cluster sampling requires that samples be taken from only a sample of the subgroups. The 30×7 cluster sampling is often referred to as "two-stage sampling". The first stage of the sampling is probability proportionate to size (PPS) and the second stage is random. Children aged 12–23 months on the day of survey were the target age group. Since this survey was conducted to represent the most recent performance of the immunization system, the youngest possible children were chosen. Children aged 12–23 months are usually the most commonly chosen target population. The determination of sample size was done as per the WHO "Immunization coverage cluster survey".[6] For sample size determinations to estimate the coverage, the following were determined, estimated or assumed beforehand:

- Anticipated level of immunization coverage
- Desired precision of the estimate
- The level of statistical confidence of the estimate (confidence level)
- Magnitude of differences of coverage among and within the clusters (design effect)

The total sample size was estimated (the total number of children to be surveyed) using the equation below.

$$n_{min} = DE \times \frac{z^2 1-\alpha/2 \times p \times (1-p)}{d^2}$$

The minimum total sample worked out to 192. Since we were going to use 30 clusters, the sample size per cluster worked out to 192 ÷ 30 = 6.2. Rounded off, number of children to be surveyed in each of the 30 clusters was 7. Thus 210 children was the total sample size for 30 cluster survey. The study was conducted from 2nd November 2015 to 14th November 2015.

A cluster is a collection of households with identifiable geographical boundaries. The clusters used for this immunization coverage assessment were villages under PHC Nakane. Based on the projected 2016 village wise population, cumulative populations, sampling interval and selection of random number, all the 30 clusters were identified. The details of cluster selection were done as per WHO 30X7 cluster survey.[6] Survey tools and data entry tools were developed. Inputs and comments were taken. Pre-testing of the survey tools was done on the day of the field coordinators' orientation, before the field survey. Pre-tested in the field was done by same field coordinators who conducted the field activities of the survey under supervision. No major concerns came up regarding the survey tools during the pre-testing.

MS Excel based data management tools were developed. The pre-testing was done by entering data collected during pre-testing of survey tools.

The field implementation for the survey was conducted as per a detailed plan devised beforehand. Establishing of households of the selected clusters was not going to be possible. Therefore the core team decided that in every cluster, the geographical center of the cluster would be visited. From there, the investigators (FCs and Supervisor) would move in a randomly chosen direction. The first house would be the house corresponding to a random number chosen beforehand. Both, the direction in which the investigator would move and the random number for choosing the first house, were generated using the computer for each cluster.

After visiting the first household the second household to be visited was the one that was nearest to the first. The nearest household is defined as the household reachable in the shortest time on foot from the household just visited. The nearest household need not be in direct line of vision or on the same side of the street or road. If there are two or more households equally near to the one just visited, select the one on the immediate right as one stands in the doorway of the house looking out. Interviews were conducted as per a structured interview format in households with eligible children. Each investigator was directly supervised by a supervisor during each interview. The child was considered as fully immunized if he/she has received a dose of BCG, 3 doses of DPT and OPV and a dose of Measles vaccine. The child was considered as unimmunized if he/she did not receive any of these vaccines and partially immunized if some vaccine doses were given.

Data entry was done internally. A strict 3-stage quality check mechanism instituted –

- Every format submitted by FCs was scrutinized by survey focal point; most errors and omissions could be corrected at submission point.
- In-built checks and balances were introduced in the data entry tool at the time of development.
- 10% random check of entered data against actual forms.

RESULTS

Table 1 indicates the distribution of 30 clusters among all the 12 villages under PHC, Kheda catchment areas. The sampling interval was calculated out to be 1282 and random number was 1117. The total population covered by the PHC was 38465. Bigger villages namely; Morane, Chaugao and Kheda had 4 or more clusters.

Out of the 210 children, 51% were male, 43.8% were the 1st child, 73.3% had institutional delivery, only 42% had their immunization cards available and parents were mostly literate. Further, 77% resided in a joint family (Table 2).

Table 1: 30×7 clusters- visiting details.

	Subcentre	Village (cluster)	Type	Population	Cumulative population	Cluster no.	Direction from centre of cluster	Number of 1st house from centre of cluster in this direction
PHC Kheda	Morane	Morane	Rural	6932	6932	1,2,3,4,5	North	13
	Morane	Nakane	Rural	3047	9979	6,7	East	12
	Morane	Mahindale –Haranmal	Rural	2859	12838	8,9,10	West	11
	Udane	Udane	Rural	3625	16463	11,12	North	15
	Udane	Var	Rural	3457	19920	13,14,15	South	23
	Udane	Kundane	Rural	2798	22718	16,17	East	27
	Chaugao	Chaugao	Rural	4427	27145	18,19,20,21	West	3
	Chaugao	Gotane	Rural	3213	30358	22,23	South	2
	Chaugao	Hingane	Rural	402	30760	24	North	7
	Kheda	Kheda	Rural	5817	36577	25,26,27,28	West	57
	Kheda	Sutrepada	Rural	747	37324	29	East	8
	Kheda	Sanjori	Rural	1141	38465	30	North	14

Sampling interval= 1282; Random number: 1117.

Table 2: Profile of sampled children.

Profile	Children	
	Number	**Percentage (%)**
Total	210	100
Residence		
Rural	210	100
Sex		
Male	107	51
Female	103	49
Birth order		
1	92	43.8
2	80	38.1
3	28	13.3
4	7	3.3
5	3	1.4
Place of delivery		
Institutional	154	73.3
Home	56	26.7
Availability of immunization card		
Available	88	42
Not available	122	58
Social categories		
SC	25	11.9
ST	66	31.4
OBC	98	46.6
Others	21	10
Educational status of mother		
Illiterate	68	32.3
Some middle school	17	8
Some high school	96	45.7
Some junior college	23	11
Graduate	6	2.9

Continued.

Profile	Children	
	Number	Percentage (%)
Educational status of father		
Illiterate	38	18
Some middle school	20	9.5
Some high school	89	42.4
Some junior college	46	21.9
Graduate	17	8.1
Type of family		
Joint	162	77.1
Nuclear	48	22.9

Table 3: Distribution of children as per the immunization status.

Variables	Fully immunized	Partially immunized	Un-immunized
Total	58.6	37.1	4.3
Sex			
Male	63.5	31.8	4.7
Female	53.4	42.7	3.9
Birth order			
1	60.9	38	1.1
2	60	36.3	3.7
3	57.1	35.7	7.1
≥4	30	40	30
Place of delivery			
Institutional	69.5	29.9	0.6
Home	28.6	57.1	14.3
Availability of immunization card			
Available	78.4	21.6	0
Not available	44.3	48.3	7.4
Social categories			
SC	56	44	0
ST	22.7	65.2	12.1
OBC	77.5	21.4	1
Others	85.7	14.3	0
Inter-personal communication			
IPC-2 messages given	64.8	35.2	0
IPC-1 message given	32	68	0
Educational status of mother			
Literate	70.4	29.6	0
Illiterate	33.8	52.9	13.2
Type of family			
Joint	59.9	36.4	3.7
Nuclear	54.2	39.6	6.2

The percentage of children who were fully immunized, partially immunized and unimmunized was found out to be 58.6%, 37.1% and 4.3% respectively. The coverage evaluation among various variables is also given in the Table 3.

The Table 4 shows distribution of availability and non-availability of immunization cards based on the sex of the child. Out of the 88 children having cards available, 53.4% were male.

Out of the 113 children not having cards available, 48.7% were male. 9 children had no card as they were unimmunized .

BCG coverage was 93.3%. Measles coverage was 71.9%. Drop-out rate (BCG to Measles) was 22.95% (Table 5).

Unaware of need for returning for subsequent doses was the reason among 60.3% of children who were partially immunized (Table 6).

Table 4: Distribution based on availability or non-availability of immunization card.

Immunization card	Available	Not available	No card
	N (%)	N (%)	N (%)
Total	88 (41.9)	113 (53.8)	9 (4.3)
Sex			
Male	47 (53.4)	55 (48.7)	5 (55.6)
Female	41 (46.6)	58 (51.3)	4 (44.4)

Table 5: Coverage of vaccines among children.

Vaccine	Percentage (%)
BCG	93.3
DPT1	94.3
DPT2	89.5
DPT3	69.5
OPV1	94.3
OPV2	89.5
OPV3	69.5
Measles	71.9
Vitamin A	67.1
Immunization status	
Fully immunized	58.6
Partially immunized	37.1
Unimmunized	4.3

Table 6: Reasons for not completing immunization/non-immunization.

Reasons for not completing immunization	Number	%
Unaware of need for returning for subsequent doses.	47	60.3
Fear of adverse effects	11	14.1
Unaware of need for immunization	9	11.5
Mother too busy	9	11.5
Vaccine not available	2	2.3
Reasons for non-immunization		
Unaware of need for immunization	6	66.7
Fear of adverse effects	3	33.3

DISCUSSION

The WHO 30×7 cluster sampling technique for evaluating vaccine coverage among children has been found to be very useful, convenient and operationally feasible by the investigators and public health administrators in developing countries. This technique allows a small number of the target population to be sampled while providing statistically valid data that can be extrapolated to the whole population.

In the current community based survey in the rural area of Dhule, Maharashtra, the percentage of children who were fully immunized, partially immunized and unimmunized was found out to be 58.6%, 37.1% and 4.3% respectively.

The District Level Health Survey-4 (DLHS-4) study conducted by the Government of India and published in 2012-13 showed that in rural area of Maharashtra the percentage of children who were fully immunized, partially immunized and unimmunized was found out to be 66.7%, 31.5% and 1.8% respectively [4]. Our findings are lower than the state average for fully immunized, partially immunized and unimmunized children. Our findings also revealed that the percentage of children belonging to ST (schedule tribe) who were fully immunized, partially immunized and unimmunized was 22.7%, 65.2% and 12.1% respectively which is strikingly much lower than the other population. Additionally, Dhule has a larger proportion of ST population. We would like to suggest it to be one of the possible explanations of lower coverage of vaccines in our study than the state average.

To the best of our knowledge and extensive review of literature we did not find any study on coverage evaluation of vaccines in Dhule, Maharashtra. So we were not able to compare our findings with other studies of the region. However, a similar study conducted by Jatti et al in Miraj, Maharashtra revealed that 60.5% children were fully immunized.[2] Negligence of parents towards immunization was the main reason for incomplete immunization in their study. Our findings show that unaware for the need of returning for subsequent doses was the main reason for not completing immunization in 60% of children.

A study conducted by Gupta et al in rural area of Pune, Maharashtra revealed that the fully immunized children were 83.6%.[1] While, Malkar et al in a study in rural area of Beed, Maharashtra concluded that 78.5% children were fully immunized.[7] Goyal et al in a study in rural area of Haryana showed the fully immunized and partially immunized percentage to be 73.15% and 23.85% respectively.[3] However, Pandey et al in their study found that fully immunized and partially immunized to be 76.19% and 22.86% respectively.[5]

BCG coverage in our study was found out to be 93.3%. Similar findings are reported by DLHS-4 study for Dhule and Maharashtra as well.[4] Jatti et al and Pandey et al in their studies also reported the BCG coverage to be around 93%.[2] BCG to Measles drop-out rate was calculated to be 22.95%. Similar higher rate of drop-out was reported by Jatti et al.[2]

Higher drop –out rate indicates the failure of the parents to bring their children for subsequent vaccine doses. Our study highlights that the parents/mother were unaware to return for subsequent vaccine doses as the main reason for not completing the immunization was. It emphasizes the importance of health workers providing vaccination

services to inform and reinforce the mother/parents to return for subsequent vaccine doses.

Our study also shows an association between sex of child, birth order, place of delivery, availability of vaccine card, social category of child, educational status of mother and immunization status of child. Higher rate of FIC (full immunization coverage) was found in male child, 1st birth order child, child born in an institution, mother having vaccine card, social category except SC and ST and literate mother.

CONCLUSION

Coverage evaluation of vaccines was found out to be 58.6%. Drop-out rate is high. Unaware to return for subsequent doses of vaccines was the main reason for high drop-out. Schedule tribe seems to be socially excluded among all the social categories as far as immunization coverage is concerned. Further, male child, 1st birth order, child born in an institution, mother having vaccine card and literate mother improved immunization coverage. Though, it requires further testing.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Research Article

A cross-sectional study on the knowledge and practice of travel vaccination and malaria prophylaxis for international travel among resident doctors of Ahmedabad city, Gujarat

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ABSTRACT

Background: Travelers play a significant role in the spread of infectious diseases across international borders, through their travel patterns and behaviors. Travel may be the only risk factor for infectious diseases that are well controlled in the travelers' country of residence, particularly vaccine-preventable diseases. **Objectives:** The aim of this study is to assess the knowledge and practice of travel vaccination and malaria prophylaxis among resident doctors of BJ Medical College and Civil Hospital, Ahmedabad. **Materials and Methods:** This was a cross-sectional study conducted at Civil Hospital and BJ Medical College, Ahmedabad. The study was conducted from July 2017 to October 2017. A pilot study was conducted among 20 resident doctors, and the prevalence of knowledge of travel vaccination was found to be 65%. Using the formula $4pq/L^2$, data were collected from 100 resident doctors. Data were collected using a semi-structured questionnaire, and data analysis was performed using Microsoft Excel 2013 and EpiInfo 7. For statistical analysis, Chi-square test was applied. Ethical consent was taken from all respondents. **Results:** 86% of the resident doctors were having knowledge about travel vaccination, and 79% were knowing about the requirement of malaria prophylaxis given to travelers. The travel vaccine knowledge was 100% among the persons above 30 years of age, and it was 86% in the younger age group (20–25 years). Country-wise knowledge about travel vaccination was more for developing countries than developed countries. Only 8.3% gave the history of taking immunization for international travel. Reasons for not taking immunization were not required for country of travel followed by non-awareness. **Conclusion:** The knowledge of travel vaccine and malaria prophylaxis was more among the 30+ age group followed by 20–25 age groups, and the knowledge of both was more among males. The practice of travel vaccination was found to be poor.

KEY WORDS: Travel Vaccination; Malaria Prophylaxis; Resident Doctors

INTRODUCTION

Travelers often play an important role in the spread of infectious diseases across borders, through their travel plans, behaviors, and patterns. Traveling might be the only risk factor for the transmission of infectious diseases that are well controlled in a certain country, especially vaccine-preventable diseases. The role of vaccination among travelers is a significant component for the prevention of travel associated infectious diseases.[1,2]

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Health risks associated with travel need to be balanced against the positive opportunities offered by inter-regional and cross-border travel.[3] The main goal of travel health and associated fields is to protect travelers from disease, accidents, and death. International travel has seen a dramatic rise during

recent times, and there has been an increase in diseases and associated public health problems. Each year, around 80 million travelers from developed countries visit developing countries where the epidemiological and sanitary conditions are different from their country of residence.[4] Thus, travelers increase the risk of exposure to travel associated health problems which include infectious diseases that may be imported back to their home country.[5]

Immunizations taken before traveling contribute to the risk reduction of specific diseases for the traveler as well as the reduction in risk of international spread of diseases. Agent, host, and environmental factors determine the risk of acquiring a disease when traveling. Most significant factors are the place that has to be visited, travel duration, and reason for travel. Among host factors, the traveler's health and his/her behavior overseas have to be considered. As a result, an agent–host–environment-based assessment of the travel plan should be done when considering which immunizations are to be taken by the traveler.[6]

India has become a popular destination for tourists in South Asia. Recent economic opportunities have resulted in a remarkable increase of business-related travel. People traveling to India can be broadly divided into the business traveler, the young economical backpacker, the medical volunteer, the holiday tourist, and the immigrant or non-resident Indian visiting family and friends. Medical graduates in India are showing interest in international travel to different countries for higher specialist courses, career growth, and better opportunities. People traveling to India are at an intermediate risk for malaria, and recent reports in the rise of chloroquine-resistant *Plasmodium falciparum* malaria in various parts of India are causing a rise in concern. Furthermore, different international travel advisory bodies vary on their opinion for malaria prophylactic regimens to be followed when traveling to India.[7-9]

Improvement in the knowledge and health education of disease transmission among travelers, following recommendations on sanitation, food, and water hygiene, avoiding arthropod bites with physical barrier methods and insect repellents, chemical prophylaxis against malaria, and taking required vaccinations are all known to reduce the risk of travel-associated diseases.[10] Since a considerable amount of travelers are at risk for having a travel-related illness or injury during their outings, there is a need for travelers to seek suitable pre-travel health education and immunizations to reduce the risk of any ailment while away from their country of residence.[11]

Objectives

The objective of this study is to assess the knowledge and practice of travel vaccination and malaria prophylaxis among resident doctors of BJ Medical College and Civil Hospital, Ahmedabad.

MATERIALS AND METHODS

A cross-sectional study was conducted at BJ Medical College and Civil Hospital, Ahmedabad. The study was conducted from July 2017 to October 2017.

A pilot study was conducted among 20 resident doctors, and the prevalence of knowledge of travel vaccination was found to be 65%. Using the formula $4pq/L^2$, data were collected from 100 resident doctors of Civil Hospital and BJ Medical College, Ahmedabad.

Data were collected using a semi-structured questionnaire, and data analysis was performed with Microsoft Excel 2013 and Epi Info 7. For statistical analysis, Chi-square test was applied. Ethical consent was taken from all respondents.

RESULTS

Figure 1 shows that 86% of the respondents had knowledge about travel vaccination while 79% of the respondents had knowledge about malaria prophylaxis.

As per the practice of travel vaccination, of the 24% who traveled, only 2 (8.3%) gave the history of taking immunization. Reasons for not taking immunization were not required for country of travel followed by non-awareness.

Table 1 shows that knowledge about travel vaccination was more in the 30+ age group (100.0%) followed by

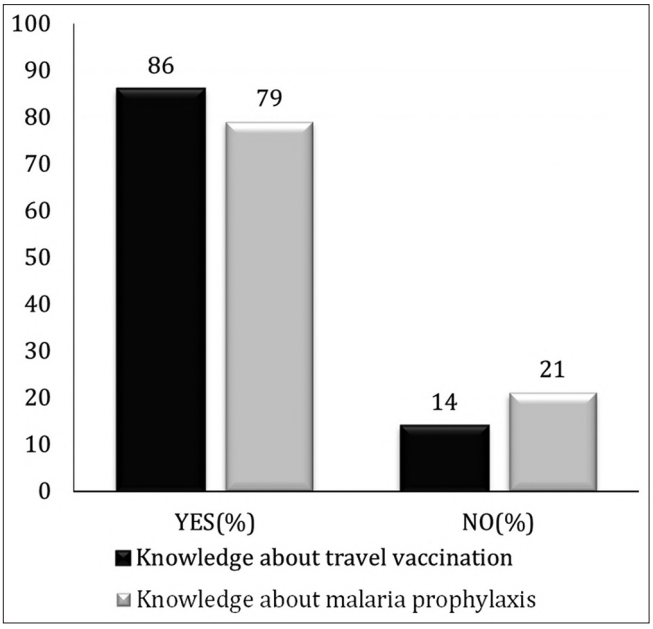

Figure 1: Overall knowledge about travel vaccination and malaria prophylaxis

Table 1: Relation of knowledge about travel vaccination with sociodemographic variables

Parameters	Respondents			
	Total	Having knowledge *n* (%)	Not having knowledge *n* (%)	*P* value
Age Group				
20–25	51	44 (86.3)	7 (13.7)	*P*=0.76
26–30	41	34 (82.9)	7 (17.1)	
30+	8	8 (100.0)	0 (0)	
Sex				
Male	51	46 (90.2)	5 (9.8)	*P*=0.34
Female	49	40 (81.6)	9 (18.4)	
Marital status				
Unmarried	72	61 (84.7)	11 (15.3)	*P*=0.79
Married	28	25 (89.3)	3 (10.7)	
Qualification				
1st-year resident	49	42 (85.7)	7 (14.3)	*P*=0.99
2nd-year resident	25	21 (84.0)	4 (16.0)	
3rd-year resident	26	23 (88.5)	3 (11.5)	

Table 2: Relation of knowledge about malaria prophylaxis with sociodemographic variables

Parameters	Respondents			
	Total	Having knowledge *n* (%)	Not having knowledge *n* (%)	*P* value
Age group				
20–25	51	44 (86.3)	7 (13.7)	*P*=0.18
26–30	41	28 (68.3)	13 (31.7)	
30+	8	7 (87.5)	1 (12.5)	
Sex				
Male	51	43 (84.3)	8 (15.7)	*P*=0.18
Female	49	36 (73.5)	13 (26.5)	
Marital status				
Unmarried	72	57 (79.2)	15 (20.8)	*P*=0.95
Married	28	22 (78.6)	6 (21.4)	
Qualification				
1st-year resident	49	40 (81.6)	9 (18.4)	*P*=0.47
2nd-year resident	25	17 (68.0)	8 (32.0)	
3rd-year resident	26	22 (84.6)	4 (15.4)	

the 20–25 years age group (86.3%) while those in the 26–30 years age group (82.9%) had the least knowledge. Knowledge was more in males (90.2%) compared to females (81.6%). Married respondents showed more knowledge (89.3%) compared to single respondents (84.7%). Knowledge about travel vaccination was highest among 3rd-year resident doctors (88.5%), followed by 1st-year residents (85.7%) and then 2nd-year Residents (84.0%).

Table 3: Country-wise knowledge about travel vaccination was more for developing countries than developed countries

Region	Percentage
USA	6
Europe	5
Australia	16
Africa	49
Southeast Asia	18
Arabian countries	13

However, no statistical significance was found between the sociodemographic variables with knowledge about travel vaccination ($P > 0.05$).

Table 2 shows that knowledge about malaria prophylaxis was more in the 30+ age group (87.5%) followed by the 20–25 years age group (86.3%) while those in the 26–30 years age group (68.3%) had the least knowledge. Knowledge was more in males (84.3%) compared to females (73.5%). Single respondents showed more knowledge (79.2%) compared to married respondents (78.6%). Knowledge about travel vaccination was highest among 3rd-year resident doctors (84.6%), followed by 1st-year residents (81.6%) and then 2nd-year residents (68.0%). However, no statistical significance was found between the sociodemographic variables with knowledge about malaria prophylaxis ($P > 0.05$).

Table 3 shows that country-wise knowledge about travel vaccination was more for developing countries compared to developed countries with that for Africa being the highest (49%) and that of Europe being the least (5%).

Figure 2 shows that 71% of the respondents were aware about the malaria chemoprophylaxis drug regimen compared to 29% which were unaware.

DISCUSSION

In our study, 86% of the respondents had knowledge about travel vaccination while 79% of the respondents had knowledge about malaria prophylaxis. In a similar study conducted in Nigeria, the knowledge about travel vaccination was found to be 96.3%.[1]

Most respondents were between 20 and 25 years of age, while in other similar studies conducted in Nigeria, Qatar, and America, majority of the respondents were of a higher age.[1,5,12] This study has an almost equal proportion of male and female respondents which is similar to an American study.[12] On the other hand, the number of male respondents were predominant in studies conducted in Nigeria and Australia, while the number of females were more in a Qatar

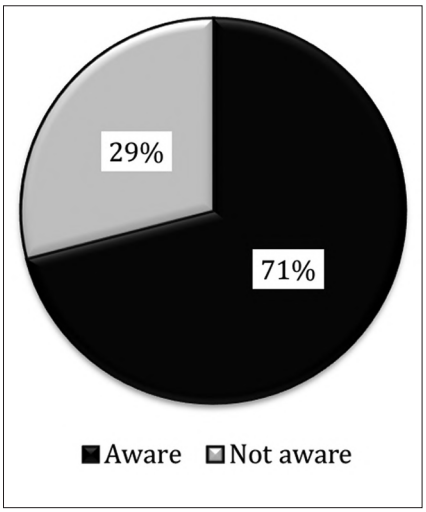

Figure 2: Awareness about malaria chemoprophylaxis drug regimen

study.[1,5,13] Most of the respondents were single which was contrary to a study conducted in Nigeria where most of the respondents were married.[1]

The practice of travel vaccination in this study was found to be very low which was similar to the findings of an Australian and Bangkok study but different from Greek and Nigerian studies where the practice of travel vaccination was found to be high.[1,2,13,14] Reasons of low practice in this study were not required for country of vaccination followed by non-awareness, while in other studies, the reasons were paucity of information on travel vaccination, distressing protocols and requirement for the vaccination, cost of vaccination as well as poor monitoring system for ensuring travel vaccination at the entry and exit points of the countries, unaware of being at risk, low knowledge of vaccination being important for traveling, cost of the vaccination, and side effects.[1,10,14]

The knowledge about travel vaccination and malaria prophylaxis was found to be good in this study which was similar to the results of other studies.[1,5,10,12-15]

Strength

The relation of sociodemographic variables with knowledge about travel vaccination and malaria prophylaxis is compared which has not been done in similar studies.

Limitation

The relation between knowledge about travel vaccination and malaria prophylaxis with sociodemographic variables was found to be insignificant, so the study should be carried out by taking a larger sample.

Recommendations

Doctors need to be updated on the latest norms of travel vaccination and malaria prophylaxis with special emphasis to be given on the importance of the practice of vaccination during international travel. This may be added to the academic curriculum because many doctors are interested in international career prospects.

CONCLUSION

It seems that the knowledge of travel vaccine and malaria prophylaxis was more among the 30+ age group followed by 20–25 age groups, and the knowledge of both was more among males. The married doctors showed more knowledge about travel vaccines, but the knowledge of malaria prophylaxis was more among single doctors. 3rd-year residents had more knowledge about both. The above groups may be more aware as they may be contemplating foreign travel in the near future. The practice of travel vaccination was found to be poor. Overall knowledge of travel vaccination and malaria prophylaxis was good.

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An Epidemiological Study to Assess Prevalence and Risk factors Associated with Diabetes Among Adolescents in Urban Areas of Udaipur

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Abstract:

Introduction: Adolescents constitute 20% of world's total population. Adolescents have become quite vulnerable to various non-communicable diseases (NCDs) like hypertension and diabetes mellitus, especially due to the tremendous changes in their lifestyle over the last few decades. The age of onset of Type 2 diabetes in India has been shifting towards ever younger people. Among Indians in their late teens [15-19 years], Type 2 diabetes already manifests itself more often than Type 1 diabetes does. **Objective:** To study prevalence and risk factors for Type 2 diabetes and pre diabetes among male and female adolescents in Udaipur city. **Method:** It was a Community based cross sectional study conducted in three urban areas of Udaipur for 6 months. A total of 1005 adolescents were included in the study. A pretested and predesigned questionnaire was used. **Results**: Prevalence of diabetes was 2.9% in males and 4.4% in females adolescents. Prevalence of smoking, alcoholism, non-vegetarian diet and hypertension was higher among males. **Conclusion:** Diabetes type 2 is a growing problem among adolescents. We need active involvement of health care workers for educating adolescents about risk factors for diabetes.

Key words: Adolescents, Diabetes, Pre-Diabetes.

Introduction:

According to the WHO, adolescence is defined as the period between 10 to 19 years, the second decade of life. This is a period of rapid growth and development for adolescents' bodies, minds and social relationships.[1] Adolescence is a process whereby an individual makes the gradual transition from childhood to adulthood and is a critical period of development, second only to the early childhood years. Adolescents constitute 20% of world's total population.[2]

According to 2011 Census of India, there are 253.2 million adolescents constituting 20.9% of the total population.[3] This number is ever increasing making it the largest generation to undergo transition from children to adults in the near future, in turn making India the youngest country of the world.

Adolescents have become quite vulnerable to various non-communicable diseases (NCDs) like hypertension and diabetes mellitus, especially due to the tremendous changes in their lifestyle over the last few decades. Over half of NCD related deaths are associated with behaviours that begin or are reinforced during adolescence, including tobacco and alcohol use, poor eating habits, and lack of exercise, compounded by the presence of obesity.[4]

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Diabetes Mellitus (DM) is a chronic disorder characterized by raised blood sugar levels that occur when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces.[5] The International Diabetes Federation has estimated that about 382 million people all over the world suffer from diabetes. If these trends continue, by 2035, about 592 million people, or every tenth person, will have diabetes.[6] In India, the overall diabetes prevalence is 8%. Prevalence is only 0.7% for non-obese, physically active, rural Indians. It reaches 11% for obese, sedentary, urban Indians.[7] There are about 1 million juvenile diabetics in India, and every year 12000 diabetic children [2-14 years] die of the disease.[8]

Global and national estimates for the prevalence of diabetes in the adolescent age group are unavailable till date. In the United States, May et al found out that the combined prevalence of prediabetes & diabetes in American adolescents was 23% in 2007-2008.[9] The largest study in India was conducted by Singh et al among 10,843 adolescents in Chandigarh during the year 2007, and they detected a prevalence of diabetes of 4.2%.[10]

Although Type 1 diabetes is the most common form in children, Type 2 diabetes poses a major health problem globally, especially in the developing world. The age of onset of Type 2 diabetes in India has been shifting towards ever younger people. Among Indians in their late teens [15-19 years], Type 2 diabetes already manifests itself more often than Type 1 diabetes does.[11] Type 2 diabetes in children and adolescents is probably under-diagnosed because it can exist without symptoms. The clinical manifestations of T2DM are preceded by an asymptomatic prodromal period called 'prediabetes'.

Against the above background, the present study was carried out with the objective to study the prevalence of diabetes and associated risk factors among individuals in the age group 10-19 years in urban areas of Udaipur, Rajasthan.

Method:

Study Design : Community based cross sectional study.

Study Area : The study was conducted in three urban areas of Udaipur – Bhuwana [population 17660], Fatehpura [2 lakhs population] and Siphon [10000 population]. The three areas were selected as they are catered by the Department of Community Medicine of the medical college.

Study Period : Study was conducted for a period of 6 months from July 2019 to December 2019.

Study Subjects : Males and females of 10-19 years residing in these areas

Sample Size : At 95% confidence level and taking the prevalence of diabetes and prediabetes to be 9.5% with a relative error of 20%, the sample size came out to be 934 using the formula

$\mathbf{n = Z_\alpha^2\, p\, q\, /\, L^2}$,

Where n = sample size

Zα = 1.96 value of the standard normal variate corresponding to level of significance alpha 5 %

p = prevalence of diabetes[12], 9.5%

q = 100 – p, 90.5%

L = precision, 20%

Accounting for a non-response rate of 20%, a total of 1027 subjects were to be included. Out of these, 22 did not give consent to be part of the study, hence 1005 adolescents were included in the study. By simple random sampling, subjects were selected from the three areas. Proportionate probability sampling was followed.

Inclusion Criteria :

1. All males and females of 10-19 years after getting consent from them and informed written consent from their parents if they are <18 years, or after getting consent from them if they are 18 years or older.
2. The person should be a resident of the area mentioned above for a minimum of 6 months.

Study Instruments : A predesigned, pretested, semi-structured questionnaire containing items on (a) identification data i.e. age, gender, religion, educational status, area of residence, socioeconomic status of the person, (b) risk factor for diabetes i.e. obesity, sedentary lifestyle, smoking, alcohol, family history, dietary habits, history of consanguinity, etc. The questionnaire was pilot tested among 20 adolescents in the village of Delwara in June 2019, and questions were later modified to ensure that the subjects would have no difficulty in understanding and answering them. Glucometer, digital sphygmomanometer, measuring tape and weighing scale were used in the study. Following criteria were used.

Hypertension: The hypertension status of the study participants was assessed by using standard criteria formulated by the American Health Association (AHA) -2017.[13]

Diabetes criteria: Blood sugar determination (fasting) was done by glucometer by glucose oxidase

Table 1: Socio-demographic profile of study subjects

Characteristics	Total [n=1005]	
	Males [n=527] n (%)	Females [n=478] n (%)
Age (years)		
10-14	271 (51.4)	236 (49.4)
15-19	256 (48.6)	242 (50.6)
Religion		
Hindu	179 (33.9)	154 (32.2)
Muslim	326 (61.9)	306 (64)
Sikh	17 (3.2)	10 (2.1)
Christian	5 (1)	8 (1.7)
Education		
Illiterate	0	0
Primary/ Just literate	27 (5.1)	43 (8.9)
Middle School	198 (37.6)	182 (38.2)
High School	227 (43.1)	219 (45.8)
Intermediate/Diploma	75 (14.2)	34 (7.1)
Occupation		
Student	403 (76.5)	353 (73.9)
School dropout	22 (4.2)	80 (16.7)
Unskilled worker*	78 (14.8)	27 (5.7)
Semi-skilled worker**	24 (4.6)	18 (3.8)
Marital Status		
Married	12 (2.3)	56 (11.7)
Unmarried	515 (97.7)	422 (88.3)

*Unskilled worker: Person who are doing work which requires neither education nor specialized training.

**Semi-skilled worker: person who are doing work which requires some training to know their routine jobs efficiently.

method as per WHO and were interpreted. In the case of fasting plasma glucose (FPG) > 126mg /dl, a second determination was performed.[14]

Obesity criteria: Body mass index of the person was calculated using height and weight by applying the formula weight (in kgs) divided by square of height (in m^2).The cutoff criteria are based on the WHO BMI-for-age growth charts. Adolescents with BMI values at or above the 95th percentile of the sex-specific BMI growth charts are classified as obese.[15]

Ethical clearance and analysis: Institutional ethical clearance was taken. [No. AIMS/IEC/2019/022]. Statistical analysis was done using SPSS version 21.0.

Results:

Table 1 shows Majority of the subjects, 403 (76.5%) males and 353 (73.9%) females, were students. It was found that 22 (4.2%) males and 80 (16.7%) females were school dropouts and not doing anything. Out of 527 males, 24 (4.55%) and 78 (14.8%) were semi-skilled and unskilled workers respectively. It was also observed that, 12 (2.3%) males and 56 (11.7%) females were married, thereby highlighting the high prevalence of teenage marriage among adolescent girls. [Table 1]

Table 2 highlights that the prevalence of diabetes was 2.9% in males and 4.4% in females but the difference was not statistically significant (χ^2=3.66, p value 0.16)

Table 3 shows prevalence of smoking, alcoholism, non-vegetarian diet and hypertension was higher among males as compared to females. However, the difference was significant only for smoking (χ2=13.93, p value<0.001), alcoholism (χ2=36.76, p value<0.001) and non-vegetarian diet (χ2=4.51, p value 0.03).

Table 2 : Prevalence of diabetes among the study subjects

Classification of Diabetes	Males [n= 527] n (%)	Females [n=478] n (%)	Total [n=1005] n (%)	χ^2 value, d.f, p value
Normal	485 (92)	423 (88.5)	908 (90.4)	3.66, 2, 0.16
Prediabetes	27 (5.1)	34 (7.1)	61 (6.1)	
Diabetes	15 (2.9)	21 (4.4)	36 (3.6)	

Table 3 : Prevalence of risk factors of diabetes according to sex among the study subjects

Risk Factors	Males (N=527) n (%)	Females (N=478) n (%)	Total [n=1005] n (%)	χ^2 value, p value
Family history of diabetes	66 (12.5)	78 (16.3)	134 (13.3)	2.94,0.08
Obesity	33 (6.3)	69 (14.4)	102 (10.2)	18.36,0.001**
Sedentary lifestyle#	78 (14.8)	107 (22.4)	185 (18.4)	9.6,0.002*
Smoking	41 (7.8)	12 (2.5)	53 (5.3)	13.93,0.001**
Alcoholism	57 (10.8)	7 (1.5)	64 (6.4)	36.76,0.001**
Non-vegetarian diet	381 (72.3)	316 (66.1)	697 (69.4)	4.51,0.03*
Hypertension	38 (7.2)	27 (5.7)	65 (6.5)	1.01,0.32

*p value <0.05 ** p value <0.001 # Sedentary: type of lifestyle with little or no physical activity.

Table 4 : Multivariate Logistic regression analysis of different risk factors for diabetes

Risk factors	Odds ratio(95% CI)	p value
Age group		
10-14 years	Reference	-
15-19 years	2.03(1.25-4.03)	0.02
Socio economic class		
Upper/ Upper middle	Reference	-
Lower middle	1.09(0.61-1.95)	0.76
Upper lower/ Lower	1.64(0.85-3.19)	0.13
BMI		
Non obese	Reference	-
Obese	1.86(1.05-3.37)	0.05
Family history of diabetes		
No	Reference	-
Yes	2.16(1.27-3.66)	0.01
Physical activity		
Moderate activity	Reference	-
Sedentary lifestyle	1.90(0.98-3.69)	0.05
Currently smoking		
No	Reference	-
Yes	0.87(0.31-1.67)	0.46
Diet		
Vegetarian	Reference	-
Non-vegetarian	1.93(0.98-2.86)	0.06
Hypertension		
Absent	Reference	-
Present	1.79(1.11-2.45)	0.050

Table 4 highlights that subjects of 15-19 years age group experienced 2.03 times greater risk of getting diabetes as compared to subjects in the age group of 10-14 years (p value 0.02). Subjects who were obese experienced 1.86 times greater risk in comparison to those who were not obese (p value 0.05). Subjects with a positive family history of diabetes experienced 2.16 times greater risk of getting diabetes (p value 0.01). Subjects who led a sedentary lifestyle experienced 1.90 times greater risk of getting diabetes as compared to those engaged in moderate activity (p value 0.05). Subjects who were hypertensive experienced 1.79 times greater risk as compared to those who were not hypertensive (0.05).

Discussion:

The prevalence of diabetes in the present study was observed to be 3.6% among study subjects (2.9% in males and 4.4% in females) while the prevalence of prediabetes was observed to be 6.1% among the study subjects (5.1% in males and 7.1%

in females). Hence, the combined prevalence of diabetes and prediabetes among the study subjects was observed to be 9.7%. This was observed to be higher than that in the previous studies conducted by Ramachandran et al[16] among adolescents [12-19 years] in Chennai in 2007 (combined prediabetes and diabetes prevalence of 5.8%), by Singh et al[10] among 10,843 schoolgoing adolescents in Chandigarh in 2007 (4.2% prevalence of diabetes and 1.6% prevalence of prediabetes), by Balagopal[17] among adolescent youth [10-17 years] in rural areas of Tamil Nadu in 2008 (combined prevalence of 5.1%), and by Reddy[18] among corporate schoolchildren [7-14 years] in Nellore, Andhra Pradesh in 2011 (combined prediabetes and diabetes prevalence of 9.5%) The present study showed an increasing prevalence of diabetes with increasing age with 2.2% prevalence of diabetes in the age group of 10-14 years, and 5% prevalence of diabetes in the age group of 15-19 years (p value=0.015). The increasing prevalence of diabetes in the present study could be attributed to urbanization, sedentary lifestyle, physical inactivity and presence of addictions like tobacco use and alcohol consumption.

The present study showed a significantly higher prevalence in subjects with a positive family history of diabetes (11.2%) as compared to those without positive family history of diabetes (2.4%, χ^2= 25.94, p value<0.001). In a multisite case-control study done in North India by Vikram et al[19] in 2006, it was found that a significantly higher number of cases had a history of type 2 diabetes in first-degree relatives as compared with controls [82.3% vs 23.2%, p value<0.001]. Anjana RM et al[20], in a community-based study on adolescents [12-19 years] in Chennai, detected that blood sugar levels were significantly higher in the group with two diabetic patients as compared to the groups with one diabetic parent, and no diabetic parents.

The present study showed an increasing prevalence of diabetes with increasing age with 2.2% prevalence of diabetes in the age group of 10-14 years, and 5% prevalence of diabetes in the age group of 15-19 years (p value=0.015).

The present study showed an increasing prevalence of diabetes with increasing body mass index (BMI), with 2.4% prevalence of diabetes in non-obese persons compared to 13.7% prevalence of diabetes in obese persons (χ^2= 30.63, p value<0.001). In a multisite case-control study conducted by Vikram et al[19] among adolescents and young adults in North India in 2006, it was observed that obesity was a risk factor for diabetes [OR=7.9(2.5-25.44)].

The present study showed that the prevalence of diabetes was significantly higher in adolescents who led a sedentary lifestyle (4.6%) as compared to those doing moderate work (1.9%, χ2= 5.25, p value 0.02). (Table 4) These findings are consistent with other studies done either in India or abroad. A multicentric study conducted by Mohan et al[21] in various parts of India from April 2003-March 2005 as part of the WHO-ICMR Indian NCD risk factor surveillance has found physical inactivity to be a strong risk factor for type 2 diabetes.

Conclusion and Recommendations:

Overall prevalence of diabetes was found to be 3.6%. Intensive IEC campaigns through multipronged strategies is needed to educate adolescents about diabetes, both in schools from primary level onwards as well as in communities, particularly focusing on – (1) prevention by recognition of important risk factors and lifestyle modifications (2) early diagnosis and treatment by recognition of symptoms.

Healthy lifestyle changes like change in food habits in terms of reduction of salty and fatty food, promotion of balanced diet complemented by regular exercise, weight reduction, etc. should be promoted through all strategies to reduce the prevalence of both diabetes.

Declaration:

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Conflict of Interest: Nil

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An Epidemiological Study to Assess Prevalence and Risk factors Associated with Diabetes Among Adolescents in Urban Areas of Udaipur

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Abstract:

Introduction: Adolescents constitute 20% of world's total population. Adolescents have become quite vulnerable to various non-communicable diseases (NCDs) like hypertension and diabetes mellitus, especially due to the tremendous changes in their lifestyle over the last few decades. The age of onset of Type 2 diabetes in India has been shifting towards ever younger people. Among Indians in their late teens [15-19 years], Type 2 diabetes already manifests itself more often than Type 1 diabetes does. **Objective:** To study prevalence and risk factors for Type 2 diabetes and pre diabetes among male and female adolescents in Udaipur city. **Method:** It was a Community based cross sectional study conducted in three urban areas of Udaipur for 6 months. A total of 1005 adolescents were included in the study. A pretested and predesigned questionnaire was used. **Results**: Prevalence of diabetes was 2.9% in males and 4.4% in females adolescents. Prevalence of smoking, alcoholism, non-vegetarian diet and hypertension was higher among males. **Conclusion:** Diabetes type 2 is a growing problem among adolescents. We need active involvement of health care workers for educating adolescents about risk factors for diabetes.

Key words: Adolescents, Diabetes, Pre-Diabetes.

Introduction:

According to the WHO, adolescence is defined as the period between 10 to 19 years, the second decade of life. This is a period of rapid growth and development for adolescents' bodies, minds and social relationships.[1] Adolescence is a process whereby an individual makes the gradual transition from childhood to adulthood and is a critical period of development, second only to the early childhood years. Adolescents constitute 20% of world's total population.[2]

According to 2011 Census of India, there are 253.2 million adolescents constituting 20.9% of the total population.[3] This number is ever increasing making it the largest generation to undergo transition from children to adults in the near future, in turn making India the youngest country of the world.

Adolescents have become quite vulnerable to various non-communicable diseases (NCDs) like hypertension and diabetes mellitus, especially due to the tremendous changes in their lifestyle over the last few decades. Over half of NCD related deaths are associated with behaviours that begin or are reinforced during adolescence, including tobacco and alcohol use, poor eating habits, and lack of exercise, compounded by the presence of obesity.[4]

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Diabetes Mellitus (DM) is a chronic disorder characterized by raised blood sugar levels that occur when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces.[5] The International Diabetes Federation has estimated that about 382 million people all over the world suffer from diabetes. If these trends continue, by 2035, about 592 million people, or every tenth person, will have diabetes.[6] In India, the overall diabetes prevalence is 8%. Prevalence is only 0.7% for non-obese, physically active, rural Indians. It reaches 11% for obese, sedentary, urban Indians.[7] There are about 1 million juvenile diabetics in India, and every year 12000 diabetic children [2-14 years] die of the disease.[8]

Global and national estimates for the prevalence of diabetes in the adolescent age group are unavailable till date. In the United States, May et al found out that the combined prevalence of prediabetes & diabetes in American adolescents was 23% in 2007-2008.[9] The largest study in India was conducted by Singh et al among 10,843 adolescents in Chandigarh during the year 2007, and they detected a prevalence of diabetes of 4.2%.[10]

Although Type 1 diabetes is the most common form in children, Type 2 diabetes poses a major health problem globally, especially in the developing world. The age of onset of Type 2 diabetes in India has been shifting towards ever younger people. Among Indians in their late teens [15-19 years], Type 2 diabetes already manifests itself more often than Type 1 diabetes does.[11] Type 2 diabetes in children and adolescents is probably under-diagnosed because it can exist without symptoms. The clinical manifestations of T2DM are preceded by an asymptomatic prodromal period called 'prediabetes'.

Against the above background, the present study was carried out with the objective to study the prevalence of diabetes and associated risk factors among individuals in the age group 10-19 years in urban areas of Udaipur, Rajasthan.

Method:

Study Design : Community based cross sectional study.

Study Area : The study was conducted in three urban areas of Udaipur – Bhuwana [population 17660], Fatehpura [2 lakhs population] and Siphon [10000 population]. The three areas were selected as they are catered by the Department of Community Medicine of the medical college.

Study Period : Study was conducted for a period of 6 months from July 2019 to December 2019.

Study Subjects : Males and females of 10-19 years residing in these areas

Sample Size : At 95% confidence level and taking the prevalence of diabetes and prediabetes to be 9.5% with a relative error of 20%, the sample size came out to be 934 using the formula

$\mathbf{n = Z_\alpha^2\, p\, q\, /\, L^2}$,

Where n = sample size

Zα = 1.96 value of the standard normal variate corresponding to level of significance alpha 5 %

p = prevalence of diabetes[12], 9.5%

q = 100 – p, 90.5%

L = precision, 20%

Accounting for a non-response rate of 20%, a total of 1027 subjects were to be included. Out of these, 22 did not give consent to be part of the study, hence 1005 adolescents were included in the study. By simple random sampling, subjects were selected from the three areas. Proportionate probability sampling was followed.

Inclusion Criteria :

1. All males and females of 10-19 years after getting consent from them and informed written consent from their parents if they are <18 years, or after getting consent from them if they are 18 years or older.
2. The person should be a resident of the area mentioned above for a minimum of 6 months.

Study Instruments : A predesigned, pretested, semi-structured questionnaire containing items on (a) identification data i.e. age, gender, religion, educational status, area of residence, socioeconomic status of the person, (b) risk factor for diabetes i.e. obesity, sedentary lifestyle, smoking, alcohol, family history, dietary habits, history of consanguinity, etc. The questionnaire was pilot tested among 20 adolescents in the village of Delwara in June 2019, and questions were later modified to ensure that the subjects would have no difficulty in understanding and answering them. Glucometer, digital sphygmomanometer, measuring tape and weighing scale were used in the study. Following criteria were used.

Hypertension: The hypertension status of the study participants was assessed by using standard criteria formulated by the American Health Association (AHA) -2017.[13]

Diabetes criteria: Blood sugar determination (fasting) was done by glucometer by glucose oxidase

Table 1: Socio-demographic profile of study subjects

Characteristics	Total [n=1005]	
	Males [n=527] n (%)	Females [n=478] n (%)
Age (years)		
10-14	271 (51.4)	236 (49.4)
15-19	256 (48.6)	242 (50.6)
Religion		
Hindu	179 (33.9)	154 (32.2)
Muslim	326 (61.9)	306 (64)
Sikh	17 (3.2)	10 (2.1)
Christian	5 (1)	8 (1.7)
Education		
Illiterate	0	0
Primary/ Just literate	27 (5.1)	43 (8.9)
Middle School	198 (37.6)	182 (38.2)
High School	227 (43.1)	219 (45.8)
Intermediate/Diploma	75 (14.2)	34 (7.1)
Occupation		
Student	403 (76.5)	353 (73.9)
School dropout	22 (4.2)	80 (16.7)
Unskilled worker*	78 (14.8)	27 (5.7)
Semi-skilled worker**	24 (4.6)	18 (3.8)
Marital Status		
Married	12 (2.3)	56 (11.7)
Unmarried	515 (97.7)	422 (88.3)

*Unskilled worker: Person who are doing work which requires neither education nor specialized training.

**Semi-skilled worker: person who are doing work which requires some training to know their routine jobs efficiently.

method as per WHO and were interpreted. In the case of fasting plasma glucose (FPG) > 126mg /dl, a second determination was performed.[14]

Obesity criteria: Body mass index of the person was calculated using height and weight by applying the formula weight (in kgs) divided by square of height (in m^2).The cutoff criteria are based on the WHO BMI-for-age growth charts. Adolescents with BMI values at or above the 95th percentile of the sex-specific BMI growth charts are classified as obese.[15]

Ethical clearance and analysis: Institutional ethical clearance was taken. [No. AIMS/IEC/2019/022]. Statistical analysis was done using SPSS version 21.0.

Results:

Table 1 shows Majority of the subjects, 403 (76.5%) males and 353 (73.9%) females, were students. It was found that 22 (4.2%) males and 80 (16.7%) females were school dropouts and not doing anything. Out of 527 males, 24 (4.55%) and 78 (14.8%) were semi-skilled and unskilled workers respectively. It was also observed that, 12 (2.3%) males and 56 (11.7%) females were married, thereby highlighting the high prevalence of teenage marriage among adolescent girls. [Table 1]

Table 2 highlights that the prevalence of diabetes was 2.9% in males and 4.4% in females but the difference was not statistically significant (χ^2=3.66, p value 0.16)

Table 3 shows prevalence of smoking, alcoholism, non-vegetarian diet and hypertension was higher among males as compared to females. However, the difference was significant only for smoking (χ2=13.93, p value<0.001), alcoholism (χ2=36.76, p value<0.001) and non-vegetarian diet (χ2=4.51, p value 0.03).

Table 2 : Prevalence of diabetes among the study subjects

Classification of Diabetes	Males [n= 527] n (%)	Females [n=478] n (%)	Total [n=1005] n (%)	χ^2 value, d.f, p value
Normal	485 (92)	423 (88.5)	908 (90.4)	3.66, 2, 0.16
Prediabetes	27 (5.1)	34 (7.1)	61 (6.1)	
Diabetes	15 (2.9)	21 (4.4)	36 (3.6)	

Table 3 : Prevalence of risk factors of diabetes according to sex among the study subjects

Risk Factors	Males (N=527) n (%)	Females (N=478) n (%)	Total [n=1005] n (%)	χ^2 value, p value
Family history of diabetes	66 (12.5)	78 (16.3)	134 (13.3)	2.94,0.08
Obesity	33 (6.3)	69 (14.4)	102 (10.2)	18.36,0.001**
Sedentary lifestyle#	78 (14.8)	107 (22.4)	185 (18.4)	9.6,0.002*
Smoking	41 (7.8)	12 (2.5)	53 (5.3)	13.93,0.001**
Alcoholism	57 (10.8)	7 (1.5)	64 (6.4)	36.76,0.001**
Non-vegetarian diet	381 (72.3)	316 (66.1)	697 (69.4)	4.51,0.03*
Hypertension	38 (7.2)	27 (5.7)	65 (6.5)	1.01,0.32

*p value <0.05 ** p value <0.001 # Sedentary: type of lifestyle with little or no physical activity.

Table 4 : Multivariate Logistic regression analysis of different risk factors for diabetes

Risk factors	Odds ratio(95% CI)	p value
Age group		
10-14 years	Reference	-
15-19 years	2.03(1.25-4.03)	0.02
Socio economic class		
Upper/ Upper middle	Reference	-
Lower middle	1.09(0.61-1.95)	0.76
Upper lower/ Lower	1.64(0.85-3.19)	0.13
BMI		
Non obese	Reference	-
Obese	1.86(1.05-3.37)	0.05
Family history of diabetes		
No	Reference	-
Yes	2.16(1.27-3.66)	0.01
Physical activity		
Moderate activity	Reference	-
Sedentary lifestyle	1.90(0.98-3.69)	0.05
Currently smoking		
No	Reference	-
Yes	0.87(0.31-1.67)	0.46
Diet		
Vegetarian	Reference	-
Non-vegetarian	1.93(0.98-2.86)	0.06
Hypertension		
Absent	Reference	-
Present	1.79(1.11-2.45)	0.050

Table 4 highlights that subjects of 15-19 years age group experienced 2.03 times greater risk of getting diabetes as compared to subjects in the age group of 10-14 years (p value 0.02). Subjects who were obese experienced 1.86 times greater risk in comparison to those who were not obese (p value 0.05). Subjects with a positive family history of diabetes experienced 2.16 times greater risk of getting diabetes (p value 0.01). Subjects who led a sedentary lifestyle experienced 1.90 times greater risk of getting diabetes as compared to those engaged in moderate activity (p value 0.05). Subjects who were hypertensive experienced 1.79 times greater risk as compared to those who were not hypertensive (0.05).

Discussion:

The prevalence of diabetes in the present study was observed to be 3.6% among study subjects (2.9% in males and 4.4% in females) while the prevalence of prediabetes was observed to be 6.1% among the study subjects (5.1% in males and 7.1%

in females). Hence, the combined prevalence of diabetes and prediabetes among the study subjects was observed to be 9.7%. This was observed to be higher than that in the previous studies conducted by Ramachandran et al[16] among adolescents [12-19 years] in Chennai in 2007 (combined prediabetes and diabetes prevalence of 5.8%), by Singh et al[10] among 10,843 schoolgoing adolescents in Chandigarh in 2007 (4.2% prevalence of diabetes and 1.6% prevalence of prediabetes), by Balagopal[17] among adolescent youth [10-17 years] in rural areas of Tamil Nadu in 2008 (combined prevalence of 5.1%), and by Reddy[18] among corporate schoolchildren [7-14 years] in Nellore, Andhra Pradesh in 2011 (combined prediabetes and diabetes prevalence of 9.5%) The present study showed an increasing prevalence of diabetes with increasing age with 2.2% prevalence of diabetes in the age group of 10-14 years, and 5% prevalence of diabetes in the age group of 15-19 years (p value=0.015). The increasing prevalence of diabetes in the present study could be attributed to urbanization, sedentary lifestyle, physical inactivity and presence of addictions like tobacco use and alcohol consumption.

The present study showed a significantly higher prevalence in subjects with a positive family history of diabetes (11.2%) as compared to those without positive family history of diabetes (2.4%, χ^2= 25.94, p value<0.001). In a multisite case-control study done in North India by Vikram et al[19] in 2006, it was found that a significantly higher number of cases had a history of type 2 diabetes in first-degree relatives as compared with controls [82.3% vs 23.2%, p value<0.001]. Anjana RM et al[20], in a community-based study on adolescents [12-19 years] in Chennai, detected that blood sugar levels were significantly higher in the group with two diabetic patients as compared to the groups with one diabetic parent, and no diabetic parents.

The present study showed an increasing prevalence of diabetes with increasing age with 2.2% prevalence of diabetes in the age group of 10-14 years, and 5% prevalence of diabetes in the age group of 15-19 years (p value=0.015).

The present study showed an increasing prevalence of diabetes with increasing body mass index (BMI), with 2.4% prevalence of diabetes in non-obese persons compared to 13.7% prevalence of diabetes in obese persons (χ^2= 30.63, p value<0.001). In a multisite case-control study conducted by Vikram et al[19] among adolescents and young adults in North India in 2006, it was observed that obesity was a risk factor for diabetes [OR=7.9(2.5-25.44)].

The present study showed that the prevalence of diabetes was significantly higher in adolescents who led a sedentary lifestyle (4.6%) as compared to those doing moderate work (1.9%, χ2= 5.25, p value 0.02). (Table 4) These findings are consistent with other studies done either in India or abroad. A multicentric study conducted by Mohan et al[21] in various parts of India from April 2003-March 2005 as part of the WHO-ICMR Indian NCD risk factor surveillance has found physical inactivity to be a strong risk factor for type 2 diabetes.

Conclusion and Recommendations:

Overall prevalence of diabetes was found to be 3.6%. Intensive IEC campaigns through multipronged strategies is needed to educate adolescents about diabetes, both in schools from primary level onwards as well as in communities, particularly focusing on – (1) prevention by recognition of important risk factors and lifestyle modifications (2) early diagnosis and treatment by recognition of symptoms.

Healthy lifestyle changes like change in food habits in terms of reduction of salty and fatty food, promotion of balanced diet complemented by regular exercise, weight reduction, etc. should be promoted through all strategies to reduce the prevalence of both diabetes.

Declaration:

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Conflict of Interest: Nil

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Original Research Article

Screening of hypertension among rural community of Nepal

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ABSTRACT

Background: Hypertension is the commonest cardiovascular disorder, posing a major public health challenge to population in socioeconomic and epidemiological transition. The objective of the study was to determine the prevalence of hypertension in the rural community.
Methods: Community-based cross sectional study was conducted in Chotkiram nagar village of Rupandehi district of Western Nepal. Door to door screening for hypertension was done using mercury sphygmomanometer. Other study variables included demographic factors only such as age and sex. The data was collected from 7th June 2016 to 20th June 2016. All the households in the village were screened and all the persons over 18 years of age in the households were subjected to blood pressure measurement. Thus the sample size comprised of all persons above 18 years of age. Total subjects enrolled were 3158. All persons above (and completed) 18 years of age and holding permanent resident status in the study area at the time of study were included in the study. Pregnant women and persons not willing to give consent were the exclusion criteria set. Though, all the participants gave their consent.
Results: The prevalence of hypertension in the study is 16.2%.
Conclusions: Though the hypertension is significant in the current study, the prevalence is much lower than the studies done in other parts of Nepal. More prevalence studies are required in the rural areas of Terai region.

Keywords: Screening, Hypertension, Prevalence, Rural

INTRODUCTION

Hypertension affects around 22% of people aged 18 years and over and is responsible for an estimated 9.4 million deaths per year globally.[1] It mostly remains asymptomatic but at the same time increases the risk of heart disease, stroke, and renal failure.[2] Hypertension is the commonest cardiovascular disorder, posing a major public health challenge to population in socioeconomic and epidemiological transition.[3]

Studies indicate that there is an epidemiological shift towards high prevalence of hypertension in developing countries as compared to developed countries.[4,5] Nepal is one such developing country where prevalence seems to increase.[6] However, more prevalence studies of hypertension are imperative to design preventive and control strategies. There are limited community based studies on hypertension in Nepal, very few in western regions. Hence, the present study done in Terai region of Western Nepal can also be considered as a baseline study in that geographical setting.

METHODS

This community-based cross sectional study was conducted in Chotkiram Nagar village of Rupandehi district of Western Nepal. This village is about 30 kms

from the city of Butwal. Geographically, Rupandehi is located in terai region of Nepal. The data was collected from 7th June 2016 to 20th June 2016. Door to door screening for hypertension was done using mercury sphygmomanometer. All the households in the village were screened and all the persons over 18 years of age in the households were subjected to blood pressure measurement. The total participants were 3158 from 880 households of the village having population of 4879.

Other study variables included demographic factors only such as age and sex. All persons above (and completed) 18 years of age and holding permanent resident status in the study area at the time of study were included. Pregnant women and persons not willing to give consent were the exclusion criteria set. Though, all the participants gave their consent. Ethical clearance was taken and written permission was obtained from Village Development Committee Office (VDC), Chotkiram nagar.

The purpose of visit was explained to the family members and consent taken. For this study, Joint National Committee (JNC-7) guideline for diagnosis of hypertension was used (SBP ≥140 mmHg and/or DBP ≥ 90 mmHg).[7] Persons on anti-hypertensive medications were considered hypertensive. Persons with isolated systolic hypertension were considered hypertensive and included in the study. The data collected was entered in the excel sheet of the computer. Statistical analysis included calculation of percentages and proportions.

RESULTS

Description of the study population

Total number of subjects enrolled were 3158. Out of which, males were 1648 (52.2%) and females were 1510 (47.8%). Around 59% of the population belonged to age group less than 35 years.

Table 1: Demographic characteristics of the study population.

Variable	Number (%)
Sex	
Male	1648 (52.2)
Female	1510 (47.8)
Age group	
18-25	938 (29.7)
26-35	916 (29)
35-45	566 (17.9)
46-55	364 (11.5)
55+	374 (11.8)

The total prevalence of hypertension was found to be 16.2%. Prevalence among males was 17.5% and in females was 14.8%.

Table 2: Prevalence of hypertension.

Sex	Total no.	Hypertensive	Prevalence (%)
Male	1648	289	17.5
Female	1510	223	14.8
Total	3158	513	16.2

DISCUSSION

Screening is a fundamental aspect of prevention. It is active search for disease among apparently healthy people. Hypertension is a disease which fulfills the criteria to be considered suitable for screening. Moreover, it is a major public health problem. It is particularly a health menace to society in socioeconomic and epidemiological transition. To plan an effective preventive and control strategy one need to quantify the health problem. Nepal is a geographically diversified country divided into Terai (plain), Hilly and Himal regions. Studies have been conducted to know the prevalence of hypertension in hilly regions and some in Himal regions but very few in Terai regions. In the current community based survey in terai region of western Nepal on subjects 18 years and above of age, the prevalence of hypertension was found to be 16.2%

A study done in 2011 by Chataut et al in Central Nepal in rural area among adults above 18 years revealed the prevalence of hypertension to be 22.4%.[8] Vaidya et al in a study at Kathmandu urban in 2006 reported the prevalence to be 33.8%.[6] The WHO STEPs surveillance conducted in 2007 in Nepal reported the prevalence to be 31.3%.[9] While Sharma et al in 2011 in a study in eastern Nepal concluded it to be 33.9%.[10] Prevalence of hypertension in the current study (16.2%) is lower than the prevalence studies done in past in Nepal. Though, the prevalence of our study is much closer to findings reported by Sharma et al in suburban areas of Kathmandu in 2005. [11] They reported the prevalence to be 19.7%. The study conducted by Lamsal and Kafle in Himal region (high hilly areas) of Nepal reported the prevalence of hypertension to be 35.7%. 214 out of total 600 subjects enrolled were found to be hypertensive in their study. They suggest that the higher prevalence of hypertension may be due to certain behavioral patterns prevailing in the area. They further opined that, higher consumption of locally made alcohol, using yak butter and salt in tea, higher rates of smoking and poor availability of fruits and vegetables may have role.[12] To the best of our knowledge and extensive review of literature we did not find prevalence studies on hypertension in Western Nepal especially the Terai region. So we were not able to compare our study findings with other studies of Western region. However, a cross-sectional study conducted by Khan et al among adult women in Terai region of Central Nepal revealed the prevalence to be 3.3%. One likely explanation of the lower prevalence was given to the young age of participants in the study by the authors.

Though, the prevalence among 46 years and above age group was 7.9% in their study. [13]

Additionally, the findings of our study are much closer to the prevalence of hypertension reported in rural areas of North India and West India. A meta-analysis study on prevalence of hypertension in India by Anchala et al in 2013 reported that the pooled prevalence of hypertension for rural North Indian population was 14.5% while for the rural West Indian population was 18.1%.[14] Alcohol, smoking and chewing tobacco, central obesity, consumption of low vegetables and fruits, high consumption of dietary fat and salt, sedentary activity were the significant modifiable risk factors for hypertension among the Indians as per this study.[14]

CONCLUSION

The prevalence of hypertension is 16.2%. Though hypertension is emerging as health concerns, in-depth study is required pertaining to the risk factors of hypertension among people to understand the reasons of lower prevalence in our study setting. More studies are also required in the rural areas of Terai region of Nepal to corroborate the findings.

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Evaluation of Indian public health standards for CHCs of Ahmedabad District with reference to physical infrastructure and manpower

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Abstract
Background: Three tier system exists in India. The upper most is the CHC. The CHC provides specialist services to the rural people and is usually located at the block level. The CHCs are under constant criticism for their inability to deliver quality services. The main reasons are the lack of proper manpower, inadequate infrastructure. In order to provide optimal level of quality health care, a set of standards called IPHS were submitted. In the above context, the present study was undertaken with the objective to assess the infrastructure facilities & availability of manpower in the CHCs of Ahmedabad district, Gujarat.
Method and Materials: Study was carried out from April 2014 to December 2015. It is Cross-sectional study. Predesigned and pretested questionnaire made from IPHS revised guideline 2012. It was planned to study at least 2/3rd (70%) of the existing means CHCs i.e. 7 CHCs. So, it was randomly selected 7 CHCs by chit method.
Result: 100% CHCs had building but only 57.14% CHCs had male female separate wards and toilets. 100% CHCs had OT and Labour room, but only 28.57% CHCs had Blood storage facility and none of the CHCs had USG facility. The availability of medical staff and support manpower was also poor. 100% CHCs had done Pathological tests. X-ray were done in 71.42% CHCs and ECG were done in 28.57% CHCs.
Conclusion: Pooling of human resources needs to be done especially Specialists and promoting partnership with the private sector in providing human resources. There is need to be strengthen physical infrastructure like male:female separate wards and toilets, investigation facility.

Keywords: IPHS, CHC, manpower, physical infrastructure

1. Introduction
The National Rural Health Mission (NRHM) was launched by the Hon'ble Prime Minister of India in the year of 2005 with the goal of improving the availability and accessibility of the quality health care to the people, especially for those residing in rural areas, the poor, and women [1, 2]. Right now, the three tier system exists in all over country in India in rural area [1, 3]. The sub centres are the first (lower most) tier of this system. The second one is primary health centre and the upper most is the community health centre.[3]. The Community Health Centre provides specialist services to the rural people and is usually located at the block level [4, 5].
Standards are a means of describing the level of quality that Health care organizations are expected to meet or aspire to. Key aim of these standards is to underpin the delivery of quality services. The performance of health care delivery organizations can be assessed against standards [6].
In order to provide optimal level of quality health care, a set of standards called Indian Public Health Standards (IPHS) were submitted the draft guidelines for "Indian Public Health Standards for CHCs in 2006 which was then revised in 2007, 2010 and 2012. IPHS is a novel concept to fix benchmarks of infrastructure, including building, manpower, equipments, drugs, quality, through introduction of treatment protocols, and accountability to the public. The study is to evaluate the functioning of the CHCs of Ahmedabad District and their effectiveness in bringing specialised health care within the reach of rural people [7].
The CHCs are under constant criticism for their inability to deliver quality services. The main reasons are the lack of proper manpower, inadequate infrastructure and facilities. In the above context, the present study was undertaken with the objective to assess the infrastructure facilities & availability of manpower in the CHCs of Ahmedabad district, Gujarat.

2. Materials and Methods
The present study was conducted in CHCs of Ahmedabad district. Study was carried out from April 2014 to December 2015. It is Cross-sectional study. Predesigned and pretested questionnaire made from IPHS revised guideline 2012 was used for the study. There were 10 CHCs in Ahmedabad district. List of all the CHCs were obtained from the Jilla Panchayat, Ahmedabad. It was planned to study at least 2/3rd (70%) of the existing means CHCs i.e. 7 CHCs. So, it was randomly selected 7 CHCs by chit method. Before conducting the study, prior permission of Chief District Health Officer, Superintendent and Medical officers respectively of CHCs was taken. For the quality assessment of the facilities at CHCs the observational and interview methods were used. Check list was prepared as per the standard of the IPHS. The respondents of the study were the persons in charge of the health facility. However, in some of the facilities, the person in charge was not available hence, another officer was interviewed

3. Result and Discussion

Table 1: Availability of physical infrastructure facilities at CHCs in Ahmedabad

Infrastructure facilities	Availability of Infrastructure facilities (7)	
	Number of CHCs	Percentage of CHCs (%)
Building	7	100.00
OPD rooms/cubicles	7	100.00
Waiting room	3	42.85
Male : Female Separate wards	4	57.14
Water supply	7	100.00
Electricity	7	100.00
Garden	6	85.71
Transport facilities	7	100.00
Telephone facility	7	100.00
E-mail facility	7	100.00
Fax facility	2	28.57
Male : Female Separate latrine	4	57.14
Board to guide patients	7	100.00
complain box	3	42.85

Table 2: Availability of physical infrastructure

Infrastructure facilities	Availability of Infrastructure facilities	
	Number of CHCs	Percentage of CHCs
Operation theatre	7	100.00
Labour room	7	100.00
Laboratory	7	100.00
Cold chain facility	7	100.00
X-ray Room	7	100.00
Blood Storage	2	28.57
Pharmacy	7	100.00
USG	0	0.00

Table 3: Availability of Medical Staff at Community Health Centres in Ahmedabad district.

Staff	IPHS (2012)	Required number	Availability	Percentage available	Existing Gap
General surgeon	1	7	2	28.57	71.43
Physician	1	7	2	28.57	71.43
OBG	1	7	5	71.42	28.58
Paediatricians	1	7	4	57.14	42.86
Anaesthetist	1	7	2	28.57	71.43
Dentist	1	7	1	14.28	85.72
M.O MBBS	2	14	14	100.00	0.00
M.O AYUSH	1	7	3	42.85	57.15
Public Health Specialist	1	7	0	0.00	100.00
Public Health Nurse	1	7	1	14.28	85.72

Table 4: Availability of Nurses and Paramedical

Personnel	IPHS (2012)	Required number	Availability at CHCs	Percentage available at all CHCs (%)	Existing gap
Staff Nurse	10	70	48	68.57	31.43
Pharmacist	1	7	7	100.00	0.00
Pharmacist – AYUSH	1	7	1	14.28	85.72
Lab. Technician	2	14	8	57.14	42.86
Radiographer	1	7	5	71.42	28.58
Dietician	1*	7*	1	14.28	85.72
Ophthalmic Assistant	1	7	6	85.71	14.29
Dental Assistant	1	7	0	0.00	100.00
Cold Chain & Vaccine Logistic Assistant	1	7	1	14.28	85.72
OT Technician	1	7	0	100.00	0.00
Community Based Rehabilitation worker	1	7	2	28.57	71.43
Counsellor	1	7	4	57.14	42.86

Table 5: Availability of Administrative and Group D Staff

Personnel	IPHS (2012)	Required number	Availability at CHCs	Percentage of available at all CHCs (%)	Existing Gap (%)
Registration Clerk	2	14	7	50.00	50.00
Data Entry Operator	2	14	7	50.00	50.00
Administrative Assistant	1	**7**	0	0.00	100.00
Account assistant	1	**7**	2	28.57	71.43
Dresser	1	7	2	28.57	71.43
Ward Boys+ sweeper	5	35	26	74.28	25.72
Driver	1	7	7	100.00	0.00

The present study revealed that 100% CHCs had E-mail facility and only 28.57 % CHCs had Fax facility. Similar study conducted at Bharatpur district, Rajasthan by P.R. Sodani *et al*. (2010) [7], showed that 84.6% CHCs had E-mail and 76.9% CHCs had Fax facility. In present study 100% CHCs had Operation theatre, Labour room, Laboratory and Cold chain facility. Similar finding were observed in study conducted by P.R. Sodani *et al*. (2010) [7], showed that 100 % CHCs had Operation theatre, Laboratory and cold chain facility, while 92.3 % CHCs had Labour room. Study done by Jayanta B Sarma *et al*., (2011) [8] shows, In Arunachal Pradesh 79.16% CHCs had functional Laboratory and 77.08% had functional OT 95.83% had functional Labour room, while in case of Assam 100% CHCs had laboratory and Labour room and 93.51% CHCs had functional OT.

In this 28.57 % CHCs had General surgeon, Physician and Anaesthetist, while 71.42 % CHCs had OBG and 57.14 % CHCs had Paediatrician.100 % MBBS Medical Officer and 42.85 % AYUSH present at all 7 CHCs. Study by P.R. Sodani *et al*. (2010) [7], also shows that 30.8% surgeon and paediatrician, while 38.5 % Physician and OBG available at CHCs, while only 41% medical officers present at CHCs, which were contradictory to our findings. Study by Jayanta B Sarma *et al*., (2011) [8] shows that none of the CHCs in Arunachal Pradesh had all 4 specialist, while in Assam 25.92% had all 4 specialist.

In present study 68.57 % Staff nurse, 100 % Pharmacist available, while 57.14% Lab technician and 71.14% Radiographer available. Study by P.R. Sodani *et al*. (2010) [7], also showed poor availability of human resources. Study revealed only 78.4% Staff nurse, 30.8 % Pharmacist, 66.7% Lab technician and only 50% Radiographer available, which were lower than present study.

In present study 100 % CHCs had Pathological tests facility, while 71.42% had X-ray facility and only 28.57% CHCs had ECG facility. Similar consistence findings were observed in study by P.R. Sodani *et al*. (2010) [7], 100% CHCs had Pathological tests facility, while 69.2% CHCs had X-ray facility and only 23% CHCs had ECG facility.

4. Conclusion

100% CHCs had building but only 57.14% CHCs had male female separate wards and toilets. 100% CHCs had OT and Labour room, but only 28.57% CHCs had Blood storage facility and none of the CHCs had USG facility.

The availability of specialists to provide various specialist services at CHCs was found to be very poor in the study district. However it was observed that there were recommended number of MBBS MO present at PHCs, while only 42.85% AYUSH MO were present.

The availability of support manpower was also poor, but found to be better at the participating CHCs compared to the specialists. 100% CHCs had done Pathological tests. X-ray were done in 71.42% CHCs and ECG were done in 28.57% CHCs. Pooling of human resources needs to be done especially Specialists and promoting partnership with the private sector in providing human resources. There is need to be strengthen physical infrastructure like male: female separate wards and toilets, investigation facility.

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Original Research Article

A Cross Sectional Study of Immunization Status Among Beneficiaries of Anganwadies of Rural Field Practice Area of AIMS & RC, Rajsamand

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Abstract

The current scenario depicts that immunization coverage has been steadily increasing but the average level remains far less than the desired. Though there is increased accessibility of health care services in rural areas, its utilization is low. Hence the present study is undertaken in an attempt to assess immunization status of children enrolled in anganwadi centers .Each Anganwadi centre was considered as a single cluster and all children from the selected anganwadi centers were included in the study. Data was analyzed. The major cause of incomplete immunization was postponement of immunization due to inter current illness of the child. There is only marginal difference in immunization coverage according to gender, education of parents. Regular health education sessions, and regular reminders and removal of misconceptions prevailing among people will solve the problems of non-immunization.

Keywords: non immunization,anganwadi

Introduction

Vaccine preventable diseases are widespread and a major cause of childhood morbidity, mortality and life-long physical disability.Immunization has been one of the most significant and cost-effective public-health interventions to decrease childhood morbidity and mortality[1].Universal Immunization Programme was started in India in 1985 with the aim to achieve 100% coverage of pregnant woman with 2 doses of tetanus toxoid(or a booster dose) and at least 85% coverage of infants with 3 doses each of DPT,OPV; one dose of BCG and one dose of measles by 1990.

Aims & objectives

•To assess immunization status among beneficiaries of anganwadies.

•To identify the reasons for partial/ non immunization among them.

•To know the impact of sex, cast, mother's education on the immunization status of the registered children of anganwadi[2-4].

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Methodology

•Study design: Cross sectional study

•Study area: Anganwadies of field practice area of AIMS & RC, Rajsamand

•Study method & sample:Registered beneficiaries of anganwadies were included in study[5-7].

5 anganwadies were randomly selected. 206 children (registered children of anganwadi>1 year of age),19 antenatal women and 56 adolescent girls(registered adolescent girls >16 years of age) were included in study.

Children, their mothers and other beneficiaries were asked to remain present on the anganwadi Centre on the days of our visit and information was collected from them & from anganwadi registers in pre designed proforma.

Data analysis: Data was entered in MS Excel and analyzed by using simple proportions and chi-square test[8,9].

Results & observations

Children: Of the 206 children, 180(87.38%) were found fully immunized &26(12.62%) were found partially immunized. None of them were found non-immunized.Coverage for individual vaccines were found as – 100% for BCG; 99.02%,96.6% and 95.14%

for OPV 1,OPV 2 and OPV 3 respectively; 98.54%,96.6% and 94.66% for DPT 1,DPT 2 and DPT 3 respectively while 89.8% for measles.The coverage of pulse polio immunization was 98.54%.

Antenatal women: Coverage for TT was found 100%. **Adolescent girls:** Only 14(25%) adolescent girls had taken complete two doses of TT.

Fig 1:Immunisation being carried out

Table 1:Variables and their processing values

Variable	Fully immunized	Partially immunized	Total	X^2 Value and p value
Sex				
Male	101(90.99%)	109(9.01%)	111(53.88%)	X^2=2.109
Female	79(83.16%)	16(16.84%)	95(46.12%)	p>0.05
Education of mother				
≥ Primary	105(93.75%)	7(6.25%)	112(54.37%)	X^2= 9.035
< Primary	75 (79.78%)	19(21.22%)	94(45.63%)	p<0.05
Caste				
General	57(93.44%)	4(6.66%)	61(29.61%)	
OBC	67(87.01%)	10(12.99%)	77(37.38%)	X^2 =3.601
SC&ST	56(82.35%)	12(17.65%)	68(33.01%)	p>0.05
Total	180(87.38%)	26(12.62%)	206(100%)	

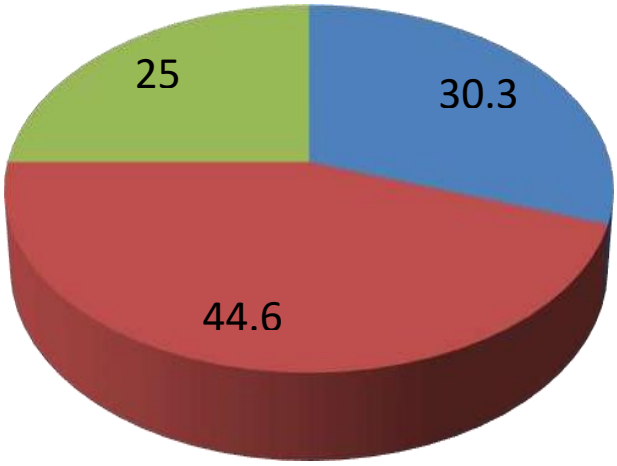

Fig 2: Immunization status among adolescent girls
[Blue area shows no dose of TT,Red area shows only one dose of TT,Green area shows two dose of TT]

Table 2: Association between education status and availability of immunization card

Education status of mother	Immunization card available	Immunization card not available	Total
≥Primary	88(78.57%)	24(21.43%)	112(54.37%)
< Primary	54(57.45%)	40(42.55%)	94(45.63%)
Total	142(68.93%)	64(31.07%)	206(100%)

X^2=10.649 ; p<0.05

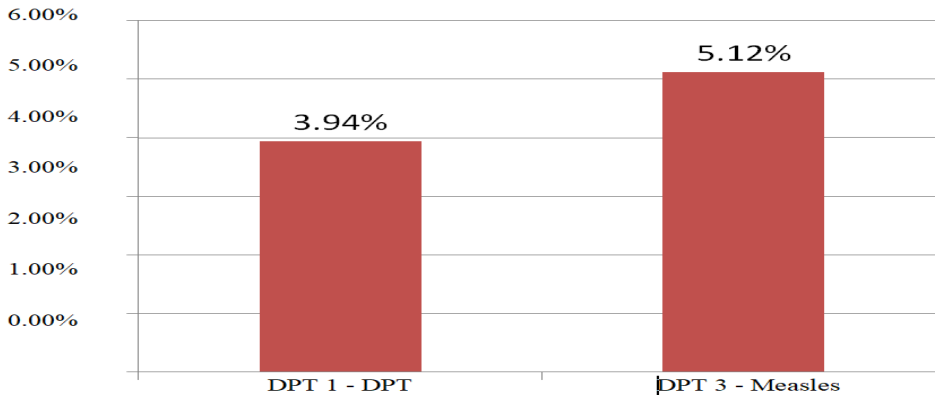

Fig 3: Drop-out rate among children

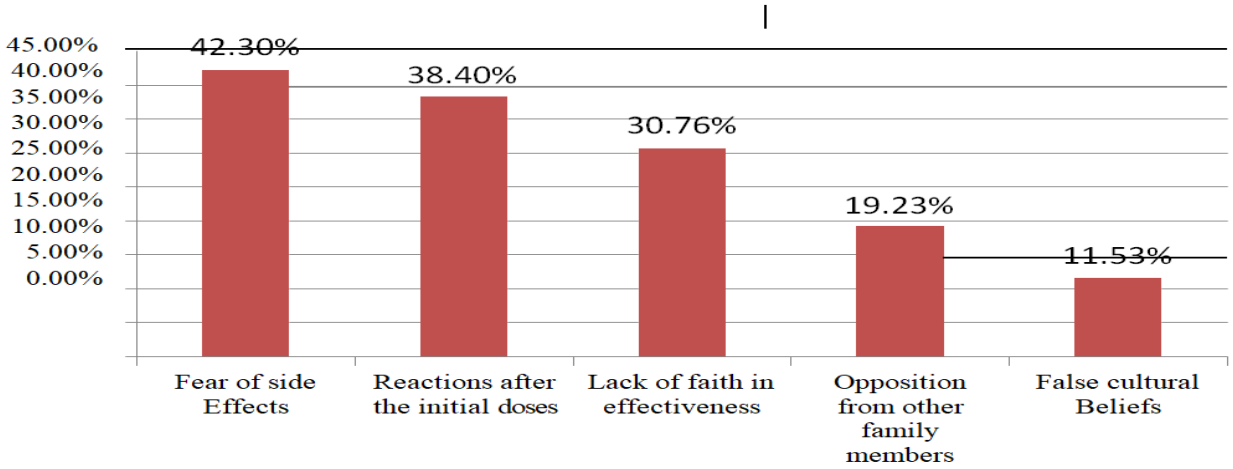

Fig 4:Reasons for partial immunization among children

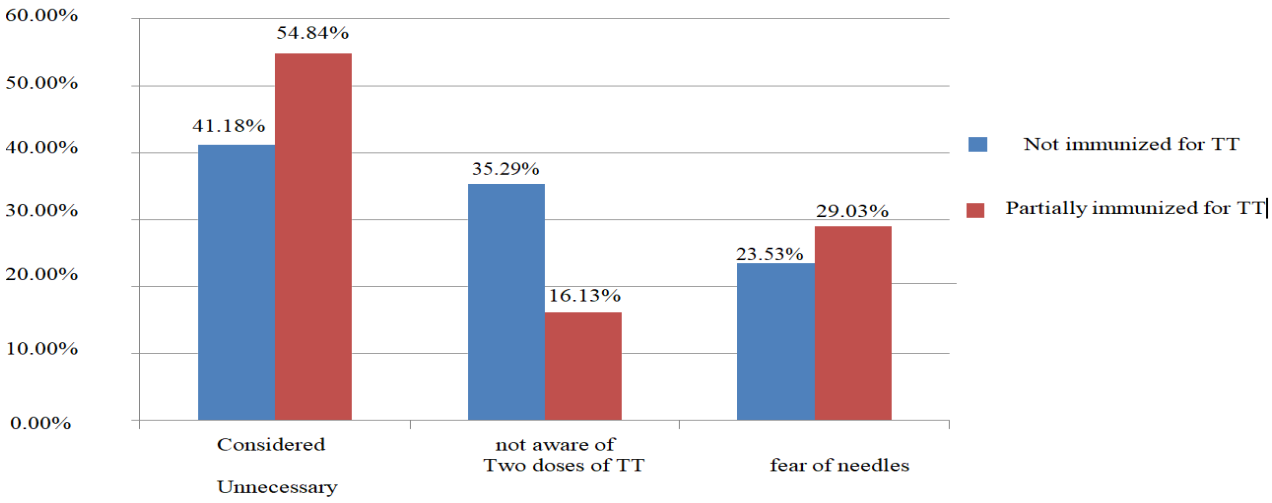

Fig 5: Reasons for Partial/Non- immunization among adolescents

Conclusion

•From the present study it is concluded that ICDS has played very successful role in increasing the immunization status of antenatal women and children.
•Immunization for Tetanus Toxoid among the adolescent girls was found low, so the need of an hour is to raise awareness among them.
•Timely health education should be provided to the mothers regarding the importance , schedule, common side effects and efficacy of the vaccines.
•Minor reactions following the injectable vaccines should be minimized.
•Interest should be developed both in local health functionaries and adolescent beneficiaries to accelerate the optimization of immunization among the adolescent girls.

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Research Article

Assessment of psychiatric illness and other comorbidities associated with patients attending obesity clinic in Ahmedabad

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ABSTRACT

Background: Psychosocial impact of obesity is of concern in the present world but remains less studied compared to its physical consequences. People who take treatment for obesity are reported to be positively associated with psychiatric illnesses and also personality characteristics or psychological conditions influence the obesity treatment. **Objective:** The objective of this study was to study the prevalence of psychiatric illness and comorbid conditions among people with overweight and obesity and to find out factors associated with psychiatric illness. **Materials and Methods:** A cross-sectional study was conducted in private obesity clinic, Ahmedabad. A total of 103 people attending obesity clinic were studied. Self-structured questionnaire and Hospital Anxiety and Depression Scale (HADS) were used. **Results:** Of 103, 87.5% (91) were female. Mean age of people attending obesity clinic was 35 ± 9.2 years. About 67.3% were housewife and 92.2% were educated up to secondary or above. Thirty-eight (38.8%) and 59 (57.2%) of 103 were found to be having overweight and obesity, respectively. About 69% of people with obesity belong to Grade 1 and 31% belong to Grade 2 and 3. Psychiatric illness was observed among 38.8% (40) of the obesity clinic attendees. Of 40, 32.5% were found to have abnormal level of HADS score and needed intervention. Of 103, 45.6% had comorbid conditions such as joint associated problems (25%), hypertension (16.5%), and hypothyroidism (14%). Among overweight and obese with comorbidities, 48.9% had psychiatric illness. Psychiatric illness was observed among 37% of people with duration of obesity >5 years. The study did not find any significant association between overweight and obese having comorbid conditions ($z = 0.63$, $P > 0.05$) and duration of obesity ($z = 0.44$, $P > 0.05$) with psychiatric illness. **Conclusion:** Both comorbidity and psychiatric illness are highly prevalent among obese people. This indicates early detection and intervention for both to decrease the morbidity and mortality among obese and overweight.

KEY WORDS: Obesity; Comorbidities; Psychiatric Illness; Hospital Anxiety and Depression Scale Score

INTRODUCTION

Obesity, across all age groups and cultures it is the most prevalent global public health problem. Obesity in recent times is referred to as "New World Syndrome," since it causes many non-communicable diseases creating large sums of socioeconomic and public health problems in developing countries. Affecting every age group, it is the most undermined health problem in accordance of the WHO.[1]

Previously, due to high prevalence of undernutrition in developing countries, including India, had limited public health resources mainly on dealing with it. However, these developing countries are now dealing with double burden of undernutrition as well as overnutrition. Body mass index (BMI) is the indicator of nourishment status in adults. The studies regarding BMI indicate that 50% of Indian adults suffer from various types of chronic energy deficiency

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in that they have a BMI <18.5 kg/m^2. In the same survey, it was observed that the BMI values were similar in men and women; however, there were more overweight/obese (BMI ≥25 kg/m^2) women (6.6%) than men (3.5%). In certain parts of the country, obesity and consequent diseases are posing a huge public health problem.[2]

We now know that the biggest global health burden for the world is related to diet and this burden is enhanced by relation with low physical activity. At present, roughly, 300 million adults worldwide are obese – a BMI of 30 and above, nearly 1 billion people are overweight. The problem affects apparently all age groups and in every socioeconomic status.[2]

Obesity statistics has risen at least 3 times since the late 20th century in Western nations. In most of the developing countries, obesity and malnutrition are coexisting in all socioeconomic strata. The growing problem is due to adoption of industrialized foods and food preferences, together with drastically decreased physical activity levels. It may trigger psychological problems that include depression, eating disorders, distorted body image, and low self-esteem. Higher rates of depression have been found in obese people in several studies. Evidence from the Swedish obese subjects study indicates that clinically significant depression is 3–4 times higher in severely obese individuals than in similar non-obese individuals. Professor Marianne Sullivan *et al.* from Sahlgrenska University Hospital, Sweden, mentioned in a journal article, "depression on a level indicating psychiatric morbidity was more often seen in the obese." The study suggests that levels of depression among obese were more or less same as chronic pain.[2]

In the developing countries, the high obesity statistics is due to change in diet and decrease in physical activity; it is known as the "nutrition transition." In Urban populations, there are higher rates of obesity as compared to rural populations. Urban areas offer a variety of food, generally at lower costs and urban population usually have less physical activity as compared to rural population.[2]

At different levels of BMI, there is difference in fat deposition and body composition. Overweight cutoffs of 25 are not applicable for Asian population, the burden is greater these populations. This resulted in the prevalence of diabetes, impaired fasting glucose and hypertension in Asians.[3]

In near future, the developing countries will suffer greater burden due to obesity. In the first quarter of the 21st century, diabetes due to obesity estimates is to be doubled in world, of which roughly three-fourth burden will be on developing countries.[4]

People with a BMI more than 30 are more likely to be diagnosed with hypertension, stroke, high cholesterol, coronary heart disease (CHD), osteoarthritis, gout, asthma, sleep disorders dermatological problems, and some types of cancer as compared to adults with normal weight.

The American Heart Association in 1998 declared that obesity is major risk factor for CHD. Obesity plays a causal role in the development of type 2 diabetes mellitus and its complication, due to which treatment of diabetes becomes less yielding.[5]

The inconsistent results found in various studies and with an increase concern about the psychological effects of overweight and obesity along with associated comorbidities warrant more research in this field. Most of the available data are from the Western world that may not be relevant in the Asian region. To address this issue, we conducted a study to investigate the prevalence of morbidity due to psychiatric disorders among obese individuals.

Objectives

The objectives of this study were to study the prevalence of psychiatric illness and other comorbid conditions among the people with overweight and obesity and to find out the factors associated with psychiatric illness among obese visiting obesity clinic.

MATERIALS AND METHODS

This study was conducted in private obesity clinic, Ahmedabad. This was a cross-sectional study performed from September 2017 to November 2017.

All the obese person attending the clinic for 3 months were included, so a total of 103 obese people attended the clinic were studied. Data were obtained using a self-administered questionnaire consisting of general information, comorbid conditions and its treatment, awareness about obesity, and Hospital Anxiety and Depression Scale score (HADS) which consist of 14 questions. Scoring was done separately for anxiety and depression, any score in between 0 and 7 considered normal, 8–10 borderline case, and 11–21 abnormal case. BMI was calculated using weight/height^2 and classified according to the WHO Asian BMI classification.[6]

Data analysis was done using Microsoft Excel 2007. For statistical analysis, Chi-square test was applied. Verbal consent was taken from all respondents.

RESULTS

Of 103, 87.5% (91) were female. Mean age of people attending obesity clinic was 35 ± 9.2 years. About 67.3% were housewife and majority (92.2%) were educated up to secondary or above [Table 1].

Thirty-eight (38.8%) and 59 (57.2%) of 103 were found to be having overweight and obesity, respectively. About 69% of people with obesity belong to Grade 1 and 31% belong to Grade 2 and 3. Nearly 40% of the attendees have a history of obesity in <5 years. The study did not find a statistically significant association between overweight and obese having duration of obesity >5 or <5 years with psychiatric illness ($z = 0.44$, $P > 0.05$). Due to small number of male participants, gender-specific comparison was not done [Table 2].

About 45.6% had comorbid conditions such as joint associated problems (25%), hypertension (16.5%), and hypothyroidism (14%). The study did not find a statistically significant association between overweight and obese having psychiatric disorder with comorbid conditions ($z = 0.63$, $P > 0.05$) [Figure 1].

Abnormal HADS score was observed among 38.8% (40) of the obesity clinic attendees. Of 40, 32.5% were found to have psychiatric illness and needed intervention [Table 3].

DISCUSSION

In the 21st century, obesity is becoming an epidemic in different regions of South Asia including India. Unique features of obesity; abdominal adiposity, high body fat, intra-abdominal fat, and high amount of subcutaneous fat are exhibited by Asian Indians.[7] Individuals who are obese tend to have more emotional problems resulting in various psychosocial and health-related issues. We retrospectively questioned 103 patients who received variety of obesity treatments. In our study, 87.5% were female, as female preponderance of obesity was observed in other studies as well. This pattern of attendees may be due to some sociocultural reason. Similar observation was made by the study at Taiwan.[8] Most of the respondents belonged to adult age group, 68% were housewife and had a better economic and educational status when compared to other studies.[8] Obesity is found to be one of the primary conditions to result in various comorbidities. In this study, 46% were having some comorbid conditions such as joint associated problems, hypertension, and hypothyroidism, and they were at ongoing treatment. In general, it is difficult to explain the potential association of comorbidities with a psychiatric disorder among the obese subjects with the available scientific evidence.[9,10] Our study also did not find a statistically significant association between overweight and obese having psychiatric disorder with comorbid conditions ($z = 0.63$, $P > 0.05$). Psychological stress is found to be more in women due to stigma of overweight and obesity, dissatisfactory thoughts for their body image, and haphazard eating habits.[11] In a community-based survey, it was found that obese females suffer from more chance of depression and anxiety.[12] The patients were evaluated on the basis of standardized questionnaire and HADS score. Abnormal level of HADS was observed among 38.8% (40) of the obesity clinic attendees and majority needed intervention. Similar prevalence was seen in another study carried out in Kerala,[9] at least one psychiatric disorder was seen in 42% of patients in a study conducted in Taiwan.[8]

Increased weight in psychiatric disorder patients involves the number and duration of depressive episodes, history of hospital admissions for depression, medicines causing increase in weight, decrease in physical activity,[13] comorbid anxiety disorders, and age.[12] About 40% of the patients reported within 5 years of weight gain, it shows their awareness of health and it was interfering with their day-to-day work, so

Table 1: Sociodemographic distribution of obesity clinic attendees

Sex	Frequency (%)
Male	12 (11)
Female	91 (87.5)
Age	
<20	04 (3.8)
20–29	31 (29.8)
30–39	39 (37.8)
40–49	24 (23.0)
>50	05 (4.8)
Occupation	
Working	23 (22.1)
Housewife	70 (67.3)
Student	10 (9.61)
Education	
Illiterate	01 (0.9)
Primary	07 (6.7)
Secondary and Higher secondary	48 (46.6)
Graduate and PG	47 (45.6)

Table 2: Classification of attendees according to BMI and years of obesity

Obese classification	BMI (kg/m^2)	Frequency
Normal	18.5–25	04
At risk of overweight (2–20 years)	85–95%	01
Overweight	25–30	40 (38.8%)
Obese Class 1	30–35	40
Obese Class 2	35–40	09
Obese Class 3	>40	09
Obese since (years)	Number of person	%
<5	41	39.8
5–10	28	27.1
10–15	13	12.6
>15	21	20.3

BMI: Body mass index

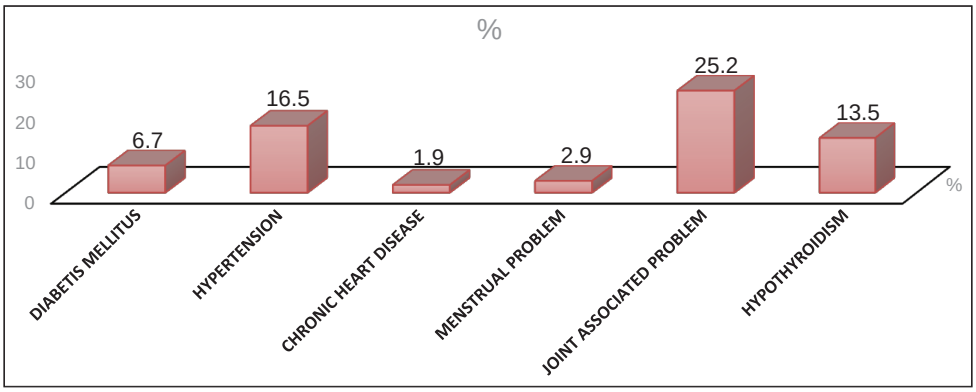

Figure 1: Number of patients (%) with comorbid conditions (Total = 47 [45.6%])

Table 3: Number of attendees with their HADS score

HADS score	Depression	Anxiety
Normal (0–7)	88	69
Borderline abnormal (8–10)	12	21
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Psychiatric illness was observed among 38.8% (40) of the obesity clinic attendees. Of 40, 32.5% were found to have abnormal level of HADS score and needed intervention. HADS: Hospital anxiety and depression scale

most of the patients were counseled for preventive measures such as diet, exercise, yoga, and walking.

Several intensive steps are required in obese patients that include medication according to metabolic profile of patients, treatment for weight loss, lifestyle modifications, and counseling for managing weight so that management can be sustained.[12,13] Depression causes low-energy level and motivation, leading person to care less about their health and causes change in their appetite. Our study found that the association was statistically not significant between obese and duration of obesity >5 or <5 years with psychiatric illness ($z = 0.44$, $P > 0.05$).

However, the meta-analytical study, it was found that the relationship between obesity and depression is bidirectional. Studies suggest that depressed people have a 58% increased chance of becoming obese, whereas obese people have 55% more chance of becoming depressed overtime.[10] Difference in our study may be due to smaller sample size. Further evaluation is required to find out possible cause of the association between depression and obesity; it may be psychological and biological.

CONCLUSION

The study showed considerable rate of psychiatric disorder in obese and overweight patients. This indicates early detection and intervention needed for both to decrease the morbidity and mortality among overweight and obese and also needed for a multidisciplinary approach in the management of obesity. Further study is required to prove that psychiatric evaluation might play an important role in completing obesity treatment. Actions need to be taken at different levels of organizations, multimedia, and educational institutions along with some changes in food distribution and policies.

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Research Article

Assessment of psychiatric illness and other comorbidities associated with patients attending obesity clinic in Ahmedabad

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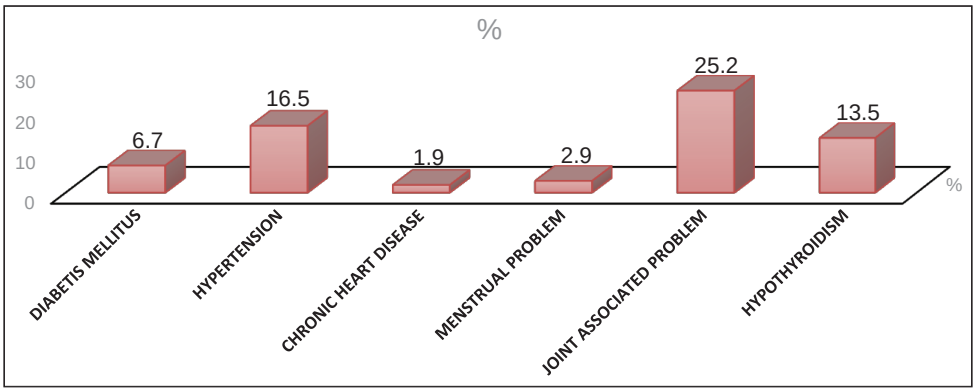

Figure 1: Number of patients (%) with comorbid conditions (Total = 47 [45.6%])

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Research Article

Study on sociodemographic variables associated with Vitamin B12 deficiency in symptomatic patients attending fever outpatient department, Civil Hospital, Ahmedabad

Utkarsh Khare[1], Chitralekha Vora[2], Pooja Soni[1], Dhaval V Parekh[1]

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ABSTRACT

Background: B12 deficiency is extremely common in India. Deficiency has varied manifestations and causes a range of disorders such as anemia, gastrointestinal, and neuropsychiatric manifestation and affects all age groups. **Objectives:** The aim of the study is to assess the clinical and sociodemographic variables associated with Vitamin B12 deficiency among symptomatic patients and to correlate the symptoms with serum level of Vitamin B12 deficiency. **Materials and Methods:** A cross-sectional observational study carried out among 97 patients attending fever outpatient department at civil hospital, Ahmedabad. Patients were interviewed with pretested questionnaire and were subjected for biochemical estimation of Vitamin B12, mean corpuscular volume, and hemoglobin. **Results:** Median age of attendees was 25 years (range: 13–64). Three out of eight symptoms were weakness (96.9%), tingling and numbness in hand and feet (60.8%), and fatigue (57.7%). All the patients who were tested on the basis of symptoms were found to be having Vitamin B12 insufficiency (<300 pg/ml). 46.3% were having severe deficiency (<150 pg/ml). Out of severely Vitamin B12 deficient patient, 47.8% were having any type of anemia. Study did not find any significant association ($P < 0.05$) between gender, diet, water supply, and level of Vitamin B12, whereas there was a significant association between religion and severity of Vitamin B12 deficiency ($\chi^2 = 6.09$, $P < 0.05$). **Conclusion:** All the patients need to be clinically screened for symptoms of B12 deficiency, and even the mild symptomatic patients should be treated to prevent the severe form of deficiency or neuropsychiatric manifestations. This will also reduce the unnecessary burden on laboratory.

KEY WORDS: Vitamin B12; Deficiency; Age; Religion

INTRODUCTION

Vitamin B12 is water-soluble vitamin, which is present in some foods naturally, added to some food items, and it is available as a prescription supplement in oral and injectable forms. Mineral "cobalt" is present in all the different forms of Vitamin B12, and therefore, these compounds with Vitamin B12 functions are called as "cobalamins." In our metabolism, two chemical forms of Vitamin B12, i.e., methylcobalamin and 5-deoxyadenosylcobalamin are active. Functions of Vitamin B12 in the human body include neurological development, synthesis of genetic material, i.e., DNA and maturation of red blood cells and other activity such as working as a cofactor for certain enzymes such as L-methylmalonyl-CoA mutase and methionine synthase.[1]

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symptoms which are often ignored, and chronic deficiency leads to neurological impairment and anemia. Therefore, prompt treatment is warranted if deficiency is found in serum Vitamin B12 levels.[2]

Neurological problems due to deficiency of Vitamin B12 include paresthesia, memory loss, ataxia, vision problem, and peripheral neuropathy. Another major effect of Vitamin B12 deficiency is due to immature red blood cells leading to megaloblastic anemia. There is a type of megaloblastic anemia called pernicious anemia caused by autoimmune mechanism; in this type of anemia, intrinsic factor (IF) of castle is destroyed by autoimmunity which is essential in the absorption of Vitamin B12 and this also increases the risk of development of stomach cancer. Vitamin B12 deficiency in the antenatal period is responsible for the neural tube defect in fetus. The deficiency also causes temporary infertility which is rare and usually improves by treating with Vitamin B12.[3]

Among the causes of Vitamin B12 deficiency, autoimmune pernicious anemia is the most common cause. Some other common causes include ileal resection, gastrectomy, pancreatic insufficiency, and malabsorption syndromes. Some less common causes include the use of drugs such as biguanides, antacids, aminoglycoside antibiotics, colchicine, and rarely malabsorption due to gastrointestinal overgrowth of bacterial and parasitic infestation. Pure nutritional deficiency is rare and usually occurs only in strict vegans.[4]

In case of specific populations, deficiency proportion is highest among pregnant women which is often associated with folate deficiency leading to developmental defects in fetus. Deficiency rates are reported to be higher in vegans than vegetarians. Among vegetarians, higher deficiency rates are seen in people vegetarian since birth compared to people who became vegetarian later in life.[5]

Early recognition of symptoms and prompt treatment has shown beneficial effect in case of serious neurological symptoms. Other than paresthesia and optic atrophy, rest all neurological symptoms are reversible if treated early.[6]

B12 deficiency is extremely common. There are many reasons for this and are related to diet, lifestyle, social, and cultural issues. In spite of being a common disorder, its recognition is delayed or missed because the manifestations are diverse in nature, affecting all the organs and systems, and is often subclinical. To add to the confusion, laboratory estimations are notoriously unreliable even from the best of centers and doctors tend to rely on laboratory estimate of B12 levels.

The present study is aimed to assess the clinical and sociodemographic variables associated with Vitamin B12 deficiency among symptomatic patients and to correlate symptoms with serum Vitamin B12 level.

MATERIALS AND METHODS

A cross-sectional study was done in fever outpatient department (OPD) of civil hospital, Asarwa, Ahmedabad. All the symptomatic patients attending fever OPD during period of September 2017–November 2017 were interviewed with pretested structured questionnaire, and those who were found positive for three symptoms out of eight, i.e., weakness, fatigue, tingling and numbness in hands and feet, soreness in mouth, poor memory and depressive symptoms, constipation, weight loss, and loss of appetite were subjected for biochemical estimation of Vitamin B12, mean corpuscular volume (MCV), and hemoglobin. Analysis was done using Microsoft Excel 2007 and Chi-square test. Ethical permission was taken. Informed consent was taken from patient after explaining about the study.

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Table 1 shows sociodemographic distribution of patients attending the fever OPD. Out of total 97 patients, 70 were females (72%) and 27 (28%) were males. Median age of attendees was 25 years (range: 13–64).

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Female	70	72.1
Male	27	27.8
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Vegetarian	62	63.9
Mixed	35	36.0
Drinking water source		
Bore well	9	9.2
Municipal supply	84	86.5
RO	4	4.1
Socioeconomic status (modified B.G. Prasad) *n*=97		
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Female	56	14		
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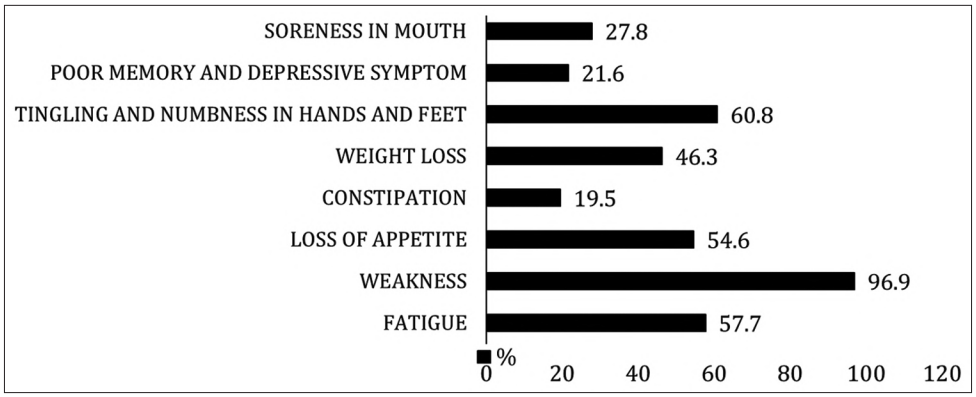
Muslim	12	07		
Hb deficiency present	35	05	1.65	>0.05
Hb deficiency absent	44	13		
Bore well	11	02	0.047	>0.05
Municipality	69	15		

Hb: Hemoglobin



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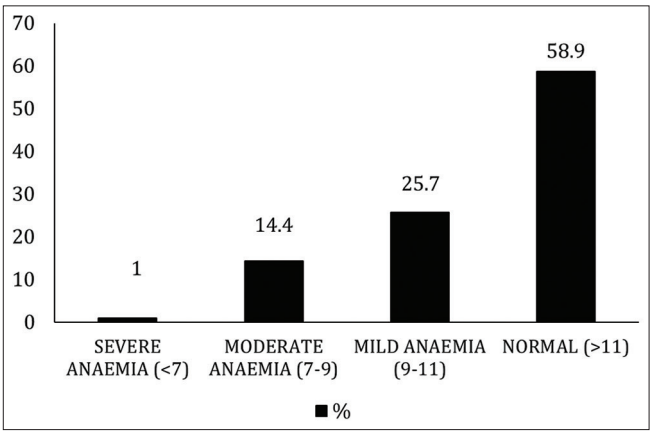

Figure 2: Hemoglobin level in patients with Vitamin B12 deficiency patients

DISCUSSION

Vitamin B12 deficiency is frequently underdiagnosed and undertreated condition due to vague symptoms which leads to chronic deficiency and irreversible neurological impairments. Therefore, clinical assessment and serology both are very important for diagnosis.[2]

This study shows that the median age of attendees was 25 years, and the number of males was not enough to make any gender-based conclusion whereas in some studies done on south Asians risk appeared to be similar for male and female.[7] Majority of the patients were vegetarian (63.9%), the deficiency even among patients who were non-vegetarian, it was found that they ate meat only occasionally. They were using municipality water supply (86.5%) and belong to lower socioeconomic class (63.8%). However, our study did not find any significant association ($P > 0.05$) between gender, diet, water supply, and Vitamin B12 deficiency. There was a significant association between religion and severity of Vitamin B12 deficiency ($\chi^2 = 6.09$, $P < 0.05$) which may be due to difference in cultural practices. Similar study done in Toronto found Vitamin B12 deficiency even among non-vegetarians.[7] Most common symptoms were weakness,

tingling and numbness in hands and feet, and fatigue which is similar to study conducted in Maharashtra.[8] All patients who were tested on the basis of symptoms (n = 97) were having Vitamin B12 deficiency of which 46.3% were having severe deficiency (<150 pg/ml), 36% were having deficiency (150–200 pg/ml), whereas 17.7% were having potential undersupply (200–300 pg/ml).[9] There is evidence that B12 deficiency might clinically present at a much higher B12 concentration, i.e., in low normal range (500–600 pg/ml). Lindenbaum *et al*. observed that many individuals presented with deficiency symptoms at serum Vitamin B12 levels as high as 350 pg/ml,[10] whereas in another group, Van Tiggelen *et al*. recommended levels to be 600 pg/ml.[11] Our study shows that 61.8% of patients had normal range of MCV, which tell us that MCV alone is not enough as a diagnostic parameter of Vitamin B12 deficiency. Out of Vitamin B12 deficient patient (n = 97), 47.8% were having any type of anemia because of the often coexisting iron deficiency could decrease MCV levels. Similar findings were seen in a study done in Toronto in south Asians.[7]

In our study, there were limitations, we did not use any other biochemical markers, for example, methyl-malonic acid or homocysteine; this study was based on serum B12 results and clinical symptoms, which alone, without other biochemical markers might be inaccurate measures of B12 deficiency. Outside our study setting, i.e., tertiary level of health facility, these findings might not be generalized.

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Recommendations

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CONCLUSION

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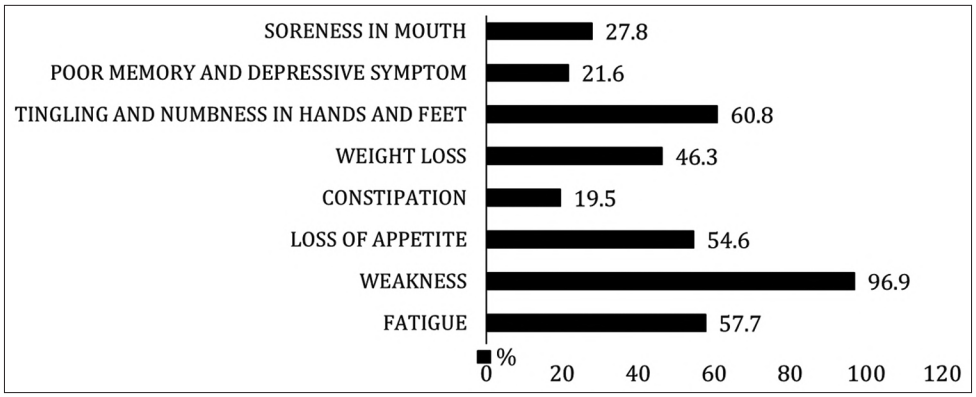

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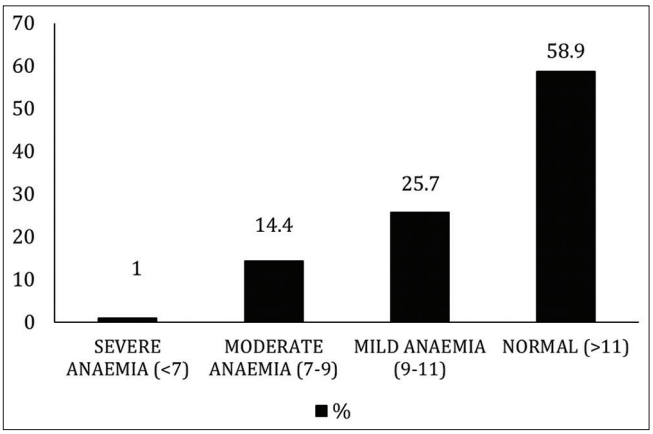

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ORIGINAL RESEARCH ARTICLE

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Assessment of Indian diabetes risk score as a tool for identifying diabetes among urban residents

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ABSTRACT

Background: Indian Diabetes Risk Score [IDRS] by Madras Diabetic Research Foundation was approved as screening tool in National programme for prevention and control of Cancer, Diabetes, Cardiovascular Diseases and Stroke (NPCDCS). This study was planned to test the utility of IDRS in screening diabetes among urban population. **Methods:** This cross-sectional study was conducted among 625 individuals residing in urban wards of Rajahmundry in 2013-14. Data was collected on socio-demographic variables, anthropometric measurements followed by testing for fasting blood sugars to diagnose diabetes. Area under receiver operating characteristic curve was calculated for presence of diabetes. **Results:** In the present study 49.92% population had high risk score (≥60) for diabetes. The prevalence of diabetes in our study was about 15.4%, and pre-diabetes was 4.5 % (total 19.9%). It was observed that obesity among females was 43.36%, among males it was 31.52%. In this study IDRS >60 had the sensitivity of 79.17% and specificity of 50.0%. IDRS >60 not only diagnoses diabetes also identifies coronary artery disease. In the community it also helps to identify metabolic syndrome.

Conclusions: IDRS is a useful screening tool for early diagnosis diabetes and initiation of appropriate lifestyle interventions to prevent various complications of diabetes mellitus.

Key Words: Diabetes mellitus, Indian Diabetes Risk Score, urban adults, Andhra Pradesh

INTRODUCTION

Diabetes Mellitus is the most common non communicable disease globally with more than 424.9 million people.[1] China having highest burden of diabetes with 114.4 million, India is in second position with 72.9 million.[2] India is expected to emerge as a global leader in diabetes mellitus by the year 2045. Even though India is having huge burden of diabetes in the world, most of them remain undiagnosed.[3] Early detection is critical for moderating the health and economic impacts of the disease. It is neither feasible nor cost effective to perform universal screening for type 2 diabetes using blood sugar estimations to cover the whole population. Targeted screening with a non-invasive test for initial selection of subjects followed by plasma glucose testing in high risk individuals only is a more efficient approach.[3] Assessment of risk of undiagnosed type 2 diabetes is commonly used to identify individuals who need to be recommended for further biochemical testing.

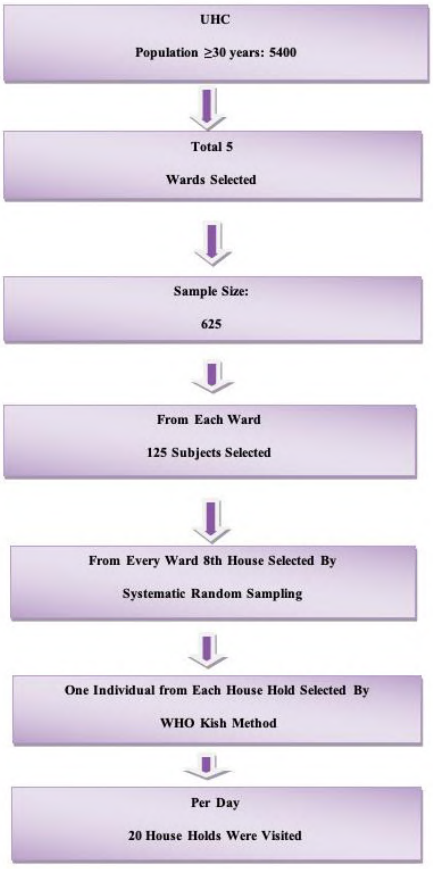
Diabetes is not only disease of affluence now it is increasing in slum areas. The increasing risk factors are like taking junk foods, high calorie and high cholesterol diets, sedentary life styles, smoking and alcohol habits.[4] This vulnerable population because of unawareness, inaccessibility to health care, health seeking behaviour also less among urban slums need interventions that are cost effective, feasible for screening and detection of diabetes and early signs of complications.[5] To detect millions of Indians by Indian Diabetes Risk Score [IDRS], which is cost effective, feasible, non-invasive and non bio-chemical Madras Diabetic Research Foundation was approved by Government of India and utilised as screening tool in National programme for prevention and control of cancer, Diabetes, Cardiovascular Diseases and stroke (NPCDCS).[6] Keeping in view of afore mentioned facts, study was carried out in the urban health centre area of a Medical College to test the utility of Indian diabetic risk score in screening diabetes among urban population.

MATERIAL AND METHODS

This study was commenced after institutional ethical committee approval. Written informed consent was obtained from respondents. The study was conducted at urban wards of Rajahmundry city in Andhra Pradesh, over a period of one year. The prevalence of known diabetes in urban areas according to ICMR is around 14-20%. The prevalence of type-2 diabetes in these areas is 13.5% at 95% confidence interval with 80% power, the expected sample size required to estimate the prevalence of diabetes was 625. The type of probability sampling adopted for this study is multistage sampling technique for selecting wards and households (Figure 1).

Data collection was done using a pretested questionnaire containing details of socio-demographic profile (Age, sex, income, education, occupation, and religion), anthropometric variables (height, weight, waist circumference and clinical details for each study participant, risk was assessed using an IDRS scoring. Fasting capillary blood glucose was determined using the glucose meter (One Touch Ultra, Life scan Johnson & Johnson) to those subjects with IDRS score >60. According to ADA guidelines fasting capillary blood >126 is diagnostic of diabetes. ADA recommended use of fasting blood glucose alone for diagnosis in epidemiological studies as well as in clinical diagnosis except in pregnant.[7] All newly diagnosed diabetic subjects were asked to confirm their diabetes with a venous OGTT or repeat plasma glucose values at the local urban health centre or at a government hospital.

Figure 1. PROCEDURE OF CONDUCTION OF STUDY



Definitions:

Diabetes: Diabetes was defined by physician diagnosis of diabetes and current use of medications for diabetes (insulin or oral hypoglycaemic agents) and/or fulfilment of criteria laid down by the WHO Consultation Group Report, i.e., capillary fasting blood glucose ≥126 mg/dl or 2 h capillary post-glucose value ≥220 mg/dl.[8]

Impaired Fasting Glucose: Impaired fasting glucose was defined based on WHO criteria, i.e., if fasting capillary blood glucose ≥110 and <126 mg/dl.[8]

Impaired Glucose Tolerance: Impaired glucose tolerance was defined according to WHO criteria where 2hr capillary post-glucose value is ≥160 but <220 mg/dl with a fasting value in the non diabetic range. All data collected were stored electronically. All statistical analyses were performed by using SPSS Software version-21 for Windows, MedCalc. Version 12.7.3.0. Software for Windows and Ms-excel 2007. Values were presented as Mean ± SD and in percentages. Chi-square tests were used for examining the association of categorical variables. Binary logistic regression was used for predicting the diabetes. For all statistical analyses $p<0.05$ was considered statistically significant. ROC curves were drawn for validating IDRS Scores.

RESULTS

Table-1: Descriptive Statistics of the Baseline characteristics (N=625)

Study Variables	Min.	Max.	Mean	Std. Deviation
Age	30	80	42.85±10.57	10.57
S.BP.	93	231	136.97±23.92	23.92
D.BP	60	211	86.99±17.76	17.76
Height	135	178	155.95±9.20	9.2
Weight	47	102	66.14±9.06	9.06
Waist	65	124	89.66±8.85	8.85
Hip	78	140	102.56±10.89	10.89
Waist/Hip Ratio	0.66	1.13	0.87± 0.06	0.065
IDRS Age	0	30	17.23±10.88	10.88
IDRS Abdominal Obesity	0	20	10.54±7.80	7.8
Physical Activity	0	30	20.85±8.47	8.47
IDRS Family History	0	20	4.11±7.19	7.19
IDRS Total	0	100	52.74±18.38	18.38
BMI	19.1	43.37	27.27±3.72	3.72
Cooking Oil Usage Kgs/Month	1	10	4.09±1.49	1.49
Cooking Oil Usage Per Person	0.3	2	0.85±.331	0.331
FBS	59	162	103.6±25.77	25.77

We collected data among 625 subjects residing at field practise area of urban health centre Socio-demographic, anthropometric data collected for all the subjects and fasting blood sugar test conducted for the subjects with

Table-2: Cross tabulation between BMI & Sex, IDRS Abdominal Obesity (N=625)

Sex			Total	IDRS Abdominal Obesity Score			Total	P Value
	Female No. (%)	Male No. (%)	No. (%)	0	10	20	No. (%)	
Normal Weight	27 (50.94)	26 (49.06)	53 -8.48	21 (39.62)	20 (37.74)	12 (22.64)	53 (8.48)	
Over Weight	56 (53.85)	48 (46.15)	104 (16.64)	29 (27.88)	49 (47.12)	26 (25)	104 (16.64)	
Obese	271 (57.91)	197 (42.09)	468 (74.88)	124 (26.50)	174 (37.18)	170 (36.32)	468 (74.88)	0.035
Total	354 (56.64)	271 (43.36)	625 (100)	174 (27.84)	243 (38.88)	208 (33.28)	625 (100)	

Table-3: Cross Tabulation between IDRS Total & FBS (n=312)

FBS		IDRS Total		Total	P-Value
		<60 (N(%))	≥60 (N(%))	(N(%))	
Group	<126	5 (17.86)	23 (82.14)	28 (22.58)	0
	≥126	-	96 (100)	96 (77.42)	
Total		5 (4.03)	119 (95.97)	124	

Table-4: Correlations between IDRS Abdominal Obesity & FBS (n=312)

Study Variables		IDRS Abdominal Obesity	FBS
IDRS Abdominal Obesity	Pearson Correlation	1	0.142*
	Significance (2-tailed)	-	0.012
FBS	Pearson Correlation	0.142*	1
	Significance (2-tailed)	0.012	-

*Correlation is significant at the 0.05 level (2-tailed)

with IDRS total >60 (n=312). It was observed that among 312 subjects, 96 of them got fasting blood sugar >126mg/dl.

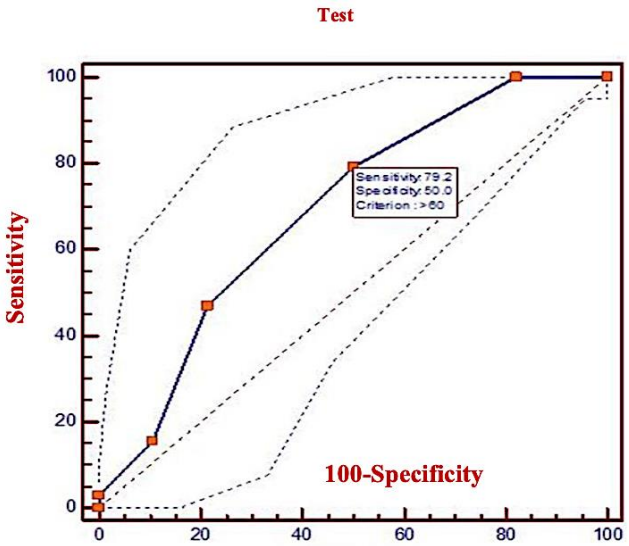
Descriptive statistics of continuous variables shows mean age of participants in this study is 42.85±10.574, mean systolic BP of the participants is 136.97 ± 23.929, mean diastolic BP is 86.99±17.762, mean weight is 66.14±9.062 which are in the hypertensive range and obese ranges. Mean IDRS total in this study is 52.74% nearer to mainly pre diabetic range. Mean cooking oil usage per person is 0.8597 kg which is higher than recommended daily usage per person i.e., 0.5 kg per person per month. Mean waist and waist hip ratios are showing on higher ranges. (Table 1)

Table-5: Linear Regression between IDRS Abdominal Obesity & FBS (n=312)

Model	Unstandardized Coefficients		Standardized Coefficients		Signifi-cance
	B	Std. Error	Beta	t	
(Constant)	97.743	2.76	-	35.409	0
IDRS Abdominal Obesity	0.482	0.191	0.142	2.531	0.012

a. Dependent Variable: FBS

Fig-2 ROC Curve for IDRS ≥60



Both over weight and obesity is seen more among females compared to males. Statistical significance (p=0.035) is seen between BMI and IDRS abdominal obesity. Abdominal obesity is dependent on BMI. (Table 2)

Interpretation: Chi square test applied between two categorical variables such as FBS (FBS categorised into <126 and > 126 as two groups) and IDRS (IDRS into two

groups <60 and > 60). Test shows IDRS scores are statistically significant (p<0.05 i.e., p=0.000) from fasting blood sugar. (Table 3) From Table 4 it is clear that there is statistical significant (p=0.012) positive correlation between IDRS abdominal obesity and fasting blood sugars.

From Table 5 prediction model also it is clear that fasting blood sugar dependent on IDRS abdominal obesity and which is statistically significant (p=0.000). From all the five tables it is clear that through Chi-square test, correlation, and through regression model IDRS abdominal obesity is a powerful predictor of diabetes. Statistical significance observed in these three tests.

Validation:

ROC curves were constructed to identify the optimum value (>60%) of IDRS for determining diabetes as diagnosed using WHO consulting group criteria. Sensitivity, specificity, positive and negative predictive values and accuracy for predicting undiagnosed diabetes were calculated for different cut off scores ROC's were obtained for IDRS and tested for newly diagnosed diabetes diagnosed using WHO criteria.

The AUC for the ROC was 0.690 (95% Confidence interval 0.601 to 0.770) with significant P value (0.0016). IDRS is valid tool for predicting diabetes.

DISCUSSION

In this study we used a simplified Indian Diabetes Risk Score for risk assessment and identifying newly diagnosed diabetic subjects in the field practise area of medical college. Further, use of such a risk score would be of great help in developing countries like India especially in urban slums[9] where there is a marked explosion of diabetes and over half of the cases remain undiagnosed. In the present study 49.92% population had high risk score (≥60) for diabetes. In a similar study[7] conducted at Chennai by Mohan et al., 43% of the population were found in high risk category to be screened with IDRS score of ≥ 60 has 72.5% sensitivity and 60.1%specificity. Another study done by Sanjay Kumar Gupta et al[10], in urban Pondicherry had 31.2% high risk subjects. This risk difference may be due to variance in life-styles of the population. Our study was done in a urban slum area, whereas Mohan et al[6], conducted the study in a metropolitan city and another study was in the urban area of Pondicherry. In Boloor diabetic study[11]by Prabha Adhikari et al 29.7% had high risk score ≥60. The prevalence of diabetes in our study is about 15.4%, and pre-diabetes is 4.5 %(total 19.9%), whereas PODIS study[9] showed 18.6% in Chennai which is a metropolitan city with affluent lifestyle.

Obesity is a potent risk factor for diabetes; in this study it is observed that obesity among females is 43.36%, among males it is 31.52%. Overweight among females is 8.96% and among males is 7.68%. Banerji et al[12], Dickinson et al[13], showed that several cross-sectional epidemiological studies suggest that obesity and abdominal obesity are strongly linked to diabetes. Sanjay kumargupta et al[10],in their study showed 39.64% are overweight, 40% are obese in Kerala which is similar to this study. Now even at low thresholds for conventional risk factors for Asian Indians.[14]

According to Eberhart, Ogden et al.[15] Approximately 55% cases of type 2 diabetes are due to obesity. Chronic obesity ultimately leads to increased insulin resistance,[16] which can develop into type 2 diabetes, because of adipose tissue (mostly that in the stomach around internal organs) is a passive source of several hormones, cytokines and chemical signals , to other tissues. Anjana et al.[17] It was found that diabetic subjects had significantly higher visceral fat (measured by CT) and central abdominal fat (measured by DEXA) compared to non-diabetic subjects, abdominal fat was significantly greater in the diabetic group. Abdominal adiposity assessed using waist circumference is considered to be more appropriate than generalised adiposity assessed by BMI by Gundurao et al.[18]

In this study screening of study population done by Indian Diabetic Risk Score developed by V Mohan et al.,(MDRF)[6]which was approved by Government of India and using in NPCDCS. The MDRF – IDRS is easy to administer and tabulate and its accuracy makes it a useful screening test for diabetes with simple four questions and one anthropometric measurement namely waist circumference.

In this study IDRS >60 has the sensitivity of 79.17% and specificity of 50.0%, in Boloor study by Prabha Adhikari et al[11], in southern part of India with sensitivity 62.2% and specificity of 73.7% and in their study they took 20 years and above as age limit. In a similar study[6]conducted at Chennai by Mohan et al., 43% of the population were found in high risk category to be screened with IDRS score of ≥ 60 has 72.5% sensitivity and 60.1%specificity.

IDRS >60 not only diagnoses diabetes also identifies[19] coronary artery disease, diabetic peripheral neuropathy, peripheral vascular disease. In the community it also helps to identify[20, 21] metabolic syndrome. IDRS can be used as tool not only for diagnosing it is a valid motivational tool[22] for life style change. This IDRS tool validated at 5 places namely Andhra Pradesh, Boloor, Madras, Pondicherry, and Vellore.

There are two steps involved in cost effective screening for diabetes at the community level. Use of Indian Diabetic Risk Score is the first step to identify persons at high risk for diabetes. Step two involves use of blood test, such as random capillary blood glucose or fasting blood sugar to further narrow validation. The validated IDRS has been successfully implemented as a practical screening tool to assess the diabetes risk and to detect undiagnosed type 2 diabetes. Moreover, it also proved suitable in prediction of metabolic syndrome and cardiovascular disease in the South Indian population. Further confirmation with GTT is required among subjects with IDRS >60 to detect early, the occurrence of diabetes. We therefore recommend that all those with FBS ≥100 mg/dl at initial screening to undergo definitive testing by OGTT as this will help to pick up everyone with any glucose intolerance, i.e., diabetes, IGT or IFG.

Besides this, lifestyle and dietary modification are to be initiated to reverse the risk factors among these people.

The limitations of our study were, use of capillary blood glucose estimation instead of venous glucose estimation, which would have been ideal. More number of female participants than male subjects in this study. The proportion of females (56%) was higher than males (44%). Men in this area are working in Municipal Corporation as drain cleaners and sweepers and they go early in the morning and come late in the evening.

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Research Article

Burden

Burden of combined obesity among students of a medical college in Guntur city of Andhra Pradesh

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Background: Obesity is a major public health problem especially in adolescent age group. Obesity is now recognized as a chronic or non-communicable disease. Medical students are not an exception to this fast spreading epidemic, despite their medical knowledge. Few studies in fact have reported higher prevalence among medical fraternity than general population. Also, based on scientific evidence of higher proportion body fat than muscle mass among Asian Indians, the actual prevalence may be higher than what is assessed by WHO cut off for BMI. In some cases central obesity is very high in individuals whom the BMI is normal. Both BMI and WC in combination would be better predictors of obesity related diseases than sole using of BMI or WC alone. Very limited knowledge is available on combined obesity. So, we planned this study to know its burden especially among medical students. **Methodology:** It was a cross-sectional study at a medical college in Andhra Pradesh. A total of 207 medical students were selected from first and third semesters by simple random selection. Data was collected on sociodemographic data and the data of height and weight (BMI, General obesity), waist circumference (Central obesity). Finally, we estimated the burden of combined obesity (BMI+C.O). **Results:** It was observed that 35 (16.91%) medical students were having combined obesity (obesity according to BMI and waist circumference G.O + C.O). Among them 15 (20%) are male, and 20 (15.15%) are female students. **Conclusions:** The present study gives an idea about the high prevalence of combined obesity in the medical students. This should be an alert signal because medical students are the future doctors, health leaders and role models to the community. So, we need to identify specific barriers among medical students and come up with workable solutions.

Keywords: BMI, Central Obesity, Combined Obesity, General Obesity, Medical Students

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Introduction

Background: Obesity is a major public health problem especially in adolescent age group. Obesity is now recognized as chronic non-communicable disease [1]. Medical students are also not an exception to come under this over weight and obesity category in spite of their medical knowledge. Stress is the major factor which contributes to obesity [2].

Medical education is highly stressful so majority of the students are having irregular unhealthy lifestyle. Due to the pressure of examinations and lack of coping skills medical students have irregular dietary habits. Medical students need to be extra conscious about overweight and obesity because its prevalence was found as high among them.

This obesity and overweight is a major risk factor for non-communicable diseases and co morbidities [3-4]. In Asian Indians evidence show that body fat is more than muscle mass. According to WHO cut off for BMI in non obese are actually obese when body fat taken into consideration [5]. In some cases central obesity is very high in individuals whom the BMI is normal which has been termed "metabolically obese" [6].

Studies shows that in The Asian Indians body fat composition is high compared to muscle mass which is the main cause for metabolic obesity. Some Indians considered non-obese by the WHO criteria of BMI cut-offs are actually obese when body fat is used to define obesity. Secondly there is a high prevalence of abdominal adiposity even in people who are otherwise considered as non-obese [7-8-9].

Central obesity is important risk factor for cardiac risk than compared to general obesity. Waist circumference is simple and easily obtainable measurement for central obesity [10-11].

In many studies BMI has taken as important parameter for obesity, but in few studies waist circumference has taken into consideration. In our study we have taken both BMI and WC combined obesity which is a potential risk factor for many diseases especially non-communicable diseases.

So this study was done with the aim to estimate the prevalence of central obesity combined with high Body Mass Index among the undergraduate medical students.

Objectives of the study: The primary objective Was to assess the burden of central obesity combined with high Body Mass Index among medical students.

Methodology

Study setting: The current study was conducted in a tertiary care teaching hospital in Andhra Pradesh

Study duration: Study was conducted for a period of twelve months in the year 2018 including study design, approval and data acquisition and analysis

Study type: Cross-sectional study

Sampling methods: We have selected 207 medical students from first and third semesters by simple random selection.

Inclusion criteria: First and third semester students of MBBS were included in the study.

Exclusion criteria: if the student was suffering from any psychiatric illness or under any antidepressant medications they were excluded from the study.

Data collection procedure: Data was collected using a structured data collection tool, comprising of self-administered close ended questionnaire on key demographic variables. The tool also had details regarding the anthropometric parameters like weight, height, waist circumference.

Initially data on self-administered questionnaire was collected in the class room, after making them seated at sufficient distance to avoid discussion and exchange of information. Later anthropometric measurements were done at the end of practical or clinical posting sessions.

Height was recorded with stature meter, while individuals stood straight with their heels, buttocks and scapula rest against a wall. Waist circumference (WC) was measured using a flexible non-elastic measuring tape. Individuals stood with their feet together, arms resting by their side.

Waist circumference was measured at the approximate midpoint between the lower margin of the last palpable rib and the top of the iliac crest according to WHO STEPS protocol [12].

The BMI was calculated using the Quetelet's equation (ratio of weight in kg and square of height in m). BMI cut off values for Indians to define overweight and obesity taken from WHO. Participants with waist circumference value higher

Than gender specific waist circumference cut off values (90 cm for males and 80 cm for females) were considered to central obesity. People with both higher BMI and higher than gender specific cut off value of waist circumference were considered as central obesity [5].

Data analysis: Data was compiled in Excel sheet and later analysed with SPSS Statistics version 21. Quantitative variables were summarized as mean and standard deviation; categorical variables were summarized as frequencies and percentages.

Association between quantitative variables was assessed by Pearson correlation coefficient. P Value < 0.05 will be considered as statistically significant.

Ethical consideration and permission: Study was commenced after Institutional ethical committee approval. Written informed consent was obtained from the participants before initiation of the study.

Results

A total of 207 students were included in the final analysis. Among 207 students, males were 75 (36.23%), females 132 (63.77%), hostellers 73 (35.3%), day scholars 134 (64.7%).

Family history nil for NCD's in 60 (29%), in 61 (29.5%) one lifestyle diseases was present, in 86 students (41.5%) more than one problem present for e.g. either hypertension, or diabetes or CAD.

Among 207 students 62 (29.9%) are not involved in any sort of exercise, 54 (26.1%) students were doing 30 minutes per day, 85(41.1%) students were involved in sports for more than 30 minutes per day.

Time spending with TV music up to one hour seen in maximum number of students 117 (56.5%), 17 students (8.2%) watching for 3 hours and more than 3 hours per day. Mobile usage of up to 1hour seen in 125 (60.4%) students, maximum of 3 hours and more seen in 33 (15.9%) students (Table 1).

Table-1: Characteristics of the study population (N=207).

Parameter	N (%)
Gender	
Male	75 (36.23 %)
Female	132 (63.77 %),
Place of residence	
Hostel	73 (35.3%),
Day scholar	134 (64.7%)
Socio economic status	
below Rs.40,000	52 (25.11%)
Rs.40,000 to Rs.1 lakh	120 (58.0%)
more than 1lakh	35 (16.9%)
Family history of NCD	
Nil	60 (29%)
One	61 (29.5%)
More than 1 NCD	86 (41.5%)
Physical activity	
Nil	62 (29.9%)
10 to 20 mints per day	6 (2.9%)
30 mints per day	54 (26.1%)
More than 30 minutes per day	85 (41.1)
Spending with TV	
Nil	11 (5.3%)
Up to 1 hour	117 (56.5%)
More than 1 hour	79 (38.2%)
Mobile phone usage	
1hour seen in	125 (60.4%)
>1 hour to <3 hours	49 (23.7)
3hours and more	33 (15.9%)

Table-2: Prevalence of Obesity as per different criteria.

Obesity	Male (N=75)	Female (N=132)	Overall (N=207)
Obesity (As per BMI)			
Yes	22 (29.33%)	27 (20.45%)	49 (23.67%)
No	53 (70.67%)	105 (79.54%)	158 (76.33%)
Obesity as per WC			
Yes	20 (26.67%)	34 (25.76%)	54 (26.09%)
No	55 (73.33%)	98 (74.24%)	153 (73.91%)
Obesity Combined			
Yes	15 (20%)	20 (15.15%)	35 (16.91%)
No	60 (80%)	112 (84.85%)	172 (83.09%)

According to waist circumference 20 males (26.67%) have central obesity (WC > 90cm), female students 34 (25.76%) have central obesity (WC > 80cm), 55 (73.33%) male students and 98 (74.24%) female students have waist circumference within normal limits (Table 2).

It was observed that 35 (16.91%) medical students were having combined obesity (obesity according to BMI and waist circumference G.O + C.O). Among them 15 (20%) are male, and 20 (15.15%) are females (Table 2).

Table-3: Correlation among different variables.

Correlations							
		Waist Circumference	Exercise	Reading	Mobile	Physical Activity	TV and Music
Waist Circumference	Pearson Correlation	1	-0.292**	0.083	-0.023	-0.320**	0.081
	Sig. (2-tailed)	-	0.000	0.236	0.741	0.000	0.245
Exercise	Pearson Correlation	-.292**	1.0	0.077	-0.008	0.723**	0.032
	Sig. (2-tailed)	<0.001	-	0.269	0.910	0.000	0.642
Reading	Pearson Correlation	0.083	0.077	1.0	-0.219**	0.263**	-0.168*
	Sig. (2-tailed)	0.236	0.269	-	0.001	0.000	0.016
Mobile	Pearson Correlation	-0.023	-0.008	-0.219**	1	0.015	0.054
	Sig. (2-tailed)	0.741	0.910	0.001	-	0.826	0.436
Physical Activity	Pearson Correlation	-0.320**	0.723**	0.263**	0.015	1	0.001
	Sig. (2-tailed)	<0.001	<0.001	<0.001	0.826	-	0.993
TV & Music	Pearson Correlation	0.081	0.032	-0.168*	0.054	0.001	1
	Sig. (2-tailed)	0.245	0.642	0.016	0.436	0.993	-
**. Correlation is significant at the 0.01 level (2-tailed).							
*. Correlation is significant at the 0.05 level (2-tailed).							

It was found significant (P<0.001) positive correlation between BMI and Waist Circumference. There is significant (P<0.001) negative correlation between Waist Circumference and exercise.

There is significant negative correlation between reading and mobile usage. TV viewing & listening music also has significant negative correlation with reading (Table 3).

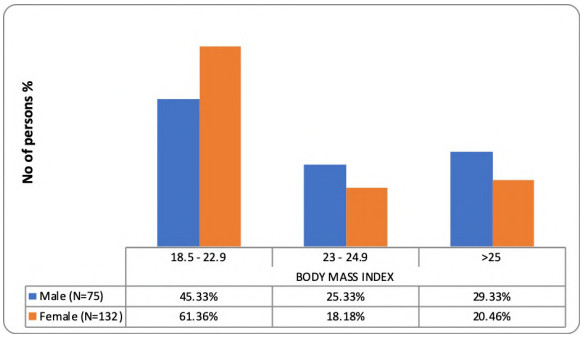

Figure 1: Prevalence of overweight and obesity according to BMI

According to BMI (WHO'S South East Asian guidelines) [13], 115 (55.56%) students comes under normal weight (BMI 18.5 to 22.9), 43 (20.77%) students comes under over weight (BMI= 23 to 24.9), 49 (23.67%) students belongs to the category of general obesity (BMI > 25) (Figure 1).

Discussion

In this study among 207 students 43 (20.77%) students are overweight and 49 (23.67%) were obese according to BMI. Central obesity according to Waist circumference observed in 54 (26.09%) medicos. Combined obesity (BMI + C.O) is seen among 35 (16.91%) medical students.

BMI and Waist circumference was positively correlated, means when BMI increasing waist circumference also increasing. Waist circumference is significantly correlated negatively with exercise or physical activity.

Similar study was conducted at Meenakshi Medical College hospital and research institute, Enathur, Kanchipuram district, Tamil Nadu, Out of 500 students, 458 (92%) participated in the study [14]. 54% among them were males and 46% were females.

The prevalence of overweight was 24.3% and the prevalence of obesity according to BMI was 8.6% according to WHO guidelines [15]. Similar study conducted at BMCRI, Bengaluru, from July-September 2014, in this study only BMI and waist circumference taken for estimating prevalence of obesity [16].

Out of the total 424 students studied, 62 (14.6%) were overweight and 48 (11.3%) were obese according to BMI. Risk factors like junk food, long hours of mobile and computer usages were taken. Out of 424 students studied, 47 males and 110 females making a sum of 157 (37%) who was considered to have central obesity according to their waist circumference [16].

Another study done at Haryana among 130 MBBS students, normal BMI was observed in 73.1%

Students, while 22.3% students were overweight, 3.1% obese [17]. A study was done at G.R medical college Gwalior among 131 second semester medical students.

In that study also BMI taken for overweight and obesity assessment and found the prevalence of overweight was 13(9.93%) and the prevalence of obesity was 2 (1.53%). The prevalence of underweight was 25 (19.08%) [18].

In this study we mainly concentrated on combined obesity which includes both BMI and waist circumference, which predicts more metabolic obesity. 20% of male students, 15.15% female students have combined obesity which is alarming.

Evidence suggests that the body composition abnormalities of Asian Indians may have an important bearing on the pathogenesis of metabolic derangements. First, their body fat is more and muscle mass less than compared with other Asian ethnic groups. Present day dietary habits, stressful routine lead to decreased physical activity is a primary drive of overweight and obesity.

Obesity leads to many medical consequences like hypertension, diabetes, coronary artery disease, stroke, and cancers. Psychological consequences are anxiety, depression, isolation, rejection, poor self-image, and poor performance and the mechanical disturbances include osteoarthritis, abdominal hernia, diaphragmatic hernia, varicose veins.

Chronic obesity ultimately leads to increased insulin resistance, because of visceral fat which is a passive source of several hormones, cytokines and chemical signals to other tissues which can develop into type 2 diabetes. Central obesity is an important predictor of metabolic disorders than BMI [19].

Obesity is not only aetiology of many diseases it also affects the quality of life and finally leads to premature death [20]. Both BMI and WC in combination would be better predictors of obesity related diseases than sole using of BMI or WC alone [21].

Medical students in this study were in prepathogenesis phase or in latent period of non-communicable diseases. The obesity problem can be reversible if we tackle them as early as possible through proper balanced diet, preventing sedentary lifestyle such as reducing TV watching time, promoting more physical activity and sports according to their interest and also coping skills for stress management.

Conclusion

The present study gives an idea about the high prevalence of overweight and obesity in the medical students. Obesity due to BMI and Waist circumference (Combined Obesity) in this study shows alarming situation in medical students. This study highlights that medicos though they are having knowledge about nutrition and physical activity could not be able to implement practically.

Students should focus on improving time management skill also they need to be encouraged to participate in physical exercise, especially sports, athletics, and other outdoor activities. Improvement in dietary habits, if made in early years of medical schooling, would produce physicians practicing and promoting healthy dietary habits. Awareness through health education was created to the medical students while measuring anthropometric measure-ments.

This should be an alert signal because medical students are the future doctors, health leaders and role models to the community. Further studies should be undertaken to identify specific barriers among medical students in practicing healthy dietary habits and come up with workable solutions. Therefore, it is of utmost importance to have early intervention programmes to prevent non-communicable diseases among these future doctors.

What this study adds to existing knowledge

The study had highlighted the prevalence of different types of overweight and obesity among medical students. The key addition of the study was it’s documentation of overall and central obesity and their overlap among the study population. The study highlights the importance assessing waist circumference, along with BMI, to avoid underestimation of the true burden of overweight and obesity.

Author contribution

Dr. SS had conceptualized the study, prepared the study protocol, and conducted the data collection, analysis and manuscript writing. She has verified all the drafts and approved the final draft. Dr. SD had provided key inputs on methodology during protocol preparation, supported data compilation and analysis. She has also edited all the drafts and

Approved the final draft of the manuscript.

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Limitations

First, the sample used in this study was a convenient sample and thus findings need to be interpreted with caution. Further qualitative studies are needed for better understanding to plan for interventions.

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Research Article

A cross-sectional study on the knowledge and practice of travel vaccination and malaria prophylaxis for international travel among resident doctors of Ahmedabad city, Gujarat

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ABSTRACT

Background: Travelers play a significant role in the spread of infectious diseases across international borders, through their travel patterns and behaviors. Travel may be the only risk factor for infectious diseases that are well controlled in the travelers' country of residence, particularly vaccine-preventable diseases. **Objectives:** The aim of this study is to assess the knowledge and practice of travel vaccination and malaria prophylaxis among resident doctors of BJ Medical College and Civil Hospital, Ahmedabad. **Materials and Methods:** This was a cross-sectional study conducted at Civil Hospital and BJ Medical College, Ahmedabad. The study was conducted from July 2017 to October 2017. A pilot study was conducted among 20 resident doctors, and the prevalence of knowledge of travel vaccination was found to be 65%. Using the formula $4pq/L^2$, data were collected from 100 resident doctors. Data were collected using a semi-structured questionnaire, and data analysis was performed using Microsoft Excel 2013 and EpiInfo 7. For statistical analysis, Chi-square test was applied. Ethical consent was taken from all respondents. **Results:** 86% of the resident doctors were having knowledge about travel vaccination, and 79% were knowing about the requirement of malaria prophylaxis given to travelers. The travel vaccine knowledge was 100% among the persons above 30 years of age, and it was 86% in the younger age group (20–25 years). Country-wise knowledge about travel vaccination was more for developing countries than developed countries. Only 8.3% gave the history of taking immunization for international travel. Reasons for not taking immunization were not required for country of travel followed by non-awareness. **Conclusion:** The knowledge of travel vaccine and malaria prophylaxis was more among the 30+ age group followed by 20–25 age groups, and the knowledge of both was more among males. The practice of travel vaccination was found to be poor.

KEY WORDS: Travel Vaccination; Malaria Prophylaxis; Resident Doctors

INTRODUCTION

Travelers often play an important role in the spread of infectious diseases across borders, through their travel plans, behaviors, and patterns. Traveling might be the only risk factor for the transmission of infectious diseases that are well controlled in a certain country, especially vaccine-preventable diseases. The role of vaccination among travelers is a significant component for the prevention of travel associated infectious diseases.[1,2]

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Health risks associated with travel need to be balanced against the positive opportunities offered by inter-regional and cross-border travel.[3] The main goal of travel health and associated fields is to protect travelers from disease, accidents, and death. International travel has seen a dramatic rise during

recent times, and there has been an increase in diseases and associated public health problems. Each year, around 80 million travelers from developed countries visit developing countries where the epidemiological and sanitary conditions are different from their country of residence.[4] Thus, travelers increase the risk of exposure to travel associated health problems which include infectious diseases that may be imported back to their home country.[5]

Immunizations taken before traveling contribute to the risk reduction of specific diseases for the traveler as well as the reduction in risk of international spread of diseases. Agent, host, and environmental factors determine the risk of acquiring a disease when traveling. Most significant factors are the place that has to be visited, travel duration, and reason for travel. Among host factors, the traveler's health and his/her behavior overseas have to be considered. As a result, an agent–host–environment-based assessment of the travel plan should be done when considering which immunizations are to be taken by the traveler.[6]

India has become a popular destination for tourists in South Asia. Recent economic opportunities have resulted in a remarkable increase of business-related travel. People traveling to India can be broadly divided into the business traveler, the young economical backpacker, the medical volunteer, the holiday tourist, and the immigrant or non-resident Indian visiting family and friends. Medical graduates in India are showing interest in international travel to different countries for higher specialist courses, career growth, and better opportunities. People traveling to India are at an intermediate risk for malaria, and recent reports in the rise of chloroquine-resistant *Plasmodium falciparum* malaria in various parts of India are causing a rise in concern. Furthermore, different international travel advisory bodies vary on their opinion for malaria prophylactic regimens to be followed when traveling to India.[7-9]

Improvement in the knowledge and health education of disease transmission among travelers, following recommendations on sanitation, food, and water hygiene, avoiding arthropod bites with physical barrier methods and insect repellents, chemical prophylaxis against malaria, and taking required vaccinations are all known to reduce the risk of travel-associated diseases.[10] Since a considerable amount of travelers are at risk for having a travel-related illness or injury during their outings, there is a need for travelers to seek suitable pre-travel health education and immunizations to reduce the risk of any ailment while away from their country of residence.[11]

Objectives

The objective of this study is to assess the knowledge and practice of travel vaccination and malaria prophylaxis among resident doctors of BJ Medical College and Civil Hospital, Ahmedabad.

MATERIALS AND METHODS

A cross-sectional study was conducted at BJ Medical College and Civil Hospital, Ahmedabad. The study was conducted from July 2017 to October 2017.

A pilot study was conducted among 20 resident doctors, and the prevalence of knowledge of travel vaccination was found to be 65%. Using the formula $4pq/L^2$, data were collected from 100 resident doctors of Civil Hospital and BJ Medical College, Ahmedabad.

Data were collected using a semi-structured questionnaire, and data analysis was performed with Microsoft Excel 2013 and Epi Info 7. For statistical analysis, Chi-square test was applied. Ethical consent was taken from all respondents.

RESULTS

Figure 1 shows that 86% of the respondents had knowledge about travel vaccination while 79% of the respondents had knowledge about malaria prophylaxis.

As per the practice of travel vaccination, of the 24% who traveled, only 2 (8.3%) gave the history of taking immunization. Reasons for not taking immunization were not required for country of travel followed by non-awareness.

Table 1 shows that knowledge about travel vaccination was more in the 30+ age group (100.0%) followed by

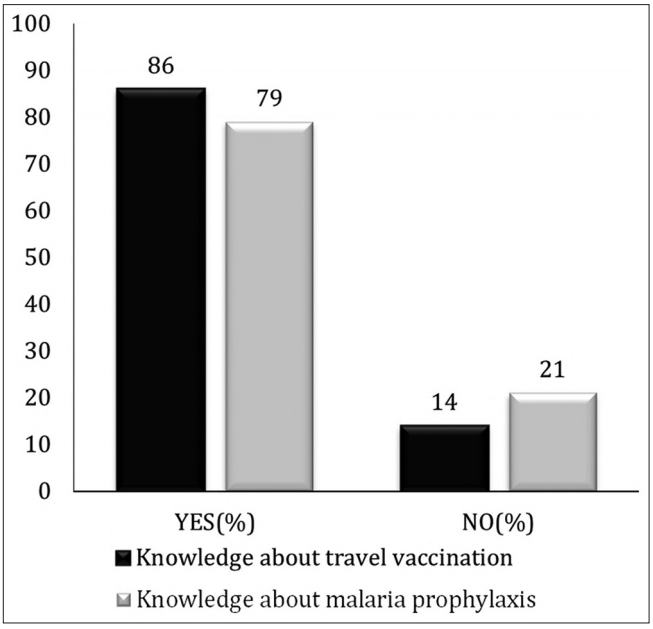

Figure 1: Overall knowledge about travel vaccination and malaria prophylaxis

Table 1: Relation of knowledge about travel vaccination with sociodemographic variables

Parameters	Respondents			
	Total	Having knowledge *n* (%)	Not having knowledge *n* (%)	*P* value
Age Group				
20–25	51	44 (86.3)	7 (13.7)	*P*=0.76
26–30	41	34 (82.9)	7 (17.1)	
30+	8	8 (100.0)	0 (0)	
Sex				
Male	51	46 (90.2)	5 (9.8)	*P*=0.34
Female	49	40 (81.6)	9 (18.4)	
Marital status				
Unmarried	72	61 (84.7)	11 (15.3)	*P*=0.79
Married	28	25 (89.3)	3 (10.7)	
Qualification				
1st-year resident	49	42 (85.7)	7 (14.3)	*P*=0.99
2nd-year resident	25	21 (84.0)	4 (16.0)	
3rd-year resident	26	23 (88.5)	3 (11.5)	

Table 2: Relation of knowledge about malaria prophylaxis with sociodemographic variables

Parameters	Respondents			
	Total	Having knowledge *n* (%)	Not having knowledge *n* (%)	*P* value
Age group				
20–25	51	44 (86.3)	7 (13.7)	*P*=0.18
26–30	41	28 (68.3)	13 (31.7)	
30+	8	7 (87.5)	1 (12.5)	
Sex				
Male	51	43 (84.3)	8 (15.7)	*P*=0.18
Female	49	36 (73.5)	13 (26.5)	
Marital status				
Unmarried	72	57 (79.2)	15 (20.8)	*P*=0.95
Married	28	22 (78.6)	6 (21.4)	
Qualification				
1st-year resident	49	40 (81.6)	9 (18.4)	*P*=0.47
2nd-year resident	25	17 (68.0)	8 (32.0)	
3rd-year resident	26	22 (84.6)	4 (15.4)	

the 20–25 years age group (86.3%) while those in the 26–30 years age group (82.9%) had the least knowledge. Knowledge was more in males (90.2%) compared to females (81.6%). Married respondents showed more knowledge (89.3%) compared to single respondents (84.7%). Knowledge about travel vaccination was highest among 3rd-year resident doctors (88.5%), followed by 1st-year residents (85.7%) and then 2nd-year Residents (84.0%).

Table 3: Country-wise knowledge about travel vaccination was more for developing countries than developed countries

Region	Percentage
USA	6
Europe	5
Australia	16
Africa	49
Southeast Asia	18
Arabian countries	13

However, no statistical significance was found between the sociodemographic variables with knowledge about travel vaccination ($P > 0.05$).

Table 2 shows that knowledge about malaria prophylaxis was more in the 30+ age group (87.5%) followed by the 20–25 years age group (86.3%) while those in the 26–30 years age group (68.3%) had the least knowledge. Knowledge was more in males (84.3%) compared to females (73.5%). Single respondents showed more knowledge (79.2%) compared to married respondents (78.6%). Knowledge about travel vaccination was highest among 3rd-year resident doctors (84.6%), followed by 1st-year residents (81.6%) and then 2nd-year residents (68.0%). However, no statistical significance was found between the sociodemographic variables with knowledge about malaria prophylaxis ($P > 0.05$).

Table 3 shows that country-wise knowledge about travel vaccination was more for developing countries compared to developed countries with that for Africa being the highest (49%) and that of Europe being the least (5%).

Figure 2 shows that 71% of the respondents were aware about the malaria chemoprophylaxis drug regimen compared to 29% which were unaware.

DISCUSSION

In our study, 86% of the respondents had knowledge about travel vaccination while 79% of the respondents had knowledge about malaria prophylaxis. In a similar study conducted in Nigeria, the knowledge about travel vaccination was found to be 96.3%.[1]

Most respondents were between 20 and 25 years of age, while in other similar studies conducted in Nigeria, Qatar, and America, majority of the respondents were of a higher age.[1,5,12] This study has an almost equal proportion of male and female respondents which is similar to an American study.[12] On the other hand, the number of male respondents were predominant in studies conducted in Nigeria and Australia, while the number of females were more in a Qatar

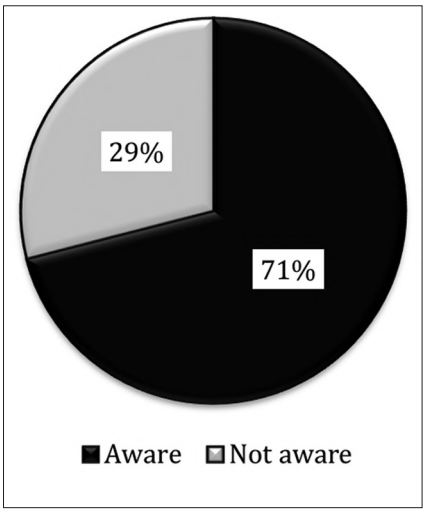

Figure 2: Awareness about malaria chemoprophylaxis drug regimen

study.[1,5,13] Most of the respondents were single which was contrary to a study conducted in Nigeria where most of the respondents were married.[1]

The practice of travel vaccination in this study was found to be very low which was similar to the findings of an Australian and Bangkok study but different from Greek and Nigerian studies where the practice of travel vaccination was found to be high.[1,2,13,14] Reasons of low practice in this study were not required for country of vaccination followed by non-awareness, while in other studies, the reasons were paucity of information on travel vaccination, distressing protocols and requirement for the vaccination, cost of vaccination as well as poor monitoring system for ensuring travel vaccination at the entry and exit points of the countries, unaware of being at risk, low knowledge of vaccination being important for traveling, cost of the vaccination, and side effects.[1,10,14]

The knowledge about travel vaccination and malaria prophylaxis was found to be good in this study which was similar to the results of other studies.[1,5,10,12-15]

Strength

The relation of sociodemographic variables with knowledge about travel vaccination and malaria prophylaxis is compared which has not been done in similar studies.

Limitation

The relation between knowledge about travel vaccination and malaria prophylaxis with sociodemographic variables was found to be insignificant, so the study should be carried out by taking a larger sample.

Recommendations

Doctors need to be updated on the latest norms of travel vaccination and malaria prophylaxis with special emphasis to be given on the importance of the practice of vaccination during international travel. This may be added to the academic curriculum because many doctors are interested in international career prospects.

CONCLUSION

It seems that the knowledge of travel vaccine and malaria prophylaxis was more among the 30+ age group followed by 20–25 age groups, and the knowledge of both was more among males. The married doctors showed more knowledge about travel vaccines, but the knowledge of malaria prophylaxis was more among single doctors. 3rd-year residents had more knowledge about both. The above groups may be more aware as they may be contemplating foreign travel in the near future. The practice of travel vaccination was found to be poor. Overall knowledge of travel vaccination and malaria prophylaxis was good.

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Rapid Assessment of Nutritional Status of Children in Rural Area of Maharashtra

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ABSTRACT

Introduction: Assessment of nutritional status by anthropometry is the simplest and most useful tool for assessing the nutritional status of children. Given the importance of nutrition in early life, this study was conducted among children between 12-36 months. Aim: To study the nutritional status of children between 12-36 months and factors associated with it.

Material and Methods: Settings: Catchment area of Kheda Primary Health Centre, Dhule. Design: Cross-sectional study based on 30 cluster sampling technique. Sample size: Worked out to be 210. Participants: 210 children between 12-36 months in 30 clusters. Study variables: Mid Upper arm Circumference measurement of children, gender, birth order, social categories, literacy status of parents, occupation of father, nuclear or joint family. Statistical analysis used: Chi square test of significance, descriptive analysis (mean -mode –median).

Results: Based on the Mid Upper Arm Circumference, the overall prevalence of malnutrition among children was 40%. The prevalence of severe malnutrition was 13%, with higher prevalence in females as compared to males. Statistically significant association was seen between malnutrition and gender of children, birth order, social categories (especially children belonging to Scheduled Tribes), literacy status of parents and type of family.

Conclusions: There is a need for geo-social mapping and "inclusion sensitive" microplanning, especially to ensure equitable access (in terms of support and information) to excluded social categories to reduce the magnitude of malnutrition.

Keywords: Malnutrition, mid upper arm circumference, social exclusion, Scheduled Tribes.

INTRODUCTION

A child is not a miniature form of adult. Growth is an indispensable feature of life of a child that distinguishes him from an adult. Environment experiences of the child during postnatal life determine the pace and pattern of his growth and development.[1]

Malnutrition is widely recognized as a major public health problem in the developing countries of the world including India. Based on the United Nations Children's fund (UNICEF) report, malnutrition in early childhood has serious, long term consequences because it delays motor, sensory, cognitive, social and emotional development.[2] Malnourished children are at a greater risk to grow into malnourished adults.[2] The prevalence of Undernutrition cannot be easily estimated from the prevalence of commonly recognized clinical syndromes of malnutrition such as marasmus and kwashiorkor because these constitute only proverbial tip of iceberg. Cases with mild to moderate Undernutrition are likely to remain unrecognized because clinical criteria for their diagnosis are inaccurate and difficult to interpret precisely.[3]

Child growth is commonly used to assess adequate nutrition, health and development of individual children and in comparison with other health assessment tools its measurement is a relatively inexpensive and easy to perform procedure.[4] Therefore, anthropometric examination is a mandatory tool in any research on health and nutritional condition in childhood.[5] Moreover, in community based studies, mid upper arm circumference (henceforth called as MUAC) appears to be a superior predictor of childhood mortality than many other anthropometric indicators.[4] MUAC yields a relatively reliable estimation of the body's muscle mass, the reduction of which is one of the most striking mechanisms by which the body adjusts to inadequate energy intakes.[6] Arm circumference cannot be used before the age of one year; between ages one and five years, it hardly varies.[6] Large studies in Latin America and South Asia have clearly established the reliability of arm circumference screening as an effective method of identifying malnourished children.[7]

During preschool age period, children have special nutrition needs because of their extensive growth and development.[4] Moreover, the direct effect of malnutrition is believed to operate largely in the first two or three years of life.[8]

With this background we decided to conduct a survey to rapidly assess the nutritional status of children between 12-36 months and factors associated with it by measuring the MUAC in the catchment area of Kheda Primary Health Centre of district Dhule, Maharashtra. The data collected would also benefit the district authorities to prepare a district action plan to address the problem of malnutrition in children in Dhule district.

MATERIAL AND METHODS

The survey was conducted in the catchment area of Kheda Primary Health Center, Dhule district, Maharashtra, India carried out from 23rd October to 1st November 2011. This Primary Health Center (henceforth called as PHC) caters to population of 38465 distributed among 30 hamlets (within 12 villages).

Approval of institutional ethical committee (IEC) and district health authorities were taken before conducting the survey. The survey design used in the current study is the World Health Organization 30X7 cluster survey method. This is a cluster

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sampling technique. This technique allows a small number of the target population to be sampled while providing statistically valid data that can be extrapolated to the whole target population. The 30 hamlets (within the 12 villages) under the catchment area of Primary Health Center formed the sampling frame for the cluster sampling technique. The target age group comprised of children aged 12-36 months. The random number and sampling interval were worked out to be 1117 and 1282. The determination of sample size was done as per the WHO 30X7 cluster survey – "Reference Manual" in the same way it is done to evaluate the immunization coverage.[9] For sample size determinations to assess the nutrition status, the following were determined, estimated or assumed beforehand:

- Anticipated level of prevalence of malnutrition in children – 60%;
- Desired precision of the estimate - ± 10%;
- The level of statistical confidence of the estimate (confidence level) - 0.05;
- Magnitude of differences of coverage among and within the clusters (design effect) - 2.

The total sample size was estimated (the total number of children to be surveyed) using the equation below.

$$n_{min} = DE \times \frac{z^2_{1-\alpha/2} \times p \times (1-p)}{d^2}$$

- Where p is expected prevalence, d is the desired width of CI, DE is design effect and Z is the multiplier from the normal distribution for the desired confidence level (α)
- Assuming a DE of 2 and d of 0.1, the minimum sample size worked out to 184.

Since we were going to use 30 clusters, the sample size per cluster worked out to 184/30 = 6.13. Rounded off, number of children to be surveyed in each of the 30 clusters was 7. Thus 210 children was the total sample size for 30 cluster survey. Keeping in view that, cluster is a collection of households with identifiable geographical boundaries; hamlet-wise population was obtained from PHC (cross checked with population data provided by Gram Panchayat) and taking 1117 as random number and 1282 as sampling interval 30 clusters were identified by using the standard technique.[9]

The field implementation for the survey was conducted as per a detailed plan devised beforehand. Establishing of households of the selected clusters was not going to be possible. Therefore the investigators decided that in every cluster, the geographical center of the cluster would be visited. From there, the investigators would move in a randomly chosen direction. The first house would be the house corresponding to a random number chosen beforehand. Both, the direction in which the investigator would move and the random number for choosing the first house, were generated using the computer for each cluster. After visiting the first household the second household to be visited was the one that was nearest to the first.

Interviews and Collection of Data: The investigators conducted interviews as per a pre-structured, pilot-tested interview format in households with children between 12-36 months. The MUAC of the children was measured and their socio-demographic profile was taken. Utmost care was taken at the time of measuring MUAC. The study teams were trained in taking MUAC to minimise the inter observer variations. The non-dominant upper arm was chosen for the measurement and the circumference of location in between the tip of the shoulder and the tip of the elbow (olecranon process and the acromian process)while the arm is hanging down the side of body and relaxed was considered as MUAC. Flexible measuring tape was used for measurement of MUAC. Arnold's classification[10] was used to classify malnutrition based on the MUAC. An arm circumference exceeding 13.5 cm was considered as a sign of a satisfactory nutritional status, between 12.5 cm and 13.5 cm was considered to indicate as mild-moderate malnutrition and below 12.5 cm, severe malnutrition.[6] The socio-demographic profile comprised of gender of the child, birth order, religion, social categories, father's occupation and education, mother's education, type of family (joint or nuclear).

Inclusion criteria: Children between 12-36 months with availability of responsible person for key information. All records entered were checked, cross-checked and randomly double checked for correctness.

Informed consent from all parents of the children was obtained. The parents of the children had the option to opt out of the study if they wished to. However, no parent refused to participate and thus there was 100% response.

STATISTICAL ANALYSIS

Chi square test of significance, descriptive analysis (mean-mode- median) were used to infer results with the help of SPSS 16.0 version.

RESULTS

A total of 210 children were included in the study, of which 107 (51%) were male and 103 (49%) were female children. Overall prevalence of malnutrition (MUAC ≤ 13.4 cm) in children was found to be 40% (36.4% males and 43.7% females).The prevalence of severe malnutrition (MUAC ≤ 12.4 cm) was found to be nearly 13% (7.5% males and 19.41% females). There were 10 (4.8%) children having MUAC 11.5 cm or less.

For overall prevalence of malnutrition, the sex differential was not statistically significant (P>0.05). Sex differential was though statistically significant (P<0.05) for prevalence of severe malnutrition.

Table-2 depicts MUAC distribution according to socio-demographic factors. It was observed that only 33.7% children with birth order 2 or less than 2 were malnourished. On the contrary, 60.5% children were malnourished when their birth order was 3 or higher. The difference was statistically significant. Additionally, 66% children with birth order 2 or less were found to be having satisfactory nutrition status (MUAC>13.5 CM), while, only 31.6% children with birth order 3 or higher were observed to be having satisfactory nutrition status, the difference being statistically significant (P<0.05).

Substantial differences in the status of nutrition were observed

MUAC	Number (%)
< 12.5 cm	28 (13.3)
12.5-13.4 cm	56 (26.7)
≥ 13.5 cm	126 (60)
Total	210 (100)

Table-1: Distribution of Mid Upper Arm Circumference (in cm) of sampled children.

Variables	Mid Upper Arm Circumference (in cm)		
	<12.5	12.5-13.4	≥ 13.5 cm
Total (n=210)	28 (13.3)	56 (26.7)	126 (60.0)
Sex			
Male (n=107)	8(7.47)	31(28.97)	67(62.61)
Female (n=103)	20(19.41)	25(24.27)	59(57.28)
Birth Order			
1 (n=92)	6(6.52)	24(26.08)	62(67.39)
2 (n=80)	6(7.5)	22(27.5)	52(65)
3 (n=28)	13(46.42)	4(14.28)	11(39.28)
4 (n=7)	3(42.85)	3(42.85)	1(14.28)
5 (n=3)	0	3(100)	0
Social Categories*			
SC (n=25)	7(28)	5(20)	13(52)
ST (66)	16(24.24)	25(37.87)	25(37.87)
OBC (n=98)	5(5.1)	24(24.48)	69(70.4)
Others (n=21)	0	2(9.52)	19(90.47)
Educational status of Mother			
Illiterate (n=68)	17(25)	24(35.29)	27(39.7)
Some Middle School (n=17)	5(29.41)	6(35.29)	6(35.29)
Some High School (n=96)	6(6.25)	20(20.83)	70(72.91)
Some Junior College (n=23)	0	5(21.73)	18(78.26)
Graduate (n=6)	0	1(16.6)	5(83.3)
Educational status of Father			
Illiterate (n=41)	16(39.02)	15(36.6)	10(24.4)
Some Middle School (n=20)	5(25)	4(20)	11(55)
Some High School (n=89)	6(6.74)	20(22.47)	63(70.8)
Some Junior College (n=46)	1(2.17)	13(28.26)	32(69.56)
Graduate (n=14)	0	4(28.6)	10(71.42)
Occupation of Father			
Labourer (n=123)	20(16.26)	36(29.26)	67(54.5)
Service (n=43)	3(6.97)	12(27.9)	28(65.1)
Farming (n=34)	5(14.7)	7(20.6)	22(64.7)
Business (n=10)	0	1(10)	9(90)
Type of Family			
Joint (n=155)	13(8.38)	44(28.4)	98(63.2)
Nuclear (n=55)	15(27.27)	12(21.81)	28(50.9)

* Social Categories of India - Scheduled Tribes (ST) and Scheduled Castes (SCs) are the socially depressed classes of India. OBCs are other backward classes. "Higher" social classes are classified as Others.

Table-2: Distribution of Mid Upper Arm Circumference (MUAC) by different variables.

among children belonging to Scheduled Tribe (ST) category and children belonging to higher category (others). There were higher chances of higher category children (90.4%) being well nourished as compared to children belonging to ST category (37.9) and this probability was observed to be statistically significant (P=0.029). Similarly, the prevalence of malnutrition (mild-moderate and severe) was also found to be higher (62%) among children belonging to ST social category as compared to children belonging to higher social category (9.5%) and this difference was found to be very significant statistically (P=0.0064).

Better education status of the mother had a positive impact on the nutrition status of children. The overall prevalence of satisfactory nutrition status (MUAC >13.5 cm) was high among the children (74.4%) having literate mothers (high school and above education) as compared to children (39.7%) with illiterate mothers. This difference was statistically significant (P=0.02). Children with illiterate mothers also had a higher probability of being malnourished (60.3%) as compared to children with literate mothers (high school and above education). This difference was extremely statistically significant (P=0.0032). It was revealed further that the prevalence of malnutrition among the children with literate fathers was comparatively lower (21.5%) than the illiterate fathers (75.6%) and the difference was also statistically very significant (P=.0020).

Lastly, it was observed that children belonging to nuclear family had higher prevalence of severe malnutrition (27.3%) as compared to children belonging to joint family (8.4%). The difference was considered to be statistically very significant (P=0.0068).

Table-3 gives the insight of statistical averages and measures of dispersion (standard deviation) of MUAC of sampled children by some social categories. The most striking feature is the statistical averages of MUAC of children belonging to Scheduled Tribes. The mean MUAC of these children is 13.33 cm (standard deviation-0.99), while the median is 13.25 cm. The mean and median are all below cut off point for malnutrition i.e. 13.5 cm.

Variables	Mean (cm)	Median (cm)	Standard Deviation
ST	13.33	13.25	0.99
SC	13.05	13.5	1.27
OBC	13.81	14	0.91
Others	13.9	14	0.7

Table-3: Mean Median and Standard Deviation of MUAC by different variables.

DISCUSSION

Nutrition is one of the important social determinants of health. In the last few years, state of Maharashtra has made significant progress in reducing infant mortality rate and maternal mortality rate.[8] The state also has significant economic growth. However, despite this context, the state has not been able to make much significant progress in improving the nutritional status of the population[8] which can be reflected by its Hunger index rank (The Indian state hunger index is computed by averaging the three underlying components of hunger index-the proportion of underweight children, the under-five mortality rate, and the prevalence of calorie Undernutrition in the population).[8] The Indian state Hunger index rank of Maharashtra is poor as compared to other Indian states which are not as economically well off. The global comparison of the hunger index rank also reveals that Maharashtra is behind some low income African and Asian countries such as Rwanda, Burkina Faso and Cambodia.[8] The question that needs to be answered here is, whether economic prosperity translates into adequate nutrition of the community?

Myatt et all in their review study in 2006 concluded that mid upper arm circumference is the best case detection method for severe malnutrition and that it is also simple, inexpensive and acceptable.[11] Velzeboer implicated in their study that, MUAC can be taken by minimally trained health workers with fewer and smaller errors as compared to other anthropometric measurements (weight for age and weight for height).[12] Given the situation that malnutrition is a major public health problem in India, can we train our grass root level workers (especially the Anganwadi workers) in mid upper arm circumference measurement to screen the children nutritionally? The question needs to be answered.

In the present study, the overall prevalence of malnutrition is 40%, while, the prevalence of severe malnutrition is 13%. The review of literature (ROL) indicates no such mid upper arm circumference based malnutrition study in Maharashtra. Thus, we are unable to compare our findings with similar studies in Maharashtra. In rest of India context, prevalence of overall malnutrition in the present study is higher than the earlier studies conducted at Orissa (31%)[13] and Punjab (38.5%)[14] States. This might be due to higher proportion of children belonging to Scheduled Tribes in our study. Based on National Nutrition Monitoring Bureau (NNMB) survey finding, in Maharashtra less than one third of the children in the age group of 1-3 years consume the recommended dietary allowances of proteins and calories. Moreover, the data on food consumption reveal that consumption of cereals and millets is only 69% (averagely) of what children need. They consume only half of the required quantity of pulses and legumes.[8]

More number of females were malnourished than males in our study, with statistical significance in pertinence to severe malnutrition. This could be due to gender bias particularly with respect to intra familial food distribution prevalent in Indian society. Similar finding was reported by Ahmad et al (2011).[15] Children with birth order one and two had better nutritional status than with higher birth order. This could be explained by the fact that in our study, large family norm was practiced by families belonging to Scheduled Tribes. Similar finding was reported by Harishankar et al (2004).[16] They opined in their study that, the proportion of malnourished children was significantly lower in birth order one as compared to birth order three and higher.[16] It was observed that, better educational status of parents had a positive impact on the nutritional status of children. Educated parents are more aware about their child's health and have a better chance of utilizing the health services as compared to the illiterate ones. This finding is suggestive of a strong association between parental literacy and nutritional status of children.

One of the main highlight of the study is the significant association of social category of the child and his/her nutritional status. The proportion of malnourished children was extremely high in ST children. Additionally, the mean, median and mode MUAC of children belonging to ST were all below cut off point for malnutrition i.e. 13.5 cm. We would like to suggest that study should be conducted on the dietary patterns (including the food habits and food fads) of the families belonging to ST social category to understand their consumption unit (CU). Given that Maharashtra and Dhule district have a large ST population, understanding the dietary patterns of these families will definitely have an impact on understanding the problem of malnutrition clearly, which eventually will help in addressing its problem.

CONCLUSION

The present study amply reveals that, as far as the child nutrition is concerned, the Scheduled Tribes seems to be the socially excluded groups among all the social categories. We think that there is a need for area specific, geo-social mapping and "inclusion sensitive" microplanning, especially to ensure equitable access (in terms of support and information) to excluded social categories in order to accomplish the goal of reducing malnutrition. Support may be in terms of knowledge and significance of best practices such as exclusive breastfeeding for first six months, starting nutritive semisolid at 6 months, use of locally available and inexpensive foods, child feeding practices, identification of risk of malnutrition etc. The role of Anganwadi workers (grass root health workers in India) seems to be critical in this.

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Original Research Article

A Cross Sectional Study on Assessment of Attitude Among Health Professionals Towards the Problem of Substance Abuse at Ananta Hospital, Rajsamand

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Abstract

Background: Drug abuse affects the health and lives of millions of individuals across the world. Discrimination faced by substance users and stigmatization becomes a barrier for them thus these patients do not receive the required care and treatment they deserve. The negative perception of healthcare professionals leads to poor therapeutic alliance between them and the patients of substance use. Current study aims to determine and assess the attitudes of the health professionals towards patients with substance use problems and to identify factors causing diverse attitudes of health professionals towards these patients.

Method:A questionnaire based cross sectional study was undertaken at Ananta hospital Rajsamand (a tertiary health care centre) which included 134 health professionals both doctor and nursing staff for a duration of one year who provided their consent for this project. The socio- demographic details of every participant was collected and all of them were given the DDPPQ tool which assessed their attitudes and perception towards drug and drug use problems.

Results: Younger age group of health professionals showed better outlook towards patients of drug abuse. A linear regression of gender, professional roles (i.e. doctors and nurses), past history of substance abuse and known history of substance abuser in the family with the principal component does not yield any significant results. Majority of the participants had either neutral opinion or positive opinion towards the problem of drug use and the drug users.

Conclusions: Healthcare professionals with age on the lower side had more positive regards and significantly positive attitudes towards the problems of substance use and therefore the

therapeutic compliance was better. Healthcare delivery needs unbiased and non-judgmental attitude of healthcare professionals towards patients of substance abuse, so in an attempt to provide holistic approach and care that overlooks socio-demographic and clinical profiles, professionals should have adequate and appropriate training and exposure accordingly.

Keywords: Professionals, nursing, staff, substance, drug, perception, attitudes, stigmatization.

Introduction

Drug abuse is a global phenomenon which affects almost every country with a variable extent. Abuse of illicit drug affects the health and lives of many individuals across the globe. The criminalization of this addictive behavior damages the reputation of the engaged person and it also deters other people, leading to stigmatization of the problem in the society. Stigmatization also discourages illicit drug users from getting health care due to fear of poor treatment by health care providers or fear of trouble with the authorities[1,2]. While stigma and discrimination may serve as deterrents to illicit drug use, these attitudes also contribute to discrimination and stigmatization experienced by illicit drug users which may be bad for drug user's health[3]. Negative attitudes of health professionals towards patients with an alcohol or other drug addiction are known to lead to poor communication between professional and patient, diminished therapeutic alliance, and mis-attribution of physical illness symptoms to substance use problems, also referred to as diagnostic overshadowing[4,5].

In this scenario, medical professionals are key persons in the provision of care for persons who exhibit problems related to use of the substances of abuse. Personal factors[6] and deficient medical education about addiction in health professionals[7] influence the under-diagnosis of substance abuse disorders. Studies have found that physicians were significantly less satisfied when caring for patients with drug problems compared to other illnesses[8]. A study on nurses found that nurses struggled with the care for patients who use illicit drugs and they had less motivation, satisfaction, role support and education[9]. Another study found that staff who had received training held fewer negative attitudes towards illicit substance users regardless of their length of clinical work experience or type of work setting[10]. Another study found that health professionals' regard was lowest for patients with drug and alcohol problems, lowest regard was found among physicians who did not work in specialized addiction services[11]. This study found that specially trained personnel's in this field such as psychologists, social workers, and professionals in the addiction services showed the highest regard while physicians who did not work in specialized addiction services had lowest regard. People with drug related disorders deserve the same level of care as patient with any other health condition. Health service need to be able to identify drug use and drug use disorder at an early stage and provide prevention, treatment and harm reduction intervention. We could not find any study in our region addressing health professional attitudes towards persons with problems related to substance use.

Aims and Objectives

Current study aims to assess and determine the attitudes of the health professionals

towards patients with substance use problems and to identify factors causing diverse attitudes of health professionals towards these patients.

Methods

Study area

The study was conducted at Ananta Hospital Rajsamand (attached to Ananta Institute of Medical Science and Research Centre, Rajsamand, Rajasthan) a tertiary care hospital.

Study Design

Questionnaire based cross sectional study

Study Participants

Health Professionals (Including doctors and nursing staff)

Study duration

One Year, September 2019 to August 2020.

Sample size

A total population of health care professional of 200 working in Ananta Institute of Medical Science and Research Centre, Rajsamand, Rajasthan, a tertiary care hospital. Minimum of 134 participants were expected to participate according to the following calculation.

$N^* = N*X / (X + N - 1)$,

where,

$$X = Z^2_{1-\alpha}\, p(1-P)/d^2$$

where alpha (α) = 0.05, estimated proportion (p) = 0.50, estimated error (d) = 0.05 and N is the population size

The Finite Population Correction is used to adjust a variance estimate when sampling without replacement.[15]

A stratified random sampling technique has been used for collection of data. A validated 22-item DDPPQ questionnaire tool has been used in the study.

Statistical analysis

Questionnaire data was analyzed using SPSS version 24. Socio demographic data were summarized using frequencies and percentages. Means and standard deviation were used for continuous variables. Mann Whitney U test was used to compare the difference among professional groups i.e. doctors and nurses. The relationship between DDPPQ scores and other relevant variables was analyzed by using Pearson Product-Moment Correlation Co-efficient. The regression analysis has been done to find out relationship between independent and dependent variables. Statistical significance was taken at the 5% level.

Data Collection Procedure

The 22-item validated version of Drug and Drug problems perception questionnaire (DDPPQ) instrument was used for the study[12]. The validated DDPPQ, comprises of 22 items and is a shorter questionnaire, having retained only the most reliable items from the original instrument. The items of the validated questionnaire are numbered consecutively from one to twenty-two. The validated DDPPQ is a self-complete 'paper and pencil' questionnaire. Respondents are asked to rate their level of agreement on a series of 22 statements about working with people who use licit or illicit drugs in a nontherapeutic way. There are seven possible responses to each item on a scale of Strongly agree' to 'Strongly disagree'. Low scores denote positive attitudes, whereas high scores are associated with negative views. Several of the items are worded negatively. These are Items 15, 16, 17 and 18. For the purpose of this study, the DDPPQ were expressed on a 5-point Likert scale ranging from 1 = strongly agree, 2 = agree, 3 =neither agree nor disagree, 4 = disagree to 5= strongly disagree

.A 5 - point Likert-type scale instead of 7-point was used to increase response rate and response quality along with reducing respondents' frustration level[13]. Factor structure of the validated DDPPQ has yielded its six factors which are role adequacy, motivation, role legitimacy, task specific self-esteem, role support and work satisfaction

Study Variables

The independent variables in the study are the socio-demographic characteristics of the study participants such as gender, age, profession, work motivation and role support of health professional. The dependent variables, attitude and perception are measured by six factors/ subscale measure (using 5- point Likert scale) in the DDPPQ. Questionnaire data was analyzed using SPSS version 24. Socio-demographic data were summarized using frequencies and percentages. Data was analyzed by using unrelated T-test, Mann Whitney U test and Pearson product moment correlation coefficient.

For the questionnaire survey, 22 items of validated version of DDPPQ questionnaire was distributed individually to the 152 professional group members in a sealed envelope and returned back in same sealed condition in order to maintain privacy of participants. One hundred and thirty-four participants returned the completely filled up questionnaire. All professional group members i.e. both doctors and nursing staff members responses to the given DDPPQ questionnaire were calculated to give a total attitude score. The minimum score for the DDPPQ is 22 and the maximum score is 110. The higher the score obtained indicates an increasingly more negative attitude.

Results

Table 1: gives description of number of participants according to the gender as well their professional roles.

Group	Number (Total=134)	Percentage
Doctors	85	63.4 %
Males	53	39.5 %
Females	32	23.8 %
Nursing staff	49	36.5 %
Males	30	22.3 %
Females	19	14.1 %

Table 1. Profile of the Sample

Table 2: shows profile of the sample according to professional group and gender.

	Number of responses	Score Range	Mean Score (SD)	Z score	P* Value
Doctors	85	24-76	49.63 (8.95)	-0.30	0.75
Nursing Staff	49	33-68	49.46 (9.52)		

Table 2. The DDPPQ Score Range for Professional Groups

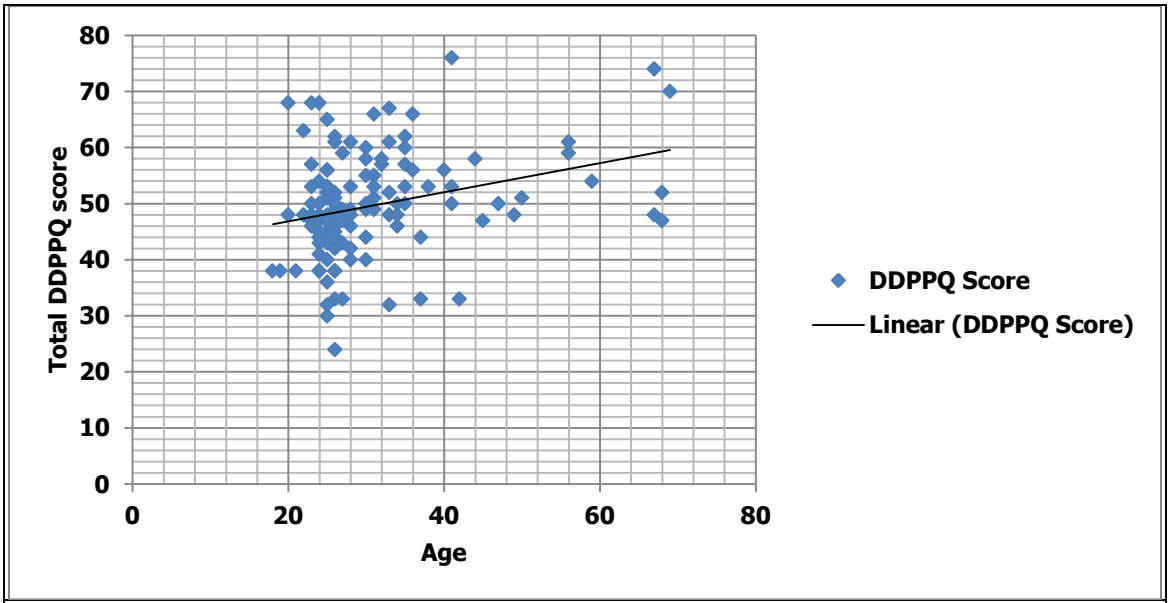
Mann Whitney U test. * The result is significant at $p<0.05$

Table 2 shows the DDPPQ score range for the participants. A Mann-Whitney U test was conducted to compare DDPPQ scores between doctor and nursing staff. The result is not significant at $p<0.05$. There is no difference between the groups.

Age of Participants Versus DDPPQ Score

Mean age of the total sample was 30.56 years (standard deviation 10.38). Mean age for doctors' group was 32.85 years (standard deviation= 11.86) and for nursing staff group was 26.59 years (standard deviation=5.21).

There is significant correlation between the age of the professional group members i.e., both doctors and nursing staff members and their respective DDPPQ scores when calculated using Pearson Product – Moment Correlation Co-efficient (2 tailed) $r = 0.29$, $n = 134$, $p = 0.00067$.



Graph 1: Distribution Graph of Age Versus Total DDPPQ Score

The graph indicates weak positive correlation between age of the participants and their corresponding DDPPQ score.

Family History versus DDPPQ Score

Participants were also asked if they had any family history of substance abuse and past history of substance abuse.

Table 3: Comparisons among Health Professional having Family History of Substance Abuse and Past History of Substance Abuse

	Response	Number of Responses	Range	Mean (Standard Deviation)	Z Score	p*Value
Family history of substance abuse	Positive	22	43-63	52.09(5.97)	-1.786	0.074
	Negative	112	24-76	49.08(9.57)		
Past history of substance abuse	Positive	23	38-65	50.17(7.16)	-0.393	0.694
	Negative	111	24-76	49.45 (9.51)		

Mann Whitney U test. * The result is significant at $p<0.05$

In Table 3, comparisons among Health professional having family history of substance abuse and past history of substance abuse are described. Using Mann- Whitney U test, we found that there is no statistical difference between the groups of health professional having past history of substance abuse and health professional who don't have past history of substance and the groups of health professional having family history of substance abuse and health professional who don't have family history of substance abuse.

A linear regression of gender, professional roles (i.e., doctors and nurses), past history of substance abuse and known history of substance abuser in the family with the principal component has not yielded any significant results.

Table 4: Health Professional Therapeutic Commitments towards Drug Abusing Patients on various Subscales of DDPPQ and total Mean Score

Subscales	Number of Questions	Mean Score Per Question (LikertScore = 1-5)	Standard Deviation
Role adequacy	8	1.99	0.65
Role Legitimacy	3	1.85	0.71
Role support	3	1.92	0.64
Work satisfaction	4	2.18	0.76
Motivation	1	3.58	1.17
Task specific Self Esteem	3	3.39	1.07
Total Score	22	49.57 (possible score 22-110)	9.13
Note: lower score denotes higher therapeutic commitment.			

Table – 4 shows a mean of total score of 49.57 (SD = 9.13) with a possible score between 22 and 110. **The diverse attitudes of Health Professionals towards substance abusers**

Table 5: Percentage of Participants in three Categories

	Frequency	Percentage
Positive [a]	36	26.86
Neutral [b]	91	67.92
Negative [c]	7	5.22
	134	100
a= Total score from 22 to 44; b) total score from 45 to 66; c) total score from 67 to 110		

The total DDPPQ scores were divided into three categories i.e. (1) Positive perception (distinctly defined perception of role), (2) Negative perception (lack of distinctly defined perception of role) and (3) neutral perception (neither distinctly defined perception of role nor lack of distinctly defined perception of role). The range for all three perceptions was determined by the possibility maximum and minimum score in 5 point- Likert scale. Table 5 shows percentage of participants in these three categories.

Discussion

Current study aimed to assess and determine the attitudes of health professionals towards patients with substance use problems in our region and to identify factors causing diverse attitudes of health professionals towards these patients. There was weak positive correlation between age of the participants and their

corresponding DDPPQ score that is older health professionals had relatively negative attitude. This was in contrast to a study that found that older nurses believed more strongly that alcoholism is an illness[14]. The two professionals' groups were assessed by comparing health professionals having family history of substance abuse and past history of substance abuse, and it was found that there is no statistical difference between the two groups of health professional. The mean DDPPQ score in these groups ranged towards lower side denoting positive attitude towards these patients, means their past or family history of substance use didn't significantly affect the attitude. Our study found that there was no statistically significant difference between the DDPPQ scores between the two groups i.e., doctors and nursing staff.

Considering all participants in a group, the lower skewed total mean DDPPQ score of 49.57 (SD = 9.13, with a possible score between 22 and 110) in our study correlated with a more positive attitude and higher therapeutic commitment to drug abusing patients. On mean Likert-format response per question (of 1= Strongly agree to 5= Strongly disagree), the highest therapeutic commitment is reflected in role legitimacy subscale which indicated the degree that professional group members felt that drug abuse history taking and counseling was a professional responsibility. Role support and Role adequacy followed the next which reflected that professional group members felt that they have adequate knowledge of drug and drug related challenges. Also whenever required, they will get support or help to resolve drug related problem. Highly skewed score in motivation and self-esteem subscale reflected lower therapeutic commitment. Role support, role adequacy, role legitimacy and work satisfaction were all somehow interconnected with each other at the basic level along with motivation and self-esteem to aid in understanding of the plight of patients of substance abuse and thereby providing therapeutic care and overall management to such patients. Our findings are in contrast to another study which found that healthcare providers struggled with the care for patients who used illicit drugs and they had less motivation, satisfaction, role support and education.[9]Crothers and Dorrian also found high scores regarding work satisfaction which indicated that nurses' attitudes regarding how much they like, and feel rewarded by, working with patients with alcohol problems, are an important determinant of the extent to which nurses are actually willing to engage in this work[15].

In an attempt to identify diverse attitudes of health professionals towards substance abusers, the sample participants were divided into three categories for ease of understanding - Positive perception, Negative perception and neutral perception; and it was found that number of healthcare professionals having neutral perception were maximum, followed by those having positive perception and least holding negative approach to the drug abuse patients. In a study nurses appeared to have, on average, attitudes that were consistently quite positive, if not neutral[14]. As healthcare professionals are the chief gatekeepers in the management of patients who suffer from substance use disorder, there is need of the hour to change both the neutral and negative attitude of the health care workers into positive attitude. To improve local services, Howard et al recommended that a training strategy should be developed with consideration to a structured programme covering all aspects of providing care to inpatients with co-occurring mental health and substance use problems; implementing training and support structures for staff will enable them to deliver more recovery and client centered interventions for patients with these co-occurring issues[10].

Healthcare delivery needs unbiased and non-judgmental attitude of healthcare professionals towards patients of substance abuse, so in an attempt to provide holistic approach and care that overlooks socio-demographic and clinical profiles, professionals should have adequate and appropriate training and exposure accordingly. We propose some ways that can be executed systematically to bring about the necessary change in the attitudes of a healthcare professional- First and foremost is sensitization of healthcare professionals (both the doctors as well as the nursing staff) which is primarily important to achieve better outcomes in management of patients of substance use disorders. Secondly, there are ways to be incorporated at the grass root level which directly and/or indirectly will have an impact on the management of such patients include: (i) training – providing education and skills to the professionals and conducting workshops at regular intervals, teaching institute – both the medical colleges and the nursing colleges are jointly responsible in training the students who take up this field and providing opportunities for them to learn,(ii) exposure – mandatory rotatory postings for every undergraduate medical/nursing student to understand patients from having them visit an addiction wing facility of outdoor and indoor patients run by the department of psychiatry at the institute where they come across such patients of substance abuse.

Conclusion

Our study found that the younger age group healthcare professionals had more positive outlook and attitude towards substance users. The lower skewed total mean score of participants denoted more positive attitude and higher therapeutic commitment. Subdivision of the participants in three groups to a step forward revealed that majority of them had either positive or neutral attitude towards patients with problem of substance abuse, leaving a minority or handful percentage of participants who had negative perception and attitude.

Implications of the Study

our study will help in identifying diverse attitude of health professional towards patients with substance use disorders and the associated factors. Awareness and proper education along with skills instilled among these healthcare professionals will strengthen the belief and trust of the patient receiving treatment and management during the prolonged period provided for deaddiction. The provision of adequate, timely guidance and motivation at every step to reduce the use of illicit substances, would help in controlling the menace of drug abuse can be well achieved.

Limitations

This was a cross sectional study with small sample size.

Future Direction

Future studies can be undertaken with large sample size to determine the changes in attitudes and knowledge of healthcare professionals prior to any kind of exposure or training received and followed up by assessing them after they have achieved skills, knowledge and training in the field of addiction psychiatry.

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Original Research Article

A Study on Cross Sectional Online Assessment of Attitude of Medical Students Towards Mental Illnesses

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Conflict of interest: Nil

Abstract

Background: Attitudes and belief toward mental illnesses are important factors that affect perception of mental health. Knowing the attitude of medical students towards psychiatry and mental illnesses is of utmost importance as they are future care provider. Current study is conducted to assess the attitude of medical students towards mentally ill patients and mental illnesses, to identify correlation of attitude score with personal and family history of mental illness and, to compare the score among students of the three year-wise groups.

Method: The study population included 219 students of first, second and third professional MBBS. We designed an online data collection tool and executed it using the Google Forms. The Google Form link to the questionnaire was sent to the enrolled participants via the identified WhatsApp groups or individual number. Beliefs toward Mental Illness (BMI) scale was used to assess attitude towards mental illnesses which is a 21-item self-report measure of negative stereotypical views of mental illness. The results of the study were examined and analyzed by using Statistical Package for Social Sciences (SPSS 25.0).

Results: Out of total 21 items of the BMI scale, students showed positive attitude on majority of items. The mean score for BMI scale and per item mean score for the scale were towards positive attitude. Majority of students agree that a mentally ill person is more likely to harm others than a normal person and that mental disorders would require a much longer period of time to be cured than would other general diseases. Higher per item mean score for dangerousness and, incurability subscale showed their negative attitude. An increasing trend of positive attitude has been seen with an increase of education level and exposure towards the subject.

Conclusions: Medical students show variable scores on belief towards mental illness scale, its subscales and, individual items. Admitting this prevailing stigma needs to be acknowledged and openly discussed with medical students in order to overcome these views. Providing adequate education on mental illnesses and attached negative attitudes or myths can change these negative beliefs.

Keywords: Medical students, psychiatry, mental illnesses, stigma, dangerousness.

1. Introduction:

Attitudes and belief toward mental illnesses are important factors that affect perception of mental health. The prejudiced and negative attitudes or stigma towards people with mental illness are widespread. In our society, health professionals have similar views about those with mental health problems and mentally ill patients. Literature suggests that people diagnosed with mental illness are considered by the majority of the society as people who are dangerous, loathed, stranger and somebody whose actions cannot be predicted.[1] Globally, psychiatry as a subject, psychiatrists as professionals, and patients with psychiatric disorders are subjected to cultural stereotypes and negative attitude by the general population. What is of alarming concern is that these prejudices exist within the medical community as well.[2-6] Stigma toward mental illness is an influential factor leading to negative views among medical students toward psychiatry. Lack of knowledge and awareness about mental illnesses among the students is associated with the negative attitudes towards mental illness in the community. For medical students during their training, educational intervention targeted towards these negative attitudes may be more effective than doctors who have already completed their training because research has shown as they carry on through their career, their attitude harden and become more resistant to change.[7] The concept of iatrogenic stigma is used to describe the stigma caused or perpetuated by mental health professionals.[8] This stigma and negative attitudes can affect the quality of life for people with mental illness. There may be various reasons for this negative attitude such as lack of accurate information about mental illness and lack of contact with individuals with mental illness.[9]

While some studies have suggested that aspiring young doctors have a favorable opinion about psychiatry as a branch[10], other studies have suggested that medical students' attitude toward psychiatry is unfavorable.[11-17]

A doctor's attitude towards persons with psychiatric illness and psychiatry should involve an impression of an empathetic listener and should have non-judgmental approach. Knowing the attitude of medical students towards psychiatry and mental illnesses is of utmost importance as they are future care provider. To improve psychiatric training in this population beliefs and attitude toward psychiatric illnesses and need to be assessed and understood.

The reasons for studying the attitude specifically among medical students are that firstly as a doctor they can play an important role in decreasing negative attitude and, secondly the results from the study will help to focus strategies to change attitudes of this group. The comparison among various groups in present study will help in understanding the impact of successive undergraduate training years. The findings may help in understanding the various points of strength and lacunae in the current undergraduate curriculum regarding mental health.

Objectives:

The objectives of the current online study were-

1. To assess the attitude of medical students towards mentally ill patients and mental illnesses
2. Correlation of attitude score with personal and family history of mental illness, and
3. Comparison among students of the three year-wise groups.

2. Methodology

Study population and study area: The study population includes all the students who have

enrolled in MBBS course (first year, second year and final year) at Ananta Institute of Medical Science and Research Centre, Rajsamand, Rajasthan. Those students who will give their consent to participate in the study will be included and rests will be excluded at their will.

Study Duration: one year, June 2020 to May 2021.

Sampling techniques and sample size

Samples were obtained using stratified random sampling method. The 3 batches of medical students viz first year professional, second year professional and third year professional which were considered as strata collectively develop a sampling frame of 450 students. The minimum sample size on assumption of 95% level of significance, 5% error and 85% expected proportion was 196. After 12% adjustment of non- responders' students the final sample size was 219.

Undergraduates in the 1st year had not received formal exposure to psychiatry yet, students of 2nd year also have not attended clinical posting or lecture in psychiatry while students of Final year students had completed clinical posting and theory lectures in psychiatry. The institute is having well-functioning psychiatry department with adequate teaching staff and a good in-flow of patients in the psychiatry OPD as well as inpatient department.

Study procedure and statistical Analysis: After unlock 1.0 was announced by the Government of India from 8th of June 2020, the cases of COVID-19 were increasing all over India including Rajasthan. Hence there was risk of disease transmission by taking interview in person therefore we decided to use WhatsApp Messenger for enrolling potential participants and Google forms for filling up their response. The study was approved by institute ethics committee.

Tools: We designed an online data collection tool and executed it using the Google Forms (via docs.google.com/forms). The Google Form link to the questionnaire was sent to the enrolled participants via the identified WhatsApp groups or individual number.

Socio-demographic variables included age, gender, marital status, background, past personal history of mental illness, known history of mental illness in the family were described using descriptive statistics.

Beliefs toward Mental Illness (BMI) scale was used to assess attitude towards mental illnesses. The BMI scale is a 21-item self-report measure of negative stereotypical views of mental illness. (18) There is a total Score and the score of three sub-scales based on factor analysis: dangerousness, poor social and interpersonal skills, and incurability. There are five items in subscale dangerousness, ten items in poor interpersonal and social skills scale and six items in incurability subscale. Items are rated on a six-point Likert scale ranging from 'completely disagree' (0) to 'completely agree' (5), with higher scores reflecting more negative beliefs. In the primary validity study, Cronbach's alpha was high among American (0.89) and Asian students (0.91). The measure holds promising evidence of validity.

The results of the study were examined and analyzed by using Statistical Package for Social Sciences (SPSS 25.0). The categorical variables were described by numbers and percentages while continuous variables were described by average and standard deviation. Normality of attitude was checked using Kolmogrov-Smirnov test. After testing normality condition, the association and relationship between the variables were tested Pearson correlation by Student's t test and one way analysis of variance (ANOVA). The level of significance was considered at $P<0.05$.

3. Results

A total 219 number of students were participated in the online study. The sample comprised of 41.55% of male students and 58.44% of female students. Majority of the students were unmarried (97.26%), belonging to urban background (79.45%), having negative past personal history of psychiatric illness (86.75%) and negative family history for psychiatric illnesses (75.79%).

Table 1: Socio-demographic characteristics of respondents

Variables	Participants N (%)
Sex	
Male	**91 (41.55%)**
Female	**128 (58.44%)**
Marital Status	
Married	**6 (2.73%)**
Unmarried	**213 (97.26%)**
Place of residence	
Urban	**174 (79.45%)**
Rural	**45 (20.54%)**
MBBS Batch	
First year professional	**49 (22.37%)**
Second year professional	**138 (63.01%)**
Third year professional	**32 (14.61%)**
Had mental illness in past:	
Yes	**29 (13.24%)**
No	**190 (86.75%)**
Is someone in your family/ friends/ relative is having mental illness:	**53 (24.21%)**
Yes	**166 (75.79%)**
No	
If yes, then	
Friends	**7(13.2%)**
Family	**26(49.05 %)**
Relative	**20(37.73%)**

Table 1 shows socio-demographic characteristics of respondents.

Attitudes of students towards mental illness

a) Attitude by Items of the subscales

Table 2: Dangerousness subscale of BMI scale (item wise responses, percentage of participants regarding statements on the beliefs about mental illness)

Statement	**Response***					
	0	**1**	**2**	**3**	**4**	**5**
A mentally ill person is more likely to harm others than a normal person	28 (12.8%)	15 (6.8%)	36 (16.4%)	85 (38.8%)	26 (11.9%)	29 (13.2%)
	79 (36%)			140 (64%)		
Mental disorders would require a much longer period of time to be cured than would other general diseases	10 (4.6%)	8 (3.7%)	19 (8.7%)	55 (25.1%)	51 (23.3%)	76 (34.7%)
	37 (17%)			182 (83%)		
It may be a good idea to stay away from people who have psychological disorder because their behaviour is dangerous	73 (33.3%)	47 (21.5%)	41 (18.7%)	41 (18.7%)	7 (3.2%)	10 (4.6%)
	161 (74%)			58 (26%)		
Mentally ill people are more likely to be criminals	69 (31.5%)	47 (21.5%)	35 (16.0%)	45 (20.5%)	13 (5.9%)	10 (4.6%)
	151 (69%)			68 (31%)		
I am afraid of people who are suffering from psychological disorder because they may harm me	80 (36.5%)	47 (21.5%)	31 (14.2%)	50 (22.8%)	4 (1.8%)	7 (3.2%)
	158 (72%)			61 (28%)		

* Denotes 0 = Completely disagree, 1 = Largely disagree, 2 = somewhat disagree, 3 = somewhat agree, 4 = Largely agree, 5 = Completely agree

Table 2 shows item wise responses and percentage of participants regarding statements on the beliefs about mental illness on dangerousness subscale of the BMI scale

Table 3: Poor social and interpersonal skills subscale of BMI scale (item wise responses, percentage of participants regarding statements on the beliefs about mental illness)

Statement	**Response**					
	0	**1**	**2**	**3**	**4**	**5**
The term 'psychological disorder' makes me feel embarrassed	123 (56.2%)	30 (13.7%)	16 (7.3%)	24 (11.0%)	12 (5.5%)	14 (6.4%)
	169 (77%)			50 (23%)		
A person with psychological disorder should have a job with only minor responsibilities	43 (19.6%)	30 (13.7%)	49 (22.4%)	58 (26.5%)	27 (12.3%)	12 (5.5%)
	122 (56%)			97 (44%)		

I am afraid of what my boss, friends and others would think if I were diagnosed as having a psychological disorder	70 (32.0%)	24 (11.0%)	24 (11.0%)	57 (26.0%)	17 (7.8%)	27 (12.3%)
	118 (54%)			101 (46%)		
It might be difficult for mentally ill people to follow social rules such as being punctual or keeping promises	37 (16.9%)	29 (13.2%)	55 (25.1%)	38 (17.4%)	37 (16.9%)	23 (10.5%)
	121 (55%)			98 (45%)		
I would be embarrassed if people knew that I dated a person who once received psychological treatment	131 (59.8%)	29 (13.2%)	17 (7.8%)	26 (11.9%)	12 (5.5%)	4 (1.8%)
	177 (72%)			61 (28%)		
A person with psychological disorder is less likely to function well as a parent	43 (19.6%)	45 (20.5%)	35 (16.0%)	57 (26.0%)	22 (10.0%)	17 (7.8%)
	123 (56%)			96 (44%)		
I would be embarrassed if a person in my family became mentally ill	150 (68.5%)	26 (11.9%)	15 (6.8%)	13 (5.9%)	7 (3.2%)	8 (3.7%)
	191 (87%)			28 (13%)		
Mentally ill people are unlikely to be able to live by themselves because they are unable to assume responsibilities	45 (20.5%)	51 (23.3%)	50 (22.8%)	43 (19.6%)	12 (5.5%)	18 (8.2%)
	146 (67%)			73 (33%)		
Most people would not knowingly be friends with a mentally ill person	33 (15.1%)	22 (10.0%)	36 (16.4%)	62 (28.3%)	27 (12.3%)	39 (17.8%)
	91 (42%)			128 (58%)		
I would not trust the work of a mentally ill person assigned to my work team	61 (27.9%)	40 (18.3%)	44 (20.1%)	53 (24.2%)	10 (4.6%)	11 (5.0%)
	145 (66%)			74 (34%)		

0 = Completely disagree, 1 = Largely disagree, 2 = somewhat disagree, 3 = somewhat agree, 4 = Largely agree, 5 = Completely agree

Table 3 shows item wise responses and percentage of participants regarding statements on the beliefs about mental illness on poor social and interpersonal skills subscale of the BMI scale

Table 4: Incurability subscale of BMI scale (item wise responses, percentage of participants regarding statements on the beliefs about mental illness)

Statement	**Response**					
	0	**1**	**2**	**3**	**4**	**5**
Psychological disorder is recurrent	17 (7.8%)	17 (7.8%)	45 (20.5%)	77 (35.2%)	34 (15.5%)	29 (13.2%)
	79 (36%)			140 (64%)		
Individuals diagnosed as mentally ill suffer from its symptoms throughout their life	53 (24.2%)	46 (21.0%)	41 (18.7%)	53 (24.2%)	10 (4.6%)	16 (7.3%)
	140 (64%)			79 (36%)		
People who have once received psychological treatment, are likely to need further treatment in the future	19 (8.7%)	38 (17.4%)	29 (13.2%)	82 (37.4%)	29 (13.2%)	22 (10.0%)
	86 (39)			133 (61%)		
I believe that psychological disorder can never be completely cured	139 (63.5%)	19 (8.7%)	21 (9.6%)	17 (7.8%)	9 (4.1%)	14 (6.4%)
	179 (82%)			40 (18%)		
The behaviour of people who have psychological disorders is unpredictable	19 (8.7%)	24 (11.0%)	33 (15.1%)	65 (29.7%)	38 (17.4%)	40 (18.3%)
	76 (35%)			143 (65%)		
Psychological disorder is unlikely to be cured regardless of treatment	53 (24.2%)	31 (14.2%)	46 (21.0%)	46 (21.0%)	17 (7.8%)	26 (11.9%)
	130 (59%)			89 (41%)		

0 = Completely disagree, 1 = Largely disagree, 2 = somewhat disagree, 3 = somewhat agree, 4 = Largely agree, 5 = Completely agree

Table 4 shows item wise responses and percentage of participants regarding statements on the beliefs about mental illness on incurability subscale of the BMI scale

b) Attitudes by Subscale

There are five items in subscale dangerousness, ten items in poor interpersonal and social skills scale and six items in incurability subscale.

Table 5: Per item Mean and 95% CI for the three subscale and overall score of BMI scale

Subscale	**M(SD)**	**95 %CI**
Dangerousness	2.17(0.90)	2.77, 1.56
Poor interpersonal and social skills	1.77(0.92)	2.99, 0.54
Incurability	2.21(0.92)	2.94, 1.47
Full BMI scale	1.99(0.80)	4.22, -0.24

* M- Mean, SD- Standard deviation, CI- Confidence interval

Table 5 shows per item mean and 95% confidence interval for the three subscales and overall score of BMI scale.

c) Associates of attitudes

The differences in the attitude scores in different independent variables have two categories were determined by independent sample t tests. And, difference in attitude score in independent variables having more than two categories was determined by the one-way ANOVA.

As per Kolmogrov-Smirnov test statistic (D)results in 0.04762 which means that data is normally distributed. So independent sample t test has been applied to find out difference in attitude score by socio demographic characteristics.

Table 6: Difference in attitude score by socio-demographic characteristics

Characteristics	M(SD)	Diff.*(95% CI)	p-value
Sex			
Male	42.67(17.20)	1.24(-3.31,5.79)	0.59
Female	41.43(16.61)		
Marital status			
Married	60.17(9.06)	18.73(5.20,32.27)	**0.007**
Unmarried	41.43(16.72)		
Place of residence			
Urban	42.80(16.32)	4.18(-1.35, 9.71)	0.13
Rural	38.62(18.48)		
Had mental illness in past			
Yes	40.10(15.14)	2.12(-4.50, 8.74)	0.52
No	42.23(17.09)		
Is someone in your family/ friends/ relative is having mental illness:			
Yes	39.64(17.34)	3.03(-2.19, 8.27)	0.25
No	42.68(16.65)		

*Diff. =Difference in mean, (lower bound, upper bound)

Table 6 shows difference in attitude score by socio-demographic characteristics. Married students (N=6) had higher BMI score than unmarried students (N=213) and the difference was statistically significant. On further analysis it was found that of these six married students, five had positive response for history of mental illness in family, friend or any relative, also two had positive history of past mental illness. The difference among groups was not statistically significant for other characteristics.

Table 7: Difference in attitude towards mental illness by education level of students

Characteristics	M(SD)	F- value	p-value	p-value trend
Batch		9.11	**<0.0001**	**<0.0001**
I MBBS	48.11(14.34)			
II MBBS	43.63(14.71)			
III MBBS	41.08(15.21)			

*M= mean, SD= standard deviation, F=degree of freedom, p= p value

Table 6 shows that There is increase trend in positive attitude in medical students with increase in their education level ($p<0.0001$).

There was significantly positive attitude towards mental illness among III MBBS students than II MBBS and, among II MBBS than I MBBS ($p<0.0001$). An increasing trend of positive attitude has been seen with an increase of education level and exposure towards the subject.

4. Discussion

The current online study was planned to assess the attitude of medical students towards mentally ill patients and mental illnesses, to find correlations of attitude score with sociodemographic and clinical variables and, to compare the score among students of the three year-wise groups.

Out of total 21 items of the BMI scale, students showed positive attitude on majority of items (fifteen items) and negative attitude on few items (six items). The mean score for BMI scale was 41.99 and per item mean score for the scale was 1.99. This score is towards positive attitude. Jilowa et al also found in their study that Nearly 84% of second-year medical students and 52% of interns had positive attitude toward psychiatry. (19) In their study, Risal et al also found overall positive or neutral attitudes towards mental illness and psychiatry among the medical students and interns in their institute. (20)

In our study we found that majority of students agree that a mentally ill person is more likely to harm others than a normal person (64%) and that mental disorders would require a much longer period of time to be cured than would other general diseases (83%). Kodakandla et al conducted a study on Attitude of interns towards mental illness and psychiatry and found that majority of the interns believed that mentally ill person is more likely to harm others and that mental illness require a much longer time to be cured than other general diseases. (21) In our study majority (58 percent) of students agree that most people would not knowingly be friends with a mentally ill person. Jyothi NU et al also found majority (96 percent) of participants agreed with the statement. (22)

In our study we found that majority of students agree that psychological disorder is recurrent (64%), that people who have once received psychological treatment are likely to need further treatment in the future (61%), and that the behaviour of people who have psychological disorders is unpredictable (65%). Kodakandla et al also found that majority of participants (76%) believed that psychological disorder is recurrent and that the behavior of patients with psychological disorder is unpredictable (79%); two third of them (68%) were of the opinion that people who have once received psychological treatment are likely to need further treatment in the future. (21) Jyothi NU et al also found similar findings in a study on college students. (22)

Students showed per item mean score 1.77 for poor interpersonal and social skill subscale which is towards positive attitude. Higher per item mean score 2.17 for dangerousness subscale and 2.21 for incurability showed their negative attitude. In a community Study on Attitudes to and Knowledge of Mental Illness in Tehran, Ghanean H et al found that around half participants agreed that people with a mental illness “are dangerous”. (23) Contrary to our findings *Kodakandla et al* found that only one third (31%) interns believed that psychological illness is unlikely to be cured regardless of the treatment. (21)

Married students showed statistically significant higher BMI score compared to unmarried students. On further analysis it was found that of these six married students, five had positive response for history of mental illness in family, friend or any relative and, two had positive history of past mental illness. So,

these two factors might have caused higher stigma in this small sample. The attitude score was not associated statistically significantly with other sociodemographic and clinical variables.

There was significantly positive attitude towards mental illness among III MBBS students than II MBBS and, among II MBBS than I MBBS ($p<0.0001$). An increasing trend of positive attitude has been seen with an increase of education level and exposure towards the subject. Similar to our study Aruna et al also highlighted exposure to psychiatry could improve the knowledge base of medical students. (24) Tharyan et al also found that psychiatric education positively influences the attitudes of medical students towards mental illness and some aspects of psychiatry. (25) However, providing clinical training in psychiatry during under graduation seems to improve the attitude toward people with mental illness. (16, 25-27) The favorable impact of psychiatry posting on the attitude of medical students towards mentally ill has been found in previous studies from western countries. (28) Work by Mas and Hatim (2002) from Malaysia found that final year MBBS students had more favorable attitude towards mentally ill as compared to the first-year students. (29)

The National medical commission (formerly Medical Council of India) has implemented Attitude, Ethics and Communication module (AETCOM) in all medical colleges in India in August 2019. (30) The cognitive components, behavioural attitudes and ethical dimensions of AETCOM module will change the approach of future doctors to psychiatry and person with psychiatric illness. Focusing more on clinical exposure and skills the new competency based medical education (CBME) programme has increased the duration of undergraduate clinical posting to total four weeks and total 40 hours for teaching from two weeks and 25 hours pre CBME respectively. This sequential introduction of clinical posting during second professional MBBS followed by theory class and clinical posting during third MBBS part-I will be more helpful in understanding of the subject. In future, mandating psychiatry as an independent subject of examination in under graduation assessment may prove a milestone step in medical education. So, it may be expected that this increased exposure will help in removing the existing negative attitudes towards psychiatry and person with psychiatric illness.

Suggestions:

Admitting the prevailing stigma needs to be acknowledged and openly discussed with medical students in order to overcome these views. Prevailing stigma and the negative attitudes about mental illnesses affect both patient caring and psychiatry as a career choice. The development of educational strategies enabling initial interest shown during the early clinical exposure needs to be maintained. Providing public education on mental illnesses and attached negative attitudes or myths can change these negative beliefs in general public. To promote psychiatry as a career, interested students need to have increased access to an in-depth experience of psychiatry, including “enrichment activities” such as electives in psychiatry.

Conclusions:

Medical students show variable scores on belief towards mental illness scale, its subscales and, individual items. Admitting this prevailing stigma needs to be acknowledged and openly discussed with medical students in order to overcome these views. Providing adequate education on mental illnesses and attached negative attitudes or myths can change these negative beliefs.

Implications of the Study:

This study will help in understanding of belief of medical students towards mental illnesses. The comparison among various groups in

present study will help in understanding the impact of successive undergraduate training years.

Limitations:

This was a cross sectional study with small sample size.

Future Direction:

Future studies can be undertaken with large sample size to determine the changes in belief of medical students admitted year 2019 onwards.

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Original Article

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Social Security Measures for Elderly Population in Delhi, India: Awareness, Utilization and Barriers

Community Medicine Section

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ABSTRACT

Introduction: World population of elderly is increasing at a fast pace. The number of elderly in India has increased by 54.77% in the last 15 years. A number of social security measures have been taken by Indian government.

Aim: To assess awareness, utilization and barriers faced while utilizing social security schemes by elderly in a secondary care hospital situated in a rural area in Delhi, India.

Materials and Methods: A cross-sectional study was conducted among 360 individuals aged 60 years and above in a secondary care hospital situated in a rural area in Delhi. A pre-tested, semi-structured schedule prepared in local language was used. Data was analysed using SPSS software (version 17.0). Chi-square test was used to observe any statistical association between categorical variables. The results were considered statistically significant if p-value was less than 0.05.

Results: A majority of study subjects were females (54.2%), Hindu (89.7%), married (60.3%) and were not engaged in any occupation (82.8%). Awareness about Indira Gandhi National Old Age Pension Scheme (IGNOAPS) was present among 286 (79.4%) and Annapurna scheme in 193 (53.6%) subjects. Among 223 subjects who were below poverty line, 179 (80.3%) were aware of IGNOAPS; while, 112 (50.2%) were utilizing the scheme. There was no association of awareness with education status, occupation, religion, family type, marital status and caste ($p>0.05$). Corruption and tedious administrative formalities were major barriers reported.

Conclusion: Awareness generation, provision of information on how to approach the concerned authority for utilizing the scheme and ease of administrative procedures should be an integral part of any social security scheme or measure. In the present study, about 79.4% of elderly were aware and 45% of the eligible subjects were utilizing pension scheme. Major barriers reported in utilization of schemes were corruption and tedious administrative procedures.

Keywords: Geriatric, Pension, Rural area

INTRODUCTION

World population of elderly (people aged 60 years and above) has increased in last two decades at a pace faster than any other times before. As per World Health Organization (WHO), between 2015 and 2050, it is expected that proportion of the world's population over 60 years will double from about 12% to 22%. Similarly, the number of people aged 80 years or older will rise from 125 million to 434 million in same period [1]. India will also not be untouched by this demographic transition in coming decades. The number of elderly in India has increased by 54.77% in the last 15 years against 42.34% rise in the working population (15-59 years of age) during the same time period [2]. The proportion of the people with age more than 60 years will grow from 8% in 2010 to 19% in 2050 while the population of those aged 80 years and older will expand from 0.8% to 3%. By the year 2042, the proportion of people aged 60 years and older will exceed that of people in 0–14 year's age group in India [3].

This profound shift in the proportion of older Indians, taking place in the context of changing family relationships and limited social support system will bring with it a variety of social, economic and health care policy challenges. One direct implication of this would be increase in the prevalence of chronic conditions such as cardio vascular diseases, chronic respiratory diseases, locomotor disorders and mental disorders etc. Estimates say that nearly 45% of India's disease burden is projected to be borne by older adults in 2030, when the population age groups with high levels of chronic conditions will represent a much greater share of the total population [3].

A number of social security measures have been taken by the Indian government. The government of India came out with the National Policy for Older Persons in 1999 to promote the healthcare, financial security, nutrition, shelter, education and welfare of senior citizens in India [4].

IGNOAPS was launched in 1995 subsequently to provide monthly pension to elderly who are Below Poverty Line (BPL). In 2000, Annapurna scheme was launched which aimed at providing food security to elderly [4].

Maintenance and Welfare of Parents and Senior Citizen Act 2007 aimed to ensure need based maintenance for parents and senior citizens, protection of their rights and welfare was introduced [4]. A comprehensive National Program for Health Care of the Elderly (NPHCE) was launched subsequently in 2010 with the vision to provide accessible, affordable and high-quality long-term, comprehensive and dedicated care services to ageing population [4].

These social security measures are important and at times the only means of support for elderly. However, to assess the impact and steps for further improvement in future of such measures, it is important to have information about the level of awareness and practical problems faced by elderly while utilizing them. Therefore, this study was conducted with an objective to assess awareness, utilization and barriers faced by elderly while utilizing social security schemes in a secondary care hospital situated in a rural area in Delhi.

MATERIALS AND METHODS

This was a cross-sectional study conducted among individuals aged 60 years and above, attending a secondary level care hospital situated in a rural area in Delhi, Pooth Khurd, who gave written informed consent to participate in the study. Sample size was calculated on the basis of a previous study by Murugen PB et al., in which prevalence of awareness about social security schemes was 73.2% and that of utilization of old age pension scheme among study subjects was 73% [5]. Taking confidence interval of 95% with absolute error of 5%, the sample size was calculated to be 313. A total of 360 subjects were included in the study. These subjects were interviewed and questionnaire was filled by the investigator during each interview. Study subjects were selected by simple random sampling method.

Data was collected using a pretested semi-structured schedule, which included socio-demographic profile, awareness and utilization of various social security schemes and other measures taken by the government for the elderly, and difficulties faced in availing these schemes. Variables were decided based on the variables used in previous similar studies [2,4,5]. Pretesting was done at the secondary level hospital in rural area of Delhi among 50 elderly subjects attending medicine OPD. Accordingly, questionnaire was edited and modified. Information was also obtained about financial dependence and family support in providing care.

STATISTICAL ANALYSIS

Data was analysed using SPSS (version 17.0). Results were presented in simple proportions and means (±SD). Chi-square test was used to observe any statistical significance of difference between proportions. The results were considered statistically significant if p-value was less than 0.05.

The study was approved by the Institutional Ethics Committee of the hospital.

RESULTS

Sociodemographic Profile

As shown in [Table/Fig-1], the study sample consisted of 318 (88.3%) subjects aged 60-74 years and 33 (9.2%) in 75-84 years age group. A majority of study participants were females-195 (54.2%) and 165 (45.8%) were males. Mainly the study samples were Hindus (89.7%), married (60.3%) and were not engaged in any occupation (82.8%). Those who were residing in joint families were 260 (72.2%) while 24 (6.7%) subjects were staying alone.

A house was owned by 266 (73.9%) subjects, 86 (23.9%) were residing in a rented house and rest stayed in old age homes.

Awareness about Social Security Measures

Awareness about IGNOAPS was higher than other social security schemes as about four fifth of the subjects were aware of this as compared to about half who were aware of Annapurna scheme and only 10 (2.8%) subjects knew about senior Citizens Act. There was significant difference in awareness about Senior Citizens Act with gender (p<0.05). Subjects who were below poverty line were more aware about Annapurna scheme with 140 (62.8%) subjects knew about the same as compared to 53 (38.7%) who were above poverty line (p<0.05). A total of 294 (81.7%) subjects were aware about Indira Gandhi National Widow Pension scheme. Females (76.4%) were significantly more aware about the same as compared to males (87.9%) (p<0.05). Subjects who were widow/separated/ single or divorced were less aware (67.8%) about the same as compared to those who were married (90.8%) (p<0.05).

[Table/Fig-2] shows results when the study subjects were inquired if they were aware about other measures of support provided to them by government. A little less than half were aware about bus travel concession provided to elderly in form of bus pass. Out of 360 subjects, 41 (11.3%) subjects were not aware about such measures of government to support elderly.

Only 36 (10.0%) subjects reported that they have done savings for old age. A small number of subjects, 7 (3.6%) among females and 29 (17.6%) among males reported that they did savings for old age which was statistically significant (p<0.05). A total of 182 (50.6%) subjects said that they were dependent on their family members for their living. Higher percentage of those who were non-working (54.0%) than working (33.9%) reported that they are dependent on family (p<0.05). When asked about family support, 213 (59.2%)

Characteristic	N=360 Number (%)	Awareness about social security schemes		
		IGNOAPS N (%)	Annapurna N (%)	Senior Citizens Act N (%)
Age:				
p-value		p=0.52	p=0.4	p=0.51
60-74 years	318 (88.3)	257 (80.8)	174 (54.7)	10 (3.1)
75-84 years	33 (9.2)	29 (87.9)	14 (42.4)	0 (0.00)
≥85years	9 (2.5)	8 (88.9)	5 (55.6)	0 (0.00)
Sex:				
p-value		p=0.01	p=0.67	p=0.04
Male	165 (45.8)	145 (87.9)*	86 (52.1)	8 (4.8)*
Female	195 (54.2)	149 (76.4)	107 (54.9)	2 (1.0)
Education:				
p-value		p=0.17	p=0.59	p=1.00
Literate	181 (50.3)	153 (84.5)	100 (55.2)	5 (2.8)
Illiterate	179 (49.7)	141 (78.8)	93 (52.0)	5 (2.8)
Occupation:				
p-value		p=0.72	p=0.78	p=0.22
Working	62 (17.2)	52 (83.9)	32 (51.6)	0 (0.0)
Not-working	298 (82.8)	242 (81.2)	161 (54.0)	10 (3.4)
Religion:				
p-value		p=0.36	p=1.00	p=1.00
Hindu	323 (89.7)	266 (82.4)	173 (53.6)	9 (2.8)
Others	37 (10.3)	28 (75.7)	20 (54.1)	1 (2.7)
Family type				
p-value		p=0.33	p=0.81	p=0.67
Nuclear	76 (21.1)	66 (86.8)	43 (56.6)	2 (2.6)
Joint	260 (72.2)	210 (80.8)	138 (53.1)	8 (3.1)
Staying alone	24 (6.7)	18 (75.0)	12 (50.0)	0 (00.0)
Caste:				
p-value		p=0.25	p=0.94	p=0.53
Scheduled casts (SC)/ Scheduled tribe (ST)	94 (26.1)	72 (76.6)	49 (52.1)	3 (3.2)
Other backward Classes (OBC)	167 (46.4)	137 (82.0)	90 (53.9)	3 (1.8)
General	99 (27.4)	85 (85.9)	54 (54.5)	4 (4.0)
Place of stay				
p-value		p=0.06	p=0.07	p=0.16
Own house	266 (73.9)	222 (83.5)	152 (57.1)	10 (3.8)
Rented house	86 (23.9)	64 (74.4)	37 (43.0)	0 (0.0)
Old age home/ Homeless	8 (2.2)	8 (100.0)	4 (50.0)	0 (00.0)
Marital status:				
p-value		p=0.01	p=0.10	p=0.74
Married	217 (60.3)	197 (90.8)*	124 (57.1)	7 (3.2)
Unmarried/Widow/ Separated/ Divorcee	143 (39.7)	97 (67.8)	69 (48.3)	3 (2.1)
Below poverty line				
p-value		p=0.40	p=0.01	p=0.04
Yes	223 (61.9)	179 (80.3)	140 (62.8)*	3 (1.3)*
No	137 (38.1)	115 (83.9)	53 (38.7)	7 (5.1)

[Table/Fig-1]: Socio-demographic profile and awareness about social security schemes among study subjects.
Figure with *mark were statistically significant (p<0.05). Chi-square test applied.

Support measures	Number	Percentage (%)
Bus travel concession	162	45
Train travel concession	58	16.1
Air travel concession	8	2.2
High interest rates by banks	37	10.2
Income tax benefits	35	9.7
NPHCE	19	5.3

[Table/Fig-2]: Awareness about social support measures among study subjects (n=319)
Frequency distribution table.

subjects reported that their family members take care of them well while 147 (40.8%) subjects responded that their family members do not take care of them well. There was significant difference between gender where 110 (66.7%) among males and 103 (52.8%) among females said that their families take care of them well ($p<0.05$). Similarly, 90 (65.7%) subjects who were above poverty line responded that their family members take care of them well than 123 (55.2%) subjects who were below poverty line ($p<0.05$). A significantly higher number of subjects who belonged to OBC category (27.5%) agreed that they were satisfied with their lives as compared to SC/ST (4.3%) and general category (13.1%) ($p<0.05$). Noticeably, only 2 (0.6%) subjects were having health insurance to meet their health security cover.

[Table/Fig-3] shows sources of information about various social security schemes and measures taken for elderly. Most common source of information was 'local leaders' as reported by 130 (36.1%) subjects. Family and friends were the next most common sources as reported by 112 (31.1%) subjects. Television was third most common source as told by 23 (6.4%) subjects. Out of the total 360, 48 (13.3%) subjects could not remember their source of information or had no such source.

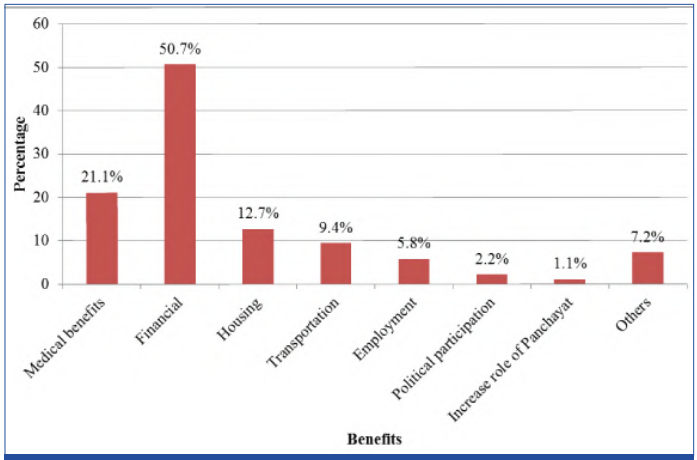
Sources of information	Number	Percentage
Local leaders	130	36.1
Family/friends	112	31.1
Television	23	6.4
Panchayat (local government members)	20	5.6
Radio	18	5.0
Hoardings	5	1.4
Posters	4	1.1

[Table/Fig-3]: Sources of information about social security schemes and measures among study subjects (n=312).
Frequency distribution table.

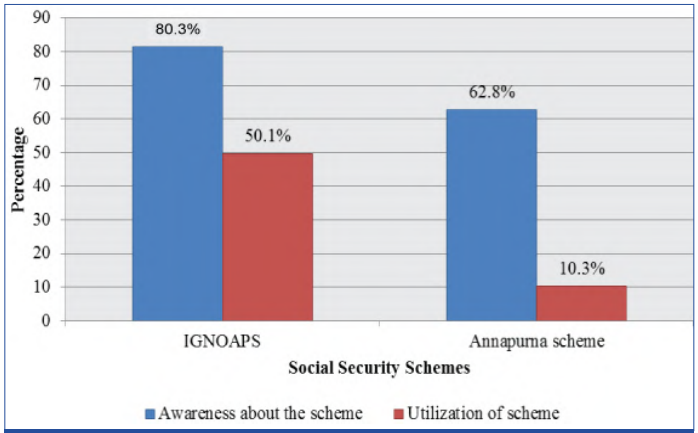
When asked about additional benefits study subjects expect from government, 76 (21.1%) subjects responded that more medical benefits, 183 (50.7%) demanded for more financial support, 46 (12.7%) said housing facilities, 34 (9.4%) expected for more transportation facilities, 21 (5.8%) asked for employment opportunities, 8 (2.2%) demanded for more political participation for them and 4 (1.1%) desired an increase in their role in local governance (panchayat) as shown in [Table/Fig-4].

Subjects below Poverty Line

Following analysis has been done only among subjects who were below poverty line and were eligible for social security schemes like IGNOAPS and Annapurna scheme. Among 223 subjects who were below poverty line, 179 (80.3%) were aware of IGNOAPS while only 112 (50.2%) of them were utilizing the scheme. Annapurna scheme was known to 140 (62.8%) subjects but only 23 (10.3%) were utilizing the same as given in [Table/Fig-5]. They were asked about the problems faced in utilization of social security schemes. The options given to the subjects were corruption, difficulty in knowing



[Table/Fig-4]: Additional benefits expected from government by study population



[Table/Fig-5]: Awareness and utilization of social security schemes among those eligible for the same among study subjects

whom and where to approach, tedious administrative formalities, other problems and no problem faced and the answers were 11.2%, 20.6%, 38.1%, 20.1% and 10% respectively. When asked if they are financially dependent on their family members, 55.2% answered yes. On probed regarding their major sources of finance, 79.4% were found to be dependent on their children and 31.8% reported that they have to borrow money from relatives often, to meet their expenses.

A high proportion of (40.8%) subjects grumbled that their family members do not take care of them well. When asked if they were satisfied with their lives, only 24 (10.8%) responded positively while 199 (89.2%) were dissatisfied with their lives.

Among below poverty line subjects, majority (87.4%) said that government has not taken adequate steps for welfare of the elderly. When enquired about the additional benefits they need from government, following responses were given – medical (18.8%), financial (57.4%), housing (13.9%), transportation (10.3%), employment opportunities (7.6%) and participation in local politics (1.3%).

DISCUSSION

The present study was conducted among 360 elderly individuals who came to seek health care services in a secondary level hospital situated in Delhi. The study population mainly comprised of subjects who were in 60-80 years age group. Hindus were found to be predominant in the study population in comparison to Muslims and Christians, which reflect the national level population structure based on religion. About half of the subjects were illiterate. Such profile was similar to the elderly profile reported by Dhanasekaran G in his study carried out in a rural area in Tamil Nadu [6].

A significant proportion of elderly were aware about IGNOAPS. It was known to 80.3% subjects and there was no association found with age, family type, caste. Lesser known than IGNOAPS

was Annapurna scheme, which was known to 53.6% subjects. Awareness was significantly higher among those who were BPL. These findings were consistent with that reported by Srivastava AK et al., in their study conducted in district Dehradun [7]. In that study, awareness of IGNOAPS was observed in 74.6% of the elderly [7]. Only 10 (2.8%) subjects knew about Senior Citizens Act, with a higher proportion of males than females were aware of the same. Bus travel concession was known to about 45% subjects but other measures like National Program for Healthcare of the elderly, interest rates etc. were known to very less subjects. This is lower than figures reported by Joseph N et al., in their study conducted in Mangalore city. The possible reasons could be higher literacy rate of subjects in that study and rural urban differentials [8].

An important finding was that despite the fact that 72.2% subjects were living in joint families, only 59% subjects replied that their family members take care of them well. There were gender differentials seen with this aspect where significantly higher number of males were taken care well by their families than females. Similarly, more literate subjects than illiterate were taken care well by families. This reflects impact of education not only in livelihood and living standard but also in social support system at household level. Such gender differentials in social support among elderly have been documented by another study also where males were more likely to be heard and involved in decision making at household level as compared to females [9].

Main sources of information were local leaders followed by family and friends. Hence, local leaders should take more steps to raise awareness about social security measures among elders in their areas and to remove barriers wherever possible. Envisioning recreation centers for elders, where they can gather together and share information with each other can prove to be an added advantage.

Major barriers reported were corruption (11.2%) and tedious administrative procedures (38.1%). This is consistent with findings of a previous mentioned study in which also bribe, procedural delay and nobody to guide were main barriers [5]. Innovative steps using information technology should be taken to make the procedure easier and to reduce the number of visits to offices for applying and tracking their applications. Corruption charges if found true should be dealt with stringent punitive actions since it deteriorates the faith of elders in system and deprive them of their rights.

Majority of subjects asked for additional financial benefits from government. The reason could be meager amount of monthly pension which is insufficient to fulfill even basic needs of a person. Insufficiency of amount has been reported by another study carried out by Nivedita BM et al., in Bengaluru as well, in which 79% subjects responded that the amount is insufficient for meeting basic needs [10]. Medical benefits were next expected need from government since health care cost of chronic illness is huge, especially in setting where majority of subjects belong to low income group. Although, government has started a separate program NPHCE for promoting geriatric health care facilities and competence among treating medical staff, the program is still in its infancy state with hardly any required infrastructure. Elderly in India are currently facing risk of dual medical problems, i.e., both communicable as well as non–communicable diseases. At present, most of the geriatric OPD services are available at tertiary care hospitals located in urban areas [11]. This tertiary care is often too expensive for people with limited income sources. As a result, those with conditions requiring tertiary care often go untreated or are left with devastating hospital bills, both of which exacerbate poverty [12]. More steps are needed by government to provide support for medical expenses for elderly population.

When analysis was done for BPL subjects who were eligible for IGNOAPS and Annapurna scheme, it was found that although 80.3% were aware of IGNOAPS only 50.2% were utilizing the scheme. This is comparable to a previously mentioned study in which 45.4% subjects were utilizing IGNOAPS [7]. Similarly, 62.8% were aware of Annapurna scheme but only 10.3% were utilizing the same. This shows a gap between awareness and actual utilization of schemes. Advertisements on mass media like television, radio, newspaper, etc., can help in increasing awareness. Corruption, difficulty in knowing whom and where to approach and tedious administrative formalities were the major barriers. Inconsistencies in identification of beneficiaries, political influence and corruption are known factors reported earlier also which poses a serious question on the implementation of this scheme [13].

LIMITATION

Firstly, the study involved subjects only from rural area. It would have been more representative of the population if elderly from urban area were also involved. Secondly, since study was conducted at secondary level hospital due to resource constraints, only those elderly patients who were coming to the hospital were included in the study. For more generalizable results, healthy elderly subjects from the residential areas also could have been included.

CONCLUSION

The present study highlights important areas of concern in providing social security for elderly population in rural area of Delhi. About 79.4% of elderly were aware and 45% of the eligible subjects were utilizing pension scheme. Awareness about other measures of social security was low. Major barriers were corruption, tedious administrative procedures and difficulty in identifying where and whom to approach for information regarding social security schemes. It is recommended that local leaders should take efforts to make elders aware of such measures. The expectations of elders for more financial security and medical benefits should be looked into in framing future polices for them. Awareness generation, provision of information on how to approach the concerned authority for utilizing the scheme and ease of administrative procedures should be an integral part of any social security scheme or measure.

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Assessment of Diabetes in accordance with Indian Diabetes Risk Score (IDRS) among Adults of Delwara, Rajsamand

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Abstract
Introduction: Diabetes Mellitus (DM) is a metabolic disorder of multiple etiologies characterized by chronic hyperglycemia with disturbance of carbohydrate, protein and fat metabolism resulting from impaired insulin secretion, insulin action, or both. Assessment of the risk of diabetes development acts as a primary prevention measure among the high-risk population.
Objectives: To assess the risk of developing Type 2 Diabetes Mellitus using Indian Diabetic Risk Score among adults of Delwara.
Methods: A cross sectional study was undertaken among adults of age more than 30 years to assess the risk of development of DM. A pre-validated, structured questionnaire was used to assess the risk of development of DM including the Indian Diabetes Risk Score. The total scores were classified into low, medium and high-risk categories.
Results: Mean age of the study population was 46.12±10.9 yrs. Nearly 62% of study population were female, 42.7% had high school education and 44.7% were daily wage employees. Majority (47%) of the study population belonged to high risk and 36.5% belonged to medium risk category for development of DM. Increasing age, BMI, waist circumference, high Blood Pressure, a positive family history, female gender, higher education, current usage of alcohol and tobacco, sedentary to mild physical activities and high waist to height ratio were significantly associated with increased risk of development of Diabetes Mellitus.
Conclusion: The risk assessment should be put forward as a major prevention tool in the DM management.

Keywords: Risk Assessment, Delwara, Diabetes mellitus.

1. Introduction

Diabetes mellitus is a global health menace which is increasing in an alarming rate.The projected global prevalence of diabetes among adults as 9.9% by 2030 from 8.3% in 2011. While communicable diseases are slowly getting controlled in India, there is a significant increase in the burden of non-communicable diseases, including but not restricted to diabetes. The age of man-made and degenerative diseases characterized by a life expectancy close to 50-60 years and unhealthy lifestyles which promote diseases like cardiovascular disease and hypertension and Diabetes Mellitus. The prevalence rate of diabetes mellitus among the adult population ranges from 3% in rural areas to 9% in urban areas in India.

A study by the American Diabetes Association reports that India will see the greatest increase in people diagnosed with diabetes by 2030. The high incidence is attributed to a combination of genetic susceptibility plus adoption of a high-calorie, low-activity lifestyle by India's growing middle class.

Complications of Diabetes Mellitus are mainly acute complications like hypoglycemia, hyperglycemic crisis, diabetic ketoacidosis (DKA), hyperglycemic hyperosmolar state (HHS) and Chronic complications like diabetic retinopathy, diabetic nephropathy, diabetic neuropathy (micro vascular complications) macro vascular complications-cardiovascular diseases such as heart attacks, strokes and insufficiency in blood flow to legs, diabetic foot disease. Other rare complications like impaired growth and development, associated autoimmune conditions, hypothyroidism, hyperthyroidism, celiac disease, vitiligo, primary adrenal insufficiency (Addison's disease), lipodystrophy (lipoatrophy and lipohypertrophy), non-alcoholic fatty liver disease, infections seen in patients with diabetes, limited joint mobility, edema. These complications are also on the rise and contribute significantly to overall morbidity and mortality. The low levels of education and poor awareness of the disease in the country are enhancing its impact on health of the population.

While comprehensive data are not available, smaller studies have been performed in various states of India to study the prevalence of diabetes. Based on these studies, the highest prevalence reported is from Ernakulum in Kerala (19.5%) and the lowest from Kashmir valley (6.1%). Most other areas have prevalence above 10%. According to National Family Health Survey 4, the prevalence of high blood sugar level among men is 13.1% and women 8.7% in Kerala.

A majority of our population is at high risk of developing Diabetes Mellitus and is not aware of it until complications arise. Our study aims to identify these people and bring about measures to prevent the early onset of Diabetes.

2. Materials and Methods

The study was done among adults of age more than 30 years without a history of Type 2 Diabetes Mellitus at Delwara, Rajsamand, Rajasthan, INDIA during a 3 months period. Sample size of 170 was reached using the formula, $n = z^2pq/d^2$, Where, z = relative deviate (at 95% confidence interval) i.e. 1.96, p = i.e. estimated 36.5% prevalence of high risk of development of DM from a study done in Pune,

Maharashtra.
Pretested, structured interview schedule was administered to collect the data after obtaining Institutional Ethics Committee approval. The interview schedule was divided into 2 parts. The first part consisted of socio demographic details of study subjects and risk factors of diabetes. The second part was Indian Diabetic Risk Score which comprised of two modifiable (Waist circumference and Physical activity) and two non-modifiable risk factors (age and family history of T2 DM).
Indian diabetic risk score (IDRS) is the screening tool widely used to assess the risk of diabetes among general population. An IDRS ≥60 had a sensitivity of 83.8%; specificity of 81.0% in prediction of T2DM, while an IDRS <60 had a sensitivity of 79.9% and specificity of 83.8%, in prediction of non-T2DM in Indian Settings.

Operational definitions
Participants with IDRS ≥60 were considered at high risk of diabetes. Family history of diabetes If either or both of a subject's parents had diabetes, they were considered to have a positive family history. Physical activity levels were graded based on WHO STEPS definitions of sedentary, mildly, moderately or vigorously physically active. Waist circumference measured to the nearest 0.1 cm at the midpoint between the tip of the iliac crest and the last costal margin in the back and at the umbilicus in the front, using a non-stretchable tape, at the end of normal expiration, with the subject standing erect in a relaxed position. Abdominal/central obesity was considered to be present when the waist circumference was ≥80 cm in women and ≥90 cm in men. Weight was measured to the nearest 0.1 kg using a digital weight recorder. Height was measured to the nearest 0.1 cm using a wall fixed stadiometer. Body Mass Index was evaluated as weight divided by height squared (kg/m2). Waist to Height Ratio was calculated as waist circumference divided by height. The data collected was entered in Microsoft Excel and analyzed using Statistical Package for Social Sciences version 16 software. Descriptive analysis was done by calculating frequencies, proportions, mean, median, standard deviations. Chi square tests used to calculate associations.

3. Results
Mean age of the study population was 46.12±10.9 yrs. Among 170 study population 87 (51.2%) belonged to the age group of 35-49 years. Nearly 67% of study population were female, 42.7% had high school education. About 39 (23%) and 41 (24%) were currently using alcohol and tobacco respectively. Nearly 98% were following non-vegetarian diet. 32 (18.8%) of study subjects had associated hypertension and on treatment. About 58 % of study subjects have family history of Diabetes. Mean waist to height ratio was 0.61±0.11. Majority 149 (87.6%) had a high waist to height ratio. 44 (25.9%) of study subjects had raised blood pressure during the interview.
Majority (90%) had a family size <5 and nearly 62% belonged to nuclear family. About 70% of females were homemaker and 44.1% of study population was daily wagers. Nearly 56% of study population didn't have any co-morbidity. 32 (18.8%) had associated hypertension and 23 (13.5%) had osteoarthritis, 20 (11.7%) had others like asthma, stroke, Acid Peptic Disease, migraine. (Figure 1)
About 80 (47%) of the study population belonged to high risk and 36.5% belonged to medium risk category for development of Diabetes Mellitus according to Indian Diabetic Risk Score (IDRS). (Table 1)
Increasing age, BMI, waist circumference, high Blood Pressure, a positive family history and female gender had a strong association with high risk of development of diabetes. We found that higher the education higher the risk for Diabetes. Current usage of alcohol and tobacco were also associated with higher risk of development of Diabetes Mellitus. Sedentary to mild physical activities and high waist to height ratio were also associated with increased risk of development of Diabetes Mellitus.

Table 1: Indian Diabetes Risk Score

IDRS	Frequency (%)
Low Risk	28 (16.5)
Medium Risk	62 (36.5)
High Risk	80 (47)

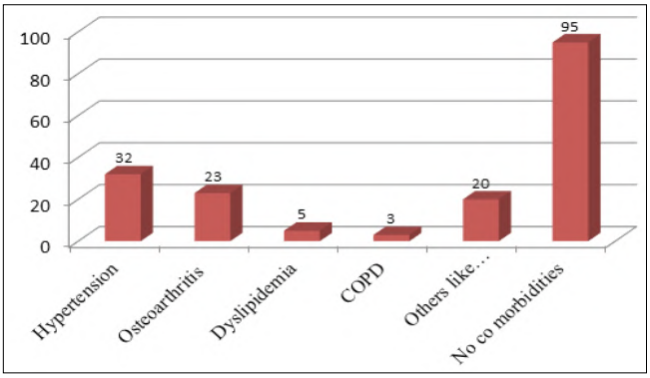

Fig 1: Associated medical conditions

4. Discussion
In this study we had found that majority of our study population belonged to age group 36-49years, nearly 62% of study population was female, 42.7% had high school education and 44.7% were daily wage employees. This was similar to a study done in Maharashtra. Using the IDRS we found that majority of 36-49 years age group belonged to moderate risk and in age group of >50, majority was under high risk of development of Type 2 Diabetes Mellitus. Many studies conducted in India showed that increasing age increases the risk of Diabetes. In another study which used Diabetes Risk Score, the age group of 55-64yrs was high risk of developing Diabetes.
In our study nearly 58% of overweight study subjects and 71% of obese people had a high risk of development of Diabetes. Studies have shown that obesity plays a major factor in the development of diabetes. Obesity and diabetes are interrelated and the term 'Diabesity' has been coined to describe the relationship between obesity and diabetes.
Another significant association was waist circumference with risk of developing Diabetes. Our study showed waist circumference and risk of developing Diabetes is directly proportionate as increased waist circumference clearly denote deposit of fat around internal organs leading to insulin resistance. Other studies showed similar results.
Among our population with high BP, about 77.3% were in the high-risk group of developing Diabetes. Diabetes damages arteries and makes them targets for hardening and atherosclerosis leading to hypertension. A population-based study done in Chennai, India among the NGT (normal glu-

cose tolerance) subjects showed about 38.2% with Hypertension came under the high-risk group of IDRS.

Apart from obesity the other risk factors for type 2 DM are age, life style factors like sedentary life style, smoking and alcohol consumption and the most important risk factor was family history of type 2 dm which has a critical role in the development of the disease which is similar to a study done in Chennai.

We did not find any significant association b/w socioeconomic status and risk of developing Diabetes. A cross-sectional study conducted at Pune, Maharashtra showed that the association between socioeconomic class and risk status was highly significant statistically (P = 0.001). We did not find any association between type of diet, occupation, family income and risk of developing Diabetes.

Every adult more than 18 years should be assessed for risk of development of Diabetes Mellitus using IDRS or any other simple tool. It will not just aid in early detection and prevention of complication of Type 2 DM but also helps to reduce the morbidity and mortality associated with it. This tool can be used as a primary prevention measure to motivate people against metabolic diseases and cardiovascular diseases. As majority of study population belonged to high and moderate risk for development of Diabetes, urgent follow up and health education are needed in the area with a Random Blood Sugar testing for all followed up by definitive diagnostic tests. Development of comprehensive health approaches including dietary and lifestyle modifications and awareness regarding the risk of Diabetes Mellitus and its complications should be done.

The assessment of risk would have been complete if qualitative component also added. That would have shed a light regarding the resistance towards adapting the healthy lifestyle.

5. Conclusion

Majority (47%) of the study population belonged to high risk and 36.5% belonged to moderate risk category for development of Diabetes Mellitus. Increasing age, BMI, waist circumference, high Blood Pressure, a positive family history and female gender had a strong association with high risk of development of diabetes. We found that higher the education higher the risk for Diabetes. Current usage of alcohol and tobacco were also associated with higher risk of development of Diabetes Mellitus. Sedentary to mild physical activities and high waist to height ratio were also associated with increased risk of development of Diabetes Mellitus.

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RESEARCH ARTICLE

ASSESSMENT AND COMPARISON OF PRE-HYPERTENSION AND ITS DETERMINANTS IN SECOND AND FINAL YEAR STUDENTS OF AIMS & RC, RAJSAMAND

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Key words:-
Pre-Hypertension, Obesity, BMI, Stress Factor, Medical Students

Abstract

Background: Pre-hypertension is associated with an increased risk of the development of hypertension and subsequent cardiovascular disease and raises mortality risk. Pre-hypertension is emerging health problem in adolescents now a days. The aim of this study was to determine the prevalence of pre-hypertension, to explore the association between pre-hypertension and established cardiovascular risk factors and compare them among second year and final year students of AIMS & RC, Rajsamand.

Methods: In this cross-sectional study a representative sample of 200 participants was selected using a Random sampling method. Pre-hypertension was observed among 73 out of Total 200 students, 31 from second year and 42 final year students, 40 for Boys and 33 for Girls.

Result: The pre-hypertensive group had higher body mass index, higher percentage of smoking, ate more added salt and less physical activity than did the normotensive group. Prevalence of prehypertension was higher among final year students than second year students due to heavy study stress.

Conclusion: Primary prevention strategies should concentrate on reducing overweight and obesity. Diet education should be given to overcome this problem. Stress is another major predictor in medical students so Medical authority should make some strategies to relieve stress in medical students.

Introduction:-

The global burden of non-communicable diseases is emerging as a major public health challenge in the world. One thing is clear: "when it comes to NCDs, inaction is not an option." According to WHO, chronic disease is modern epidemic. 60% of all deaths and 47% of burden of diseases are due to non-communicable diseases; these figures are expected to rise to 73% and 60%, respectively, by 2025. Hypertension is a well-known risk factor for the development of CVD, heart attack, and stroke. Hypertension is responsible for 57% of stroke deaths and 24% of coronary heart disease deaths in India. Due to change in life style, environmental and Socio-demographic risk factors the prevalence of Pre-hypertension and hypertension is increasing constantly. Pre-hypertension is associated with an increased risk of the development of hypertension and subsequent cardiovascular disease and raises mortality risk. Persons with pre-hypertension have a greater risk of developing hypertension than do those with lower blood pressure levels. Pre-hypertension is also an emerging health problem in adults and adolescents now a day. Medical Students are more prone to be exposed with established cardiovascular risk factors.

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Aims:
The study was aimed to know the prevalence of Pre-hypertension and its determinants in Second year and Final year students of AIMS & RC, Rajsamand and compare them.

Objectives:-

1. To determine the prevalence of pre-hypertension
2. To explore the association between pre-hypertension and established cardiovascular risk factors
3. Compare those risk factors among a second year and final year students of AIMS & RC, Rajsamand

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Methodology:-

Sample Size: Prevalence of pre-hypertension was 34% in various studies among adolescents and adults. Sample size was calculated by the Following formula.

Sample Size (N) = $4pq/L^2$
Where, p = Prevalence of pre-hypertension=34%
q = 100-p = 66%
L = 20% of p = 6.8
So Sample size (N) = 4*34*66/46.51

The estimated sample size was 193. Sample size of 200 was decided.100 students from second year and 100 students from final year.

Study design:
In this cross-sectional study, Participants were selected using a Random sampling method. (Chit method)

Study Area:
AIMS & RC, Rajsamand

Study Population:
Second year and Final year students of AIMS & RC, Rajsamand.

Data collection:
All Students were interviewed with predesigned questionnaire.

Blood pressure was measured after the students had rested for at least 5 minutes and from right arm placed at the heart level. Two measurements were taken by a mercury sphygmomanometer with at least 5 minutes between successive measurements and lower one was recorded. According to the Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and treatment of High Blood Pressure (JNC 7) in 2003, prehypertension is defined as blood pressure range with a systolic BP of 120–139 millimeters of mercury (mmHg) and/or a diastolic BP of 80–89 mmHg. Body weight was measured with light cloth and without shoes, a common weighing machine was used for that.

Height was measured to the nearest 0.5 cm, without shoes using a measuring tape

Body mass index (BMI) was calculated as weight (in kilograms) divided by height (in meters) squared.

Data Analysis:
Statistical analysis was performed using Microsoft excel and EPI INFO version 7 software.

Results:-

Pre-hypertension was observed among 73 (36.5%) out of 200 students, 34 (34%) from second year and 42 (42%) final year students while 5(5%) were hypertensive in second year and 8(8%) in final year.

Table 1:- Presence of different risk factors among Normotensive and Pre-hypertensive SECOND YEAR Students.

Risk Factors	Normotensive	Pre-hypertensive	P

	(61) (61%)	(34) (34%)	value
Family history of hypertension	11 (18.32%)	6 (17.64%)	0.9643
Stress Factor	10 (16.39%)	8 (23.52%)	0.3948
Male sex	37 (60.65%)	18 (52.94%)	0.4653
Excessive salt intake	30 (45.45%)	19 (55.88%	0.5307
Smoking	14 (21.21%)	9 (26.47%)	0.7014
Lack of physical activity	24 (36.36%)	16 (47.05%)	0.4653
Overweight/obese	32 (48.48%)	19 (55.88%)	0.7482

Table 1 showing different risk present among second year students of AIMS & RC. Male sex, excessive salt intake and overweight and obese were major risk factors which were observed in second year students AIMS & RC, Rajsamand.

Table 2:- Presence of different risk factors among Normotensive and Pre-hypertensive FINAL YEAR Students.

Risk Factors	Normotensive (50) (50%)	Pre-hypertensive (42) (42%)	P value
Family history of hypertension	12 (24%)	10 (23.80%)	0.8301
Stress Factor	09 (18%)	17 (40.47%)	0.017
Male sex	27 (54%)	24 (57.14%)	0.7629
Excessive salt intake	21 (42%)	22 (52.38%)	0.3202
Smoking	11 (22%)	11 (26.19%)	0.6390
Lack of physical activity	19 (38%)	18 (42.85%)	0.6390
Overweight/obese	22 (44%)	26 (61.90%)	0.08

Table 2 Showing different risk present among final year students of AIMS & RC. Major risk factors which were observe in final year students were almost same as in second year students of AIMS & RC, Rajsamand

Table 3:- Association of Pre-hypertension with Stress.

Year	Total Pre-hypertensive Students	Pre-hypertensive Students With Stress
Second Year	34	8(23.52%)
Final Year	42	17(40.47%)

Second Year: chi squire value 0.401, df =1, P=0.52657 (P>0.05), Test is not significant.
Final Year: chi squire value 5.591, df =1, P=0.018059 (p<0.05), Test is significant.

Discussion:-

The pre-hypertensive group had higher body mass index, higher percentage of smoking, ate more added salt and less physical activity than did the normotensive group. (Table 1)

(Table 2) These findings are consonant with previous reports on risk factors in pre-hypertension for cardiovascular disease[8]. Prevalence of pre-hypertension was higher among final year students than second year students may be due to heavy study stress. Analysis showed that Stress is major risk factor to developing Pre-hypertension and also hypertension. (Table 3)

Analysis showed that obesity and overweight were the strongest predictors of pre-hypertension.

Conclusions:-

Overweight and obesity are major determinants of the high prevalence rate of pre-hypertension detected in students of AIMS & RC, Rajsamand. Therefore, primary prevention strategies should concentrate on reducing overweight and obesity. Diet education should be given to overcome this problem.

Stress is another major predictor in Final Year medical students so Medical authority should make some strategies to relieve stress in medical students.

The normotensive Group also having higher percentage of these risk factors so they are also prone to develop pre hypertension in future. so preventive step should take in Normotensive students like health education.

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Original Research

Nocturnal enuresis-prevalence and risk factors among school going children in Udaipur, Rajasthan, India

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Abstract
Background: Nocturnal Enuresis also called bedwetting is involuntary urination while asleep after the age at which bladder control starts developing in children. Nocturnal Enuresis is a common problem affecting school aged children worldwide. It can cause a feeling of failure and result in guilt and stress in children as well as in their families.
Aims and Objective: To find out prevalence and underlying its risk factors in the age group of 6-16 years.
Material and Methods: It is a population-based study conducted during the year June2018 to January 2019 on 328 children in the age group of 6 to 16 years residing at Neemachmata area of urban Udaipur (Raj.).
Result: The study was conducted on 328 children aged between 6 to 16 years. The prevalence of enuresis was 17.37% There was a significant relationship between the prevalence of enuresis and age, sleep pattern, as well as high intake of substances like tea, coffee &soda. Stress and positive family history of bedwetting also affect the prevalence. Highest number of enuretics were found in the age group of 6 to 8 years (32.14%) out of total numbers of enuretics (57). 28 (17.7%) were male & 29(17.05) females. This show that nocturnal enuresis was common in both the sexes. Lowest number of enuretics were found in the age group of 15 to 16 years of age. Number of enuretics were found to be higher in modified B.G. Prasad socio-economic class IV & least in socio-economic class II. Positive family history was present in 36 (37.50%) out of 57 enuretic children.

Keywords: Prevalence, nocturnal enuresis, risk factors

Introduction
Nocturnal enuresis affects approximately 5-7 million children in USA and 9-13% children in India. It's a common problem in pediatric patients. Inspite of the causative factors are not well-established resulting in depression (low self-esteem) & school withdrawal among children and stressed parents appropriate intervention is justified for the affected child because of the potential consequences of family stress, social withdrawal and poor self-esteem [1].
Enuresis refers to the persistence of inappropriate voiding of urine beyond the age of anticipated bladder control (age 4 to 5 years at the latest) or as the loss of continence after at least 3 months of dryness. The diagnosis is made when wetting occurs twice a week for 3 consecutive months [2].
Enuresis may be further classified into nocturnal & diurnal [2].
Aims & objective Aim of this study was to find out the prevalence & underlying its risk factors in the age groups 6-16 years.

Material and Methods
It is a population-based study was conducted on 328 children in the age group of 6 to 16 years residing at Neemachmata area of urban Udaipur Data were collected via a questionnaire completed by parents after taking consent and collected from door to door personally. The relationship has been found between the prevalence of Enuresis and the patient's age, gender, family history, sleep pattern, and use of tea, coffee, soda and the education level and employment status of parents and their monthly income. These findings were tested by means of X^2 test and $P< 0.05$ was accepted as statistically significant.

Ethical clearance

Clearance from Institutional Ethics Committee was taken before start of study.

Result

The study was conducted on 328 children aged between 6 to 16 years. Chi square test was used and we found the prevalence of enuresis was 17.37%. Relationship was formed between the prevalence of Enuresis and age, positive family history, sleep pattern, intake of tea, coffee, soda and stress. In the whole group enuresis was found to be equally common in both the sexes. No relationship was found with family size, Parents education level and employment.

The prevalence rate of nocturnal enuresis in our study was (17.37%) Highest number of enuretics were found in the age group of 6 to 8 years (32.14%) out of total numbers of enuretics (57). 28 (17.7%) were male & 29(17.05) females. This show that nocturnal enuresis was equally common in both the sexes. Lowest number of enuretics were found in the age group of 15 to 16 years of age.

Number of enuretics were more in modified B.G. Prasad socio-economic class IV & least in socio-economic class II. Positive family history was present in 36 (37.50%) out of 57 enuretic children.

Table 1: Distribution of nocturnal enuresis according to Age & Gender (n= 328)

Character	Nocturnal enuresis				X^2 P- Value
	Yes (n=57)		No (n= 271)		
	Number	Percentage (%)	Number	Percentage (%)	
1. Gender					
Male (158)	28	17.72	130	82.27	NS
Female (170)	29	17.05	141	82.94	
2. Age (in years)					
6-8 years (56)	18	32.14	38	67.85	P=0.001
9-11 years (105)	23	21.90	82	78.09	
12-14 years (121)	12	9.99	109	90.08	
15-16 years (46)	4	8.69	42	91.30	

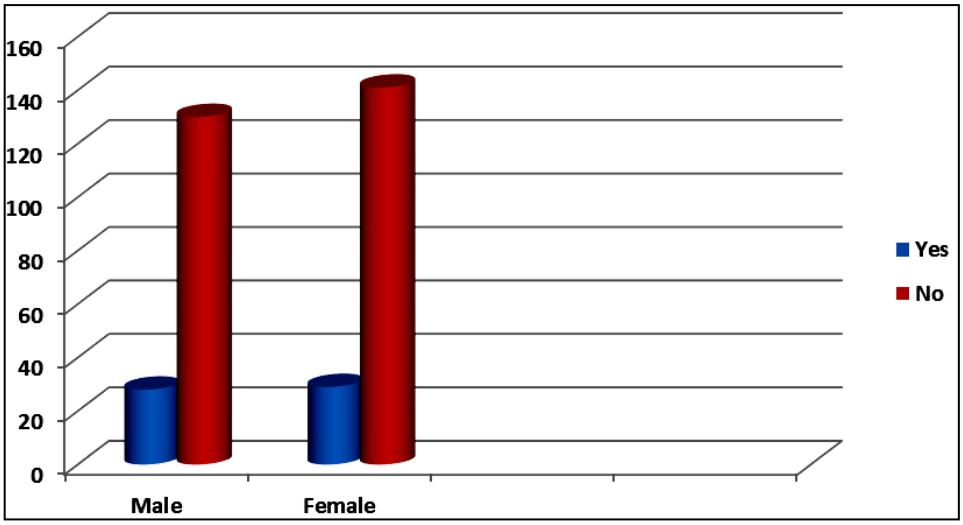

Fig 1: Diagram showing distribution nocturnal enuresis according to gender

Table 2: Family characteristics & nocturnal enuresis

Family characteristics	Nocturnal enuresis				X^2 P- Value
	Yes (n=57)		No (n= 271)		
	Number	Percentage (%)	Number	Percentage (%)	
1. Family size					
i) 2-4 (30)	6	20.00	24	80.00	NS
ii) 5-7 (185)	34	18.37	151	81.62	
iii) 7-9 (113)	17	15.04	96	84.95	
2. Economic status					
i) Class I (59)	10	16.94	49	83.05	NS
ii) Class II (117)	17	14.52	100	85.47	
iii) Class III (135)	25	18.51	110	81.48	
iv) Class IV (10)	3	30.00	7	70.00	
v) Class V (7)	2	28.57	5	71.42	
3. Mothers education					
i) Middle School (216)	42	19.44	174	80.55	NS
ii) High school (99)	13	13.13	86	86.86	
iii) Graduate & above (13)	2	15.38	11	84.61	
4. Father's education					
i) Middle School (115)	15	13.04	100	86.95	NS

ii) High School (64)	14	21.87	50	78.12	
iii) Graduate & above (149)	28	18.79	121	81.20	
5. Mother's occupation					
i) Working (48)	7	14.58	41	85.41	NS
ii) Non-working (280)	50	17.85	230	82.14	
6. Father's occupation					
iii) Working (230)	34	14.78	196	85.21	NS
iv) Non-working (98)	23	23.46	75	76.53	

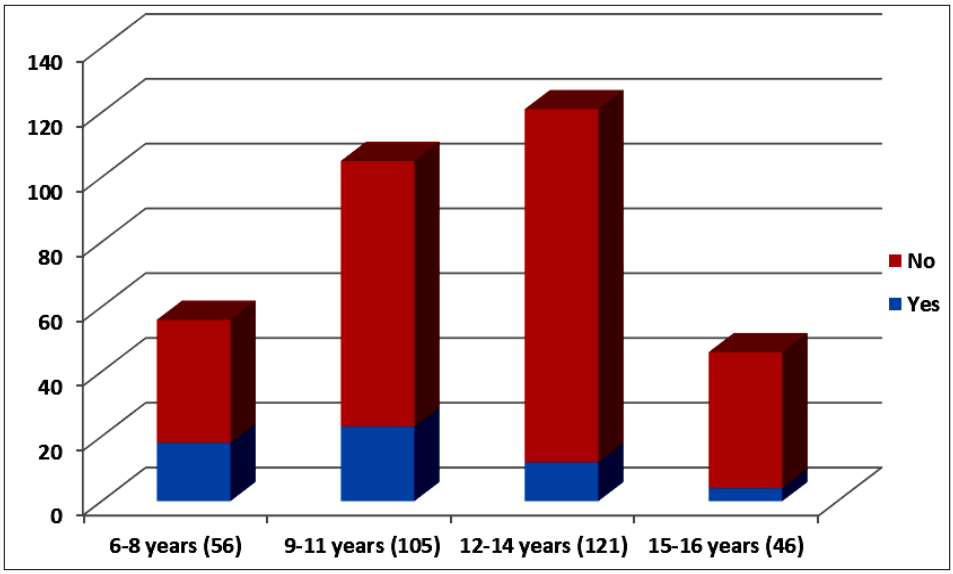

Fig 2: Diagram showing distribution nocturnal enuresis according to Age.

Table 3: Distribution of Nocturnal enuresis according to type & frequency (n=57)

1. Frequency		
v) Once/day	27	47.36
vi) 2-3 times/week	21	36.84
vii) 1-3 times/month	6	10.52
viii) > 2 times/ 6 month	3	5.26

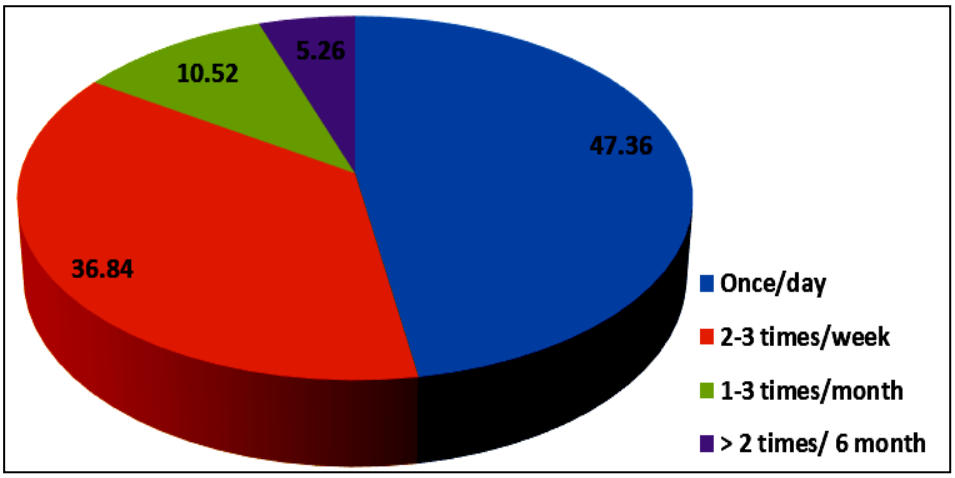

Fig 3: Diagram showing distribution of nocturnal enuresis according to frequency.

Table 4: Nocturnal enuresis in relation to family history

Family history of nocturnal enuresis	Nocturnal enuresis				X^2 P- Value
	Yes (n=57)		No (n= 271)		
	Number	Percentage (%)	Number	Percentage (%)	
Positive (96)	36	37.50	60	62.50	P=0.000
Negative (232)	21	9.05	211	90.94	
Parents (7)	3	42.85	4	57.14	
Siblings (74)	23	31.08	51	68.99	
Others (15)	10	66.66	5	33.33	P=0.000
Non-enuretics (232)	21	9.05	211	90.94	

Table 5: Children's characteristics & nocturnal enuresis

Characteristics	Nocturnal enuresis				X^2 P- Value
	Yes (n=57)		No (n= 271)		
	Number	Percentage (%)	Number	Percentage (%)	
1. Sibling number					
i) None (4)	1	25.00	3	75.00	NS
ii) One (80)	15	18.75	65	81.25	
iii) Two (140)	24	17.14	116	82.85	
iv) Three (64)	12	18.75	52	81.25	
v) > Three (40)	5	12.50	35	87.5	
2. Birth order					
i) First (72)	10	13.88	62	86.11	NS
ii) Second (79)	13	16.45	66	83.54	
iii) Third (62)	16	25.80	46	74.19	
iv) Forth (115)	18	15.65	97	84.34	
3. Sleep					
i) Deep (98)	25	25.5	73	74.48	P=0.011
ii) Light (230)	32	13.91	198	86.08	
4. Day time enuresis					
i) Yes (6)	3	50.00	3	50.00	P=0.031
ii) No (322)	54	16.77	268	83.22	
5. Tea/ Coffee/ soda drinking habits					
i) Yes (73)	23	31.50	50	68.49	0.001
ii) No (255)	34	13.30	221	86.66	
6. Stressful events					
i) Yes (135)	33	24.44	102	75.45	P=0.005
ii) No (193)	24	12.43	169	87.56	

Discussion

In this study, the prevalence rate of nocturnal enuresis is (17.37%) almost comparable with that reported in epidemiological studies from various countries [3, 6].

The prevalence of enuresis showed a decreasing trend in older children's [3].

This study showed no gender differences in prevalence rate. Supported by the other study [6].

Conclusion

Our findings suggest that nocturnal enuresis was a common problem among school children especially with low income, stress, and deep sleep pattern, higher intake of tea, coffee, soda, and family history of enuresis.

Enuresis is a common pediatric problem and resulting in low school performance. The preventive, etiological, psychological & curative measures has be taken. We conclude that nocturnal enuresis is more common in the age groups of 6–8 years & it is found higher in families with B.G. Prasad socio-economic class IV.

It is a self-limiting problem with a spontaneous cure rate of 14% per year in children 5- 9 years old and 16% per year in adolescents.

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Original Research Article

ASSESSMENT OF KNOWLEDGE, ATTITUDE AND PRACTICES OF BIOMEDICAL WASTE MANAGEMENT AMONG NURSING STAFF OF HOSPITALS OF RAJSAMAND DISTRICT, RAJASTHAN

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ABSTRACT

Background: Biomedical waste defined as any waste which is generated during the diagnosing, treating, and surgical intervention and immunizing and also conducting research activities on humans as well as on animals. Health care facilities are aimed to provide health care services to the general population to remove potential health hazards to people. **Material & Methods:** The present observational, prospective and cross-sectional study was conducted at the Department of Community Medicine of our medical college and hospital. The study duration was of six months, from May 2017 to October 2017. We include the nursing staff of our medical college along with two other hospitals of Rajsamand district, Rajasthan in the present study. Clearance from Institutional Ethics Committee was taken before the start of the study. **Results:** In the knowledge domain 51% of study participants answered Correct response on color-coded bags with respective waste and 77% of study participants answered Correct response on knowledge about colour coded bags. In the attitude domain, 94% of study participants had a positive attitude towards bio-medical waste (BMW) management categorization needs and 96% of study participants had a positive attitude towards bio-medical waste management necessary and reduction of health hazard. In the practice domain, 62% of study participants show a positive response towards disinfecting bio-medical waste (BMW) and 70% of study participants had a positive response towards the bio-medical waste treatment. **Conclusion:** We concluded from the present study that nursing staff had good knowledge and had a positive attitude towards biomedical waste management and positive findings towards practices related to BMW. However there still a knowledge attitude and practice gap exit. Therefore, the training programs for the nursing staff should be necessary to reduce this KAP gap related to biomedical waste management.

Keywords: Bio-medical waste management, knowledge, attitude, practice.

INTRODUCTION

Biomedical waste defined as any waste which is generated during the diagnosing, treating, and surgical intervention and immunizing and also conducting research activities on humans as well as on animals. Health care facilities are aimed to provide quality health care services to the general population and to remove potential health hazards of people **(1)**. During the processes of health care methods in health care facilities various wastes are generated, these wastes are hazardous to the general population. If these health care facilities generated waste (Biomedical waste) is handled poorly, it can be a potential health hazard for not only the general population but also to the health care providers,

doctors, nurses and all other health care and other hospital staff which are exposed to these biomedical wastes. Apart from humans, these biomedical wastes are highly hazardous to the environment, water bodies, groundwater, air and community, and animals. Some previous studies reported that developed countries generate more biomedical waste than developing and underdeveloped countries **(2)**.

Various studies reported that out of total waste generated in the health care facilities 90-85% volume of that waste is non-infectious or no hazardous. It means only 10-15% of the total waste generated in the health care facilities is infectious or hazardous which includes toxic or radioactive waste also. Therefore, the first and most important step of biomedical waste management should be the segregation of the total waste generated in the health care facilities. By the proper segregation of waste, we can reduce the volume of infectious waste from 100% to 15% by interrupting the mixing of non-hazardous waste to infectious or hazardous waste **(3)**. Hence, we have new guidelines for biomedical waste which allow us to segregate the total waste generated in the health care facilities in different colour coded bins, containers, and bags. In the disposal of total waste generated in the health care facilities, we use only non-chlorinated bags for safer disposal in the environment **(4)**. Workers who are engaged in the laundries, transportation of the waste and workers at the landfilling site are also at risk for hazardous exposure of biomedical waste. We conduct the present study to assess the knowledge, attitude, and practices of biomedical waste management among nursing staff of Rajsamand district, Rajasthan.

MATERIALS & METHODS

The present observational, prospective and cross-sectional study was conducted at the Department of Community Medicine of our medical college and hospital. The study duration was of six months, from May 2017 to October 2017. We included the nursing staff of our medical college along with two other hospitals of Rajsamand district, Rajasthan in the present study. We enrolled study participants by the simple random sampling up to the study sample size of 100 participants calculated by epi info software at a 95% confidence interval and 10% acceptable margin of error. Clearance from Institutional Ethics Committee was taken before the start of the study and written informed consent for the study purpose was obtained from all the enrolled participants.

The study was performed by using pretested and semi-structured proforma. The data collected from each study participants includes details of all the various demographic variables and details regarding knowledge, attitude, and practices for biomedical waste handling and its management. Knowledge, attitude, and practices were evaluated on correct and wrong responses. Data were entered in the MS office 2010 spreadsheet and Epi Info v7. Data analysis was carried out using SPSS v22. Qualitative data were expressed as the percentage (%) and Pearson's chi-square test was used to find out statistical differences between the study groups. If the expected cell count was < 5 in more than 20% of the cells then Fisher's exact test was used. All tests were done at alpha (level significance) of 5%; means a significant association present if the p-value was less than 0.05.

RESULTS

In the present study, a total of 100 nursing staff were enrolled after taking informed written consent, who were nursing staff of our medical college along with two other hospitals of Rajsamand district, Rajasthan. Out of the total study participants, 58% were males and 42% were females. The age group of study participants was ranged from 23 years to 27 years with a mean age group of 24.8 ± 1.2 years. Among the total study participants, on the assessment of knowledge we found that 76% of study participants had knowledge about disease occurring from biomedical wastes, 77% study participants had knowledge about colour coding of BMW bags, 70% study participants had knowledge about steps of disposal of biomedical waste and 73% study participants had knowledge about biohazard symbol. (Table 1)

Table 1: Distribution according to the knowledge of study participants.

Knowledge	No. of participants (%)
Diseases from BMW	76
Colour coded bags	77
Steps of disposal	70
Biohazard symbol	73

In the present study among the total study participants on the application of knowledge, attitude and practice domains we found that after

analysis that in the knowledge domain 51% of study participants answered correct response on colour coded bags with respective waste and 77% of study participants answered correct response on knowledge about colour coded bags. In the attitude domain, 94% of study participants had a positive attitude towards bio-medical waste (BMW) management categorization needs and 96% of study participants had a positive attitude towards bio-medical waste management necessary and reduction of health hazard. In the practice domain, 62% of study participants show a positive response towards disinfecting bio-medical waste (BMW) and 70% of study participants had a positive response towards the bio-medical waste treatment. (Table 2)

Table 2: Distribution according to knowledge, attitude and practice correct response.

Question	Related domain	Answered correctly by (%)
A correct response on colour coded bags with respective waste.	Knowledge	51
Knowledge about colour coded bags.	Knowledge	77
The attitude of the nursing staff on bio-medical waste (BMW) management categorization need.	Attitude	94
BMW management necessary and reduction of health hazard	Attitude	96
Disinfecting BMW.	Practice	62
BMW treatment	Practice	70

DISCUSSION

In the present study, a total of 100 nursing staff were enrolled in our medical college along with two other hospitals in Rajsamand district, Rajasthan. Out of the total study participants, 58% were males and 42% were females. The age group of study participants was ranged from 23 years to 27 years with a mean age group of 24.8 ± 1.2 years. Among the total study participants, on the assessment of knowledge we found that 76% of study participants had knowledge about disease occurring from biomedical wastes, 77% study participants had knowledge about colour coding of BMW bags, 70% study participants had knowledge about steps of disposal of biomedical waste and 73% study participants had knowledge about biohazard symbol. Similar results are found in a study conducted by Kaviraj Motakpalli et al among the students of nursing in their study and found nearly similar results to the present study. They reported higher knowledge ranging from 77% - 97% on the biomedical waste management and also were higher attitude and practice response **(5)**. Similar results are found in a study conducted by Prachi Priya et al among the students of interns of the medical college in their study and found nearly similar results to the present study. They reported higher knowledge ranging from 86% - 94% on biomedical waste management and also higher attitude and practice response **(6)**.

In the present study among the total study participants on the application of knowledge, attitude and practice domains we found that after analysis that in the knowledge domain 51% of study participants answered correct response on colour coded bags with respective waste and 77% of study participants answered correct response on knowledge about colour coded bags. In the attitude domain, 94% of study participants had a positive attitude towards bio-medical waste (BMW) management categorization needs and 96% of study participants had a positive attitude towards bio-medical waste management necessary and reduction of health hazard. In the practice domain, 62% of study participants show a positive response towards disinfecting bio-medical waste (BMW) and 70% of study participants had a positive response towards the bio-medical waste treatment. Similar results are found in a study conducted by Aastha Pandey et al among the students of interns of the medical college in their study and found nearly similar results to the present study. They reported higher knowledge ranging from 68% - 94% on biomedical waste management and also higher attitude and practice response **(7)**.

Contrary results were found in a study conducted by S Shah et al among the students of interns of the medical college in their study and found nearly contrary results to the present study. They reported poor knowledge of intern doctors on biomedical waste management and also poor attitude and practice response **(8)**. Contrary results were found in a study conducted by Kirti Deshpande et al among the health care staff of tertiary care centre in their

study and found nearly contrary results to the present study. They reported poor knowledge of health care staff of tertiary care centre on the biomedical waste management and also poor attitude and practice response **(9)**.

CONCLUSION

We concluded from the present study that nursing staff of our medical college along with two other hospitals of Rajsamand district, Rajasthan had good knowledge and had a positive attitude towards biomedical waste management and positive findings towards practices related to BMW. However, there is still a knowledge attitude and practice gap exit. Therefore, the training programs for the nursing staff should be necessary to reduce this KAP gap related to biomedical waste management.

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Original Research Article

Prevalence of Depression, stress and anxiety symptoms among type 2 diabetics attending life style modification setting - A descriptive cross-sectional study

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Abstract

Introduction: Coexistence of diabetes and depression, stress and anxiety increase the risk of diabetes complications and reduces the overall quality of life. **Objectives:** To assess the prevalence of depression, stress and anxiety among patients with type 2 diabetes mellitus attending a community-based and peer-led life style modification setting.**Materials and methods**: Descriptive study was carried out among 145 purposively selected clinically diagnosed type 2 diabetics attending community-based and peer-led life style modification setting from February 2019 to July 2019. Patients were interviewed regarding depression, stress and anxiety using the Patient Health Questionnaire-9 (PHQ- 9) and Generalized Anxiety Disorders-7 (GAD-7) and Cohen's perceived stress scale (PSS-10). Data were analysed using coGuide software. The level of statistical significance assumed in all the calculations was $p<0.05$.**Results:**The mean age was 52.39± 5.79 years with equal proportion of males 73 (50.34%) and females 72 (49.66%). The mean duration of diabetes was 7.41± 6.39 years. The Cohen perceived stress score was low in 27(18.62%),moderate in 101(69.66%) and high in17(11.72%) participants. The GAD-7 anxiety score was mild in 55 (37.93%),moderate in 31 (21.38%)and high in 17(11.72%) participants. The PHQ score was mild in 42(28.97%) and was severe in only 8(5.52%) participants. The association of depression, stress and anxiety was significant only for gender *(p* -value of 0.006).**Conclusion:**Prevalence of depression, stress and anxiety was mild to moderate among patients with type 2 diabetes mellitus attending a community-based life style modification setting

Keywords: Diabetes, Type II diabetes mellitus, Depression, Anxiety, Stress

Introduction

Diabetes is a lifelong journey that results in fundamental changes in the patients' lifestyles and may cause increased psychological anxiety and distress, financial burdens, and adverse health effects [1]. The number of people with diabetes in India has been projected to increase to 109 million by 2035. Diabetes is associated with an increased risk of both physical and psychological complications, both of which impact on mortality. Depression, stress and anxiety are highly prevalent psychological disorders in the diabetic population[2].It was estimated that diabetic patients have at least twice the risk of depression or anxiety that is associated with increased risk of comorbidities, interference with daily activities and quality of life, higher health care costs, and more complications when compared to normal patients[3]. Worldwide estimates of the prevalence of depression and anxiety among diabetic patients appear to vary by nations; though data is scarce from developing countries, studies from Asia (including India) report prevalence rates of depression ranging from 17% to 44% and for anxiety it is from 4% to 58%[4]. A recent meta-analysis of 16 studies[5] had revealed analarming significant association between depression and increased risk of mortality (odds ratio, OR = 1.5) in patients with diabetes.Stress is a nonspecific bodily response to any demand made upon it. As adherence to various self-management practices is the cornerstone of daily management of type 2 diabetes, perceived stress could negatively impact the long-term health outcomes of the affected individuals[6]. Stressful life events are, however, prone to happen and it is important to identify how perceived stress impacts blood glucose levels, of individuals with diabetes using perceived stress scale by Cohen's[7].Depression has been recognized as a common comorbidity in patients with type 2 diabetes associated with poor glycaemic control, functional impairment, increased risk of diabetic complications and mortality, and reduced societal productivity[8]. The 9-item Patient Health Questionnaire (PHQ-9) is one of the most popular self-administered screening tools that has been validated in many populations[9].There are many previous individual studies reported by Thour et al[2] ,Wolfgram et al[10]and Wiernik et al[11] that hypothesized the association of stress, depression and anxiety on diabetes using these screening tools. In another cross-sectional study among adult patients with T2DM in five public primary care centres in the western region of Saudi Arabia by Alzahrani A et al [12]the prevalence of depression, anxiety, and stress were 33.8%, 38.3%, and 25.5%, respectively and the major predictors of psychological distress were age, sex, the presence of comorbidities, duration since T2DM diagnosis, and serum level of hemoglobin A1c. Another study by Gupta Y et al[13]from India reported the prevalence of depression as

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41% using (PHQ score ≥15).Depression was significantly more prevalent in rural subjects (57%) when compared to urban ones (31%, *P* = 0.049). Due to varying prevalence rate of diabetes as well as depression and anxiety from various parts of India, the exact disease burden still remains unclear. The prevalence of comorbid diabetes, depression and anxiety is limited in India.This study adds to the limited available information on the prevalence of anxiety, stress and depression checked using screening tools among diabetics inIndia. To the best of our knowledge, the utility of generalized anxiety disorders 7-item (GAD-7) scale, Patient Health Questionnaire (PHQ-9) and Perceived stress scale by Cohen's has been evaluated for the first time in India to study this association. This data will be helpful for the healthcare providers to plan collaborative care in healthcare settings.

Aims and objectives

To assess the prevalence of depression, stress and anxiety among type 2 diabetics attending a community-based peer- led lifestyle modification setting.

Materials and methods

Study design

A descriptive cross-sectional study

Source population

Subjects attending a community-based lifestyle modification setting

Study population

Subjects diagnosed with type 2 diabetes and attending a community-based lifestyle modification setting.

Study setting

The study was conducted at a community centre.

Study period

For a period of 6 months from February 2019 to July 2019

Sample size and sampling technique

All 145 patients with type 2 diabetes mellitus attending the lifestyle modification centre were selected according to convenience sampling for the feasibility of the study**.**

Ethical and informed consent

Prior permission was obtained from ethical members of the community centre and written informed consent was taken from all the subjects before the study started. Confidentiality was maintained all along.

Inclusion criteria

- Both male and females aged 18-60 years.
- Subjects who can comprehend the questionnaire
- At least diabetic since a year and on medication

Exclusion criteria

- Previous clinical diagnosis of anxiety, depression, and other psychiatric disorder**.**
- Taking drugs like–sedatives,glucocorticoids, and immune osuppressive
- Not receiving any psychiatric treatment which could have an effect on the result.

Data collection

The psychological assessment was carried under a team of data collectors who were trained in the questionnaire (GAD-7, PHQ-9, PSS-10). Prior permissions were obtained from all the originators of the questionnaires to use them in this study.

Generalized anxiety disorder

The GAD- 7 scale was used for evaluation of anxiety, and relevant clinical details were obtained. Anxiety was assessed by administering the GAD-7 scale. This scale is useful for evaluating the presence and severity of GAD in clinical practice. This tool has several advantages. First, a 7-item anxiety scale - the GAD-7 - is a useful tool with strong criterion validity for identifying probable cases of GAD. Second, the scale is also an excellent severity measure as increasing scores on the GAD-7 are strongly associated with multiple domains of functional impairment and disability days. Third, although many patients had anxiety and depressive symptoms, factor analysis confirms GAD and depression as distinct dimensions, GAD-7 measuring GAD with high sensitivity and specificity with appropriate cut-offs. It assesses the symptoms experienced by participants during the 2-week period before they take the survey. On the basis of participant response to the frequency of any particular symptom (0 = not at all, 1 = several days, 2 = more than half of the days, and 3 = nearly every day), a total score ranging from 0 to 21 was obtained, with higher scores indicating patients increased self-report of anxiety severity. The division of GAD-7 scores into ratings of mild (5-9), moderate (10-14), and severe anxiety (≥15) was used in this study[14].

Cohen's perceived stress scale

The PSS-10, (Cohen et al.,1983) measures an individual's appraisal of their life as stressful (i.e., unpredictable, uncontrollable and overloading). Item examples include, 'How often have you felt nervous or stressed?' and 'How often have you felt confident about your ability to handle your personal problems?' People rated how often they had experienced these feelings in the last week on a Likert scale from 0 = never to 4 = very often. PSS-10 scores were obtained by reversing the scores on the four positive items; the items were 4, 5, 7 and 8. Total scores range from 0 to 40, with higher scores indicating greater overall distress. Coefficient alpha reliability was 0.86 for a newly diagnosed breast cancer population consistent with alphas from 0.75 to 0.86 in the general literature (Cohen et al., 1983)[7].

Patient health questionnaire

The PHQ-9 is derived from the DSM-IV diagnostic criteria, and consists of 9 questions pertaining to the frequency of depressive symptoms during the preceding two weeks. Each item is scored from 0 (not at all) to 3 (nearly every day), with a total score ranging from 0 to 27. Cut-off values of 5, 10, 15 and 20 have been widely used to define mild, moderate, moderately severe, and severe depressive symptoms (Kroenke et al., 2001)[9].

Investigations:The values of the glucose measures – HbA1c and systolic blood pressure and diastolic blood pressure were measured. Next, questionnaire studies were carried out which was accompanied by brief information such as: age, sex, place of residence, education, marital status, professional activity, body mass, height, used stimulants, comorbidities, the duration of diabetes, the occurrence of diabetes complications and the taken drugs.

The questionnaire was filled in personally and anonymously by the patients.

Life style modification centre

The study was an inpatient holistic intervention conducted in Nadiad and Bhavnagar in Gujarat.Vegetarian diet, daily practice of Raja Yoga Meditation, attending daily class on positive thoughts, avoidance of tobacco, refraining from consumption of alcohol or any harmful substances, along with the associated beliefs listed above, form a part of "Brahma Kumari's Raja Yogi Lifestyle". The patient after screening for inclusion and exclusion criteria were taken for the study. 4 camps were conducted.

Study variables

Prevalence of depression, stress and anxiety were considered as dependent or primary outcome variables. Age, sex, marital status, residence, religion, level of education, duration of diabetes, having diabetic complications, smoking status, status of alcohol consumption, comorbidities were considered as independent variables.

Statistical analysis: The statistical analysis was performed using the coGuide software. The level of statistical significance assumed in all the calculations was $p<0.05$. Basic statistics, i.e., the mean and the standard deviation were calculated for quantitative data. The Chi-square test were used for checking the occurrence of relationships between the considered variables. The reliability of the applied questionnaires was checked by calculating the Cronbach's alpha coefficient (> 0.7 was considered acceptable) for (GAD-7, PHQ-9, PSS-10)coGuide version V.1.0 was used for statistical analysis[15].

Results

The mean age was 52.39± 5.79 years in the study population. Proportion of males was 73 (50.34%) and 72 (49.66%) were female, majority of 135 (93.1%) was married. Majority as 71 (49.10%) were graduated and professionals, 37 (25.52%) did high school and 20 (13.79%) completed higher secondary. Hindu were 144 (99.31%) and 139 (95.86%) were living in urban area. Majority 106 (73.10%) were

from nuclear family. The mean duration of diabetes was 7.41± 6.39 (in year), majority 73 (50.3%) had diabetes >5 years in study population. As onset of disease, majority 108(74.5%) reported insidious. Diabetes diagnosed through Routine check-up for other illness in 84(57.9%) and in 40(27.6%) it was diagnosed while health screening. Majority of 114(78.6%) had obesity, 53(36.6%) had hypertension, 50(34.5%) had dyslipidaemia and 41(28.3%) had OA. Majority of 30(20.7%) had neuropathy followed by 3 (2.1%) had retinopathy and 1 (0.7%) had Neuropathy as micro vascular complications where Macro vascular Complication reported as 7 (4.8%) with CAD followed by 2 (1.4%) with PVD and 9 (6.2%) had ED as Other Complication. (Table 1)

Table 1: Baseline socio-demographic characteristics and clinical parameters of the study population (N=145)

Parameter	Variables	Summary
Age (mean±SD)		52.39± 5.79 (range 35 to 60)
Gender	**Male: female (ratio)**	73:72
Marital status	Single	4 (2.8%)
	Married	135 (93.1%)
	Widower/widow/divorced	6 (4.1%)
Education	Illiterate	4(2.76%)
	Middle school	13(8.97%)
	High school	37(25.52%)
	Higher secondary	20(13.79%)
	Graduate and professional	71 (49.10%)
Religion	Hindu	144(99.31%)
	Muslim	1(0.69%)
Locality	Urban	139(95.86%)
	Rural	6(4.14%)
Type of family	Nuclear	106(73.10%)
	Joint	39 (26.90%)
Duration of diabetes in years	**<1 year**	17 (11.70%)
	1 to 5 years	55 (37.9%)
	>5 year	73 (50.3%)
Mode of onset	Acute	14(9.7%)
	Sub-Acute	23(15.9%)
	Insidious	108(74.5%)
Co-Morbid conditions	Obesity	114(78.6%)
	Hypertension	53(36.6%)
	Dyslipidemia	50(34.5%)
	Hypothyroidism	22(15.2%)
	Cataract	11(7.6%)

Never smokers were 134 (92.4%), 8 (5.5%) were past smokers and 3 (2.1%) were current smokers. Alcohol habit was found only in 7(4.8%) participants. Majority 120 (82.8%) were doing sedentary work, followed by 21 (14.5%) working in light outdoor places, whereas 137 (94.5%) participants were vegetarian. (Table 2)

Table 2: Baseline lifestyle-related characteristics of the study population (N=145)

Lifestyle-relatedcharacteristics	Parameter	Summary
Smoking	Current	3(2.1%)
	Past	8(5.5%)
	Never	134(92.4%)
Alcoholic	Current	7(4.8%)
	Past	4(2.8%)
	Never	134(92.4%)
Type of work/ occupation	Sedentary	120(82.8%)
	Light outdoor	21(14.5%)
	Heavy outdoor	4(2.8%)
Dietary preference	Mixed vegetarian & non vegetarian	8(5.6%)
	Vegetarian	137(94.5%)

The Cohen perceived stress score was low in 27(18.62%), moderate in 101(69.66%) and high in 17(11.72%) participants. The GAD-7 anxiety score was mild in 55 (37.93%), moderate in 31 (21.38%) and high in 17(11.72%) participants. The PHQ score was mild in 42 (28.97%) and was severe in only 8(5.52%) participants. (Table 3)

Table 3: Summary of stress, anxiety and PHQ scores in the study population (N=145)

Baseline	Summary
Cohen perceived stress total score	18.77 ± 5.77 (ranged 1 to 33)
Low stress	27 (18.62%)
Moderate stress	101(69.66%)
High perceived stress	17 (11.72%)
Anxiety Severity	7.77 ± 4.91 (ranged 0 to 20)
Minimal anxiety	42(28.97%)
Mild anxiety	55 (37.93%)
Moderate anxiety	31 (21.38%)
Severe anxiety	17 (11.72%)
PHQ	8.34 ± 6.24 (ranged 0 to 27)

Normal	9 (6.21%)
Minimal depression	41 (28.28%)
Mild depression	42 (28.97%)
Moderate depression	27 (18.62%)
Moderately severe depression	18 (12.41%)
Severe depression	8 (5.52%)

The association of depression, stress and anxiety with different demographic parameters like Age, Education, locality, type of family and Duration of diabetes found to be insignificant with a *p* value (0.369, 0.478, 0.345,0.574, 0.515) respectively. Between gender there was statistically significant difference in severity of disease observed with a *p*-value of 0.006. (Table 4)

Table 4: Association of depression, stress and anxiety with demographic parameters (N=145)

Demographic parameters	Severe Disease		Chi square	P value
	Yes	No		
Age Group				
Up To 50 (N=45)	11 (24.44%)	34 (75.56%)	0.806	0.369
>50 (N=100)	18 (18%)	82 (82%)		
Gender				
Male (N=73)	21 (29.17%)	51 (70.83%)	7.511	0.006
Female (N=72)	8 (10.96%)	65 (89.04%)		
Education				
Illiterate (N=4)	2 (50%)	2 (50%)	3.498	0.478
Middle School (N=13)	3 (23.08%)	10 (76.92%)		
High School (N=37)	9 (24.32%)	28 (75.68%)		
Higher Secondary (N=20)	3 (15%)	17 (85%)		
Post-Graduate Or Professional Degree (N=71)	12 (16.9%)	59 (83.1%)		
Locality				
Rural (N=6)	2 (33.33%)	4 (66.67%)	0.695	0.345
Urban (N=139)	27 (19.42%)	112 (80.58%)		
Type Of Family				
Joint (N=39)	9 (23.08%)	30 (76.92%)	0.316	0.574
Nuclear (N=106)	20 (18.87%)	86 (81.13%)		
Duration of diabetes				
<1 Year (N=17)	2 (11.76%)	15 (88.24%)	1.327	0.515
1 To 5 Years (N=55)	10 (18.18%)	45 (81.82%)		
>5 Years (N=73)	17 (23.29%)	56 (76.71%)		

Discussion

The study aimed to assess the prevalence of depression, stress and anxiety among type 2 diabetics attending a community-based, peer-led lifestyle modification setting in India. The mean age was 52.39± 5.79 years in the study population with almost equal male and female ratio. The mean duration of diabetes was 7.41± 6.39 years. The Cohen perceived stress score was moderate among 101 (69.66%) participants. The GAD-7 anxiety score was moderate in 31 (21.38%) participants. The PHQ score was severe in only 8(5.52%) participants. The association of depression, stress and anxiety with different demographic parameters like Age, Education, locality, type of family and Duration of diabetes found to be insignificant with a P value (0.369, 0.478, 0.345,0.574, 0.515) respectively. Between gender there was statistically significant difference (p value of 0.006).Of 145 patients with type 2 diabetes mellitus, nearly 53(36%) of the patients exhibited moderate to severe depression and majority 118 (83%) showed perceived stress and nearly 48 (33%) had generalized anxiety disorders. This finding was very much similar to a cross-sectional study bySharma K et al[16] in Nepal where out of 296 patients with type 2 diabetes mellitus, more than half (57.8%) of the patients exhibited depression and nearly half (49.7%) showed generalized anxiety disorders. Regarding severity of depression, 42 (28.97%), 45(31%), 8(6%) patients had mild, moderate, and moderately severe, and severe depression, respectively. Although data related to severity from India are limited, a study in Saudi Arabia showed mild, moderate, severe, and extremely severe depression among 9.3%, 14.0%, 7.1%, and 3.3% of patients with type 2 DM, respectively[17]. Regarding severity of anxiety 55 (37.93%) , 31 (21.38%) and 11(17%) had mild, moderate and severe anxiety. Our finding is slightly higher than the finding reported by the study in India which showed overall prevalence of anxiety among 34% of patients where mild, moderate, and severe anxiety was found in 22%, 8%, and 4%, of patients, respectively, by GAD-7 scale [18]. In the present study 73 (50.3%) participants reported >5 years of duration of diabetes. This finding was similar to a cross-sectional study byGeleta BA et al [19] in southwest Ethiopia where the mean duration of stay with type 2 diabetes was 5.5 (SD = 3.9). Unlike the current study, the measurement tool used to measure depression was Beck Depression Inventory (BDI) scale questionnaire. Respondents aged 52.39± 5.79 (range 35 to 60) years 40–49 years more often showed emotional states of depression, stress and anxiety. This finding was similar to a cross-sectional study by [20] where logistic regression analysis indicated that age 40-49 years (OR=2.57, 95% CI: 1.59-4.13) as a predictor of depression and anxiety.Unlike the current study, the measurement tool used to measure depression, stress and anxiety was DASS-21. In the present study almost equal male and female ratio was observed 73:72. This finding was in contrast to a multicentric study by Ali Khan K et al [21] where there was a slight preponderance of females (57.5%) and Anxiety and depression was measured by using the Hospital Anxiety and Depression Scale (HADS). Various factors, such as age, education, locality, type of family and duration of diabetes were predicted to be associated with depression, stress and anxiety. But our study failed to prove this association. This finding was in contrast to a study by Camara A,[22] among African patients in Guinea, where variables such as gender, marital status, level of education, DM duration, smoking status, number of doctor's visits, DM therapy, and comorbidities, were predicted to be associated with depression, stress and anxiety. In the current study high perceived stress was observed in 17 (11.72%) participants. This finding can be compared to a subset analysis of the nationwide cross-sectional survey, conducted across Indian zones under the National Multicentric Diabetes Control Program by Mishra A et al [23] where people with prediabetes were under more stress as compared to those with diabetes in India. The life style modification

program to reduce the levels of HbA1c and to reduce the burden of depression, stress and anxiety was very much similar to Kerala diabetes prevention program (K-DPP) [24] where the context was interlinked with evidence-based behaviour change techniques that benefited policy makers, action implementers, service providers, and eventually wider populations in India and similar countries.The lessons learnt from the implementation of such interventions would also have applicability to other rapidly developing low- and middle-income countries in the Asia, Pacific and African regions where there is an urgent need of such interventions to control psychological burden of diabetics.

Strength

This study adds to the limited information available regarding anxiety and depression and stress among type 2 diabetics attending a community centre for life style modification in India. According to authors knowledge, this was the first study to examine co- occurrence of depression, anxiety and stress among type 2 diabetics attending a life style modification centre in India using three different scales.

Limitations

It is descriptive cross-sectional study which could not explore the causal relationship between anxiety, stress and depression with other associated factors. The study was conducted at a life style modification centre and only type 2 diabetic patients were considered which did not allow for generalizability of the findings to the entire diabetics. The study sample was also low that can affect the study findings. The study was based on participants response to questionnaire and hence can be subjected to recall bias. Considering these limitations, further multicentric interventional population-based studies are recommended to support the findings of the present study.

Conclusion

Depression, stress and anxiety was high among type 2 diabetics. An integrated model to manage symptoms of depression, stress and anxiety is to be developed focusing on early screening and counselling by psychiatrists. While planning and implementing the program for this risk groups in the healthcare settings, early screening and counselling can enhance the efficacy of treatment regimens and reduce overall burden and improve quality of life of diabetics.

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ORIGINAL ARTICLE

Comparative Study of Using Epley's Maneuver Alone or Epley's Maneuver with Medication in Treating Benign Paroxysmal Positional Vertigo

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ABSTRACT

BACKGROUND: Vertigo is a very common medical condition with a broad spectrum of diagnoses and requires an integrated approach to patients through a structured clinical interview and physical examination. The main cause of peripheral vertigo in primary care is benign paroxysmal positional vertigo (BPPV), which should be confirmed by a positive Dix-Hallpike positional test and treated with repositioning maneuvers. The objective of this study is to compare the effectiveness of Epley's maneuver alone or Epley's maneuver with medications in the treatment of BPPV. **MATERIALS AND METHODS:** the study was a randomized clinical trial conducted in the department of otorhinolaryngology at pacific Medical college & Hospital, Udaipur from January, 2014 to January, 2015. A total of 70 patients of BPPV confirmed by Dix-Hallpike test were included in the study out of which 35 patients were treated by Epley's maneuver alone and rest 35 were treated by Epley's maneuver along with medications. **RESULTS:** Total 70 patients were included in our study out of which 35 patients who received medications along with Epley's therapy were considered as cases and rest 35 patients who received only Epley's therapy were considered as controls. The mean age of cases was 55.23, that of the control group was 53.74. 15 patients (42.85%) among cases were having associated nausea and vomiting while 12 patients (34.28%) in the control group were having associated nausea and vomiting. 1 day after treatment, 27 patients (77.14%) among the cases and 26 patients among controls were free of positional vertigo (p-value=0.001). similarly, after follow up of 1 week, 1 month and 6 month duration, the number of patients relieved after respective treatment were similar in both cases and control. **CONCLUSION:** Epley's maneuver alone is safe and effective method to treat BPPV. However, medical treatment can be used to treat associated symptoms like nausea and vomiting.

Keywords: BPPV, Betahistine, Dix-Hallpike maneuver, Epley's maneuver, Vertigo

INTRODUCTION

Vertigo is the feeling that you or your environment is moving or spinning. It differs from dizziness in that vertigo describes an illusion of movement. When you feel as if you yourself are moving, it's called subjective vertigo, and the perception that your surroundings are moving is called objective vertigo. Vertigo can be caused by problems in the brain or central nervous system (central vertigo) or the inner ear (peripheral vertigo).

The most common cause of vertigo is a peripheral vestibular dysfunction called benign paroxysmal positional vertigo[1]. This is an acute condition that always presents with a combination of positional vertigo and Nystagmus[1,2]. The diagnosis of BPPV is based on both subjective symptoms and objective signs. A provoking maneuver called the Dix-Hallpike test is used on patients who are complaining of vertigo symptoms and are suspected of having BPPV. It is performed by keeping the individual's head in slight extension and 45 degrees of rotation to the test side. The individual is then moved by the tester from sitting to supine. If there is an up-beating, rotatory nystagmus toward the ear that is lower, then the test is considered positive. A positive Dix-Hallpike test and complaints of vertigo symptoms are considered the gold standard for diagnosing BPPV[3].

It is theorized that BPPV is due to either canalithiasis or cupulolithiasis[1]. Both etiologies are explained by displacement of the otoconia from the macula due to trauma, infection, or unknown cause[2]. Canalithiasis occurs when the displaced particles are floating in one or more

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the endolymph[1]. The cupula is then bent by this flow and sends an incorrect signal to the brain regarding the body's movement in relation to gravity[3]. Cupulolithiasis, on the other hand, occurs when the displaced particles stick to the cupula itself. Ultimately, this produces the same effect that canalithiasis does because is produces an abnormal bending of the cupula and an incorrect signal to the brain[1]. Regardless of the theorized mechanism, both conditions result in vertigo. Currently, the standard treatment for BPPV is the canalith repositioning procedure[4]. The physical therapy maneuver we usually use is called the Epley's maneuver. First, while sitting up, the patients head is turned about 45 degrees to the side that normally provokes the vertigo. Then the patient is quickly laid down backwards with their head just over the edge of the examining table. This position usually provokes strong vertigo. The head is kept in this position for about 30 seconds and then turned 90 degrees to the opposite side. After another 30 seconds, the head and the body are turned together in the same direction so that the body is pointing towards the side, and the head is pointing down toward the ground at a 45 degree angle. After 30 seconds in this position, the patient is brought upright again. This is repeated as many as five or six times until neither vertigo nor nystagmus are elicited when the head is brought into the bad ear down position. Usually no medications are required for BPPV unless the patient has severe nausea or vomiting. If extreme nausea does exist, anti-nausea medications can be prescribed before and/or after the treatment. In present study, we compared the effectiveness of using Epley's Maneuver alone or Epley's maneuver with medications like labyrinthine sedative (i.e. beta-histine) in the treatment of BPPV.

MATERIALS AND METHODS

This study was a randomized clinical trial and was conducted among patients attending the Department of Otorhinolaryngology at Pacific Medical College and Hospital, Udaipur during the period from January 2015 to January 2016 and at Ananta Institute of Medical sciences, Rajsamand during the period from Febrary 2016 to September 2016. A total of 70 patients of BPPV were included in the study. The clinical diagnosis of BPPV was confirmed by Dix-Hallpike maneuver. **Exclusions:** The patients [illegible] BPPV [illegible] ongoing CNS disease (stroke or TIA), and cardiovascular disease and pregnant women beyond 24 weeks were excluded from this study. All the 70 patients with positive Dix-Hallpike test were divided in two groups each consisting of 35 patients. One group of 35 patients who received medical therapy with Epley's maneuver were considered as the cases and the other group of 25 patients who received only Epley's maneuver were considered as the controls. Epley's maneuver was repeated until symptomatic relief. We used labyrinthine sedative drug beta-histine 16mg tds in all the 35 cases. We followed the patients for one year with review visit after 1 week, 1 month and 6 months. The results were assessed on following criteria:

1. Negativization of the D-H test at a week, a month and six month follow-up
2. Answer to the dichotomous (yes/no) question regarding presence of vertigo in the previous week.
3. Number of new episodes of vertigo between medical visits.
4. Time from the baseline visit to the first new episode.

Those who meet the following three criteria: presenting no exclusion criteria, all inclusion criteria met, and signed informed consent, were randomized to the intervention group or the control group. The responsibility for guarding and supervising the randomization list was rest on a staff member of center who was not directly involved in the trial.

RESULTS

Total 70 patients were included in our study out of which 35 patients who received medications along with Epley's therapy were considered as cases and rest 35 patients who received only Epley's therapy were considered as controls. The mean age of cases was 55.23 that of the control group were 53.74. There was no statistically significant difference between the age groups (p-value=0.5093). In the study group 45.71% were male and 54.29 % were female while in the control group, 37.145 were male and 62.86% were female. Sex ratio difference between two groups was not statistically significant (p-value=0.6275). 57.15% of cases were having left sided BPPV and remaining 42.85% were having right sided BPPV. [illegible]

having left sided disease and 31.43% were having right sided BPPV. There was no statistically significant difference was found in terms of affected sides. Patients diagnosed with bilateral BPPV were excluded from the study. 15 patients (42.85%) among cases were having associated nausea and vomiting while 12 patients (34.28%) in the control group were having associated nausea and vomiting. Treatment response was detected by negative Dix-Hallpike test at the follow up after 1 day, 1 week, 1 month and at 6 month. 1 day after treatment 27 patients (77.14%) among the cases and 26 patients among controls were free of positional vertigo. similarly, after follow up of 1 week, 1 month and 6 month duration, the numbers of patients relieved after respective treatment were similar in both cases and controls (p-value=0.99) 2 patients among cases developed recurrence at 4th and 6 month respectively while 1 patient in controls developed recurrence in 4th month and they were treated in similar manner.

Table 1: Dose response relationship between cases and controls among BPPV patients

	1 Day No(%)	1 week No(%)	1 Month No(%)	6 Month No(%)	Recurrence No(%)
Cases	27 (77.14)	32 (91.42)	35 (100)	35 (100)	2 (5.71)
Controls	26 (74.28)	32 (91.42)	34 (97.14)	35 (100)	1 (2.85)

Table 2: Number of patients with associated symptoms (nausea, vomiting) relieved after respective treatment

	1st day	1 week	1 month
Cases (n=12)	7 (58.33%)	11 (91.66%)	12 (100%)
Controls (n=15)	5 (33.33%)	12 (80%)	15 (100%)

After 1 day of treatment, 7 patients (58.33%) among 12 patients with nausea and vomiting in cases were recovered completely from symptoms while only 5 cases(33.33%) among 15 patients from control group with nausea and vomiting treated completely (p-value < 0.001). after 1 week follow up, 91.66% of suffered cases and 80% of controls were treated completely. At 1 month follow up, all the cases and controls were free of associated symptoms.

DISCUSSION

Schuknecht developed the cupulolithiasis theory in studies concerning pathogenesis of this disorder in 1963[5]. However, later on, Epley claimed that BPPV was a result of canalolithiasis him[6]. Several other authors developed techniques and therapy protocols to be used in treatment of BPPV. For example Semont describes Semont maneuver[7], Cawthern developed 'rehabilitation therapy'[8], Brandt and Daroff described home exercise programs named after their names[9]. The relevance of medical treatment in BPPV is controversial. Betahistine dihydrochloride, which has a mechanism of action based on interaction with H1 and H2 receptors, is being used in the treatment of vertigo. This molecule acts through inhibition of activation in vestibular nuclei, diminishing the resting flow of ampullary hair cells in the labyrinth and increasing cochlear blood flow[10]. Hence, various studies are focused on this matter. Cavaliere compared the Liberatory and Brandt-Daroff procedures on their own and with Betahistin and in the short term, he achieved a higher success in the Betahistin group. However, achievement of complete cure in all the groups at the end of three months suggests that BPPV recovers spontaneously[11]. However, there is controversy on whether the consideration of subjective criteria obtained from patients as an indication for success in this study is beneficial, especially for the basic mechanism of the disease or for the imbalance period that follows. In the present study, we found that up to 91.42% of patients reported benefit after the first follow-up period of one week. In a randomised study, 90% of patients were either improved or cured after a single session with either Semont's or Epley maneuver [12]. Epley himself reported a success rate of more than 90% following a single treatment session. Among 35 case patients, 27 (77.14%) recovered from vertigo immediately after the Epley maneuver and 32 (91.42%) patients recovered from vertigo at first week of follow up. The remaining 3 case patients recovered from vertigo during second and third follow-up visits, whereas, among 35 control patients, 26 (74.28%) recovered from vertigo immediately after one day 32 (91.42%) participants recovered from the vertigo at first follow up after one week.. This clearly indicates that Epley's maneuver alone is sufficient for the treatment of BPPV and addition of medical therapy does not improve or affect the response. In our study labyrinthine sedatives beta-histine 16 mg thrice a day was given to all 35 cases

the patient is symptom free. Labyrinthine sedatives did not change the effectiveness of Epley's maneuver in treating BPPV even after prolonged use, although they may provide minimal relief in associated symptom like nausea and vomiting in some patients. A review of the literature revealed the extremely good results of the Epley maneuver. In one study, the success rate after1week was 63.6%, which increased to72.7% after 2 weeks[13]. One Brazilian study also revealed similar results [14]. A meta-analysis done by Prim-Espada et al. on the efficacy of Epley's maneuver in benign paroxysmal positional vertigo using a critical review of the medical literature concluded that the patients on whom Epley'smaneuver was performed had six and half times more chance of their clinical symptoms improving compared to the control group of patients (OR = 6.52, 95% CI, 4.17–10.20)[15]. The efficacy of Epley's maneuver in the treatment of BPPV was assessed in a study of 62 patients conducted by Khatri et al. Patients were selected based on symptoms of positional vertigo and positive Dix-Hallpike's test. At the end of 1 month patients were assessed subjectively by visual analogue scale (VAS) and objectively by Dix-Hallpike's positional test. On VAS, 85.7% of patients had complete resolution of symptoms of BPPV in both groups. Objectively 88.2% did not have positional nystagmus after 1 month in first group, whereas in the second group 86% had complete response at the end of 1 month of therapy[16]. In a prospective study liberatory maneuver-betahistine and Brandt-Daroff-betahistine groups did significantly better than liberatory maneuver and Brandt and Daroff groups ($p < 0.05$). This study signifies the added efficiency of betahistine with particle repositioning maneuver in treating BPPV [17]. However there are very few studies which have compared the medical therapy with the particle repositioning maneuver. In present study, addition of beta-histine did not change the efficacy of Epley's maneuver in treating BPPV, but relief in associated symptoms like nausea and vomiting was more in cases where we used beta-histine than controls that were treated with Epley's maneuver alone.

CONCLUSION

BPPV is a very common disease in society and Neuroclinics. The symptoms of BPPV are very distressing for the patient and can deteriorate the quality of life of the patient. Luckily, it is an easily diagnosed and treated cause of vertigo. In present study, we have investigated whether a change in treatment success occurs when Epley's maneuver is combined with medications. There was no significant difference among the groups. Applying only the Epley's maneuver to the patients we diagnosed to be with BPPV seems to have been sufficient for achieving a cure. However, in case of associated symptoms like nausea and vomiting that can occur during the treatment and dizziness that can continue after the treatment, medical treatment can be of use.

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Original Research Article

A Study of Surgical Outcomes of Tympanoplasties with and without Cortical Mastoidectomy

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ABSTRACT

Background: Tympanoplasty, also called eardrum repair, refers to surgery performed to reconstruct a perforated tympanic membrane (eardrum) or the small bones of the middle ear. Eardrum perforation may result from chronic infection or, less commonly, from trauma to the eardrum.

Objective: The Objective of the study is to evaluate the surgical outcomes of tympanoplasties with and without mastoidectomies in terms of graft uptake and hearing improvement.

Methods: A total of 56 patients undergoing tympanoplasties with and without mastoidectomy were included and followed up for a period of one year.

Results: There was no significant difference in the surgical outcomes of both the surgeries in terms of graft uptake and hearing improvement. In unilateral cases Belfast rule of thumb application enables the actual hearing benefit of the patient.

Conclusion: There is no difference in related to outcome. The addition of cortical mastoidectomy to tympanoplasty did not improve the outcome of surgeries done for mucosal type of chronic suppurative otitis media.

KEY WORDS: Cortical Mastoidectomy, Tympanoplasty, Belfast Rule.

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INTRODUCTION

Tympanoplasty, also called eardrum repair, refers to surgery performed to reconstruct a perforated tympanic membrane (eardrum) or the small bones of the middle ear. Eardrum perforation may result from chronic infection or, less commonly, from trauma to the eardrum.

The tympanic membrane of the ear is a three-layer structure. The outer and inner layers consist of epithelium cells. Perforations occur as a result of defects in the middle layer, which contains elastic collagen fibers. Small perforations usually heal spontaneously. However, if the defect is relatively large, or if there is a poor blood supply or an infection during the healing process, spontaneous repair may be hindered. Eardrums may also be perforated as a result of trauma, such as an object in the ear, a slap on the ear, or an explosion [1]. The purpose of tympanoplasty is to repair the perforated eardrum, and sometimes the middle ear bones that consist of the incus, malleus, and stapes. Tympanic membrane grafting may be required. If needed, grafts are usually taken from a vein

or fascia (muscle sheath) tissue on the lobe of the ear [2]. Synthetic materials may be used if patients have had previous surgeries and have limited graft availability. The mastoid is a honeycomb cavity in the temporal bone, which lies directly behind the ear and is connected to the middle ear space. When a hole arises in the eardrum due to previous injury or infection, or when a long-standing infection persists with tissue in the middle ear or mastoid, mastoid surgery often becomes necessary to alleviate this infection. This part of the procedure is called mastoidectomy. Surgery for tubotympanic type of chronic suppurative otitis media is the commonest otological surgical procedure in our country [3].

This study discusses the various pre-operative factors which play a major role in the post-operative success of two various surgeries – myringoplasty and cortical mastoidectomy with type 1 tympanoplasty. The hearing benefit is determined by Air bone gap closure and also subjective evaluation of hearing is done by applying Belfast rule of thumb.

MATERIALS AND METHODS

This Prospective study was conducted at RNT medical college and attached M.B hospital, Udaipur, Rajasthan from Dec 2009 to Dec 2011. Study involves total 56 patients attending ENT OPD with mucosal disease at Our hospital for a period of one year and the patients were followed up for a period of one year. Among them, 6 patients did not turn up for follow up and they were excluded from the study.

Inclusion criteria: Patients between 15 to 50 years of both sexes, after elimination of focal sepsis, having either wet or dry ears and pure tone audiometry showing conductive hearing loss.

Exclusion Criteria: Patients with congenital or acquired abnormalities of ear, unsafe ear, undergone ear surgeries previously and with pure tone audiometry showing mixed and sensorineural hearing loss were excluded from the study.

Methodology: Minimum duration of discharge for the patients under study was 1year and maximum was 15 years. Minimum duration of hearing impairment was 6 months and maximum was 10 years. For all patients, under study with wet ears, ear swabs were taken from middle ear and for patients with culture positive results, treated with specific antibiotics prior to surgery.

All cases were admitted, pre-operative examination done under microscopy, subjected to endoscopic eustachian tube evaluation (those with normally looking pharyngeal end of eustachian tube orifice were taken up for study) and hearing assessment done with tuning fork tests and pure tone audiogram. All patients were informed about their need for a follow up period of one year. Informed written consent to undergo surgery was obtained from all patients. Mastoid shaving and local preparation was done in the ward prior to surgery. All cases were done under GA. Premedication and local infiltration was same for all cases.

Group A: About 25 patients with dry ear for more than 6 weeks and with only conductive hearing loss, were subjected to myringoplasty and considered as Group A. About 13 patients with unilateral disease and 12 patients with bilateral disease were taken up for study. For patients with bilateral disease, worse ear was taken up for surgery. All patients were taken up for surgery under GA. Trans canal approach was followed in 21 cases and in 4 cases with narrow external auditory canal post- aural approach was followed. 4 quadrant local infiltration was given with 2% xylocaine with adrenaline premixed solution. Temporalis fascia graft harvested by a separate incision over supra auricular region for patients done through trans-canal approach & in patients done through post-aural approach, graft was harvested via the same incision. Temporalis fascia graft kept by underlay technique. All cases were followed up for 3,6 months and one year for graft uptake and postoperative hearing evaluations done at 3,6 months and one year. Results of hearing benefit, compared with pre-op and post-op air bone gap and for unilateral disease Belfast rule of thumb applied.

Group B: About 25 patients with wet ear and with no active infection as per microbiological report & with conductive hearing loss were subjected to cortical mastoidectomy with type 1

tympanoplasty and considered as Group B. About 15 patients with unilateral disease and 10 patients with bilateral disease were taken up for study. For patients with bilateral disease, worse ear was taken up for surgery.

All patients were taken up for surgery under GA. Post-aural approach was followed in all cases. Postaural incision made, temporalis fascia graft harvested through the superior aspect of the incision as the first step, incision deepened and mastoid cortex exposed. Pinna retracted anteriorly, incision made in the posterior canal wall skin from 6 o'clock to 12 o'clock position and tympanomeatal flap was elevated. Granulations if present in the tympanum were removed, mobility of ossicular chain were checked. Mastoid cortex was drilled out in all cases, patency established. For about 21 patients granulations noted in antrum removed and in 4 patients antrum found free of disease. For all patients, temporalis fascia graft kept by underlay technique, tympanomeatal flap repositioned and post-aural wound closed in layers. All cases were followed up for 2, 6 months and 1 year for graft uptake and post-operative hearing evaluations done at 3, 6 months and 1 year. Results of hearing benefit, compared with pre-op and post-op air bone gap and for unilateral disease, Belfast rule of thumb applied.

Even though socio-economic status does influence the disease, all the patients attending RNT Medical College and M B Hospital Hospital belongs to lower socio-economic group. Hence this parameter is not included in this study.

RESULTS

Total number of cases registered in this study was 56 patients, who came to the ENT Department with Mucosal disease. Among them 6 patients did not turn up for follow up and hence they were not included in the study.

The overall graft take up rate in both the surgeries was 88.33%. The overall hearing benefit was 90%, excellent with < 10dB ABG in 51.67% and Good with < 20dB in 38.33%. There was no postoperative complications, deterioration in hearing or sensorineural hearing loss in all 50 patients.

In Group A ,15 were females & 10 were males, 13 patients had unilateral and 12 had bilateral disease, 20 had medium sized central perforation and 05 had subtotal perforation, 10 had good pre-op Air bone gap of 10 to 20 dBHL 15 patients had a fair pre-op Air bone gap of 20 to 30 dBHL.

1. Overall graft take up rate was 86.6%.

2. Otoscopic evaluation of 20 patients with medium sized perforation at the end of 2 months, revealed 15 to be intact, 5 residual perforation in the antero - inferior quadrant. In 5 patients with subtotal perforation,3 were intact,1 with residual perforation & 1 grafts got rejected because of post-op wound infection. Otoscopic examination at the end of 6months & 1 year revealed – for all 20 patients with medium size perforation, tympanic membrane was intact and out of 5 patients with subtotal 2 were with residual perforation & 1 with rejection of graft. Hence the size of the perforation does have a role in graft take up rate. This is statistically significant by applying chi square test with p value < 0.05.

3. In 10 patients with good pre-op ABG, the post-op ABG was excellent. In 15 patients with fair pre-op ABG, the post-op ABG results were, excellent in 9, good in 8 and fair in 3 patients accounting for 46.66% in excellent, 40% in good and 13% in fair groups. By applying Chi square test, these results are statistically significant Hence, for the patients with lesser pre-operative Air bone gap have a better post-operative hearing.

4. When Belfast rule of thumb was applied to 13 patients with unilateral disease, 10 of them with medium sized perforation, felt subjectively better and out of 3 of them with subtotal perforation, 2 felt better &1 patient felt hearing same as the pre operative status. These results are statistically significant with p value<0.05, implies that Belfast rule of thumb interpret the post-operative hearing benefit in a better way than the Air bone gap ,which tells about only the technical success.

5. The correlation coefficient between the duration of discharge and the pre-op ABG is 0.4172 and that between the duration of hearing impairment with pre-op ABG is 0.3821 and is statistically significant. The correlation coeffici-

-ent between the duration of discharge and the post-op ABG is 0.4544 and that between the duration of hearing impairment with post-op ABG is 0.4489 and is statistically significant, implies that the patients with lesser duration of discharge and hearing impairment had better post operative hearing than the patients with longer duration of disease and hearing impairment.

6. The other parameters, such as age, sex, weight does not have influence on the outcome of results in this study.

7. The type of approach does not have a significant p value with graft intake in this study. Applying chi square test, the Pearson value is 0.

In Group B, 17 were females & 8 were males, 15 patients had unilateral and 10 had bilateral disease. 18 had medium central perforation and 07 had subtotal perforation. 08 had good pre-op Air bone gap of 10 to 20 dBHL 17 patients had a fair pre-op Air bone gap of 20 to 30 dBHL.

1. Overall graft take up rate was 90%.

2. The relationship between Graft take up rate and size of the perforation is statistically significant by applying chi square test with person value of 0.02535.

Otoscopic evaluation of 15 patients with medium sized perforation at the end of 2 months, revealed 14 to be intact, 1 residual perfpration in the antero-inferior quadrant. In 07 patients with subtotal perforation, 05 were intact, 2 with residual perforation. Otoscopic examination at the end of 6 months & 1 year revealed – for all 18 patients with medium size perforation, tympanic membrane was intact and out of 07 patients with subtotal 3 were with residual perforation. Hence the size of the perforation do have a role in graft take up rate even when cortical mastoidectomy is done along with repair of tympanic membrane.

3. In this study, out of 18 patients with medium sized perforation, 8 had a good & 17 had fair pre-op ABG. Out of 07 patients with subtotal perforation, 6 patient had good & 01 had fair pre-op ABG, implies that 85.71 %of the patients with subtotal perforation had pre-op ABG of 20 to 30 dB.

4. Out of 25 patients, included in this procedure -re, 50% had excellent, 50% had good &10% had fair post-op ABG. Those with medium sized perforation had better results than those with subtotal perforation.

5. On comparison of pre-op ABG & post-op ABG, all 8 patients with good pre-op ABG improved to excellent, out of 17 with fair ABG, 3 were excellent, 12 were good and 2 were fair post-operatively. This result is highly statistically significant with pearson value of 0.00006 .

6. Graft intake in 4 patients with disease free antrum mucosa is 100%.

7. Out of 25 patients, 21 patients had disease in the antrum & 4 had a healthy antrum. 77.85% of the patients with healthy antrum and 9.5% of the patients with diseased antrum had good pre-op Air bone gap 90.5% with diseased and 22.2% with healthy antrum had fair preop Air bone gap.

8. In patients with healthy antrum, the post-op ABG was excellent in 88.9% and 66.7% of the patients

with diseased antrum had a good ABG post-operatively.

9. On applying Belfast rule of thumb to 15 patients with unilateral disease, 83.3% had better hearing, implies the post-operative hearing benefit better than assessment with Air bone gap.

10. The correlation coefficient between the duration of discharge and the pre-op ABG is 0.3803 and that between the duration of hearing impairment with pre-op ABG is 0.3776. The correlation coefficient between the duration of discharge and the post-op ABG is 0.3794 and that between the duration of hearing impairment with pre-op ABG is 0.3729 and are statistically significant, implies that the patients with lesser duration of discharge and hearing impairment had better post-operative hearing than the patients with longer duration of disease and hearing impairment.

11. The other parameters, such as age, sex, weight does not have influence on the outcome of results in this study.

DISCUSSION

Analysis of 50 cases undergone surgery for tubotympanic disease is presented here and the

same is compared with similar and related studies available in literature.

1. Graft Take Up Rate: The overall graft take up rate in Myringoplasty in this study was 86.6%, which is within the range to the studies available. The graft take up rate in various studies were [Table 1].

Table 1: Graft take up rate [1]

Study	No of cases	year	Graft take up rate
Gibb, Chang et al [5]	365	1982	91.40%
Black, PJ Wormald [3]	261	1995	78%
Raj A Vidit [1]	50	1999	84%
Kotecha et al [7]	107	1999	82.20%
Yasuo, Mishiro et al [1]	104	2001	94.40%
Kageyama et al [6]	290	2001	82.10%
Alberra et al [2]	85	2006	86%

The graft take up rate in Cortical mastoidectomy with type 1 tympanoplasty is 90% which is also within the range to the studies available in literature [Table 2].

Table 2: Graft take up rate [2].

Studies	No of cases	Graft take up rate
Yasuo, Mishiro et al [1]	147	90%
Adnan saleem et al [2]	85	92.95%
McGrew et al [2]	100	791%
Rehl CM et al [2]	135	90.40%

2. Graft Failure Rate: Graft failure rate in various studies were [Table 3].

Table 3: Re-perforation Rate % [1].

Studies	Re-perforation Rate %
Alberra et al [2]	7 to 21
Vartiainen et al [14]	10.6
Adnan, saleem et al [2]	7.05

In this study, in myringoplasty series the rate of residual perforation is 6.7% and the rate of rejection of graft is 6.7%. The probable cause of residual perforation is the slippage of the graft from its position and the cause for rejection is the post operative infection of the operated site, which is same as the reason cited by the study of Vartianien et al and Kotecha et al.[7,14] Study of Alberra et al also includes the efficiency of the surgeon and the surgical techniques [2].

3. Pre-operative Hearing: In this study the pre operative pure tone average in Myringoplasty series was between 30 to 40 dB with average being 38 dB and in Cortical mastoidectomy with type 1 tympanoplasty series between 30 to 55 dB with average being 42.16 dB. As the perforation size increases, the preoperative hearing threshold also increases – this is consistent with the study conducted by Mehta et al, Bhusal et al Nepal A Bhandary et al, Kageyama etal, Alberra et al and Saeed et al.[1,2]

4. Post Operative Hearing Benefit: Hearing improvement in various studies quoted in literature were [Table 4];

Table 4: Hearing improvement [2,3].

Study	Hearing Improvement
Adnan et al [2]	85.88%
Riser et al [2,3]	84.90%
Raj A Vidit et al [2]	68%
Kotecha et al [7]	67%

In this study, the overall post operative hearing benefit based on Air bone gap was 90% with <10 Db in 51.67% and <20db in 38.33%. As hearing benefit is better assessed with the subjective evaluation, in this study we have applied Belfast rule of thumb in patients with unilateral disease. In 23 patients with unilateral disease in Myringoplasty series, 95.7% felt significant improvement in hearing and 4.3% felt no improvement. In 18 patients with unilateral disease in Mastoidectomy with type 1 tympanoplasty series, 83.3% felt significant improvement in hearing and 16.7% felt no improvement.

CONCLUSION

From Our study we Would like to conclude that the success of Myringoplasty in terms of graft uptake and hearing improvement is better in patients with lesser duration of disease, less preoperative Air bone gap and with medium sized perforations when compared to subtotal perforations. The success of Cortical mastoidectomy with type tympanoplasty in terms of graft uptake and hearing improvement is better in patients with lesser duration of disease and less pre-operative Air bone gap.

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Dear Authors, Rajiv Kumar Saxena, Hemendra Bamaniya (Corresponding author), H.S. Bhuie

We are pleased to inform you that your Original Research Article (Title: Role of Nasal Douching in Chronic Allergic Rhinitis) has been accepted for publication in Tropical Journal of Ophthalmology and Otolaryngology.

We are planning to finalize and publish your article in the issue of April June 2019 (in Volume- 4, Issue 2 of 2019 will be published in next 2-3 weeks) of our Tropical Journal of Ophthalmology and Otolaryngology. We may ask you for any minor corrections if we found anything at drafting and finalizing the article.

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Your accepted article no is: TJOO 2019-12

Date: 18th May 2019

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Acceptance Letter for Publication of Research Article

To,

1. Rajiv Kumar Saxena, Associate Professor, Department of ENT, Ananta Institute of Medical Sciences, Rajsamand
2. Hemendra Bamaniya, Associate Professor, Department of ENT, Ananta Institute of Medical Sciences, Rajsamand
3. H.S. Bhuie, Professor, Department of ENT, Ananta Institute of Medical Sciences, Rajsamand

Sub: Acceptance of Original Research Article for Publication in Print Journal- International Journal of Research and Review

Dear Sir,
We are pleased to inform you that your article entitled **"Serum Vitamin D levels in chronic Allergic Rhinitis"** has been accepted for publication under *Original Research Article* category in Vol.6; Issue 6; June 2019 Issue of International Journal of Research and Review. The article is contributed by Rajiv Kumar Saxena, Hemendra Bamaniya and H.S. Bhuie.
Corresponding author is Dr. Hemendra Bamaniya.

Best wishes to all authors/coauthors!

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ORIGINAL ARTICLE

Comparison between Voice Handicap Index and Voice Symptom Scale by Subjective Analysis of Voice Disorders

[1]Hemendra Samariya, [2]Alok K Vaishnav, [3]Shashank Joshi, [4]Harbinder S Bhuie, [5]Rajiv K Saxena

ABSTRACT

Objective: Purpose of the present study was to use and compare two patient-derived scales voice handicap index (VHI) and voice symptom scale (VoiSS) for the assessment of the quality of life in patients of voice disorders and to assess their response to treatment.

Design: Longitudinal, cohort comparison study.

Setting: Department of Otorhinolaryngology, Maharana Bhupal Government Hospital, Udaipur, Rajasthan.

Participants: Fifty patients with a complaint of change in voice attended ear, nose and throat outpatient department at Maharana Bhupal Government Hospital and Rabindranath Tagore Medical College, Udaipur from 7th July 2010 to 30th June 2011.

Materials and methods: Two self-reported patients derived scale VHI and VoiSS were applied to all 50 patients of voice disorders both before as well as after treatment and compared the effect sizes of both the scales.

Result: Out of 50 cases, predominant cases included in the study were of malignant growth larynx (30%) followed by vocal nodule (18%). A total of 60% were male, and 40% were female. Maximum cases were of 41 to 60 years of age group (48%). Both the patient-derived scales VHI and VoiSS were found equally useful in assessing the quality of life in patients of voice disorders. Outcomes were similar in both the scales. The mean scores in both the scales before treatment were reduced to almost half after the respective treatment.

Conclusion: The result suggested that both the scales (VHI and VoiSS) are equally important as the results were highly correlated and no strong evidence was found to favor either of the scales. These scales are very useful in the assessment of the impact of voice disorders on patient's life and improvement in the quality of life after respective treatment as well as in assessing response to treatment.

Keywords: Dysphonia, Quality of life, Voice handicap index (VHI), Voice disorders, Voice symptom scale (VoiSS).

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INTRODUCTION

Voice is a complex phenomenon that is produced by interaction among the respiratory, laryngeal and resonance sub-systems.[1]

The phonation or voice is produced when the air is expelled from the lungs through the glottis, creating a pressure drop across the larynx. The oscillations of vocal cords modulate the pressure and flow of the air through the larynx, and this modulated airflow is the main component of the sound of most voiced phones.

Describing the vocal function and evaluating the voice problems are, likewise, complex tasks.

Voice measurement can improve our understanding of voice production, helps us to identify links between laryngeal disorders and voice production, and document change with interventions. It is also an important part of all phonatory surgery.[2]

Voice measures are divided into three categories:

1. Patient scales
2. Perceptual evaluation
3. Measures

Patient Scales

- VHI
- VoiSS
- Voice Related Quality of Life (V-RQOL)
- Voice activity and participation profile (VAPP)
- Reflux symptom scale (RSI)
- Patient questionnaire of vocal performance (VPQ)
- Voice outcome survey (VOS)

Perceptual Evaluation

- Auditory perceptual scale
  - Grade, roughness, breathiness, asthenia, and strain (GRBAS)

b. Consensus auditory perceptual evaluation-voice (CAPE-V),
c. Vocal profile analysis (VPA)
- Visual perceptual scale
- Tactile perceptual evaluation

Measures

Measuring voice is accomplished using:
- Acoustic analysis,
- Aerodynamic assessment, and
- Source measures.

Dysphonia can be defined as an impairment of the speaking or singing voice. It arises from an abnormality of the structures and or functions of the voice production system and can cause bodily pain, personal communication disability or an occupational or social handicap. The etiology of dysphonia is multifactorial. Genetic and psychological factors may predispose an individual to voice disorders.[2]

There are so many acute and chronic variables which can precipitate dysphonia. These include occupational vocal demands, trauma, environment, medications, health problems and lifestyle choices. Dysphonia is as disruptive to quality of life as any other chronic disease like angina, sciatica and chronic sinusitis.[3] The communicative issues associated to dysphonia can lead to depression, social withdrawal, and occupational handicap.[4]

OBJECTIVE

The objective of the present study is to use and compare VHI and VoiSS for the assessment of the quality of life in patients with voice disorders and their response to treatment.

Voice Handicap Index

It is a voice-specific outcome, measures patients' disability from voice disorders.

The index consists of a 30-item questionnaire, and each statement is noted from 0 (never) to 4 (always) composing a total score from 0 to 120, the higher the standard score, the higher the VHI (Table 1).

Voice Symptom Scale

This scale is yet in progress.

VoiSS consists of 43 items on a five-point equal appearing interval scale that reflects the frequency of occurrence. The total score is 0 to 172 (Table 2).

The questions in VoiSS represent five aspects (or domains) of voice pathology-communication problems, throat infection, psychosocial distress, voice sound, and variability and phlegm.

MATERIALS AND METHODS

This study was carried out on 50 patients that came to Otorhinolaryngology OPD at Maharana Bhopal (M.B.) Hospital and R.N.T. Medical College, Udaipur from 7th July 2010 to 30th June 2011 with a clinical diagnosis of dysphonia.

All patients then underwent thorough history-taking, general physical examination, and uniformly documented detailed local examination.

The routine laboratory tests, viz. blood for Hb, TLC, DLC, ESR, urinalysis, sklagram soft-tissue neck lateral view, sklagram chest PA view were done in all cases.

An indirect laryngoscopic evaluation was performed in all cases. Direct laryngoscopy and histopathological examination were done in required cases.

Thus the clinical diagnosis was made of all the cases with voice problems. Then the 43-item questionnaire of VoiSS and 30-item questionnaire of VHI were applied to all patients. The results and scores of both the voice analysis tools (VoiSS and VHI) were then compared to each other.

All the patients under study were kept under follow up until the proper treatment of voice disorder was carried out. The follow-up period for the different patient was different as the treatment duration for all diseases is not the same.

The patients were assessed thoroughly again, and both the VHI and VoiSS questionnaire were reapplied to all the patients after treatment.

Only those patients who were able to complete the posttreatment questionnaire were included in the study. Laryngectomized and tracheostomized patients were excluded from the study.

The comparisons between pre and post-intervention VHI scores and pre- and post-intervention VoiSS scores as well as between VHI and VoiSS scores were carried out to assess the role of these scores in deciding treatment pattern for the voice disorders as well as in assessing the quality of life of patients of voice disorders.

The improvement in the quality of life following treatment of voice disorder was assessed using the difference between pre and post VHI and VoiSS score.

RESULTS

The maximum number of cases of dysphonia, we encountered was of malignant growth larynx followed by a vocal nodule, globus and so on, as plotted on the following table (Table 3).

Since the cases included in the present study were only those, who were able to complete our questionnaire

Table 1: Voice handicap index

S.No	Questionnaire	Score				
	Part I-F	0	1	2	3	4
1.	My voice makes it difficult for people to hear me.					
2.	People have difficulty understanding me in a noisy room.					
3.	My family has difficulty hearing me when I call them throughout the house.					
4.	I use the phone less often than I would like to.					
5.	I tend to avoid groups of people because of my voice.					
6.	I speak with friends, neighbors, or relatives less often because of my voice.					
7.	People ask me to repeat myself when speaking face-to-face.					
8.	My voice difficulties restrict my personal and social life.					
9.	I feel left out of conversations because of my voice.					
10.	My voice problem causes me to lose income.					
	SUBTOTAL _____					
	Part II-P					
1.	I run out of air when I talk.					
2.	The sound of my voice varies throughout the day.					
3.	People ask, "What's wrong with your voice?"					
4.	My voice sounds creaky and dry.					
5.	I feel as though I have to strain to produce voice.					
6.	The clarity of my voice is unpredictable.					
7.	I try to change my voice to sound different.					
8.	I use a great deal of effort to speak.					
9.	My voice is worse in the evening.					
10.	My voice "gives out" on me in the middle of speaking.					
	SUBTOTAL _____					
	Part II-E					
1.	I am tense when talking to others because of my voice.					
2.	People seem irritated with my voice.					
3.	I find other people don't understand my voice problem.					
4.	My voice problem upsets me.					
5.	I am less outgoing because of my voice problem.					
6.	My voice makes me feels handicapped.					
7.	I feel annoyed when people ask me to repeat.					
8.	I feel embarrassed when people ask me to repeat.					
9.	My voice makes me feel incompetent.					
10.	I am ashamed of my voice problem.					
	Subtotal _____					
	Total _____					

0 = Never, 1 = Almost Never, 2 = Sometimes, 3 = Almost always, 4 = Always

of VHI and VoSS and were supposed to come for the follow up till the intervention for their voice disorder completed, so the data of prevalence of voice disorders may be different than in present study.

In the present study, the prevalence of voice disorders was found to be more in male (60%) patients as compared to female (40%) patient.

Also, the prevalence of cancer larynx and laryngopharynx was found to be more in male and prevalence of globus was more in female patients.

Globus pharyngis, in most cases, is caused by inflammation of one or more parts of the throat, such as the larynx and/or hypopharynx, gastroesophageal reflux disorder, due to cricopharyngeal spasm, laryngo-pharyngeal reflux or oesophageal versatility.[7]

In a few cases, the cause of globus is unknown, and the symptoms may be attributed to a psychogenic cause, i.e., a somatoform or anxiety disorder. It has also been recognized as a symptom of depression, that responds to antidepressive treatment.[8]

Table 2: Voice symptom scale

S.No	Questionnaire	0	1	2	3	4
1.	Do you have difficulty attracting attention?					
2.	Do you get frustrated by your voice problem?					
3.	Do you have problems singing?					
4.	Do people ignore you?					
5.	Is your throat sore?					
6.	Are you able to shout?					
7.	Is your voice hoarse?					
8.	When talking in company do people fail to hear you?					
9.	Do you lose your voice?					
10.	Does your voice problem reduce your social life?					
11.	Are you able to read aloud?					
12.	How often do you worry about catching a throat infection?					
13.	Do you cough or clear your throat?					
14.	Do you have pains in the chest?					
15.	Do you have a weak voice?					
16.	Do you have problems talking on the telephone?					
17.	Do you feel miserable or depressed because of your voice problem?					
18.	Does it feel as if there is something stuck in your throat?					
19.	Do you have swollen glands?					
20.	Do you talk less than you normally would?					
21.	Are you embarrassed by your voice problem?					
22.	Do you find the effort of speaking tiring?					
23.	Does your voice problem make you feel stressed and nervous?					
24.	Do you have difficulty competing against background noise?					
25.	Are you unable to shout or raise your voice?					
26.	Are you able to ask for things in shops?					
27.	Does your voice problem put a strain on your family and friends?					
28.	Do you have a lot of phlegm in your throat?					
29.	Do you run out of air when you talk?					
30.	Does the sound of your voice vary throughout the day?					
31.	Do people seem irritated by your voice?					
32.	Do you have a blocked nose?					
33.	Do people ask what is wrong with your voice?					
34.	Does your voice sound creaky and dry?					
35.	Do you feel you have to strain to produce voice?					
36.	Do you find other people do not understand your voice problem?					
37.	Do you try to change your voice to sound different?					
38.	How often do you get throat infections?					
39.	Is your voice worse in the evening?					
40.	Does your voice 'give out' in the middle of speaking?					
41.	Do you feel annoyed when people ask you to repeat?					
42.	Does your voice make you feel incompetent?					
43.	Are you ashamed of your voice problem?					
	Total					

0 = Never, 1 = Occasionally, 2 = Some of the time, 3 = Most of the time, 4 = All of the time

A total of 44% of cases examined in the present study were having a history of smoking or alcohol intake.

Moreover, all case of cancer laryux and laryngopharynx were having a history of smoking or alcohol intake or both which significantly proves cigarette smoking and alcohol intake as the important risk factor of cancer larynx and laryngopharynx.[7]

A total of 24% of all cases in the present study were having a history of vocal abuse either due to occupation or due to habit.

All cases of the vocal nodule, vocal cord papilloma, and vocal polyp were having a history of vocal abuse, which is showing the relationship between vocal abuse and development of vocal nodule or polyp.[8] Though vocal cord papilloma is a viral disease and is not associated with vocal abuse, in our case there was a coincidental history of vocal abuse.

Majority of the cases (48%) included in this study were of the age group of 41 to 60 years and the rests were as shown in Table 4.

Table 3: Clinical diagnosis of patients with voice disorders

No.	Diagnosis	No. of cases	Percentage
1.	M.G. larynx	15	30%
2.	Vocal nodule	9	18%
3.	Globus pharyngis	6	12%
4.	M.G. pharynx	5	10%
5.	Laryngitis	5	10%
6.	Pharyngitis	3	6%
7.	Vocal cord palsy	2	4%
8.	Vocal cord polyp	1	2%
9.	Vocal cord papilloma	1	2%
10.	Puberphonia	1	2%
11.	Goitre	1	2%
12.	Acute bronchial Asthma	1	2%
	Total	50	100%

Table 5: Presenting complaints of the patients

S.No.	Presenting complaints	No. of cases	Percentage
1.	Change in voice	35	70
2.	Difficulty in breathing	03	06
3.	Difficulty in swallowing	05	10
4.	Stridor	04	08
5.	Neck swelling	03	06
6.	Total	50	100

The presenting complaint of most of (70%) patients included in the present study, was the change in voice. The change in voice varied from simple harshness in laryngitis to hoarseness in carcinoma larynx. Six percent of the patient came with the complaint of neck swelling associated with dysphonia. 10% of patient were having to present complains of difficulty in swallowing, 8% were having stridor, and 6% patients came with complaints of difficulty in breathing (Table 5).

VHI scores of all the patients both before and after treatment were noted, and also the differe nce between them was calculated (Table 6 and Fig. 1).

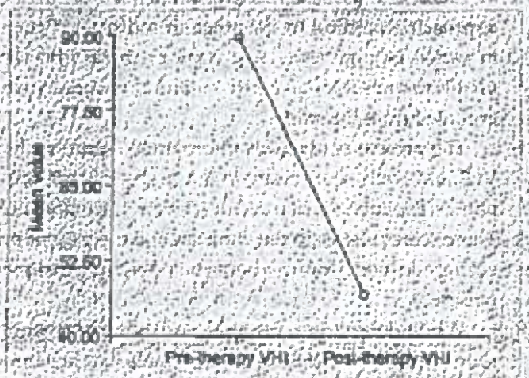

Fig. 1: Plot of mean sections of pre- and post-therapy VHI score

Table 4: Age wise distribution of patients

S. No.	Age-group	No of cases	Percentage
1.	11–20	5	10
2.	21–30	5	10
3.	31–40	8	16
4.	41–50	12	24
5.	51–60	12	24
6.	61–70	07	14
7.	71–80	01	02
	Total	50	100

Table 6: Pre- and post-treatment VHI score

	Pre-treatment VHI score			Post-treatment VHI score			
Total count	Mean	Standard deviation	Standard error	Mean	Standard deviation	Standard error	Mean of difference
50	89.7	26.54	3.75	49.96	29.315	4.14	42.14

Table 7: Pre- and post-treatment VoiSS score

	Pre-treatment VoiSS score			Post-treatment VoiSS score			
Total count	Mean	Standard deviation	Standard error	Mean	Standard deviation	Standard error	Mean of difference
50	119.28	37.98	5.37	83.16	35.32	4.99	58.12

A significant difference between pre- and post-treatment VHI score was found which shows the improvement in the quality of life of the patient after treatment of voice disorder.

Similarly, scores of VoiSS both before and after treatment were also noted and statistical analysis was done (Table 7 and Fig. 2).

In case of VoiSS questionnaire also, a similar type of scores found showed improvement in the quality of life of the patient after treatment of the voice disorder.

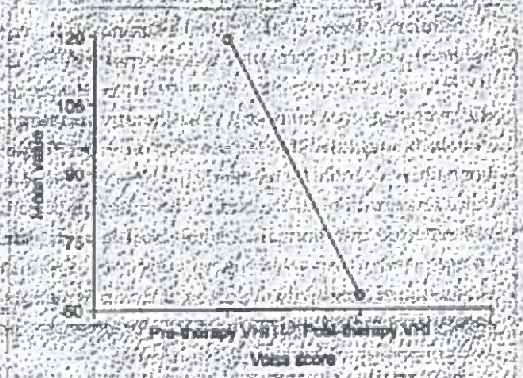

Fig. 2: Plot of mean sections of pre and post therapy VoiSS score

VoiSS score; more is the improvement in the quality of life of the patient.

CONCLUSION

In the present study, the results of both VHI and VoiSS were similar and highly correlated, and the comparative study did not favor any of the scale more for the evaluation purpose.

Thus the study showed that both VHI and VoiSS are important tools to assess the disability caused by voice disorders and also very useful to measure the functional outcomes of medical, behavioral and surgical treatment of voice disorders. These scores help the clinician and the patient to compare various treatment options. The improvement in the quality of life of the patient as well as the effectiveness of various voice intervention can be assessed using these scales.

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Original Research Article

A Study of Surgical Outcomes of Tympanoplasties with and without Cortical Mastoidectomy

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ABSTRACT

Background: Tympanoplasty, also called eardrum repair, refers to surgery performed to reconstruct a perforated tympanic membrane (eardrum) or the small bones of the middle ear. Eardrum perforation may result from chronic infection or, less commonly, from trauma to the eardrum.

Objective: The Objective of the study is to evaluate the surgical outcomes of tympanoplasties with and without mastoidectomies in terms of graft uptake and hearing improvement.

Methods: A total of 58 patients undergoing tympanoplasties with and without mastoidectomy were included and followed up for a period of one year.

Results: There was no significant difference in the surgical outcomes of both the surgeries in terms of graft uptake and hearing improvement. In inlaid technique Ballast Rule of 3 thumb application enables the actual hearing benefit of the patient.

Conclusion: There is no difference in related to outcome. The addition of cortical mastoidectomy to tympanoplasty did not improve the outcome of surgeries done for mucosal type of chronic suppurative otitis media.

KEY WORDS: Cortical Mastoidectomy, Tympanoplasty, Ballast Rule.

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INTRODUCTION

Tympanoplasty, also called eardrum repair, refers to surgery performed to reconstruct a perforated tympanic membrane (eardrum) or the small bones of the middle ear. Eardrum perforation may result from chronic infection or, less commonly, from trauma to the eardrum.

The tympanic membrane of the ear is a three-layer structure. The outer and inner layers consist of epithelium cells. Perforations occur as a result of defects in the middle layer, which contains elastic collagen fibers. Small perforations usually heal spontaneously. However, if the defect is relatively large, or if there is a poor blood supply or an infection during the healing process, spontaneous repair may be hindered. Eardrums may also be perforated as a result of trauma, such as an object in the ear, a slap on the ear, or an explosion [1]. The purpose of tympanoplasty is to repair the perforated eardrum, and sometimes the middle ear bones that consist of the incus, malleus, and stapes. Tympanic membrane grafting may be required. If needed, grafts are usually taken from a vein,

or fascia (muscle sheath) tissue on the lobe of the ear [2]. Synthetic materials may be used if patients have had previous surgeries and have limited graft availability. The mastoid is a honeycomb cavity in the temporal bone, which lies directly behind the ear and is connected to the middle ear space. When a hole arises in the eardrum due to previous injury or infection, or when a long-standing infection persists with tissue in the middle ear or mastoid, mastoid surgery often becomes necessary to alleviate this infection. This part of the procedure is called mastoidectomy. Surgery for tubotympanic type of chronic suppurative otitis media is the commonest otological surgical procedure in our country [3].

This study discusses the various pre-operative factors which play a major role in the post-operative success of two various surgeries – myringoplasty and cortical mastoidectomy with type 1 tympanoplasty. The hearing benefit is determined by Air bone gap closure and also subjective evaluation of hearing is done by applying Belfast rule of thumb.

MATERIALS AND METHODS

This Prospective study was conducted at RNT medical college and attached M B hospital, Udaipur, Rajasthan from Dec 2009 to Dec 2011. Study involves total 56 patients attending ENT OPD with mucosal disease at Our hospital for a period of one year and the patients were followed up for a period of one year. Among them, 6 patients did not turn up for follow up and they were excluded from the study.

Inclusion criteria: Patients between 15 to 50 years of both sexes, after elimination of focal sepsis, having either wet or dry ears and pure tone audiometry showing conductive hearing loss.

Exclusion Criteria: Patients with congenital or acquired abnormalities of ear, unsafe ear, undergone ear surgeries previously and with pure tone audiometry showing mixed and sensorineural hearing loss were excluded from the study.

Methodology: Minimum duration of discharge for the patients under study was 1year and maximum was 15 years. Minimum duration of hearing impairment was 6 months and maximum was 10 years. For all patients, under study with wet ears, ear swabs were taken from middle ear and for patients with culture positive results, treated with specific antibiotics prior to surgery.

All cases were admitted, pre-operative examination done under microscopy, subjected to endoscopic eustachian tube evaluation (those with normally looking pharyngeal end of eustachian tube orifice were taken up for study) and hearing assessment done with tuning fork tests and pure tone audiogram. All patients were informed about their need for a follow up period of one year. Informed written consent to undergo surgery was obtained from all patients. Mastoid shaving and local preparation was done in the ward prior to surgery. All cases were done under GA. Premedication and local infiltration was done for all cases.

Group A: About 25 patients with dry ear for more than 6 weeks and with only conductive hearing loss, were subjected to myringoplasty and considered as Group A. About 13 patients with unilateral disease and 12 patients with bilateral disease were taken up for study. For patients with bilateral disease, worse ear was taken up for surgery. All patients were taken up for surgery under GA. Trans canal approach was followed in 21 cases and in 4 cases with narrow external auditory canal, post aural approach was followed. 4 quadrant local infiltration was given with 2% xylocaine with adrenaline premixed solution. Temporalis fascia graft harvested by a separate incision over supra auricular region for patients done through trans-canal approach & in patients done through post aural approach, graft was harvested via the same incision. Temporalis fascia graft kept by underlay technique. All cases were followed up for 3,6 months and one year for graft uptake and postoperative hearing evaluations done at 3,6 months and one year. Results of hearing benefit, compared with pre-op and post-op air bone gap and for unilateral disease Belfast rule of thumb applied.

Group B: About 25 patients with wet ear and with no active infection as per microbiological report & with conductive hearing loss were subjected to cortical mastoidectomy with type 1

tympanoplasty and considered as Group B. About 15 patients with unilateral disease and 10 patients with bilateral disease were taken up for study. For patients with bilateral disease, worse ear was taken up for surgery.

All patients were taken up for surgery under GA. Post-aural approach was followed in all cases. Post aural incision made, temporalis fascia graft harvested through the superior aspect of the incision as the first step, incision deepened and mastoid cortex exposed. Pinna retracted anteriorly, incision made in the posterior canal wall skin from 6 o'clock to 12 o'clock position and tympanomeatal flap was elevated. Granulations if present in the tympanum were removed, mobility of ossicular chain were checked. Mastoid cortex was drilled out in all cases, patency established. For, about 21 patients granulations noted in antrum removed and in 4 patients antrum found free of disease. For all patients, temporalis fascia graft kept by underlay technique, tympanomeatal flap repositioned and post-aural wound closed in layers. All cases were followed up for 2, 6 months and 1 year for graft uptake and post-operative hearing evaluations done at 3, 6 months and 1 year. Results of hearing benefit, compared with pre-op and post-op air bone gap and for unilateral disease, Belfast rule of thumb applied.

Even though socio-economic status does influence the disease, all the patients attending RNT Medical College and M B Hospital Hospital belongs to lower, socio-economic group. Hence this parameter is not included in this study.

RESULTS

Total number of cases registered in this study was 56 patients, who came to the ENT Department with Mucosal disease. Among them 6 patients did not turn up for follow up and hence they were not included in the study.

The overall graft take up rate in both the surgeries was 88.33%. The overall hearing benefit was 90%, excellent with < 10dB ABG in 51.67% and Good with < 20dB in 38.33%. There was no postoperative complications, deterioration in hearing or sensorineural hearing loss in all 50 patients.

In Group A ,15 were females & 10 were males, 13 patients had unilateral and 12 had bilateral disease, 20 had medium sized central perforation and 05 had subtotal perforation. 10 had good pre-op Air bone gap of 10 to 20 dBHL 15 patients had a fair pre-op Air bone gap of 20 to 30 dBHL.

1. Overall graft take up rate was 86.6%.

2. Otoscopic evaluation of 20 patients with medium sized perforation at the end of 2 months, revealed 15 to be intact, 5 residual perforation in the antero - inferior quadrant. In 5 patients with subtotal perforation 3 were intact, 1 with residual perforation & 1 grafts got rejected because of post-op wound infection. Otoscopic examination at the end of 6months & 1 year revealed – for all 20 patients with medium size perforation, tympanic membrane was intact and out of 5 patients with subtotal 2 were with residual perforation & 1 with rejection of graft. Hence the size of the perforation does have a role in graft take upirate. This is statistically significant by applying chi square test with p value < 0.05.

3. In 10 patients with good pre-op ABG, the post-op ABG was excellent. In 15 patients with fair pre-op ABG, the post-op ABG results were, excellent in 9, good in 8 and fair in 3 patients accounting for 46.66% in excellent, 40% in good and 13% in fair groups. By applying Chi square test, these results are statistically significant. Hence, for the patients with lesser pre-operative Air bone gap have a better post-operative hearing.

4. When Belfast rule of thumb was applied to 13 patients with unilateral disease, 10 of them with medium sized perforation, felt subjectively better and out of 3 of them with subtotal perforation, 2 felt better & 1 patient felt hearing same as the pre operative status. These results are statistically significant with p value<0.05, implies that Belfast rule of thumb interpret the post-operative hearing benefit in a better way than the Air-bone gap ,which tells about only the technical success.

5. The correlation coefficient between the duration of discharge and the pre-op ABG is 0.4172 and that between the duration of hearing impairment with pre-op ABG is 0.3821 and is statistically significant. The correlation coeffi-

-ent between the duration of discharge and the post-op ABG is 0.4544 and that between the duration of hearing impairment with post-op ABG is 0.4489 and is statistically significant, implies that the patients with lesser duration of discharge and hearing impairment had better post-operative hearing than the patients with longer duration of disease and hearing impairment.

6. The other parameters, such as age, sex, weight does not have influence on the outcome of results in this study.

7. The type of approach does not have a significant p value with graft intake in this study. Applying chi square test, the Pearson value is 0.

In Group B, 17 were females & 8 were males, 15 patients had unilateral and 10 had bilateral disease. 18 had medium central perforation and 07 had subtotal perforation, 08 had good pre-op Air bone gap of 10 to 20 dBHL, 17 patients had a fair pre-op Air bone gap of 20 to 30 dBHL.

1. Overall graft take up rate was 96%.

2. The relationship between graft take up rate and size of the perforation is statistically significant by applying chi square test with person value of 0.02535.

Otoscopic evaluation of 15 patients with medium sized perforation at the end of 2 months, revealed 14 to be intact, 1 residual perforation in the antero-inferior quadrant. In 07 patients with subtotal perforation, 05 were intact, 2 with residual perforation. Otoscopic examination at the end of 6 months & 1 year revealed – for all 18 patients with medium size perforation, tympanic membrane was intact and out of 07 patients with subtotal 3 were with residual perforation. Hence the size of the perforation do have a role in graft take up rate even when cortical mastoidectomy is done along with repair of tympanic membrane.

3. In this study, out of 18 patients with medium sized perforation, 8 had a good & 17 had fair pre-op ABG. Out of 07 patients with subtotal perforation, 6 patient had good & 01 had fair pre-op ABG, implies that 85.71 % of the patients with subtotal perforation had pre-op ABG of 20 to 30 dB.

4. Out of 25 patients included in this procedure -re, 50% had excellent, 50% had good &10% had fair post-op ABG. Those with medium sized perforation had better results than those with subtotal perforation.

5. On comparison of pre-op ABG & post-op ABG, all 8 patients with good pre-op ABG improved to excellent, out of 17 with fair ABG, 3 were excellent, 12 were good and 2 were fair post-operatively. This result is highly statistically significant with pearson value of 0.00006

6. Graft intake in 4 patients with disease free antrum mucosa is 100%.

7. Out of 25 patients, 21 patients had disease in the antrum & 4 had a healthy antrum. 77.85% of the patients with healthy antrum and 9.5% of the patients with diseased antrum had good pre-op Air bone gap 30.5% with diseased and 22.2% with healthy antrum had fair preop Air bone gap.

8. In patients with healthy antrum, the post-op ABG was excellent in 88.9% and 66.7% of the patients

with diseased antrum had a good ABG post-operatively.

9. On applying Rellfast rule of thumb to 15 patients with unilateral disease, 83.3% had better hearing, implies the post-operative hearing benefit better than assessment with Air bone gap.

10. The correlation coefficient between the duration of discharge and the pre-op ABG is 0.3803 and that between the duration of hearing impairment with pre-op ABG is 0.3776. The correlation coefficient between the duration of discharge and the post-op ABG is 0.3794 and that between the duration of hearing impairment with pre-op ABG is 0.3729 and are statistically significant, implies that the patients with lesser duration of discharge and hearing impairment had better post-operative hearing than the patients with longer duration of disease and hearing impairment.

11. The other parameters, such as age, sex, weight does not have influence on the outcome of results in this study.

DISCUSSION

Analysis of 50 cases undergone surgery for [illegible]

same is compared with similar and related studies available in literature.

1. Graft Take Up Rate: The overall graft take up rate in Myringoplasty in this study was 86.6%, which is within the range to the studies available. The graft take up rate in various studies were [Table 1].

Table 1: Graft take up rate [1].

Study	No of cases	year	Graft take up rate
Gibb, Cleary R.M [5]	345	1982	91.60%
Black, PJ Wormald [3]	261	1995	78%
Raj A Vidit [2]	50	1999	84%
Kotecha et al [7]	107	1999	82.20%
Tasso, Mishira et al [1]	104	2001	94.60%
Kageyama et al [6]	190	2001	82.30%
Alberra et al [2]	85	2008	86%

The graft take up rate in Cortical mastoidectomy with type 1 tympanoplasty is 90% which is also within the range to the studies available in literature [Table 2].

Table 2: Graft take up rate [2].

Studies	No of cases	Graft take up rate
Tasso, Mishira et al [1]	147	94.20%
Adnan saleem et al [2]	85	92.95 %
Alberra et al [2]	100	91%
Rahi CM et al [2]	135	90.40%

2. Graft Failure Rate: Graft failure rate in various studies were [Table 3].

Table 3: Re-perforation Rate % [1].

Studies	Re-perforation Rate %
Alberra et al [2]	7 to 21
Vartiainen et al [14]	10.6
Adnan, saleem et al [2]	7.05

In this study, in myringoplasty series the rate of residual perforation is 5.7% and the rate of rejection of graft is 6.7%. The probable cause of residual perforation is the slippage of the graft from its position and the cause for rejection is the post operative infection of the operated site, which is same as the reason cited by the study of Vartiainen et al and Kotecha et al [7,14] Study of Alberra et al also includes the efficiency of the surgeon and the surgical techniques [2].

3. Pre-operative Hearing: In this study the pre operative pure tone average in Myringoplasty series was between 30 to 40 dB with average type 1 tympanoplasty series between 30 to 55 dB with average being 42.16 dB. As the perforation size increases, the preoperative hearing threshold also increases – this is consistent with the study conducted by Mehta et al, Bhusal et al Nepal A Bhandary et al, Kageyama et al, Alberra et al and Saeed et al [1,2]

4. Post Operative Hearing Benefit: Hearing improvement in various studies quoted in literature were [Table 4];

Table 4: Hearing Improvement [2,3].

Study	Hearing improvement
Adnan et al [2]	85.88%
Khan et al [1,2]	84.90%
Raj A Vidit et al [2]	68%
Kotecha et al [7]	67%

In this study, the overall post operative hearing benefit based on Air bone gap was 90% with <10 Db in 51.67% and <20db in 38.33%. As hearing benefit is better assessed with the subjective evaluation, in this study we have applied Belfast rule of thumb in patients with unilateral disease. In 23 patients with unilateral disease in Myringoplasty series, 95.7% felt significant improvement in hearing and 4.3% felt no improvement. In 18 patients with unilateral disease in Mastoidectomy with type 1 tympanoplasty series, 83.3% felt significant improvement in hearing and 16.7% felt no improvement.

CONCLUSION

From Our study we Would like to conclude that the success of Myringoplasty in terms of graft uptake and hearing improvement is better in patients with lesser duration of disease, less preoperative Air bone gap and with medium sized perforations when compared to subtotal perforations. The success of Cortical mastoidectomy with type tympanoplasty in terms of graft uptake and hearing improvement is better in patients with lesser duration of disease and less pre-operative Air bone gap.

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Original Research Article

Aerobic Bacteriology of Chronic Suppurative Otitis Media in Rajsamand District of Rajasthan

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ABSTRACT

Objectives: The objective of our study was to examine the aerobic bacteriological profile and antibiotic sensitivity pattern to locally available antibiotics in chronic suppurative otitis media (CSOM) in Rajsamand district of Rajasthan state in India.

Materials and methods: This prospective study was conducted in the department of otorhinolaryngology, Aranya Institute of Medical Sciences, Rajsamand for a period of one year from February 2017 to February 2018. Aural swabs were taken on the first day of attendance of the patients to ENT OPD before any local medication was given to the patient, using sterile cotton wool swabs and sterile ear specula and sent for culture and sensitivity.

Results: A total of 150 cases of CSOM were selected for the study out of which 109 cases were of unilateral CSOM and 41 cases were having bilateral disease. Thus, a total of 191 swabs were taken for analysis. Out of 191 swabs processed, microbial growth was seen in 176 samples while 15 samples showed no growth. 121 (68.75%) samples showed mono-microbial growth while 55 (31.25%) samples showed poly-microbial growth. The peak incidence of CSOM was found in the age group 31-45 years (34.66%) followed by age group 16-30 years (27.33%). Females (62%) were more commonly affected than males (38%) and the female: male ratio was 1.6:1. *Pseudomonas aeruginosa (38.63%) was the most commonly isolated bacterial pathogen followed by staphylococcus aureus (35.22%) and Klebsiella sp. (10.22%).*

Conclusion: A thorough and precise knowledge of the etiological agents causing CSOM and their antimicrobial susceptibility is of essential importance for an effective and efficient treatment and thus in further prevention of both complications and development of antibiotic resistance which is becoming more common now a days.

Keywords: Chronic suppurative otitis media, antibiotic resistance, staphylococcus aureus, Amikacin

INTRODUCTION

Chronic suppurative otitis media (CSOM) is a major problem globally since prehistoric times with higher incidence in developing countries because of poor socio-economic status and lack of health education.[1]

CSOM is a long standing infection of a part or whole of the middle ear cleft. Clinically, CSOM is divided into two major types: Tubotympanic CSOM i.e. 'Safe' or 'Benign' type of CSOM and Atticoantral i.e. 'unsafe' or 'dangerous' type of CSOM.[2]

CSOM is found to be the single major cause for conductive deafness (66.3%) and it is also responsible for 1.5% of speech disorders.[3]

The indiscriminate, haphazard and half hearted use of antibiotics and poor follow up of the patients have resulted in

persistent changes in the bacteriological pattern of the disease, the advent of new antimicrobials, anti-inflammatory and anti-histamine agents make an evaluation of bacterial flora of CSOM important. [4]

The objective of our study was to examine the bacteriological profile and antibiotic sensitivity pattern to locally available antibiotics in CSOM.

MATERIALS AND METHODS

This prospective study was conducted in the department of otorhinolaryngology, Ananta Institute of Medical Sciences, Rajsamand for a period of one year from February 2017 to February 2018.

Aural swabs were taken on the first day of attendance of the patients to ENT OPD before any local medication was given to the patient, using sterile cotton wool swabs and sterile ear speculs. The collected samples were enclosed in airtight plastic tubing and then transported to the microbiology test laboratory. The samples were always taken before cleaning/suctioning the ear canals of the excess purulent exudates. Samples from bilaterally discharging ears were collected separately. The material was inoculated on Sheep Blood agar, Mac Conkey's agar, Chocolate agar, Robertson's Cooked meat broth for aerobic and anaerobic bacteria. The swabs were incubated for 48 hr and 72hr. Organisms were identified using standard procedures. [5] Antimicrobial sensitivity testing for aerobic isolates was carried out by Kirby Bauer disc diffusion method on Muller Hinton agar. Results were interpreted in accordance with central laboratory standards institute guide-lines. [6]

RESULTS

A total of 150 cases of CSOM were selected for the study out of which 109 cases were of unilateral CSOM and 41 cases were having bilateral disease. Thus, a total of 191 swabs were taken for analysis.

Out of 191 swabs processed, microbial growth was seen in 176 samples while 15 samples showed no growth. 121 (68.75%) samples showed mono-microbial growth while 55 (31.25%) samples showed poly-microbial growth.

In present study, age of the patients ranges from 10 months to 73 years. The peak incidence of CSOM was found in the age group 31-45 years (34.66%) followed by age group 16-30 years (27.33%). Females (62%) were more commonly affected than males (38%) and the female: male ratio was 1.6:1. (table.1)

Microbiological profile of isolates from patients of CSOM and their antibiotic sensitivity pattern is depicted in table.2 and table.3 respectively.

Table.1 Age wise distribution of patients with CSOM.

S.No.	Age group (years)	Number	Unilateral	Bilateral	Mono-microbial	Poly-microbial	Sterile	Total
1.	10-15	23	11	12	22	9	4	35
2.	16-30	41	34	7	33	12	3	48
3.	31-45	52	44	8	38	17	5	60
4.	46-60	20	12	8	11	13	4	28
5.	61-75	14	8	6	4	4	2	20
	Total	150	109	41	121	55	15	191

Table.2 microbiological profile of aerobic isolates from patients of CSOM.

S.No.	Type of organism	Number of samples	Percentage
1.	Pseudomonas aeruginosa	68	38.63
2.	Staphylococcus aureus	62	35.22
3.	Klebsiella sp.	18	10.22
4.	Proteus mirabilis	17	09.65
5.	E.coli	8	04.54
6.	Enterococcus faecalis	3	01.70
	Total	176	100

Table 3 Antibiotic sensitivity pattern of organism isolated in present study

S.No.	Antibiotic	Pseudomonas sp.	Staph. Aureus	Klebsiella sp.	Proteus mirabilis	E. coli	Enterococcus faecalis
1.	Ampicillin	0	11 (17.74%)	0	0	0	0
2.	Cloxacillin	0	18 (27.41%)	0	0	0	0
3.	Ampicillin + clavulanate	0	48 (77.41%)	0	0	0	0
4.	Amikacin	59 (86.76%)	38 (61.29%)	8 (44.44%)	7 (41.17%)	4(36%)	0
5.	Gentamicin	47 (69.11%)	39 (62.90%)	2 (11.11%)	3 (17.64%)	0	0
6.	Netilmicin	48 (70.58%)	42 (67.74%)	0	3 (17.64%)	2 (22%)	0
7.	Vancomycin	64 (94.11%)	47 (75.80%)	0	0	0	0
8.	Ciprofloxacin	38 (55.88%)	22 (35.48%)	6 (33.33%)	3 (17.64%)	3(31.3%)	1 (33.3%)
9.	Levofloxacin	36 (44.11%)	15 (24.19%)	4 (22.22%)	2 (11.76%)	1(12.5%)	1 (33.3%)
10.	Ceftriaxone	4 (60.29%)	44 (70.96%)	2 (11.11%)	3 (17.64%)	4(50%)	0 (66.66%)
11.	Cefotaxime	27 (39.70%)	28 (41.93%)	1(5.55%)	3 (17.64%)	3(37.5%)	0
12.	Ceftazidime	5 (7.3%)	44 (70.96%)	1(5.55%)	9 (52.94%)	0	0
13.	Piperacillin+ Tazobactam	51(75%)	53 (85.50%)	6 (33.33%)	6 (35.29%)	3(41.3%)	1 (33.3%)

DISCUSSION

CSOM is a long standing infection of a part or whole of the middle ear cleft. Clinically, CSOM is divided into two major types: Tubotympanic CSOM i.e. 'Safe' or 'Benign' type of CSOM and Atticoantral i.e. 'unsafe' or 'dangerous' type of CSOM. [2]

The definitive treatment of CSOM is by surgery (tympanoplasty and/or mastoidectomy), nevertheless, initial treatment by ear toilet and ototopical agents is necessary to prepare the ear for surgery. The selection of local or systemic antibiotic for therapy depends greatly on the type of the organism isolated in such cases.

In present study, microbial growth was seen in 176 (92.14%) samples out of 191 swabs used. 15 samples (7.8%) showed no growth. The culture results are found correlated with previous studies. [7-11] Negative cultures can be attributed to Non-bacterial growth, Anaerobic growth, Prior-antibiotic therapy and/ or Presence of antimicrobial enzymes i.e. lysozyme alone or in combination with immunoglobulins that suppress the bacterial growth. [4,10]

121 (68.75%) samples showed mono-microbial growth while 55 (31.25%) samples showed poly-microbial growth. Our study is correlated with Rama Rao et al. (1980) [9] found equal incidence of mixed and pure culture and Barnak et al. (1972) [12] found predominance of mixed culture.

In present study, most commonly affected age group was 31-45 years (34.66%) followed by age group 16-30 years (27.33%). In most of the earlier studies, the most commonly affected age group is 0-30 years. [13-16] The reason for high prevalence in higher age group in present study may be because of low socioeconomic status and poor awareness of the patients in villages near the hospital.

In the present study, Pseudomonas aeruginosa (38.63%) was the most commonly isolated bacterial pathogen followed by staphylococcus aureus (35.22%) and klebsiella sp. (10.22%).

Pseudomonas is the predominant cause of CSOM in tropical region does not usually inhabit the upper respiratory tract, its presence in the middle-ear cannot be ascribed to an invasion through eustachian tube and it should be considered as secondary invader gaining access to the middle-ear via tympanic membrane perforation. [17] Proteus mirabilis was seen in 9.65%% of the cases and Escherichia coli were isolated from 4.5% cases, and these findings were similar to the reports in earlier studies. [14,16]

In the present study the most effective antibiotic against Pseudomonas aeruginosa was found to be Vancomycin (94.11%) followed by amikacin (86.76%), piperacillin+Tazobactam, ceftazidime, netilmicin, Gentamicin, ceftriaxone and ciprofloxacin. This finding was corroborated by studies of numerous other authors. [13,18,19]

Staphylococcus aureus was found to be the second most common organism in the present study. The antimicrobial susceptibility pattern of Staphylococcus

aureus revealed highest sensitivity to piperacillin+tazobactam (88.70%) followed by amoxicillin+ clavulanate (77.41%), Vancomycin (75.80%), ceftriaxone & ceftazidime (70.96%), Netilmicin (67.74%) and Amikacin (61.29%) and least sensitivity to quinolones. In case of Klebsiella sp, Proteus, E.coli and Enterococcus faecalis-ceftriaxone, Amikacin and piperacillin with Tazobactam were found to be equally effective. These findings are in accordance with previous study done by Gulati et al (1997). [9]

CONCLUSION

A thorough and precise knowledge of the etiological agents causing CSOM and their antimicrobial susceptibility is of essential importance for an effective and efficient treatment and also in further prevention of both complications and development of antibiotic resistance which is becoming more common now a days.

Conflict of interest:

No conflicts of interest exist for these authors. No relevant financial relationship exists between the authors and procedures or products used in this manuscript.

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Acute Fibrinous and Organizing Pneumonia—A Rare Lung Pathology

Jyotsna Naresh Bharti, MD/DNB Pathology, B. Tulasi Satyendra, MD Pathology,**
Raghvendra Singh Shekhawat, MD Forensic Medicine,† and Asharam Gorchiya, MD Forensic Medicine†

(*Am J Forensic Med Pathol* 2021;00: 00–00)

CASE BACKGROUND

A 37-year-old man had an alleged history of assault with brick on his neck. The patient was brought to the hospital with complaints of fever, shortness of breath, and later, he developed a loss of power in the upper and lower limbs. The patient was managed with a Philadelphia neck collar, intravenous (IV) fluids, tracheostomy, mechanical ventilation, cervical traction, and inotropic support for neurogenic shock and IV antibiotics. Within a week, the patient developed bedsore, ARDS, and ventilator-associated pneumonia. The patient's condition deteriorated, and the patient was declared dead on the 20th day of hospital admission. Both the lungs weighed 972 and 994 g, respectively. The lungs were edematous and showed blackish discoloration on the surface. The cut section of both the lungs showed congestion and scattered areas of consolidation. There was an expulsion of thick mucoid material on manual compression (Fig. 1). The brain weighed 1194 g, and the cut section showed mild congestion. The vertebral column was accessed by the anterior approach, and the body of the C5 to C6 vertebrae showed fracture dislocation. The spinal cord from C1 to T1 did not show any gross abnormality.

The microscopic examination from both the lungs showed a patchy distribution of intra-alveolar fibrin balls, which involved more than 50% of the alveolar spaces (Fig. 2). There was interstitial expansion by vascular congestion and inflammatory cells. The loose plugs of the fibroblastic collagen matrix, that is, Masson bodies, were also present (Fig. 3). The features were of acute fibrinous organizing pneumonia. However, there was no evidence of aspirated material, hyaline membrane, eosinophilic or granulomatous inflammation, and vasculitis. Special stains were negative for bacteria, fungus, and acid-fast bacilli. Samples for culture were taken from the patient, while alive and at the time of autopsy, showed no growth.

The cerebral hemisphere and cerebellum with brain stem measured 18 × 14 × 8 cm and 11 × 10 × 3 cm and weighed 1050 and 137 g. Grossly, no hemorrhage or infarct was identified both on the surface and on serial slicing. Sections from the cerebral cortex and cerebellum showed only vascular congestion, whereas pons and medulla, and focal areas in the midbrain showed swollen neuronal cell bodies, central chromatolysis from the peripheral dispersion of nissl substance in eosinophilic cytoplasm with the absence of nuclei, that is, red neurons. Few axons showed variable segmental and irregular thickening (Fig. 4). Axonal injury was seen in the focal areas of the midbrain, pons, and medulla.

The part of the spinal cord measured 11 cm in length and weighed 9.5 g. The spinal cord showed marked degeneration of gray matter, total loss of all neuronal cell bodies along the length (Fig. 5). The preserved white matter showed features of axonal injury, that is, axon spheroids, retraction balls, and axons with variable diameters. Axons with empty and filled myelin sheaths were present (Fig. 6). The spinal cord showed sheets of histiocytes (Fig. 7). The present case report highlights an acute clinical condition of spinal shock with respiratory failure as the immediate cause of death. However, the antecedent cause of death was blunt force trauma to the C-spine and the manner of death was a homicide.

DISCUSSION

Beasley, in 2002, first described the acute fibrinous and organizing pneumonia (AFOP) in a series of lung injury patients.[1] Acute fibrinous and organizing pneumonia is a rare histological pattern of interstitial pneumonia with acute or subacute clinical presentation. The acute and fulminant course typically leads to respiratory failure and death, and the patients requiring mechanical ventilation are associated with poor outcomes, like in the present case.[1, 2]

Acute fibrinous and organizing pneumonia has been associated with collagen vascular disorders, autoimmune disorders, transplantation, bacterial or viral infection, acute respiratory distress syndrome, exposure to few drugs, occupational/environmental exposures, and it may be idiopathic also.[3]

FIGURE 1. Piece of lung shows inspissated mucoid substance.

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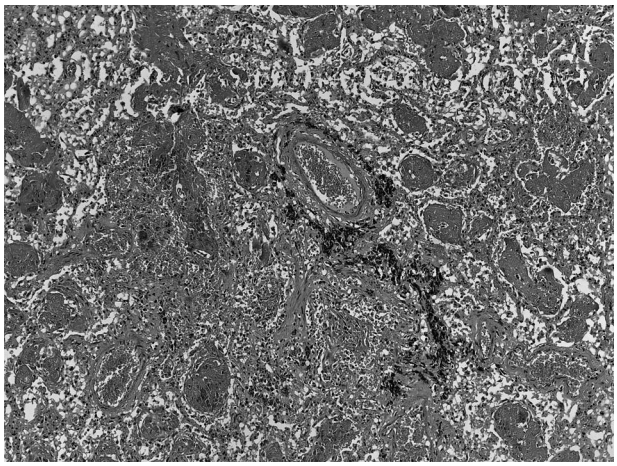

FIGURE 2. Fibrin balls in many alveoli and anthracotic laden macrophages [H&E, 40×].

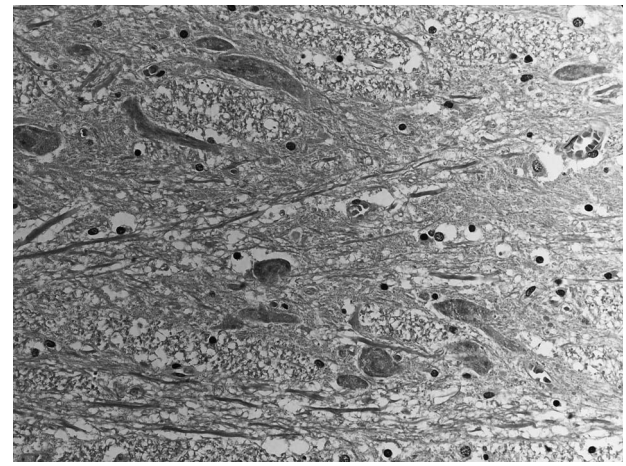

FIGURE 4. Red neuron admixed with variable diameter of axons (H&E, 40×).

Acute fibrinous and organizing pneumonia is characterized by patchy distribution of the intra-alveolar plugs of fibrin deposition, loose intraluminal connective tissue within the alveolar ducts and bronchioles, type 2 pneumocyte hyperplasia and/or minimal edematous interstitial inflammation and widening in an area adjacent to intra-alveolar fibrin with intervening parenchyma showing minimal changes. Acute fibrinous and organizing pneumonia confirmation depends on the biopsy.[1]

Acute fibrinous and organizing pneumonia clinical and histopathological features overlap with diffuse alveolar damage (DAD), cryptogenic organizing pneumonia, and eosinophilic pneumonia. All have different outcomes and well-established morphological criteria, making them distinct entities. Acute fibrinous and organizing pneumonia must be distinguished from DAD and cryptogenic organizing pneumonia, which shows hyaline membranes and fibromyxoid tissue loose plugs. The diffuse in DAD refers to the damage to all elements of the alveolus, and the histological changes are seen throughout the lung parenchyma. The eosinophilic pneumonia is characterized by prominent eosinophilic infiltrates. The clinical course may vary from complete recovery to rapid progression and death.[4] However, the present case was treated as ventilator-associated pneumonia and was put on IV antibiotics. At no point in time, he was given steroids. To date, the treatment for AFOP remains controversial and both steroids and immunosuppressive agents have been reported with favorable outcomes, but patients with advanced age may experience side effects.[1]

It is important for forensic pathologists to be familiar with the AFOP pattern simply to recognize that a severe acute lung injury has occurred, and a forensic pathologist should approach a case showing AFOP in a manner identical to a case showing DAD. In fact, many in the field consider AFOP to simply represent a variant form of DAD.

Cases showing AFOP mandate an appropriate workup for infection like special stains for microorganisms, a search for aspirated material, and microbiologic cultures if possible, and evaluation for other potential causes of severe acute lung injury, for example, an adverse drug reaction, or acute flare of autoimmune disease and occupational/environmental exposures.

The spinal cord injury at any spinal segment can result in respiratory impairment because of respiratory muscle's dysfunctional activity. This is mainly because of the interruption of bulbospinal respiratory projections to phrenic motor neuron groups in the third and fifth cervical regions,[5] whereas the neurogenic shock mainly results in hemodynamic compromise.[6] Most of the patients with injuries of the brainstem and upper cervical

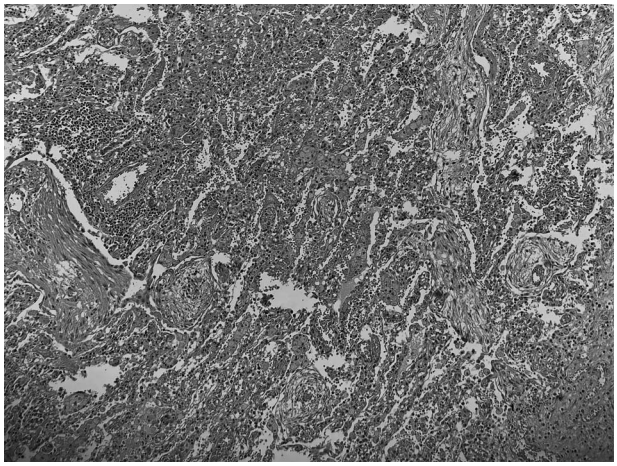

FIGURE 3. Loose plugs of fibroblastic collagen (Masson bodies) (H&E, 40×].

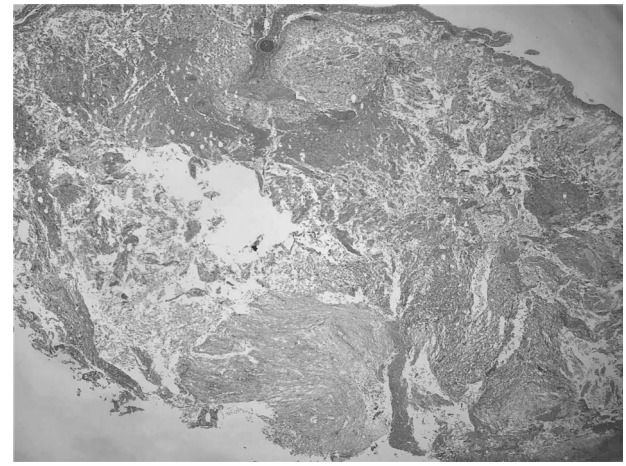

FIGURE 5. Spinal cord shows degeneration (H&E, 2×).

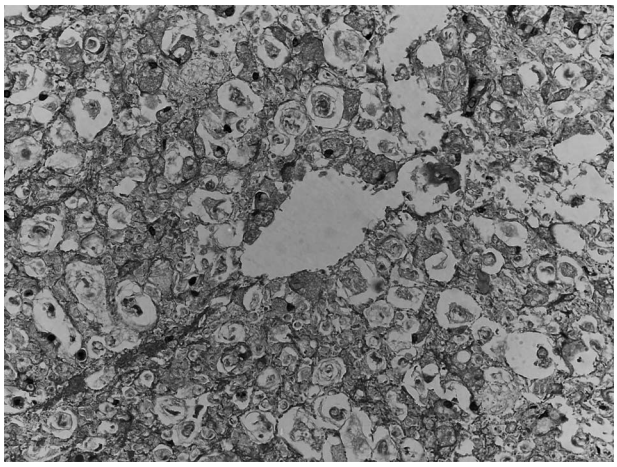

FIGURE 6. Ballooning ellipsoid of empty and filled myelin sheaths by tissue debris or axonal spheroids (H&E, 40×).

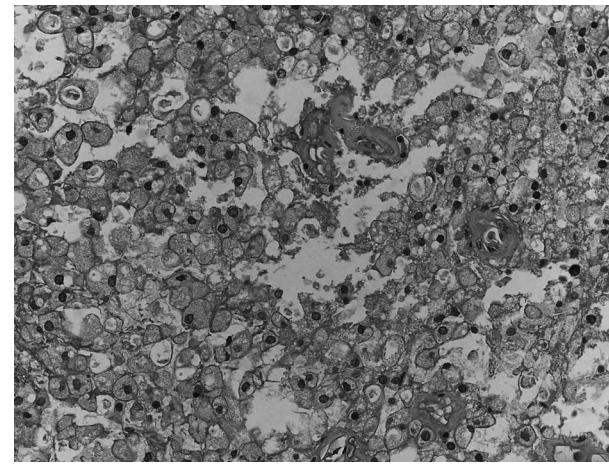

FIGURE 7. Sheets of macrophages (H&E, 40×).

spinal cord die instantly;[7] however, exceptional cases may survive.[8] The neuropathological events in spinal cord injury are infarction, axonal damage, and maybe the perseveration of white matter at periphery at the level of injury. Sheets of macrophage clear the debris. Late sequelae include replacement by collagenous scar, Wallerian degeneration of pathways, nerve root proliferation, spinal stenosis, and posttraumatic syringomyelia, manifesting many years after the initial injury.[9]

CONCLUSIONS

Acute fibrinous and organizing pneumonia is an uncommon pattern of acute lung injury, with a broad differential diagnosis. Acute fibrinous and organizing pneumonia has a variable course, depending on the underlying etiology. It should be included in the differential diagnosis in diffuse lung diseases with respiratory failure with or without shock. Spinal cord injury may lead to spinal and neurogenic shock resulting in morbidity or mortality, depending on the injury's level and extent.

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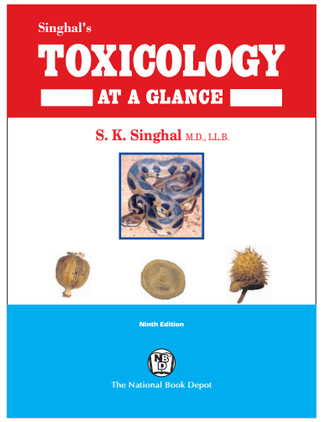

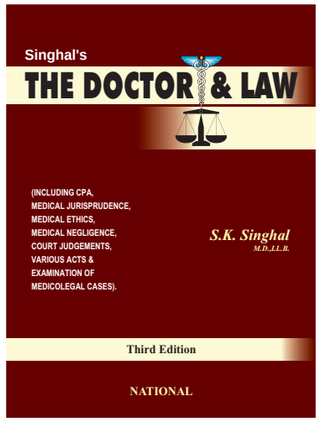

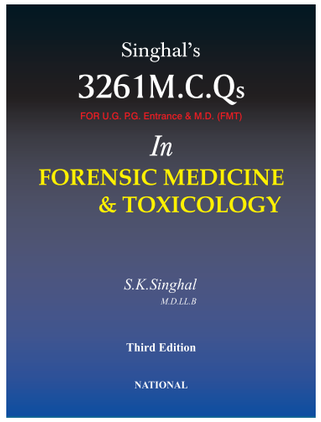

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ANALYSIS

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Gun violence in north-western India

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ABSTRACT

Gun violence is one of the important indicators of level of social and mental health. It is a global problem and causes considerable hazards in a developing country like India, where poverty and violence are not uncommon. Firearms and their use are modifiable risk factors, which if recognized and addressed, could help decrease the burden of violent death. Our Hospital based Descriptive Observational Study was aimed to assess the socio-demographic parameters of firearm injuries cases in North-Western India, conducted at the Department of Forensic Medicine S.M.S. Medical College, Jaipur during May 2014 to October 2015 period. The burden of gunshot violence is 0.49% (115 cases). Males outnumber females (9:1). Majority of victims were in the second and third decade age group. Incidence is higher in married, literate and rural population. Homicides were the most common manner of death. Property disputes, revenge, robbery are common underlying factors. Educational efforts, individual and community approaches are needed to alleviate firearm injuries. The epidemiologic reviews in this research shall enhance our understanding of various forms of gun violence, inform interventions, and help chart directions for future research.

Key Words: Firearm, Gun-Violence, Homicide, Jaipur

Abbreviations: W.H.O. - World Health Organization, S.M.S. – Sawai Maan Singh

1. INTRODUCTION

Gun violence is violence committed with the handling of a gun (firearm or small arm).[1] It is a global problem and causes considerable hazards in a developing country like India, where poverty and violence are common. The World Health Organization (W.H.O.) report on violence invokes member nations to scientifically and comprehensively adopt tactics to address this global health problem.[2] The estimated total number of guns (both licit and illicit) held by civilians in India is 40 million.[3] This probably explains that gunshot injuries in civilian environment in recent years have increased considerably in various parts of India with wide regional variations. Such injuries have a serious psychological and social impact on the family and community. Medical, legal and emotional costs of such violence impose an enormous burden on urban and rural hospitals, court of law, families, and the society as a whole.

Firearms and their use are modifiable risk factors, which if recognized and addressed, could help decrease the burden of violent death.[4]

Many researchers have studied the various aspects of the firearm injuries in different part of the world. The incidence of Gun violence is increasing day by day in north-western India (Jaipur-region) yet scanty of data is available. Our pioneer study is aimed to assess the socio-demographic parameters of firearm injuries cases in this region.

2. MATERIAL & METHOD

Descriptive Observational Study carried out during May 2014 to October 2015 at the Department of Forensic Medicine and Toxicology, S.M.S. Medical College and attached hospitals, Jaipur. All fatal and non-fatal medico-legal cases of firearm injuries reported at the study setting. Inclusion criteria include firearm injuries cases admitted for treatment purpose in the hospital and cases undergone for autopsy at the departmental mortuary.

Air gun injuries cases, explosion injuries cases and cases that did not provide informed written consent for the study were the exclusion criteria. A pre-validated questionnaire was developed to record socio-demographic data pertaining to firearm injury cases. The investigator contacted the subject and informed about the purpose of the study. A legally valid well informed written consent was obtained from patients themselves or from nearest relative, in case of subjects those who were recruited from the mortuary. The questionnaire included information on age, sex, marital status, residence, occupation, education, outcome (survival or death) and motive behind incidence happened. Data were entered in MS excel sheet and descriptive statistical analysis was done. Ethical clearance for the study was obtained from Institute Ethics Committee of S.M.S. Medical College, and attached group of Hospitals, Jaipur.

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3 RESULTS

A total of 23,584 medico-legal cases were reported during study period at the Department of Forensic Medicine, S.M.S. Medical College and attached Hospital, Jaipur. Among them 115 cases were concluded to be of firearm injuries with a burden of 0.49 %. About 67% of cases were from 20-39 years of age with peak incidence in age group of twenties (38%) and mean age was concluded 31.45 years. Male victims (about 90% cases) predominated over females (as illustrated in table 1). Married population sharing 80% of the study population affected with gun-violence. 89% cases belong to rural region. Most of victims (79% cases) were literate and rest was illiterate.

Table 1

Age and Sex Wise Distribution of Victims of Firearm Injuries (N= 115)

Age group (in yrs)	No. of Males Victims	No. of Females Victims	Total No. of Victims	Percentage of Victims
<10	01	01	02	1.74
10-19	08	01	09	7.83
20-29	42	02	44	38.26
30-39	28	05	33	28.70
40-49	13	01	14	12.17
50-59	09	02	11	9.57
> 60	02	00	02	1.74
Total	**103 (89.57%)**	**12 (10.43%)**	**115**	**100**

Table 2

Distribution of Victims of Firearm Injuries according to the Motive behind the gun-shot injuries (GSI) (N= 115)

Motive behind GSI	Number of cases	Percentage
Property disputes	49	42.61
Revenge	16	13.91
Robbery	14	12.17
Unknown	12	10.43
Accidental (no motive)	10	08.70
Group Quarrel	08	06.96
Love Affair	03	02.61
Defense	03	02.61
Grand Total	**115**	**100**

Agriculture was the most common occupation of victims of gun-shot injuries followed by self-employed people (as displayed in figure 1). Majority of the incidences of gun-shot injuries were homicidal in nature (78%) followed by accidental episodes (16.5%)

Surprisingly, there were only 2 cases of suicidal gun- shot injury. Property disputes were the most common motive behind firearm injuries followed by revenge (as shown in table 2).

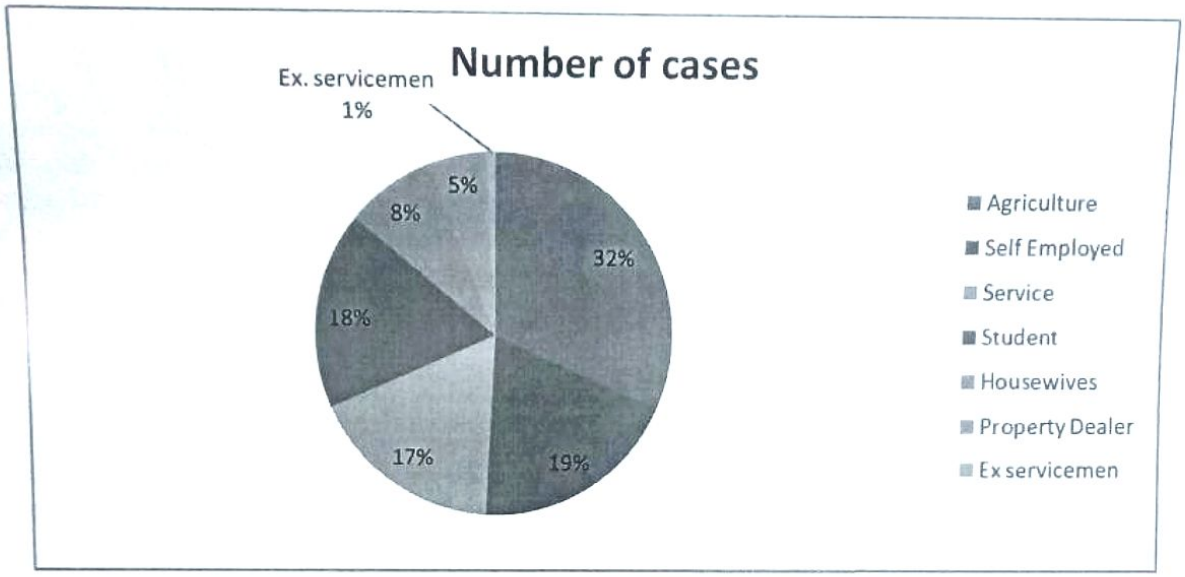

Figure 1
Distribution of Victim of Firearm Injuries according to Occupational Status (N= 115)

4. DISCUSSION

Present study was conducted at the tertiary health care centre situated in Jaipur which provides health care to large number of referral population of the various districts of Rajasthan as well as other adjoining states of Haryana, Uttar Pradesh, Madhya Pradesh and Bihar

During study period 23,584 medico-legal cases were received at the Department of Forensic Medicine. Out of these 115 cases were of gunshot injuries with burden of 0.49%. A total of 5,135 autopsies were conducted and among them 11 cases (0.22%) were fatal firearm injuries. This is quite less as compared to other past studies of Patowary A[5], Kumar P et al[6], Mehmat T et al[7], Capt Mirza F et al [8], Kumari S[9] but similar to other researchers viz Amiri A. et al [10], Sachan R et al [11], Shashikant VK et al [12], Chaurasia N[13], Davies MJ et al [14], Rao D [15]). The reason for this great variation owes to the geographical variations in the different places of study.

In the present study maximum numbers of cases were from 20-39 years of age (66.96%) with peak incidence in age group of twenties (38.26%) which are the reproductive and active members of the society. The observations of the present study were similar to those of Patowary A [5], Kumar P et al[6], Sachan R et al[11], Shashikant VK et al[12], Chaurasia N[13] (peak incidence between 21-40 years of age in all). However, the results of the present study are variable from those of Kumari S[9]. The probable reason for this variation is the minor cultural and periodical differences as most other studies from the same state.

Males (89.57%) outnumbered the females (10.43%) with a male: female ratio of about 8.9:1 .Similar results have been reported by Patowary A[5] (88.9% males) and Kumari S[9] (90% males). Males are the active participants of the society and more commonly engaged in outdoor activities. Moreover, they are more prone to episodes of rage and revenge. This explains the male preponderance in all studies.

About 80% victims of both sexes were married in the present study. It bears no correlation with such incidences but any type of outrageous behaviour is more common after marriage due to the burden of responsibilities that come hand in hand with it.

The victims of firearm injuries showed a rural preponderance (88.70%) while 11.30% victims belong to urban population. Chaurasia N [13] also showed preponderance of rural victims with slight variations in proportions of the two (72.9& rural & 27.1% urban victims) in both studies. Rural preponderance (46.3%) was also reported by Shashikant VK et al [12]. This is probably due to the easy availability of illegal firearms in rural regions owing to easier violation of laws. It is difficult to implement strict laws in rural

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areas for many reasons, like large area, lower literacy rates, cultural influences, socio-political constraints etc. also, there are more disputes regarding land and property, honor and prestige issues, caste conflicts, social strictures, etc in villages as compared to modern cities, thus resulting in outrage and quarrel are more often.

The literacy status of our study population is high. It is expected from educated people to use such deadly weapons judiciously However the literacy rates are not an indicator of the level of education. Educational status has not been described as a variable in most studies

Among the occupational status of the victims, it was observed that agriculture was the most common occupation among victims (31.30%) which is quite obvious owing to the preponderance of rural population in this study. The higher numbers of persons from agricultural field is also attributable to the fact that land is an important cause of disputes leading to such heinous crimes either in impulse or with planning. Our results are also in accordance with those of Shashikant VK et al [12].

Homicides (78.26%) were the most common manner of firearm injuries in the present study followed by accidental and suicidal pattern. Similar observations were concluded by other researches of Kumari S[9] (88.34%),Sachan R et al [11] (92%) and Chaurasia N [13] (85.4%) . Studies of Patowary A [5] and Kumar P et al [6] have restricted study of only homicidal pattern or suicidal firearm injuries (Rao D [15]) The preponderance of homicide in gun-shot injuries is explainable as these deadly weapons are generally used in planned manner assault or impulsively

Land and property disputes were the most common reason behind firearm injuries in this study (42.61%) followed by revenge & robbery (13.91% & 12.17% respectively);

According to Patowary A [5] and Kumar P et al[6] most cases were due to militant activities, encounters, riots, robberies or family quarrel. This variation from our study is due to the regional variations in the areas of study as Guwahati and Imphal are militant activity prone areas. The results of the present study are quite similar to those of

Sachan R et al [11] who reported 29.51% gun-shot injuries due to property disputes. 21.1% for dacoity. But in slight variation to those of Chaurasia N [13] where maximum (53 %) homicides occurred for personal enmity.

5 CONCLUSSION AND RECOMMENDATIONS

- The firearm homicide in Jaipur region is drastically increasing which is an eye opener to the Indian society.
- Our study conclusive of certain transformations may reduce the mortality, morbidity, and economical loss to the community.
- Inspection of Public health model to curb the gun violence.
- Indian Gun policy regarding armed violence prevention, gun control laws and the small arms trade needs improvisation.
- Young males of the population must be targeted for lifestyle adjustments such as training to refrain from anger or disputes and to prevent the easy access of firearms as a weapon to settle disputes.
- It is applicable to examine that sloppy firearm control is a great contributor to civilian gunshot injuries.
- Higher percentage of unemployment and poverty may be granting to the raised incidence of youth agitation, armed wrongdoing and related gunshot assaults.
- Strong laws are required to provide competent security for the brimming population.
- Promote access to adequate mental health services.

SUMMARY OF RESEARCH

1 Gun violence is a global health hazard.

2 Firearms and their use are modifiable risk factors, which if recognized and addressed, could help decrease the burden of violent death.

3.Educational efforts and individual, community approaches are needed to alleviate gun violence.

FUTURE ISSUES

The epidemiologic reviews in this research enhance our understanding of various forms of gun violence, inform interventions, and help chart directions for future research.

DISCLOSURE STATEMENT

There is no special financial support for this research work from any funding agency.

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Assessment of Load and Medico-legal Profile of Firearm Injuries and Associated Deaths at SMS Hospital, Jaipur During the Year 2014-2015

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ABSTRACT

Background: Gun shot injuries are a great challenge for medical professionals because of high mortality rate. Survival of victim depends upon the extent of damage and promptness of medical services.

Objective: Present study was undertaken to analyse medico-legal aspects of fatal gunshot injuries to provide data in Jaipur region.

Study Type: Hospital based Descriptive Observational Study.

Place and Duration : Department of Forensic Medicine and Toxicology , SMS Medical College and attached hospitals, Jaipur (A tertiary health care centre in north-western INDIA) during the study period of 17 months (May 2014 to October 2015) .

Observation and Results: Out of 23,584 registered medico-legal cases 115 were cases of gunshot injuries with burden of 0.49%. 11 cases were of fatal out of 5135 autopsies conducted. 05 fatal cases died within 6 hours , Homicides were the most common manner of incidence, Rifled firearm weapons were the preferred employed firearm weapon , more than half cases of distant fires were the offending shot in the present study.

Conclusion: Rifled firearm weapons were the most commonly employed firearm weapon. Coma and Shock resulting from gunshot injuries were the cause of death in most fatal cases.

Keywords: *Firearm Injuries, Singeing, Abrasion Collar, Hemorrhagic Shock*

INTRODUCTION

Firearm is any instrument or device designed to propel a projectile by means of explosion of gases generated by combustion of an explosive substance.[1] Firearm (FA) injuries pose great health burden and presents enormous challenge for health and national economies.[2] Firearm are the most dreaded killing tool used by human being. Firearm injury is a global problem and causes considerable problems in a developing country like ours, where poverty and violence are common. External injuries seen trivial but majority of them prove fatal due to extensive damage of vital organs and major blood vessels. In this study the medico-legal aspects of Gunshot injuries were studied in the cases brought to SMS hospital Jaipur for injury report or post-mortem examination.

MATERIAL & METHOD

Study design: This descriptive observational study was carried out during May, 2014 to October, 2015.

Study setting: The study setting was the Department of Forensic Medicine and Toxicology, SMS Medical College and attached Hospitals, Jaipur. This is the largest public hospital of the Rajasthan state which is situated in the Capital of Rajasthan.

Study subjects: All fatal and non-fatal medico-legal cases of firearm injuries reported the Department

of Forensic Medicine and Toxicology, SMS Medical College and attached Hospitals, Jaipur.

Inclusion criteria

1.Cases admitted for treatment.

2.Cases whose autopsy was done in the mortuary of the Department of Forensic Medicine & Toxicology.

Exclusion criteria

1.cases of air gun injuries

2.cases of explosion injuries and

3.cases whose informed written consent was not undertaken.

Study tool

A questionnaire was developed and pre-tested to record type of injury / firearm, outcome (in case, the subject admitted for treatment) and motive behind firearm injury.

Data collection

The investigator contacted the subject, and informed about the purpose of the study and obtained informed written consent from patients themselves, or from nearest relative, in case of subjects those who were recruited from the mortuary.

The questionnaire included information on age, sex, marital status, residence occupation, education, outcome (survival/ death), duration of survival after admission, and motive behind accident happened.

Analysis

Data were entered in MS excel sheet and descriptive statistical analysis was done.

OBSERVATION & RESULTS

9.57% of all firearm cases died and 90.43% survived and discharged routinely after appropriate treatment. Among the 11 fatal cases, about half of the cases died within 0-6 hours including 3 spot deaths. Only single patient survived for more than 3 days. 18% patients died within 6 to 24 hours after the incidence. 27% cases died within 1-3 days after the incidence.

TABLE 1: Distribution of Victims according to their Duration of Survival after sustaining the Gun-shot injuries (N= 11)

Duration of survival in fatal cases	Number of Cases	Percentage
0-6 hours	05	45.45
6-24 hours	02	18.18
1-3 days	03	27.27
>3 days	01	09.09
Total	**11**	**100**

Majority of the incidences of gun-shot injuries were homicidal in nature (78.26%) followed by accidental episodes. 2 cases were of suicidal gun- shot injury. Rifled weapon were most commonly used weapon in about 72% cases. Shotgun was employed for fire arm injuries in 27.83% cases.

Table 2: Distribution According to Type of Firearm Weapons used for offending the victims N= 115

Type of Weapon	Total No. of cases	Non fatal cases	Fatal cases	%
Rifled firearm weapon	83	72	11	72.17
Smooth bore fire arm weapon	32	32	00	27.83
Grand Total	**115**	**104**	**11**	**100**

Incidences of rifled firearm weapons were fatal in 13.25% cases. None of the victim offended with shotguns succumbed to it. Rifled fire arm weapons were significantly related to fatality.

In majority of the cases, gun-shot injuries was fired from distant range (52.17%) and in another major lot of cases, the range remained undetermined (36.52%); possibly may be deciphered in conjunction with a ballistic expert. 6.96% cases were of contact fire, 3.48% of close and a single case (0.87%) of near range of fire.

Table 3: Distribution according to the range of Fire Arm Weapon Used for offending

N= 115

Range of Fire	No. of Cases	Percentage
Distant	60	52.17
Not Determined	42	36.52
Contact	08	6.96
Close	04	3.48
Near	01	0.87
Total	**115**	**100**

In 45.5% cases hemorrhagic shock was the cause of death which was equally contributed by coma in 5 cases. Only one victim died due to septicemic shock who was the victim who survived for 21 days after sustaining gun-shot injuries.

The commonest targeted body parts were the peripheries including the upper and lower limbs (33.04%). The next to follow was the chest in 36 cases (31.30%). Abdomen including pelvis was targeted in 18.26% cases and head was the soft target in only 14.78% cases. Lease affected body part was neck with only 3 cases.

The anatomical locations of fatal gunshot injuries were determined in all 11 cases.

The head (54.55%) was the most common site of fatal gun-shot injuries followed by chest (36.36%). In 9.09% cases the fatal gunshot was an abdominal region and resulted in death due to haemorrhagic shock. A single case of head injury died due to septicemic shock. All cases of fire arm injuries on the chest region also died due to shock and haemorrhagic.

Table 4: Distribution of Victims of Firearm Injuries according to the targeted body part in gun-shot injuries and range of fire

N=115

Body Parts	Range of fire					Total	Percentage
	Distant	Undetermined	Contact	Close	Near		
Periphery	22	12	02	02	00	38	33.04
Chest	15	19	01	00	01	36	31.30
Abdomen	11	09	00	01	00	21	18.26
Head	11	01	05	00	00	17	14.78
Neck	01	01	00	01	00	03	2.61
Total	**60**	**42**	**08**	**04**	**01**	**115**	**100**

Entry wounds were analyzed on the basis of their characteristics appearance to naked eyes, presence of blackening. Scorching, tattooing and singeing were in cases of close range fire at the same time presence of inverted margins, abrasion and contusion collar etc. in distant range fire.

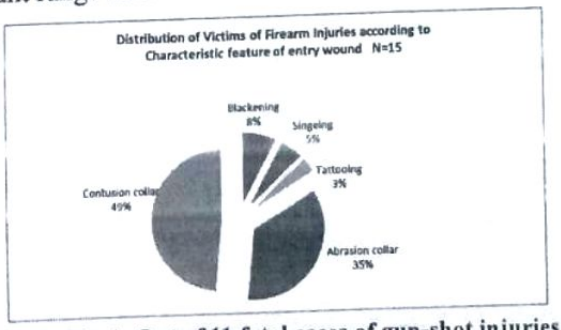

FIGURE NO. 1: Out of 11 fatal cases of gun-shot injuries, brain was the most commonly affected vital organ (54.55%) followed by heart (18.18%), liver & Intestine in one case each.

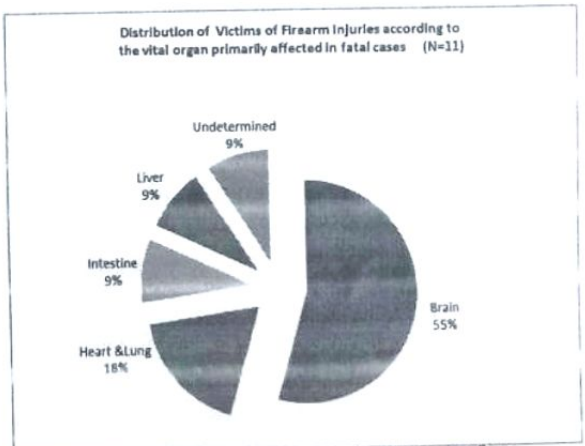

FIGURE 2. In a single case of gunshot injury of an unidentified individual whose dead body was recovered as partially skeletonised being in the advanced stage of putrefaction, foreign bodies were recovered from both skull and thoracic cage due to which the vital organ primarily affected could not be assessed definitely.

DISCUSSION

Out of 115 victims of firearm injuries, only 9.57% people suffered fatal injuries. Most of the other authors have studied only fatal firearm injuries. Among the fatal cases, 05 (45.45%) died within 6 hours including 3 spot deaths; 02 (18.18%) in next eighteen hours i.e. in 6-24 hours after the injury. Rest 04 patients (36.36%) victims survived the event for more than one day. Sachan R et al Kanpur 2013 [3] reported similar results.

Homicides (78.26%) were the most common manner of firearm injuries in the present study followed by 19 (16.52%) accidental and 02 (1.74%) suicidal firearm injuries.

Homicidal intent was predominant in most other studies like of Sachan R et al Kanpur 2013 (92%) [3], Chaurasia N Varanasi 2014 (85.4%)[4], Patnaik K K et al Behrampur 2014 (96%)[5], Kumari S et al Agra 2014 (88.34%).[6] Other studies have considered either only homicidal like of Patowary AJ et al Guwahati 2005[7], Pradipkumar KH et al Imphal 2005[8] or suicidal firearm injuries by Rao D Bangalore 2015[9]. The preponderance of homicide in gun-shot injuries is explainable as these deadly weapons are generally used in planned manner or more so impulsively in a planned assault.

Rifled firearm weapons (72.17%) were the most commonly employed firearm weapon to offend the victims in the present study followed by smooth bore fire arm weapon (27.83). But, our results are not in accordance with those of Kumari S et al Agra 2014.[6]

Distant fires (52.17%) were the predominant offending shot in the present study similar to that reported by Pradipkumar KH et al Imphal 2005.[8] In 36.52% cases the range remained undetermined due to lack of the characteristic features of firearm wounds. Close (3.48%) and contact (6.96%) range fires were found in less numbers, which is quite obvious owing to the lesser representation of suicidal gun-shot injuries in this study. distant fires had produced most fatal wounds in this study, followed by contact shots. But our findings were quite low in comparison to those of Kumari S et al Agra 2014 (53.3%)[6] and Sachan R et al Kanpur, 2013 (60.66%). [3]

There was presence of entry wounds in all 100% victims. In 52.04% cases there was a single entry wound as also reported by Patowary AJ Guwahati 2005[7] which was quite low from that of Kumari S et al Agra 2014 (95% with only 5% cases of double firing)[6] but findings of the present study were quite low in comparison to other studies done in the same state, Kumar R, Varanasi 2013[10] and Sachan R et al. Kanpur 2013[3]. This is explainable as the majority of the gun-shot wounds in this study were distant fires. In the present study, a single exit wound was found in 16.52% cases and in 1.74% cases there were two exit wounds. These results are quite low in comparison to those of Kumar R Varanasi 2013[10] and Kumari S et al Agra 2014 [6] who reported presence of exit wounds in 61.36% (with one exit wound in 18.18%, two in 19.31%, three in 10.22% and more than three exit wounds in 13.63% victims) & 60% victims (with single exit wound in 86.7% and double exit wounds in 13.3% cases) respectively. Abrasion and contusion collars were the most consistent findings in entry wounds of rifled firearm weapons. The characteristic features of blackening, singeing and tattooing were seen in relatively fewer number of entry wounds, because the majority of gun-shot entry wounds in this study were distant fires. Blackening was seen in 12 cases and tattooing were in 5 cases. These findings of the present study are very low from those of Kumar R Varanasi 2013[10] and Kumari S et al Agra 2014 [6] and can be attributed to the variation in the predominantly used firearm weapon and range of fire in both studies.

Chest (31.3%) remained the most commonly targeted body region in this study followed by abdominal region (18.26%) and, head & face (14.78%). These results bear slight variation with those of Kumari S et al Agra 2014 [6](most common site was abdomen- 30.9%, followed by chest- 21% and head- 16%). In 33.04% cases firearm wounds were found on peripheries and neck was the least affected part of the body (2.61%) and those of Sachan R et al Kanpur 2013 [3] where abdomen followed by head & neck was the commonest site.

In fatal cases of firearm injuries, head (54.55%) was the most commonly targeted body part followed by chest (36.36%) and abdomen (9.09%); similar to observations of Pradipkumar KH et al Imphal 2005.[8] Head region also remained the target in both cases of suicidal deaths being the most vulnerable site for suicide with firearm weapon. But, these are variable from those of Kumar R Varanasi 2013[10] and Patowary AJ Guwahati 2005 [7] where chest followed by neck and head and Patnaik K K et al Behrampur 2014 [5] where chest followed by head were the most commonly offended body parts in

fatal cases with 25% fatal entry wounds in abdomino-pelvic region too. In the present study, peripheries and neck were not affected in fatal gun-shot injuries as also reported by Patnaik K K et al Behrampur 2014[5] who reported only 7% firearm wounds in lower limbs in fatal cases.

Brain and meninges (54.55%) were the most commonly injured vital organ in fatal cases followed by lung& heart (18.18%); similar to that reported by Kumar R Varanasi 2013.[10] However, this was not so in the observations of Patnaik K K et al Behrampur 2014 [5]who reported highest involvement of lungs (29%) followed brain, stomach and intestine (16% each). Liver and intestines were the least affected internal organs in this study (9.09% each); which is again quite low as that reported by Patnaik K K et al Behrampur 2014[5] but the differences are easily attributable to the differences of the pattern of gun-shot injuries sustained by victims in the two studies. No other vital structures were observed to be affected in fatal cases of gun-shot injuries.

In 90.43% cases, gun-shot injuries was the only injury sustained on the body and in rest 9.57% cases; associated injuries of blunt trauma were seen on the body possibly due to struggle or secondary impacts after firearm injuries, but these were not fatal. The findings are similar to those of Kumar R Varanasi 2013[10] who reported the presence of associated injuries in 8.33% victims suffering fatal injuries; but quite high from those reported by Pradipkumar KH et al Imphal 2005 (2.99%).[8] Foreign body was recovered from the body in 34.78% cases. Wound debridement was the most commonly employed treatment modality, possibly due to preponderance of distant fires on peripheral parts of the body. Exploratory laparotomy, chest tube drainage and craniotomy were the other treatment modalities employed in different patients according to the type and site of gun-shot wounds suffered.

Coma due to head injury and Shock & hemorrhage resulting from gunshot injuries (45.45% each) were the cause of death in most fatal cases. Only one case (9.09%) died due to septicemia consequent to firearm injury. Hemorrhagic shock was the most common cause of death in the study of Patowary AJ Guwahati 2005[7], Kumari S et al Agra 2014[6] and Sachan R et al Kanpur 2013.[3]

CONCLUSSION

- Rifled firearm weapons (72.17%) were the most commonly employed firearm weapon to offend the victims in the present study followed by smooth bored weapon in 27.83%.
- Distant fires (52.17%) were the predominant offending shot in the present study.
- In 52.04% cases there was a single entry wound. More than one fire was found in 19.13% cases in the present study. Exit wounds were present in only 18.26% cases.
- In 73.04% cases, only a single body region was inflicted upon by use of firearm weapon.
- Coma due to head injury and Shock & hemorrhage resulting from gunshot injuries (45.45% each) were the cause of death in most fatal cases.

Ethical Clearance: Ethical clearance for the study was obtained from Institute Ethics Committee of SMS Medical College, and attached group of Hospitals, Jaipur.

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Conflict of Interest: Nil

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ORIGINAL ARTICLE

Assessment of Socio-Demographic Profile among the Victims of Firearm Injuries, at sms Hospital, Jaipur During the Year 2014-2015

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ABSTRACT

BACKGROUND: Firearm injury is a global problem and causes considerable problems in a developing country like ours, where poverty and violence are common. **AIMS AND OBJECTIVE:** To assess the load and analyze the cases of firearm injuries and associated deaths reported at the Department of Forensic Medicine, SMS Medical College & Hospital, Jaipur. **MATERIAL & METHODOLOGY:** The present prospective study had been conducted in the Department of Forensic Medicine & Toxicology, Govt. SMS Medical College & Hospital, Jaipur during the period from May 2014 to October, 2015. **RESULT & OBSERVATION:** In our study majority of case [44 cases (38.26%)] were observed in the age group of 20-29 years. Majority of victims [102 cases (88.70 %)] belongs to rural area. Out of 115 cases of firearm injuries victim 79.13% were literate and 24 cases (20.87%) were illiterate. Property disputes were the most common motive in our study (42.61%) followed by revenge (13.91%), robbery (12.17%). Agriculture was the most common occupation of victims of gun-shot injuries (31.30%) followed by self employed (19.13%).80% victims were found to be married and rest 20% were unmarried. **CONCLUSION:** Educational efforts, and individual, community and societal approaches are needed to alleviate firearm related injuries.

Key Word: Firearm injury, Gunshot, Prospective study, Jaipur

INTRODUCTION

Firearm injury is a global problem and causes considerable problems in a developing country like ours, where poverty and violence are common. Firearms have been used, and continue to be used, both for homicidal and suicidal purposes, offering an easy and quick mode of injury or death. Intimately related to firearm use is the availability of firearm weapons of various types to the public in most parts of the world.[1] Firearms provide a means whereby a person can be killed without any physical contact between the victim and the assailant and provide an opportunity for escape by the offender and therefore, are becoming a weapon of choice. Firearm death is one of the important indicators of level of social and mental health. Firearm injuries have a serious psychological and social impact on the family and community. Pattern of firearm injuries is a reflection of the prevailing social set up and mental status of the region.[2] Data on firearm injury in a particular geographic area can also give the reflection of its law and order situation. A low value can be described in favour of peace, harmony and security to human life.

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AIMS & OBJECTIVES

To assessment of socio-demographic profile of victims of firearm injuries reported at the Department of Forensic Medicine, SMS Hospital, Jaipur during the study period from May, 2014 to October, 2015.

- To study the medico-legal profile of firearm injuries.
- To suggest recommendations for preventing fire arm injuries so precious human life can be saved.

MATERIALS & METHOD

All the cases of firearm injuries, irrespective of age, gender and socioeconomic status received at the

casualty of SMS Hospital, Jaipur, dead or alive, later admitted to various wards of SMS Hospital, Jaipur were included in the study during the period from May 2014 to 31st Oct 2015. Hence, 115 cases of firearm injuries reported at the Department of Forensic Medicine, SMS Hospital, Jaipur were analyzed to find out the load of firearm injuries. The personal details pertaining to socio-demographic profile were recorded in detail followed by physical examination.

OBSERVATIONS & RESULTS

Out of 115 cases, majority of the cases were in the age group of 20-29 years (38.26%) followed by age group of 30-39 years (28.70%) which comprised about 66.96% of total cases. The least affected age groups with only 2 cases each were < 10 years and > 60 years. The males were the predominantly affected sex comprising of 89.57% cases with only 12 females among these 115 cases and male: female ratio in this study was 8.58:1.

Table 1: Age and Sex Wise Distribution of 115 Victims of Firearm Injuries

Age group (in yrs)	No. of Males Victims	No. of Females Victims	Total No. of Victims	Percentage of Victims
<10	01	01	02	1.74
10-19	08	01	09	7.83
20-29	42	02	44	38.26
30-39	28	05	33	28.70
40-49	13	01	14	12.17
50-59	09	02	11	9.57
>60	02	00	02	1.74
Total	103 (89.57%)	12 (10.43%)	115	100

There was a rural preponderance (88.70%) in the victims of firearm injuries. 11.30% victims were from urban regions.

Table 2: Distribution of 115 Victims of Firearm Injuries according to Domiciliary Status

Domicile	No. of cases	Percentage
Rural	102	88.70
Urban	13	11.30
Grand Total	115	100

Out of 115 cases of firearm injuries victim 79.13% were literate and 24 cases (20.87%) were illiterate. It was proposed to gather information of the educational status of victims to correlate it to judicious and non judicious use of firearms according to level of education.

Table 3: Distribution of 115 Victims of Firearm Injuries according to literacy Status

Literacy Status	Number of Cases	Percentage
Literate	91	79.13
Illiterate	24	20.87
Grand Total	115	100

Motive of victim were identified by detailed history by relatives and eyewitness. Property disputes were the most common motive behind the incidence (42.61%) followed by revenge 13.91%), robbery (12.17%) and group quarrel (06.96%). In 10.43% cases the motive behind the incidence remained undetermined. The least common motive behind gun-shot injuries in this study was love affairs and defensive actions (02.61% each). [Table No. 4]

Table 4: Distribution of 115 Victims of Firearm Injuries according to the Motive behind the gun-shot injuries

Motive behind GSI	Number of cases	Percentage
Property disputes	49	42.61
Revenge	16	13.91
Robbery	14	12.17
Unknown	12	10.43
Accidental (no motive)	10	08.70
Group Quarrel	08	06.96
Love Affair	03	02.61
Defence	03	02.61
Grand Total	115	100

Agriculture was the most common occupation of victims of gun-shot injuries (31.30%) followed by self employed (19.13%), people in jobs and students (17.39% each). A handful of property dealers (5.22%) were also victims of gun-shot injuries. 7.83% victims were housewives which comprised 75% of total females. Ex-serviceman was 0.87% of victims. [Table No. 5]

Table 5: Distribution of 115 Victim of Firearm Injuries according to Occupational Status.

Occupational Status	Number of cases	Percentage
Agriculture	36	31.30
Self Employed	22	19.13
Service	20	17.39
Student	20	17.39
Housewives	09	07.83
Property	06	05.22
Ex servicemen	01	00.87
Not applicable	01	00.87
Grand Total	115	100

Marital status of victims was recorded among studied cases and 80% victims were found to be married and rest 20% were unmarried. Married men and women were more commonly affected with gun-shot injuries. [Table No. 6]

Table 6: Distribution of 115 Victim of Fire Arm Injuries cases According to Marital Status and Sex.

Marital Status	No. of Male	No. of Female	Total No. of cases	Percentage
Married	82	10	92	80.00
Unmarried	21	02	23	20.00
Total	103 (89.57%)	12 (10.43%)	115	100

Maximum incidences took place in village in accordance with the rural preponderance of victims. A major handful of them took place at home with least numbers occurring at workplace and in school. In 1 case the place remained undetermined as the dead body for shifted from scene of crime for concealment of the incidence, probably of homicidal intent. 66.95% incidences of firearm injuries occurred in outdoor settings whereas 32.18% incidences occurred in indoor settings.

Table 7: Distribution of 115 Victims of Firearm Injuries according to the place of incidence.

Incidence Place	Number of Cases	Percentage
Village	47	40.87
Home	30	26.09
Farm	11	9.57
City & Streets	10	8.70
State highways	09	7.83
Work place	06	5.22
School	01	0.87
Unknown	01	0.87
Grand Total	**115**	100

DISCUSSION

Maximum numbers of cases were from 20-39 years of age (66.96%) with peak incidence in 20-29 years (38.26%) which are the productive and active members of the society. The observations of the present study were similar to those of **Patowary AJ et al[3] ; Pradipkumar KH et al[4]; Sachan R et al[5] ; Kumar K et al[6] and Chaurasia N et al[7]** (peak incidence between 21-40 years of age in all). However, the results of the present study are variable from those of **Kumari S et al[8]** who reported maximum number of cases in 11-20 years followed by 21-30 years. The probable reason for this variation is the minor cultural and periodical differences as most other studies from the same state also report the highest incidences of such cases between 21-40 years. [Table No. 1] Males (89.57%) outnumbered the females (10.43%) in the present study with a male: female ratio of about 8.58:1 .Similar results have been reported by **Patowary AJ et al[3]**, (88.9% males); and, **Kumari S et al[8]** (90% males). Males are the active participants of the society and more commonly engaged in outdoor activities. Moreover, they are more prone to episodes of rage and revenge. This explains the male preponderance in all studies. [Table No. 1] The victims of firearm injuries in this study showed a rural preponderance (88.70%) with only 11.30% victims from urban population. **Chaurasia N et al[7]** also showed preponderance of rural victims with slight variations in proportions of the two (72.9& rural & 27.1% urban victims) in both studies. This is probably due to the easy availability of illegal firearms in rural regions owing to easier violation of laws. It is difficult to implement strict laws in rural areas for many reasons, like, large area, lower literacy rates, cultural influences, socio-political constraints etc. [Table No. 2] 79.13% victims in the present study were literate in the present study and 20.87% were illiterate. Although there was a rural preponderance in the study population yet the literacy status of the study population was high. It is expected from educated people to use such deadly weapons judiciously. However the literacy rates are not an indicator of the level of education. Educational status has not been described as a variable in most studies. [Table No. 3] Land and property disputes were the most common reason behind firearm injuries in this study (42.61%) followed by revenge & robbery (13.91% & 12.17% respectively); group quarrel accounted for another 6.96% cases. The results of the present study are quite similar to those of **Sachan R et al[5]** , who reported 29.51% gun-shot injuries due to property disputes; 21.1% for dacoity; 13.11% for personal enmity & 22.95% in group quarrel. But, in slight variation to those of **Chaurasia N et al[7]** and, **Kumar K et al[6]**, where maximum homicides occurred for personal enmity (58.3% & 51% respectively). Considering the occupational status of the victims, it was observed that agriculture was the most common occupation among victims (31.30%), which is quite obvious owing to the preponderance of rural population in

this study. 19.13% victims were self employed. In all, 81.74% victims were from non service sector including agriculture, business (24.35%), students (17.39%). 75% of females were housewives (7.83% of all cases). Occupation of one victim was unknown. The higher numbers of persons from agricultural field is also attributable to the fact that land is an important cause of disputes leading to such heinous crimes either in impulse or with planning. The business sector also included property dealers who comprised 5.22% of the total population. Our results are quite similar with slight variations to those of **Chaurasia N et al**[7] (90.6% victims from non service sector). [Table No. 5] About 80% victims of both sexes were married in the present study. It bears no correlation with such incidences but any type of outrageous behavior is more common after marriage due to the burden of responsibilities that come hand in hand with it. Data pertaining to marital status is not descriptive in most other studies but is quite evident by the majorly affected age ranges in those studies. [Table No. 6] The overall incidences in outdoor scenes were 66.95%. Home (26.09%) was the preferred incidence place, possibly in planned homicides for personal enmity and revenge, where the victim was attacked when relaxed in home. A total of 32.18 % cases occurred in indoor settings like home, school and work place. Our results are in accordance with those of **Kumar K et al**[6]. The place of incidence remained unknown in a single case. Among the two suicidal cases, one occurred at home of victim and the other at workplace.

CONCLUSION

The results of the present study support the argument that rigorous pursuit of campaign firearms without a license and country made guns may prove useful in reducing the number of firearm injuries in society. Following efforts, and individual, community and societal approaches are needed to alleviate firearm related injuries.

- Proper employment facility for the youth.
- Social stability and creation of proper political environment
- Strong and effective measures to control the unlicensed arms.
- Private gun ownership should be strictly limited.
- The issue of medical certificates for acquiring license of fire arms should be strictly monitored for psychiatric assessment.
- There should be proper training of maintenance, cleaning & handling of fire arm weapons at the time of sale to minimize accidental gunshot injuries.

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Load of Firearm Cases in Male at SMS Medical College, Jaipur

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Abstract

Introduction: A Firearm is a thermodynamic machine in which the potential energy of the gun- powder is transformed into the kinetic energy of the projectile.

Aims and Objective: To assess the load and analyze the male cases of firearm injuries.

Material and Methodology: The present prospective study had been conducted in the Department of Forensic Medicine, SMS Medical College & Hospital, Jaipur, Rajasthan during the period of One & half year from May 2014 to October 2015. All cases of firearm injuries that were received dead or live at SMS Hospital and its attached Hospitals, Jaipur was included in our study.

Result and Observation: In our study majority of firearm injury case [43 cases (40.78%)] were observed in the age group of 20-29 years followed by the age group of 30-39 years [28 cases (27.18%)]. Majority of the incidences of gun-shot injuries were homicidal in nature (80.58%) followed by accidental episodes (14.56%). Land and property disputes were the most common reason behind firearm injuries in this study (42.72%) followed by revenge & robbery (15.53% & 13.59 % respectively);Majority of the incidences occurred during evening in 43 cases (41.75%), followed by afternoon 40 cases (38.83%). There was presence of firearm entry wound in all victims. Overall,52 cases (50.49%) had a single entrance wound, 13 cases(12.62%) had two entry wounds, In summer season 43 cases (41.75%), spring 24 cases (23.30%), winter 20 cases (19.42%), autumn 16 cases (15.53%), were reported in studied cases. In majority of the cases (81.55%), there was no exit wounds while one exit wound was found in 17 cases (16.51%).In rest of the two cases, two exit were found in two cases.

Conclusion: The results of the present study support the argument that rigorous pursuit of campaign firearms without a license and country made guns may prove useful in reducing the number of firearm injuries in society.

Keyword: *Firearm Injury, Male, Prospective study, Jaipur.*

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Introduction

A Firearm is a thermodynamic machine in which the potential energy of the gun- powder is transformed into the kinetic energy of the projectile[1].

Firearms and explosives constitute convenient means of destroying human life from considerable distance, providing opportunity to the offender to escape;

it has been the weapon of choice for gangsters, terrorists, extremists, antisocial and anti-national elements for eliminating their victims. Its use is increasing in recent years because of easy availability due to manufacture of huge amount of arms, ammunition and explosives and free snuggling across the international borders[2].

Data on firearm injury in a particular geographic area can also give the reflection of its law and order situation. A low value can be described in favour of peace, harmony and security to human life[3].

There is growing concern about the indiscriminate use of firearms on a large scale, particularly in the last decade. The availability of firearms known as small arms and light weapons (SALW) has been described as a cancer spreading across the developing world[4].

This study was thus undertaken to assess the load of gun-shot injuries among in Jaipur region and to ascertain the medico-legal and socio-demographic profile of cases presented at SMS Medical College, Jaipur during the study period along with associated deaths in Jaipur region to look for reason behind them; and also to suggest few recommendations which may prove useful in bringing down the toll of firearm injuries in this region.

Aims and Objectives: To assess the load and analyze the cases of firearm injuries and associated deaths reported at the Department of Forensic Medicine, SMS Hospital, Jaipur during the study period (May, 2014 to October, 2015).

To study the load of firearm injuries and associated deaths reported at the Department of Forensic Medicine during the study period .

To study the medico-legal profile of firearm injuries.

To study the socio-demographic profile of victims of firearm injuries.

Material and Methodology

All the cases of firearm injuries, irrespective of age, gender and socioeconomic status received at the casualty of SMS Hospital, Jaipur, dead or alive, later admitted to various wards of SMS Hospital, Jaipur were included in the study. All cases of firearm injuries that were received dead at SMS Hospital and its attached Hospitals, Jaipur was autopsied at the mortuary of SMS Hospital, Jaipur and included in the study. Also the cases of non fatal firearm injuries admitted to various wards of SMS Hospital and its attached hospitals, Jaipur were included in the study after receiving an informed consent for the same. All the observations were recorded in the pre proposed Performa as detailed above. The results of the present study were further compared to other contemporary studies from various parts of the country.

Observations and Result

Table 1: Age and Sex Wise Distribution of Firearm Injuries Cases.

Age group (in yrs)	Total no. of cases	Percentage (%)
<10	01	0.97
10-19	08	7.77
20-29	42	40.78
30-39	28	27.18
40-49	13	12.62
50-59	09	8.74
>60	02	1.94
Total	**103**	**100**

Out of 103 cases, majority of the cases were in the age group of 20-49 years [(42 cases (80.58%)] which is productive age group of society. Among these, maximum cases were in the age group of 20-29 years which comprised about 40.78% of total cases. The other age groups affected in descending order were the 4th, 5th, 6th and 2nd decades. The least affected age groups with only 2 cases and 1 case below 10 years and above 60 years respectively.

Table 2: Manner Wise Distribution of Firearm Injuries Cases.

Manner	Total no. of cases	Percentage (%)
No. of Homicidal case	83	80.58
No. of Accidental case	15	14.56
Unknown cases	3	2.91
No. of Suicidal case	2	1.94
Total no. of cases	**103**	**100**

Homicides (80.58%) were the most common manner of firearm injuries in the present study followed by 15 cases (14.56%) accidental and 02 cases(1.94%) suicidal firearm injuries. The manner remained undetermined in 03 cases (2.91%).

Table 3: Motive Behind the Incidence Wise Distribution of Firearm Injuries Cases.

Motive behind incidence	Total no. of cases	Percentage (%)
Property disputes	44	42.72
Revenge	16	15.53
Robbery	14	13.59
Unknown	09	8.74
Accidental (no motive)	09	8.74
Group Quarrel	05	4.85
Love Affair	03	2.91
Defence	03	2.91
Grand Total	**103**	**100**

Land and property disputes were the most common reason behind firearm injuries in this study (42.72%) followed by revenge & robbery (15.53% & 13.59 % respectively); group quarrel accounted for another 5 cases(4.85%) and there were 03 cases each (2.91%) for defense and love matters/sexual jealousy. In 9 cases (8.74%), the motive remained undetermined.

Table 4: Time of Incidence Wise Distribution of Firearm Injuries Cases.

Day of Incidence	Total no. of cases	Percentage (%)
Evening	43	41.75
Afternoon	40	38.83
Morning	9	8.74
Night	10	9.71
Unknown	01	0.97
Total	**103**	**100**

Majority of the incidences occurred during evening in 43 cases (41.75%), followed by afternoon 40 cases (38.83%), night 10 cases (9.71%) & morning 9 cases (8.74%) The time of incidence remained undetermined in a single case (0.97%).

Table 5: Season of Incidence Wise Distribution of Firearm Injuries Cases.

Season of incidence	Total no. of cases	Percentage (%)
Summer	43	41.75
Spring	24	23.30
Winter	20	19.42
Autumn	16	15.53
Total	**103**	**100**

In summer season 43 cases (41.75%), spring 24 cases (23.30%), winter 20 cases(19.42%), autumn 16cases (15.53%), were reported in studied cases. Maximum were in summer and least in autumn.

Table 6: Number of Exit Wounds in Gun-Shot Injuries Wise Distribution of Firearm Injuries Cases.

Number of Exit wounds	Total no. of cases	Percentage (%)
None	84	81.55
One	17	16.51
Two	02	1.94
Total	**103**	**100**

In majority of the cases [84 cases (81.55%)], there were no exit wounds while one exit wound was found in 17 cases (16.51%).In rest of the two cases, two exit wound were found in two cases.

Discussion

Maximum numbers of cases were from 20-39 years of age (67.96%) with peak incidence in 20-29 years (40.78%) which are the productive and active members of the society. The observations of the present study were similar to those of **Patowary AJ et al[4], Sachan R et al[5], Kumar K et al[6]** (peak incidence between 21-40 years of age in all). However, the results of the present study are variable from those of **Kumari S et al[7]** who reported maximum number of cases in 11-20 years followed by 21-30 years. The probable reason for this variation is the minor cultural and periodical differences as most other studies from the same state also report the highest incidences of such cases between 21-40 years.

Homicides [83 cases (80.58%)] were the most common manner of firearm injuries in the present study followed by 15 cases (14.56%) accidental and 02 cases (1.94%) suicidal firearm injuries. The manner remained undetermined in 03 cases (2.91%). Homicidal intent was predominant in most other studies **Sachan R et al[5], Kumar K et al[6] and Kumari S et al[7].** Other studies have considered either only homicidal **Patowary AJ et al[4]**or suicidal firearm injuries. The preponderance of homicide in gun-shot injuries is explainable as these deadly weapons are generally used in planned manner or more so impulsively in a planned assault. It is not very easy to procure such weapons and not that very easy to carry it due to legal restraints, so, they are not

the weapon of choice in fights and assaults. They are mostly used in planned episodes of homicidal or suicidal injuries. Accidental injuries with firearms are also not uncommon as users are prone to such episodes while cleaning, maintenance or erratic handling of loaded guns. Accidental injuries were seen in this study in 16.52% cases but these results are quite high as compared to studies of **Kumar K et al[6] and Kumari S et al[7]**.

Land and property disputes were the most common reason behind firearm injuries in this study [44 cases (42.72%)]followed by revenge 16 cases(15.53%) & robbery 14 cases (13.59 %); group quarrel accounted for another 5 cases (4.85%) and there were 03 cases each (2.91%) for defense and love matters/sexual jealousy. In 9 cases (8.74%), the motive remained undetermined. As per **Kumar K et al[6]** the motive remained undetermined in a single case of accidental firing (1.73%). This difference is attributable to the variation in the proportion of accidental incidences in the two studies. There were 10 cases of purely accidental gun-shot injuries where motive was lacking. According to **Patowary AJ et al[5] .** Most cases were due to militant activities, encounters, riots, robberies or family quarrel. This variation from our study is due to the regional variations in the areas of study as Guwahati and Imphal are militant activity prone areas. The results of the present study are quite similar to those of **Sachan R et al[5]**. But, in slight variation with **Kumar K et al[6]** where maximum homicides occurred for personal enmity. The motives behind the homicidal attack with firearm weapons were well represented in different cases with property land disputes majorly responsible followed by personal enmity and robbery.

Most of the events of firearm injuries occurred during evening hours (41.75%) followed by afternoon (38.83%). These are the hours of work and business, thus prone to activity during which the untoward event took place. 8.74% incidences took place in morning hours. Thus, it was observed that in 47.57% cases, the incidence took place in broad daylight and 52.43% cases occurred after sunset; as also reported by **Kumar K et al[6].** The late night hours witnessed the least numbers of gun-shot injuries (8.7%) in the present study which is in contrast to the findings of **Kumari S et al**. The suicides (two cases) were committed in morning and evening each.

None of the season was poorly represented by episodes of firearm injuries and deaths. However, summer season was most flooded with events of firearm injuries in the present study (41.75%) followed by spring (23.30%) and winter (19.42%). This is quite explainable as maximum events in this study took place for land disputes in villages. Summer season is a comparatively relaxing one for those engaged in Agriculture as the main crop of this region is through by the end of spring. After the harvest of the crop, the disputes probably come to surface owing to distribution of revenue generated.

Exit wounds were present in only 84 cases (18.26%) i.e. in majority of the victims, firearm exit wounds were not present. These are quite less in number due to the predominance of distant fires in this study. In the present study, a single exit wound was found in 17 cases (16.51%) and in 2 cases (1.74%) there were two exit wounds. These results are quite low in comparison to those of **Kumar R et al[2]** and, **Kumari S et al[7]** who reported presence of exit wounds in 61.36% & 60% victims respectively.

Conclusion

This study indicated that the most common victims of firearm injuries were young males of bread earning age followed by youth which raises concern towards this issue. Certain changes may minimize mortality and disability due to firearm injuries, also reducing the costs to the community. As a result of the invention of more advanced firearms and availability at the global level, death rates due to firearm injuries have increased recently. There is a powerful correlation between acquisition of a firearm and its use in murders, suicides and unintentional deaths. So, there is a need to decrease the number of firearms used and sold in India.

The results of the present study support the argument that rigorous pursuit of campaign firearms without a license and country made guns may prove useful in reducing the number of firearm injuries in society. Educational efforts and individual, community and societal approaches are needed to alleviate firearm related injuries.

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Conflict of Interest: Nil

Acknowledgement: Nil

Ethical Clearance: It is taken from Ethical committee of SMS Medical College, Jaipur before starting of study.

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Delay in treatment proves fatal

By Radhika D Srivastava
Times News Network

NEW DELHI: Hindu Rao Hospital which is equipped with a non-functional CT scan machine and no neurosurgeons, kept a road accident victim with a head injury for 15 hours before referring him to a specialised hospital.

The delay proved to be fatal as the victim could have been easily saved otherwise.

Jasbir Singh, 23, met with an accident near Wazirpur on September 12 around 7.30 pm. He was apparently riding a two-wheeler which was hit by a heavy vehicle.

Brought to Hindu Rao Hospital around 8.30 pm, doctors found his pupils dilated and that he was not responding to "painful stimulus." Singh quite clearly had head injuries.

He was admitted and administered decongestant drugs. His condition was described as "extra-dural haematoma", a situation when blood collects between the brain's outermost protective membrane and the skull.

A doctor explained, "Just a simple, small hole — known as a Burr Hole — could have been made in the skull and the blood drained out."

All through the night Singh bled inside the head. The hospital's CT scan machine had not been functioning for the past two years, but Singh was not referred to another hospital.

The next morning, September 13, Singh's condition had visibly deteriorated, and his family was told to take him to Sushrut Trauma Centre on Ring Road.

Neurosurgeons at the centre were appalled by the delay. A doctor said, "If a hospital does not have a CT scan machine it has no business to keep a head injury patient for over 15 hours."

Within hours Singh was operated on. He remained in intensive care for four days and died on September 17.

Hindu Rao hospital's chief medical officer Dr A K Pasrecha said, "When Singh was brought to us he appeared to be under the influence of alcohol. The doctor on duty did not see any sign of head injury."

Dr Pasrecha added, "The next morning when the alcohol influence reduced, we suspected a head injury and referred him to Sushrut Trauma Centre." The case history from Hindu Rao sent along with Singh made no mention of alcohol.

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Traumatic inguinal hernia: An uncommonly reported entity

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Case report

Traumatic inguinal hernia: An uncommonly reported entity

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Devendra Jadav, Asharam Gorchiya, Raghvendra Singh Shekhawat and Tanuj Kanchan

Abstract

Traumatic abdominal wall herniation, especially of the groin region, is a rare condition and typically results from a high-energy trauma to the abdominal wall. We report a fatal case of a road-traffic collision involving a young male motorcyclist who collided with a speeding lorry. The victim sustained multiple injuries over the chest and abdomen, with traumatic inguinal herniation causing gross distension of the scrotum. At autopsy, multiple lacerations of thoracic and abdominal organs were seen, along with traumatic disruption of the right inguinal canal. The contused terminal ileum was present in the scrotal sac. A literature search has revealed a limited number of reported cases of gross inguinal herniation following thoracoabdominal trauma. In cases of high-energy trauma to the thoraco-abdominal region with unilateral or bilateral distension of the scrotum, the possibility of herniation of the abdominal contents into the scrotal sac should be considered by the forensic pathologist.

Keywords

Traffic accident, autopsy, blunt injury, abdominal injury, traumatic inguinal hernia

Introduction

A traumatic abdominal wall hernia (TAWH) is described as a hernia produced due to trauma disrupting the muscles and fascia without penetrating the overlying skin and in the absence of a previous hernia defect at the site of the impact.[1] TAWH was first documented by Selby[2] more than a century ago. TAWH, especially of the inguinal region, is a rare condition in the clinical setting, with a high risk of associated intra-abdominal injuries.[3] The three potentially weak areas of the abdominal wall – the inguinal region, the region lateral to the rectus muscle and the region above the iliac crest in the flank region – are the common sites for TAWH.[4] The inguinal canal lies over medial half of the inguinal ligament and extends from the deep inguinal ring to the superficial inguinal ring. The literature on traumatic cases with gross disruption of the inguinal canal is limited.[5,6] We present a fatal case of traumatic inguinal herniation with complete disruption of all boundaries of the inguinal canal, including deep and superficial rings, causing traumatic herniation of 90 cm of the terminal ileum into the scrotal sac. The reported case highlights an incidental finding of traumatic inguinal hernia, which at times can have serious clinical and medico-legal considerations.

Case report

A 20-year-old male motorcyclist was brought dead to the emergency room with an alleged history of a side-on collision and subsequent run over by a speeding lorry. During autopsy, on external examination, multiple impact and grazed abrasions were present over the chest and abdomen (Figures 1 and 2). Gross distention of the scrotum was evident (Figure 1). Internal examination revealed a fissure fracture of the anterior and middle cranial fossa on the left side, a complete transection of the cervical vertebrae between C5 and C6 and multiple fractures of the sternum, clavicle and ribs bilaterally. Thoracic and abdominal wall examination revealed multiple contusions. All the thoracic and abdominal organs had multiple contusions and lacerations. A significant defect was evident in the lower abdominal wall through which around 90 cm of the

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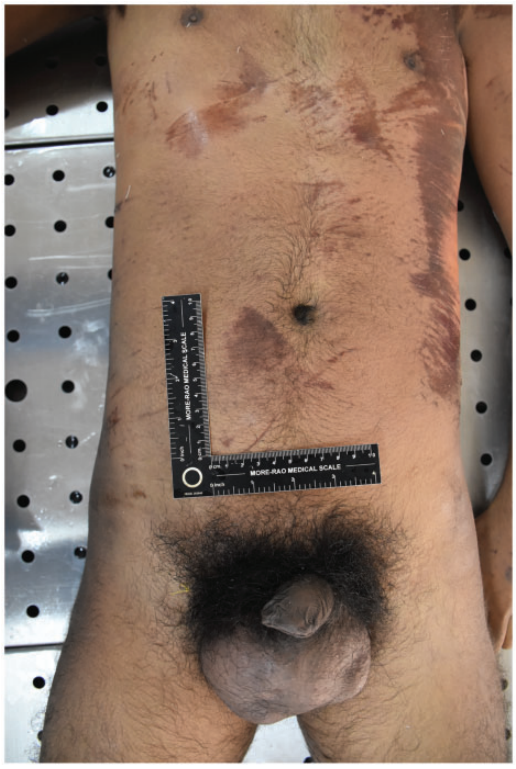

Figure 1. Multiple grazed abrasions over the left side of the trunk and gross distension of the scrotum.

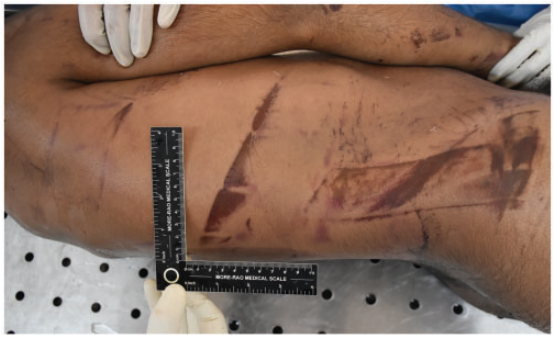

Figure 2. Multiple impact abrasions over the right side of the trunk suggestive of tyre imprint abrasions caused by run over.

terminal ileum was herniating into the scrotal sac (Figures 3 and 4). The cause of death was opined as multiple injuries sustained to the head, neck and trunk. Prior history of inguinal hernia was excluded by asking relatives.

Discussion

The association of blunt trauma to the abdomen and a traumatic inguinal hernia is not infrequently reported in surgical practice. However, traumatic

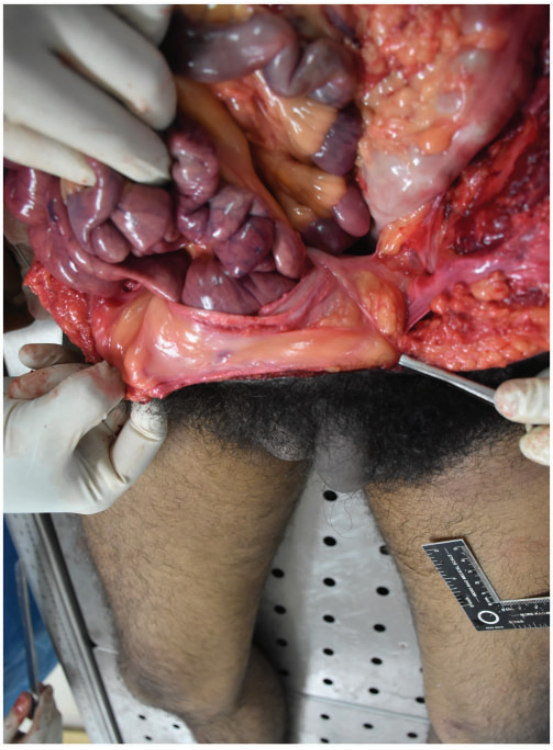

Figure 3. Large defect in the right-sided lower part of the anterior abdominal wall through which the terminal ileum is herniated into the scrotum.

herniation of the intestine remains a rarity in medico-legal autopsies. The most common aetiological factors for traumatic herniation include low-energy trauma such as handlebar injury, bullhorn, sports and seatbelt injuries and high-energy trauma due to road-traffic accidents.[7]

Three types of TAWHs are defined according to the mechanism of injury: type 1 TAWH that describes small hernia in the anterio-inferior abdominal wall and inguinal region caused by low-energy blunt trauma (e.g. handlebar injuries); type 2 TAWH that are large hernia defects caused by high-energy trauma such as road-traffic accidents; and type 3 TAWH that are rare variants seen in acute deceleration injuries.[8]

Blunt trauma to the abdomen can lead to the application of tangential and shearing forces over the abdominal wall, which causes disruption of the abdominal wall muscles and fascia that may result in herniation of the abdominal viscera. As traumatic forces on the abdomen are distributed over a broad area and the skin is more elastic than other layers, the skin usually remains intact.[9] A sudden increase in intra-abdominal pressure along with the shearing effect on the abdominal muscle and fascia is considered the primary aetiological mechanism in the development of traumatic

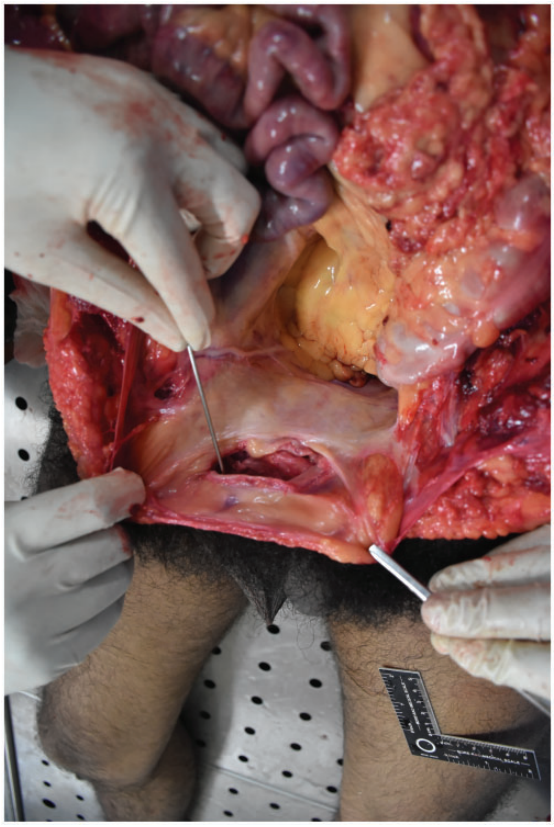

Figure 4. Large defect in the right-sided lower part of the anterior abdominal wall with complete disruption in the inguinal canal, as evident after removal of the terminal ileum that traversed through it into the scrotum. A probe was inserted through it into the scrotum.

hernias. Further, diffuse high-energy impact to the abdomen can cause a large abdominal wall defect, and its association with intra-abdominal injuries is very high. The incidence of intra-abdominal injuries in cases of TAWH is reported in 25–70% of cases.[10]

Netto et al.[3] in their retrospective evaluation of 34 patients with TAWHs, highlighted the mechanism and severity of injuries and made clinical recommendations. First, the mechanism of injury should be taken into consideration in patient management, as high-energy traumas often require urgent exploration. Second, the visible hernia has a high probability of associated intra-abdominal injuries. Third, an occult hernia diagnosed only by radiological means may not require urgent surgical management. Clinically, the appearance of a bulge or tender swelling on the abdominal wall with or without associated skin lesions after an incident of blunt trauma to the abdomen helps establish its traumatic origin, and in doubtful cases, a contrast-enhanced computed tomography scan of the abdomen is considered a valuable tool for early detection of traumatic hernias.[7,11] TAWH in itself can be a primary cause of death. It is recognised that delayed diagnosis of this condition can lead to bowel ischaemia/infarction, whilst it may also be associated with bowel perforation, both of which can prove fatal if untreated.

In cases of high-energy trauma, extra-abdominal injuries such as fractures of vertebrae and the ribs may accompany it.[12] Multiple fractures of the thoracic cage, skull and complete transection of cervical vertebrae were observed in our case which itself signifies the involvement of high-energy crush and shearing forces in the reported case. There is a high possibility of severe intra-abdominal injuries in the case of TAWH following high-energy trauma of the abdomen. Unilateral or bilateral distension of the scrotum following high-velocity trauma to the thoraco-abdominal region should raise a suspicion of TAWH after ruling out scrotal haematoma and emphysema.

Declaration of conflicting interests

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Prevalence of microalbuminuria in patients with essential hypertension- A clinical study

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Abstract

Background: The present study was conducted to record prevalence of Microalbuminuria in patients with essential hypertension.

Materials & Methods: The present study was conducted on 102 patients of diagnosed essential hypertension of both genders. Microalbuminuria was measured in all patients in a 24h urinary sample.

Results: Out of 102 patients, males were 62 and females were 40. Out of 102 patients, microalbuminuria was present in 40 patients. Maximum cases were seen in age group >70 years (20) followed by 6-70 years (14), 50-60 years (4) and 40-50 years (2).

Conclusion: Authors found the presence of microalbuminuria in a significant number of newly detected and untreated patients of essential hypertension.

Keywords: Essential hypertension, microalbuminuria, coronary heart disease

Introduction

Hypertension is a disorder of circulatory regulation. Sustained hypertension causes accelerated atherosclerosis with consequent coronary heart disease (CHD), heart failure, and stroke and renal failure. If untreated, approximately 50% of patients develop heart disease, 33% develop stroke, and 10%–15% develop renal failure [1].

Hypertension (HT) is a growing public health problem and it is now being widely reported in many rural and urban parts as one of the commonest cause of morbidity and mortality [2]. The reasons for this growing burden are multiple, ranging from socio-economic changes and genetic influence. At a genetic level, there is growing evidence showing an association between elevated diastolic BP and CaMK4 affecting endothelial functions like controlling vascular resistance hence increasing the risk of HT [3].

Microalbuminuria is an early indicator of renal damage and has been demonstrated as one of the principal predictive factors of cardiovascular (CV) complications, all cause and cardiovascular mortality independent of the traditional risk factors like dyslipidemia, hypertension [4]. Left ventricular hypertrophy (LVH) determined either by standard 12-lead electrocardiography (ECG) or echocardiography is also a marker of subclinical organ damage related to hypertension and an independent predictor of cardiovascular morbidity/mortality. Hypertension affects the heart by increasing after load resulting in the left ventricular hypertrophy (LVH) and stiffening of the left ventricle leading ultimately to increase in the left ventricular mass (LVM). LVH is the most common abnormality in patients with hypertension and significant marker of subclinical cardiovascular disease [5].

Screening of all recently diagnosed patients of essential hypertension for microalbuminuria may be a reasonable strategy to predict the presence of ongoing vascular damage, cardiac geometric adaptation, and the future risk for cardiovascular events [6]. The present study was conducted to record prevalence of Microalbuminuria in patients with essential hypertension.

Materials & Methods

The present study was conducted in the department of general medicine. It comprised of 102 patients of diagnosed essential hypertension of both genders. The study was approved from ethical committee. All patients were informed and their consent was obtained.

Demographic profile of the patients was recorded. Patients satisfying inclusion and exclusion criteria were subjected to detailed history and physical examination with special emphasis on the examination of cardiovascular system.

Microalbuminuria was measured in all patients in a 24h urinary sample. Others investigations are blood urea and serum creatinine, plasma glucose – fasting and postprandial, serum electrolytes–sodium and potassium, serum uric acid, serum calcium and phosphate, lipid profile, x-ray chest and electrocardiography. Results thus obtained were statistically analyzed.

Results

Table I: Distribution of patients

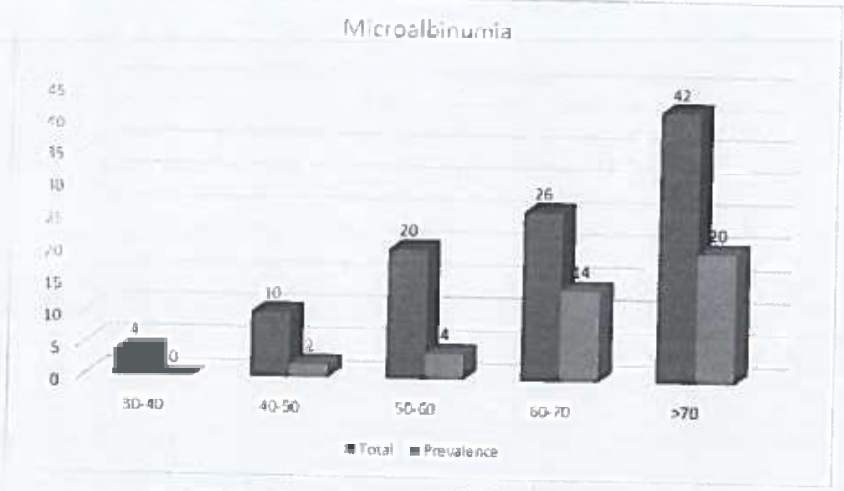
Total- 102		
Gender	Male	Female
Number	62	40

Table I shows that out of 102 patients, males were 62 and females were 40.

Table II: Prevalence of microalbuminuria based on age groups

Age groups (Years)	Total	Prevalence
30-40	4	0
40-50	10	2
50-60	20	4
60-70	26	14
>70	42	20

Table II, graph I shows that out of 102 patients, microalbuminuria was present in 40 patients. Maximum cases were seen in age group >70 years (20) followed by 6-70 years (14), 50-60 years (4) and 40-50 years (2).



Graph I: Prevalence of microalbuminuria based on age groups

Discussion

Hypertension is one of the major public health problems. Worldwide prevalence of hypertension is as much as 1 billion while 7.1 million deaths may be attributable to hypertension [7]. The JNC 7 report states that high blood pressure is the number one attributable risk for death in the world. Uncontrolled hypertension is directly associated with end organ damages including CHD, CHF, LVH, stroke, and peripheral vascular disease. Limited evidence is available among Indian patients regarding significance of microalbuminuria (MA) in context of hypertension and future cardiovascular morbidity [8]. The present study was conducted to record prevalence of Microalbuminuria in patients with essential hypertension.

In present study out of 102 patients, males were 62 and females were 40. Maggon *et al.* [9], determined the prevalence of MA in hypertensive patients and to examine its correlation with severity of hypertension, left ventricular hypertrophy (LVH), and common carotid intima-media thickness (CCIMT). This study demonstrates the presence of MA in a significant number of newly detected and untreated patients of essential hypertension. Further, MA had a statistically significant relationship with LVH and CCIMT. Thus, screening of all recently diagnosed patients of essential hypertension for MA may be a reasonable strategy to predict the presence of future cardiovascular risk. We found that out of 102 patients, microalbuminuria was present in 40 patients. Maximum cases were seen in age group >70 years (20) followed by 6-70 years (14), 50-60 years (4) and 40-50 years (2). Nabbaale *et al.* [10], determined the prevalence of microalbuminuria, LVH in patients with microalbuminuria and the correlation between microalbuminuria and LVH among newly diagnosed black adult hypertensive patients attending a large outpatient hypertension. The mean age/standard deviation of the study participants was 54.3 ± 6.2 years with a female predominance (162, 63.3%). The prevalence of microalbuminuria among newly diagnosed hypertensive patients was 39.5%. The prevalence of LVH among patients with microalbuminuria was found to be 17%. There was a positive correlation between microalbuminuria and left ventricular hypertrophy among the newly diagnosed adult hypertensive patients. This study demonstrates that microalbuminuria is highly prevalent among newly diagnosed black hypertensive patients and in the presence of LVH. There is also a positive correlation between microalbuminuria and LVH among newly diagnosed hypertensive patients. Since it is a less costly and readily available test, it can be used to predict presence of LVH especially in resource limited settings where ECHO services are not readily available.

Hypertension doubles the risk for symptomatic CAD, including acute myocardial infarction and sudden death and more than triples the risk for CHF. Hypertension places increased tension on the left ventricular myocardium that is manifested as stiffness and hypertrophy, which accelerates

the development of atherosclerosis within coronary vessels [10].

The combination of increased demand and lessened supply increases the likelihood of myocardial ischemia and thereby leading to a higher incidence of myocardial infarction, sudden death, arrhythmias, and congestive failure in hypertensive patients. Endothelial dysfunction and chronic inflammation have been suggested as possible causes to explain the association between MA and cardiovascular disease. Microalbuminuria is an early manifestation of kidney damage and independently predicts cardiovascular disease (CVD). Left ventricular hypertrophy (LVH) is also an early marker of cardiac manifestation of target organ damage among hypertensive patients [12].

Conclusion

Authors found the presence of microalbuminuria in a significant number of newly detected and untreated patients of essential hypertension.

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Original Research

Treatment response in pulmonary tuberculosis patients: An observational study

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ABSTRACT:

Background: Current drug regimens grew out of empiric observations and failure of early clinical strategies. Treating tuberculosis with streptomycin, isoniazid, or pyrazinamide monotherapy in the 1950s and 1960s led to an initial favorable response that was quickly abolished by the emergence of resistance. **Aim of the study:** To evaluate treatment response in pulmonary tuberculosis patients. **Materials and methods:** The study was conducted in the Department of General Medicine of the Medical Institute. A total of 100 patients were studied, information retrieved from the records includes socio-demographic profile of the patients; date of TB diagnosis and treatment outcome. All the patients underwent DOTS therapy for the treatment of pulmonary TB. **Results:** Mean age of the patients was 46.98 years. Number of male and female patients was 51 and 49 respectively. The number of PTB+ patients was 71 and the number of PTB- patients was 29. Successful treatment outcome was seen in 73% patients. Unsuccessful treatment outcome was seen in 27% patients. **Conclusion:** The treatment response is fairly successful. 29% patients had unsuccessful treatment response. Regular follow up of patients with unsuccessful treatment response and awareness creation through health education for rural patients in the course of treatment is vital.

Keywords: TB treatment, isoniazid, treatment outcome.

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Introduction:

Current drug regimens grew out of empiric observations and failure of early clinical strategies. Treating tuberculosis with streptomycin, isoniazid, or pyrazinamide monotherapy in the 1950s and 1960s led to an initial favorable response that was quickly abolished by the emergence of resistance.[1-3] Use of combination therapy led to reduction in the emergence of drug resistance and became the standard for antituberculosis therapy.[4] A related rationale has been a belief that in cavitary tuberculosis, there are thought to be three populations of Mycobacterium tuberculosis: bacilli in log-phase growth, slowly replicating bacilli under acidic conditions, and nonreplicating bacilli under hypoxic conditions.[5] Drugs such as rifampin, isoniazid, and pyrazinamide are thought to have selective action on each of these populations, making it necessary to use multiple-drug therapy to eradicate all bacilli. Isoniazid is thought to kill bacilli in log-phase growth, whereas pyrazinamide is thought to kill slowly replicating bacilli during the first 2 months of the inital phase of therapy. Rifampin is thought to slowly kill nonreplicating persistent bacilli during the 6 months of therapy, with isoniazid added to prevent resistance during the continuation phase. These very popular concepts were developed to explain observed therapeutic actions of drugs, but have yet to be stated as falsifiable hypotheses and interrogated with use of modern experimental techniques.[6] Hence, the present

study was conducted to evaluate treatment response in pulmonary tuberculosis patients.

Materials and methods:

The study was conducted in the Department of General Medicine of the Medical Institute. The ethical clearance for the study was obtained from the ethical board of the institute prior to commencement of the study. For the study, we retrospectively viewed the medical records of the TB patients reporting at TB clinic of the medical hospital. A total of 100 patients were studied. Information retrieved from the records includes socio-demographic profile of the patients, date of TB diagnosis and treatment outcome. All the patients underwent DOTS therapy for the treatment of pulmonary TB. Data were collected in data collection format prepared for this purpose. In our study, smear-positive pulmonary TB (PTB+) was defined as patients with at least two positive sputum specimens for acid fast bacilli (AFB) by microscopy. Smear-negative pulmonary TB (PTB-) was defined as patients with symptoms suggestive of TB, with at least two sputum specimens which were negative for AFB by microscopy, and with chest radiographic abnormalities consistent with active PTB. The treatment outcome was categorized according to WHO as successful outcome and unsuccessful outcome. Success outcome was defined as cured TB patients (negative smear microscopy at the end of treatment and on at least one previous follow-up test) or completed treatment with resolution of symptoms. Unsuccessful outcome was defined as treatment failure (remaining smear-positive after 5 months of treatment), defaulted (patients who interrupted their treatment for two consecutive months or more after registration), or died.

The statistical analysis of the data was done using SPSS version 20.0 for windows. The Student's t-test and Chi-square test were used to check the significance of the data. The p-value less than 0.05 was predetermined as statistically significant.

Results:

A total of 100 TB patients were studied. Table 1 shows the demographic data of the patients. Mean age of the patients was 46.98 years. Number of male and female patients was 51 and 49 respectively. The number of PTB+ patients was 71 and the number of PTB- patients was 29. Table 2 shows the treatment outcome of TB patients. Successful treatment outcome was seen in 73% patients. Unsuccessful treatment outcome was seen in 27% patients. 7% patients were defaulted, 12 % died and 8% patients had treatment failure. On comparing the results were found to be statistically significant ($p<0.05$)[Fig 1 and 2].

Table 1: Demographic data of the patients

Parameters	Study group
Mean age (years)	46.98
Male/Female patients	51/49
No. of PTB+ patients	71
No. of PTB- patients	29

Fig 1: Demographics

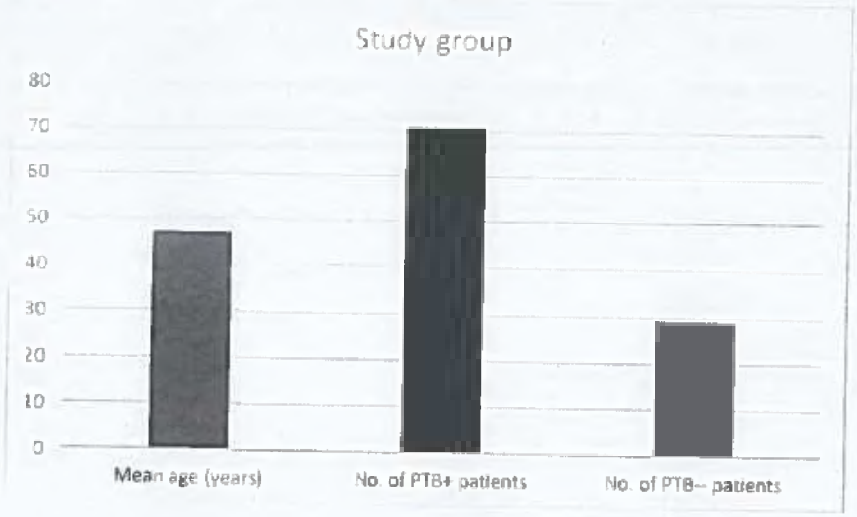
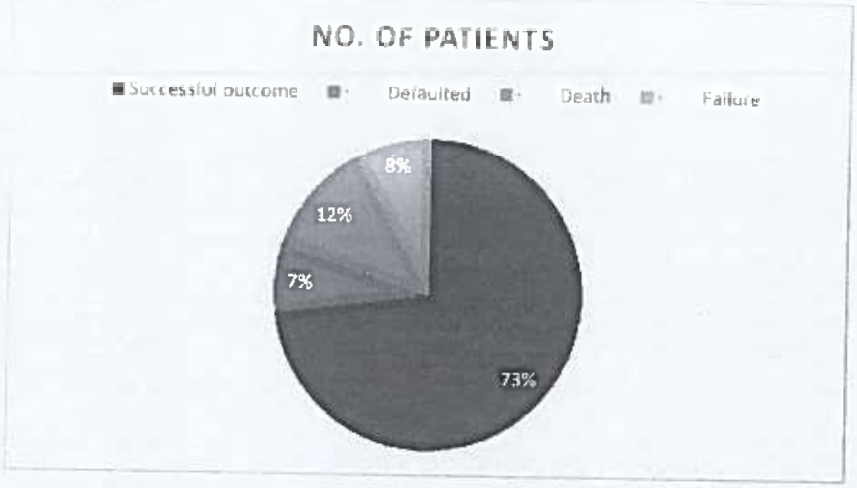


Table 2: Treatment outcome of TB patients

Treatment outcome	No. of patients	p-value
Successful outcome	73 (73%)	0.02
Unsuccessful outcome		
• Defaulted	7 (7%)	
• Death	12 (12%)	
• Failure	8 (8%)	

Fig 2: Treatment outcome



Discussion:

In the present study we evaluated treatment response in pulmonary tuberculosis patients. We observed that treatment response was successful in 71% of patients but unsuccessful in 29% patients. The results were statistically significant. The results were compared with previous studies and results were consistent with previous studies. Feleke BE et al assessed time to clinical response, the incidence density for clinical response and determinants of clinical response of tuberculosis (TB) patients in the intensive phases of TB treatment. Prospective cohort study design was implemented. The target population for this study was all patients following the directly observed therapy. Baseline data has been collected during the start of the directly observed TB treatment strategy. They have been collected updated data after the seven days of the baseline data collection, then after every seven days updated data has been collected from each pulmonary and extra pulmonary TB patients. Kaplan Meier curve was used to estimate time to clinical response. Incidence density using person days was used to estimate incidence of clinical response. Cox proportional hazard model was used to identify the predictors of clinical responses. A total of 1608 TB patients were included with a response rate at 99.5%. The mean age of the respondents was 24.5 years [standard deviation (SD) 14.34 years]. The incidence density for clinical response was 1429/38529 person days. One fourth of the TB patients showed clinical response at day 14, 25% of at day 21 and 75% a at day 31. Predictors of clinical response for TB patients includes: age), type of TB, Previous history of TB, Intestinal parasitic infection, hemoglobin, weight gain, Micronutrient supplementation, male sex. The clinical responses for extra-pulmonary TB patients were slower than pulmonary TB. Deworming and micronutrient supplementation should be considered as the additional TB treatment strategy for TB patients. Djoba Siawaya JF et al investigated the profiles of 30 proinflammatory, anti-inflammatory and angiogenic factors [epidermal growth factor, eotaxin, fractalkine, granulocyte colony-stimulating factor, granulocyte–macrophage colony-stimulating factor, interleukin (IL)-1α, IL-1β, IL-1ra, IL-2, IL-4, IL-5, IL-6, IL-7, IL-8, IL-10, IL-12p40, IL-12p70, IL-13, IL-15, IL-17, interferon-γ, interferon-inducible protein-10, Krebs von den Lungen-6, monocyte chemotactic protein-1, macrophage inflammatory protein (MIP)-1α, MIP-1β, sCD40L, transforming growth factor-α, tumour necrosis factor-α and vascular endothelial growth factor] in the plasma of 12 healthy tuberculin skin test-positive community controls and 20 human immunodeficiency virus-negative patients with active tuberculosis (TB) and

identified potential biomarkers for early treatment response. We showed differences in the level of circulating cytokines between healthy controls and TB patients, but also between fast responders and slow responders to anti-tuberculosis treatment. The general discriminant analysis based on pre-treatment and week 1 measurements identified 10 sets of three-variable models that could classify fast and slow responders with up to 83% accuracy. Overall, this study shows the potential of cytokines as indicators of anti-tuberculosis treatment response. [7, 8]

Abebe G et al investigated the treatment outcome and associated factors with an unsuccessful outcome at Jimma University Medical Center (JUMC), Southwest Ethiopia. A 5-year retrospective analytical study, including all types of TB cases who sought care at JUMC between September 1, 2012, and August 31, 2017, was conducted. Treatment outcomes and TB types were categorized according to the National TB Control guideline. Bivariate analysis was used to analyze the association between treatment outcome and potential variables. Overall data from 1249 patients' records were included in the study. The proportion of male patients was higher (815, 65.3%) than that of females. The mean age (± standard deviation, range) of the cases was 26 (±11. 6, 1-71) years. Of the total, 292 (23.3%) were smear-positive pulmonary TB (PTB), 489 (39.2%) smear-negative PTB, and 468 (37.5%) extra-PTB (EPTB) cases. Available treatment outcomes indicate that 253 (20.2%) were cured, 850 (68.0%) completed therapy, 58 (4.8%) died, 83 (6.6%) defaulted, and 5 (0.4%) failed the therapy. About 76 (5.6%) cases were transferred out and 44 (3.2%) cases were lost to follow-up. In total, 146 (11.7%) patients had an unsuccessful outcome. Unsuccessful treatment outcome was associated with smear-negative PTB, EPTB, and unknown human immunodeficiency virus (HIV) status. They concluded that the treatment success rate of overall TB patients is lower than end TB Strategy target of ≥90% success rate. Smear-negative PTB, EPTB cases, and those with unknown HIV status tend to have unsuccessful outcome. Gebrezgabiher G et al determined the treatment outcome of TB patients and investigate factors associated with unsuccessful outcome at Dilla University Referral Hospital, southern Ethiopia. Five years TB record of TB clinic of the hospital was reviewed. A total 1537 registered TB patients with complete information were included. Of these, 942 were male, 1015 were from rural areas, 544 were smear positive pulmonary TB (PTB+), 816 were smear negative pulmonary TB (PTB-) and 177 were extra pulmonary TB (EPTB) patients. Records of the 1537 TB patients showed that 181 (11.8%) were cured, 1129(73.5%) completed treatment, 171 (11.1%) defaulted, 52 (3.4%) died and 4 (0.3%) had treatment failure. The overall mean treatment success rate of the TB patients was 85.2%. The treatment success rate of the TB patients increased from 80.5% in September 2008-August 2009 to 84.8% in September 2012-May 2013. Tuberculosis type, age, residence and year of treatment were significantly associated with unsuccessful treatment outcome. The risk of unsuccessful outcome was significantly higher among TB patients from rural areas compared to their urban counterparts. Unsuccessful treatment outcome was also observed in PTB- patients and EPTB compared to the PTB+ patients. In conclusion, it appears that DOTS have improved treatment success in the hospital during five years. Regular follow-up of patients with poor treatment outcome and provision of health information on TB treatment to patients from rural area is recommended. [9, 10]

Conclusion:

Within the limitations of the present study, it can be concluded that the treatment response is fairly successful. 29% patients had unsuccessful treatment response. Regular follow up of patients with unsuccessful treatment response and awareness creation through health education for rural patients in the course of treatment is vital.

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ORIGINAL ARTICLE

Assessment of Cases of Dengue Fever in Study Population- A Clinical Study

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ABSTRACT:

Background: Dengue viruses are mosquito-borne flavi viruses that plagued people for centuries. Dengue fever (DF) and its more severe form i.e. dengue hemorrhagic fever (DHF), are caused by any one of the four serotypes of dengue virus belonging to the genus flavivirus transmitted by Aedes aegyptei. The present study was conducted to assess the cases of dengue in study population. **Materials & Methods:** This study was conducted in the department of general medicine in year 2015. It included 450 patients of both gender. After taking the history, clinical examination and laboratory investigation like complete hemogram, urea, creatinine, liver function test, chest, X-ray, ECG and ultra sound of abdomen was taken. Platelet counts were estimated. The diagnosis of pleural effusion was confirmed by X-chest. In ECG finding tachycardia was present in all the patients of shock and haemorrhage. All were subjected to serology NS1, IgM, IgG/IgM with rapid kit test. **Results:** Out of 450 patients, males were 220 and females were 230. The difference was non- significant (P-1). Age group 21-30 years consisted of 180 patients, age group 31-40 years had 135 patients, age group 41-50 years had 77 patients and >50 years had 58 patients. The difference was significant (P- 0.04). Common clinical manifestations in patients were fever (410), headache (250), myalgia (205), rash (157), bleeding (42), GIT manifestations (386) and shock (12). The difference was significant (P- 0.05). Platelets counts were <10000/cmm in 50 patients, <250000/cmm in 135 patients, <75000/cmm in 210 patients and 75000-150000/cmm in 55 patients. The difference was significant (P- 0.05). Serological test showed NS1 in 140 patients, IgM in 178 patients and IgG in 132 patients. Most of cases were seen in winters, September (125), October (210), November (70), December (35), January (5), February, may and july (1) each and September (2). The difference was significant (P- 0.05). **Conclusions:** Dengue is a viral fever caused by biting of mosquito. Proper care should be taken to avoid accumulation of water to prevent spread of mosquitoes. Bleeding, fever and decrease in platelets counts should be dealt seriously.

Key words: Aedes aegyptei, Dengue fever, flavi viruses

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INTRODUCTION

Dengue viruses are mosquito-borne flavi viruses that plagued people for centuries. Dengue fever (DF) and its more severe form i.e. dengue hemorrhagic fever (DHF), are caused by any one of the four serotypes of dengue virus (DEN-1, DEN-2, DEN- 3, DEN-4) belonging to the genus flavivirus transmitted by Aedes aegyptei. Infection by one serotype generates life-long immunity against the same serotype, but gives transient/partial protection against the other serotypes.[1]

Sequential infection with another serotype can result in the more severe DHF. Immunology of Dengue Fever if characterized by an initial viremic phase which corresponds to the first 3 days of illness followed by a critical immune phase spanning from 3rd to 6th day of illness. The phase of dengue beyond 6th day of illness is called recovery phase. A sizable number of patients take longer to recover.[2]

During the febrile stage, people may also have: pain all over their bodies, headache a rash (this happens in 50% to 80% of people who get sick from dengue), petechiae (small red spots on the skin). These are caused by capillaries breaking. This makes the blood leak out and shows up under the skin. Small amounts of bleeding from the mucous membranes in the mouth and nose

The febrile stage usually lasts 2 to 7 days. This stage ends when a person's high fever is gone. It can cause altered mental status. This happens in 0.5% to 6% of people with very bad dengue fever. It can happen when the dengue virus causes an infection in the brain.[3] It can also happen when important organs, like the liver, are not working correctly

because of dengue. Neurological disorders involving brain and the nerves, like Guillain-Barré syndrome [5] and Post-dengue acute disseminated encephalomyelitis. Rarely, it can result into infection of the heart, or sudden liver failure.[6]
Dengue infection represents a considerable disease burden in many tropical and sub-tropical countries, particularly in children and young adults, living in urban and semi-urban areas. Globally about 50 million infections occur which is projected to increase. In endemic areas, dengue infection is a leading cause of hospitalisation and deaths among children.[5] The present study was conducted to assess the cases of dengue in study population.

MATERIALS & METHODS

This study was conducted in the department of general medicine in year 2015. It included 450 patients of both gender. All were informed regarding the study and written consent was taken. General information such as name, age, gender etc. was recorded in patients record file. After taking the history, clinical examination and laboratory investigation like complete hemogram, urea, creatinine, liver function test, chest, X-ray, ECG and ultra sound of abdomen was taken. Platelet counts were estimated. The diagnosis of pleural effusion was confirmed by X-chest. In ECG finding tachycardia was present in all the patients of shock and haemorrhage. All were subjected to serology NS1, IgM, IgG/IgM with rapid kit test. Results thus obtained were subjected to statistical analysis using chi-square test. P value ≤0.05 was considered significant.

RESULTS

Table I shows that out of 450 patients, males were 220 and females were 230. The diference was non- significant (P-1). Table II shows that age group 21-30 years consisted of 180 patients, age group 31-40 years had 135 patients, age group 41-50 years had 77 patients and >50 years had 58 patients. The difference was significant (P- 0.04). Graph I shows that common clinical manifestations in patients were fever (410), headache (250), myalgia (205), rash (157), bleeding (42), GIT manifestations (386) and shock (12). The difference was significant (P- 0.05). Graph II shows that platelets counts were <10000/cmm in 50 patients, <250000/cmm in 135 patients, <75000/cmm in 210 patients and 75000-150000/cmm in 55 patients. The difference was significant (P- 0.05). Graph III shows that serological test showed NS1 in 140 patients, IgM in 178 patients and IgG in 132 patients. Graph IV shows month wise distribution of patients. Most of cases were seen in winters, September (125), October (210), November (70), December (35), January (5), February, may and july (1) each and September (2). The difference was significant (P- 0.05).

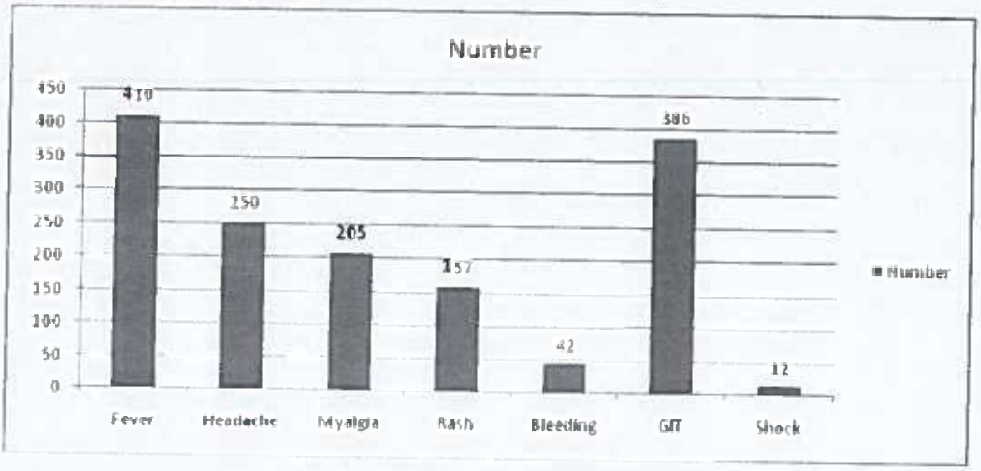
Table I Distribution of patients

Total - 450		
Males	**Females**	**P value**
220	230	1

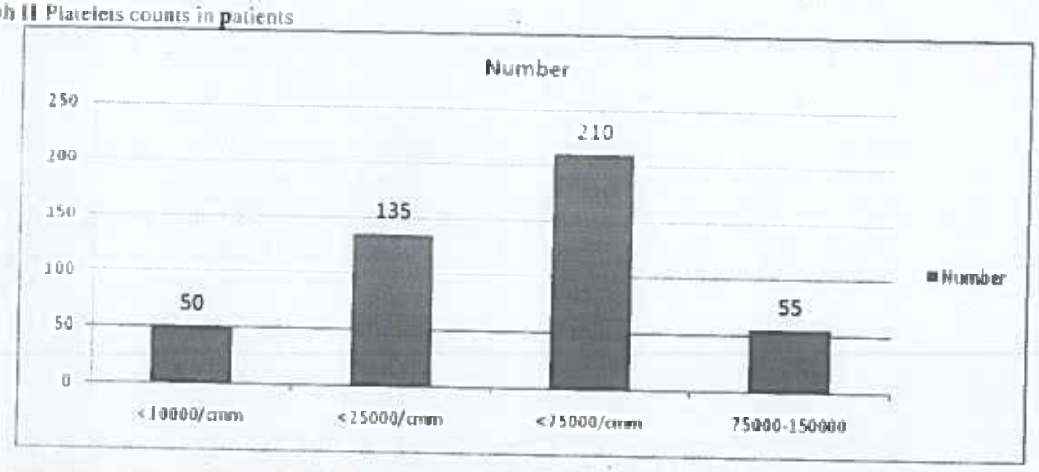
Table II Age wise distribution of patients

Age group	Number	P value
21-30	180 (40%)	0.04
31-40	135 (30%)	
41-50	77 (17%)	
>50	58 (12%)	

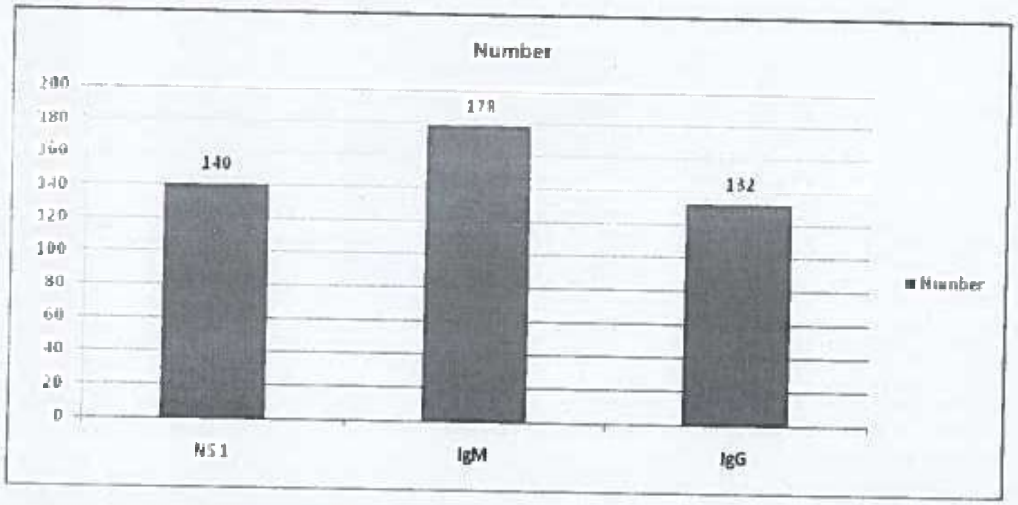
Graph I Clinical manifestations in patients



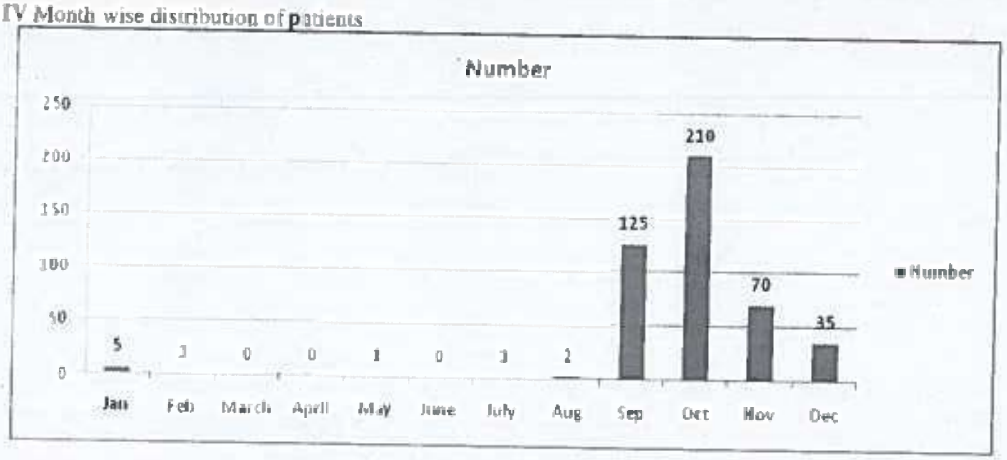
Graph II Platelets counts in patients



Graph III Serological distribution of Rapid test



Graph IV Month wise distribution of patients



DISCUSSION

In some people, the disease proceeds to a critical phase as fever resolves. During this period, there is leakage of plasma from the blood vessels, typically lasting one to two days. This may result in fluid accumulation in the chest and abdominal cavity as well as depletion of fluid from the circulation and decreased blood supply to vital organs.[5] This critical phase, while rare, occurs relatively more commonly in children and young adults. The present study was conducted to assess the cases of dengue in study population.

In our study, out of 450 patients, males were 220 and females were 230. Age group 21-30 years consisted of 180 patients, age group 31-40 years had 135 patients, age group 41-50 years had 77 patients and >50 years had 58 patients. This is in agreement with Scott.[7]

We found that common clinical manifestations in patients were fever, headache, myalgia, rash, bleeding, GIT manifestations and shock. There may also be organ dysfunction and severe bleeding, typically from the gastrointestinal tract. Shock (dengue shock syndrome) and hemorrhage (dengue hemorrhagic fever) occur in less than 5% of all cases of dengue, however those who have previously been infected with other serotypes of dengue virus ("secondary infection") are at an increased risk. This is in agreement with Sarkar JK.[8]

We observed that platelets counts were <10000/cmm in 50 patients, <250000/cmm in 135 patients, <75000/cmm in 210 patients and 75000-150000/cmm in 55 patients. Sharma S[9] in his study concluded that majority of patients shows low level of platelets and further decrease in its counts may be harmful. Serological test showed NS1 in 140 patients, IgM in 178 patients and IgG in 132 patients. Graph IV shows month wise distribution of patients. Most of cases were observed in october followed by september, november, December and january etc. DF is regulated by seasonal variations especially during monsoon period when there is abundant rainfall and high humidity, with daily temperature reaching 30°C.[10] These climatic conditions provide excellent ground for mosquito breeding.

CONCLUSION

Dengue is a viral fever caused by biting of mosquito. Proper care should be taken to avoid accumulation of water to prevent spread of mosquitoes. Bleeding, fever and decrease in platelets counts should be dealt seriously.

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ORIGINAL ARTICLE

Epidemiological and Risk Factor Evaluation of Epileptic Patients: A Clinical Study

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ABSTRACT:

Introduction: Epileptic seizures are one of the most emerging neurologic disorders worldwide. A number of etiologic factors are responsible for this. The major risk factors are cerebrovascular accidents and strokes followed by infections and tuberculosis. The goal of this study is to assess the prevalence of different etiologic agents in causation of epilepsy. **Material and methods:** The present prospective study was conducted with a sample size of 200 patients. A written consent was taken from all the patients and complete information was provided about the study. The data was collected from patients and analysis was done using SPSS software. **Results:** In the prospective study, the major cases of seizure patients were of cerebrovascular accident (45%), followed by Idiopathic (27%), Neuroinfection (15%), and alcohol withdrawal (4%). Whereas the stroke cases in elder age group was 62.5%. **Conclusion:** From the study we concluded that cerebrovascular accidents are the major etiologic factor responsible for seizure.

Keywords: Cerebrovascular, epilepsy, neuroinfection, seizure, stroke.

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INTRODUCTION

A seizure is defined as a paroxysmal episode due to abnormal excessive and synchronous neuronal activity occurring in the brain. Epilepsy is emerging as one of the most serious neurological disorders worldwide. It is estimated that 5 to 10% of the overall world population will have atleast one seizure, predominantly occurring in infancy and late adulthood. The average range of epilepsy incidences is 0.3 – 0.5% in various populations throughout the world. These incidences are comparatively higher in developing countries like Africa and latin America than the developed countries like USA and Europe.[1] The all over prevalence of epilepsy incidences has been estimated as 5-10 individuals per 1000[2]. In the year 1997, WHO is association with International league against epilepsy and international bureau for epilepsy started a Global Campaign against epilepsy with noble approach. The chief etiology of epilepsy was cerebrovascular diseases, CNS infections and metabolic abnormalities. The tubercular meningitis; common type of chronic meningitis in India also presents with a manifestation of seizures.[3]The morality rate of the population is significantly associated with the comorbid conditions. The underlying etiology is signified with the very first attack of seizures.[4]. In southern part of India women usually presenting with headache and low grade fever have a cerebral venous thrombosis. Most commonly the focal seizure occur but they can eventually generalize to status epilepticus.[5] The aids for diagnosis plays a crucial role in the accuracy of made diagnosis. With advancement in technology, convenient and reliable diagnostic aids like magnetic resonance imaging (MRI) and video electroencephalogram (VEEG), are being used and even the smallest of structural abnormalities predisposing to epileptogenic foci are captured[6]. Thus a significant number of cases are found to be symptomatic. Through this hospital-based study we aim to assess the etiologic spectrum of symptomatic epilepsies, also as the hospital based studies are rare in the developing countries and this study will fill the voids in literature.

MATERIAL AND METHODS

This study selected 200 patients newly admitted to the hospital with complain of onset of seizures. Prior approval was obtained from the institutional ethical committee before the start of study. A written consent was also obtained from the subjects after giving them complete information about

the study.The clinical data of these patients were consecutively, systematically, and prospectively recorded in a database. Patients and eyewitness of the seizure episodes were questioned regarding the complete history and clinical examination was also done. Hb level, blood urea, serum creatinine, routine urine, TLC, DLC, ESR, RBS, Na/K/P/Ca were investigated in each patient. Also the MRI brain and CT scan was done in selective cases.

Inclusion Criterion

- Patients presenting with history of new onset seizures were included in the study
- Age of the patients must be above 3 years

Exclusion Criteria

Patients with associated problem of hyperventilation, psychogenic seizures, narcolepsy were excluded from the study

STATISTICAL ANALYSIS

After collecting all the data from patients, SPSS software was used to analyze the data arranged in tabulated form and the results were expressed as percentage of total.

RESULT

The study included of 200 subjects. In our study patient's average age ranged from18-90 years, with mean age of 45.78 years with SD 18.6. The general gender predilection of seizures was seen as male/female = 1.32/1.

The etiology of epileptic seizures is shown in TABLE 1. 45% of the total episodes of seizures were due to cerebrovascular accidents out of which 14 cases were due to haemorrhage and 8 cases were of infarcts. In 27% of the cases the etiology was unknown, therefore they were entitled as idiopathic. 4 cases were of subdural haemorrhage while 2 cases were of extradural haemorrhage. Neuroinfection was seen in 15% of cases. Out of which, 7% were of meningitis, 2% were of meningoencephalitis. 4 cases were of neurocysticercosis and 8 cases of tuberculosis of central nervous system. 4% seizures were seen in alcohol withdrawal cases. 5% cases were of metabolic causes for seizures. 1% cases of hypoglycemia were seen, 2 case each of uraemia and hyperglycemia were present. There were 4 cases of glioma and 2 cases each of secondaries and meningioma were seen. 4% of cases were of tumor induced seizures.

Fig. 1A shows the frequencies of different etiologies in seizure patients for the youngest age group (<18 years). In this age group CNS infection, MTS and CD were signified as most common causes of seizures. 55% of cases were of viral meningitis, whereas 12% cases were of tuberculosis and nuerocysticercosis. The cases of TBI were accounted for 10.4% cases and 8% cases were of encephalomalacia.

Fig. 1B depicts the frequencies of etiologies of seizures in the second age group of 18–50 years. TBI and infection were the primary causes in 40% of cases. While tuberculosis was seen in 32% of cases. Whereas 25% of cases were of neurocysticercosis.

Fig. 1C shows the frequency of different etiologies in the oldest age group (>50 years). In this age group ischemic stroke accounted as the predominant causes of seizure in whole of the population.

TABLE 1: Distribution of etiologies in patients with seizures (n=200)

Etiology	Number of cases	Percentage
1. Cerebrovascular accident	90	45
Infarcts	08	04
Haemorrhage	18	09
Old CVA with scar epilepsy	32	16
CVT	24	12
SDH	04	2
EDH	04	2
2. Idiopathic	54	27
3. Neuroinfection	30	15
Meningitis	14	7
Meningoencephalitis	04	2
CNS tuberculosis	8	4
Neurocisticercosis	4	2
4. Alcohol withdrawal seizure	8	4
5. Metabolic	10	5
Hypoglycemia	2	1
Hyperglycemia	4	2
Uraemia	4	2
6. Tumors	8	4
Glioma	4	2
Meningioma	2	1
Secondaries	2	1
7. Miscellaneous	2	1

Figure 1 A: Etiologic factor at < 18 years of age group

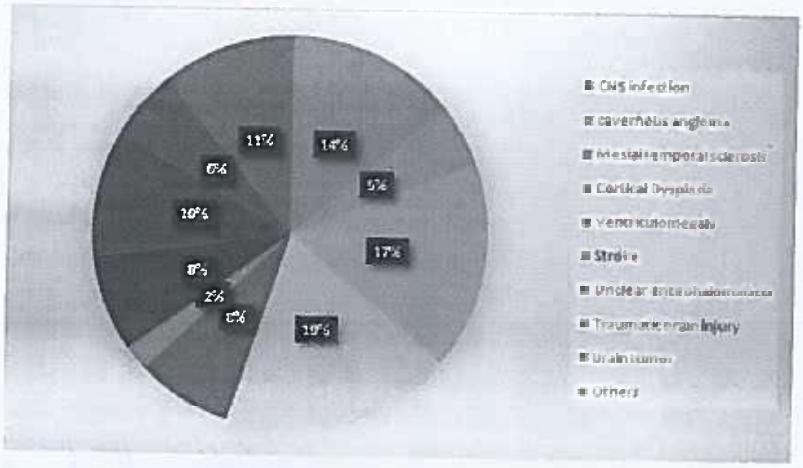


Figure 1 B: Etiologic factors in age group 18-50 years

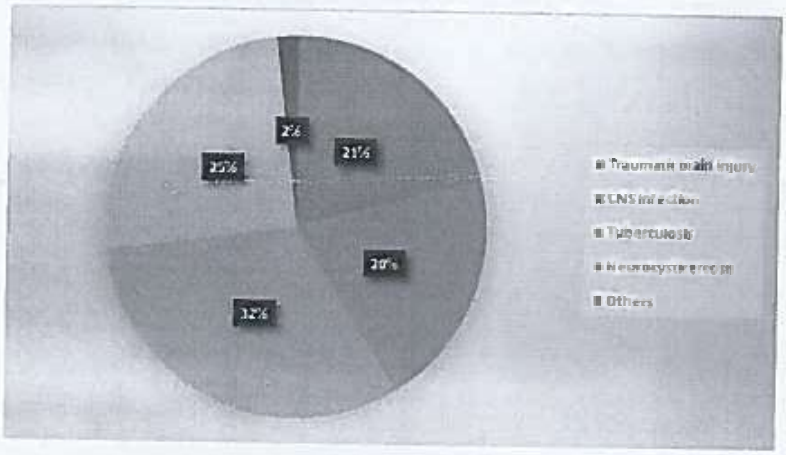
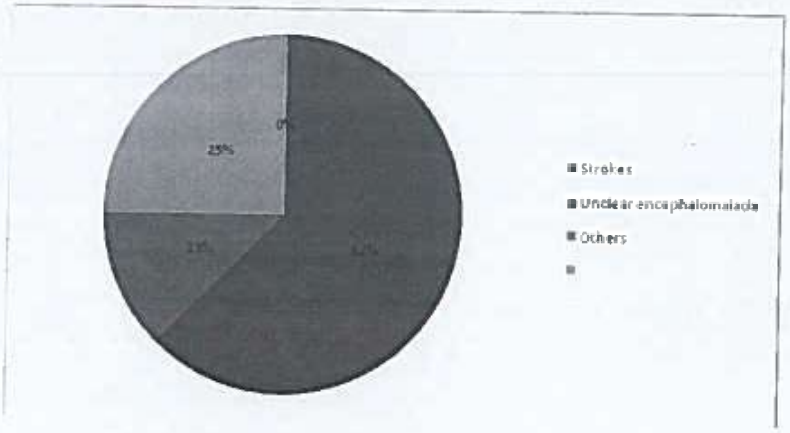


Figure 1C: Etiologic factors in age group of > 50 years



DISCUSSION

Seizures are common disorders found all over the world and are encountered frequently during medical practice in variety ofsettings. Patients from developing countries may represent the majority of all epilepsy cases worldwide because of the large gap in treatment availability and modernity.[2] The etiological spectrum of new onset symptomatic seizures and outcome may be different in developing countries when compared to developed countries. So this study on "seizures" was done to know the various etiologies of new onset seizures in adults in this region.

As compared to the outcomes of our study, in which 45% of seizure cases were due to cerebrovascular etiology, A study done by Sander[8] et al the vascular etiology was found only 15%, and in a study by Hauser[9] et al the figure was seen to be 18%. In our study only 4% of the cases were related to alcohol withdrawal which is less than that of Sander[8] et al study results of 9% and Chalasani S [9] et al results of 11%. According to a study by Shanker P saha[10] the CNS infection percentage was only 15.7% which is comparable to our results of 15%. There were 68.4% idiopathic cases which is more than our study results of 27% cases. Whereas in a study by Sinha S[11] et al the idiopathic cases were only 18.8%.

However it was seen that the most common etiology of seizure in elder age group remained to be stroke which is 62.5% in our study and 56.8% in a study done by Pandey[12] et al. In a study conducted by K. S. Amaravathi et al[13] and Sowntharyawt al[14] at a tertiary care hospital, the most common aetiology of seizures was Stroke, constituting to 38% of cases.

CONCLUSION

More than one third of newly diagnosed epilepsy cases were shown to be symptomatic via careful history-taking and laboratory examinations. Cerebrovascular accidents and strokes were the most common causes among symptomatic epilepsies in the study region. Given this etiological distribution, prevention strategies tailored to different age groups may be an efficient way for reducing the occurrence of seizures. The government should pay more attention to the social problems that contribute to provide the solutions.

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To evaluate the Correlation between Serum Bilirubin Levels and Coronary Artery Disease patients

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ABSTRACT

Aims: To evaluate the correlation between serum bilirubin levels and coronary artery disease patients.

Material and methods: A cross-sectional study was conducted in the Department of medicine. Total of 100 subjects were included in the study with 50 cases and 50 controls. General and systemic examination was conducted on all study subjects including laboratory investigations like complete blood count, renal function test, lipid profile, viral markers such as HBsAG, HCVIgM and liver function test which includes total bilirubin, direct and indirect, liver enzymes, albumin and globulin levels.

Results: The entire study subjects were divided into two groups of 50 cases (with CVD) and 50 controls. The mean age among the cases male and female respectively was 62.6±5.8 and 63.2±7.9 and controls group were 61.9±9.6 and 62.9±7.7 years male and female respectively. 60% were male and 40% female in case group and 62% patients were male and 38% patients were female in control group. The most common risk factors for CVD like diabetes, hypertension, smoking, obesity and family history of CVD was found to be slightly higher among the cases than the control groups but it was not found to be statistically significant and it proves that the controls were matched for almost all the risk factors for CVD except for dyslipidemia which was found to be significantly higher among the CVD patients than the controls. The duration of CVD among the cases varied from 1 years to 10 years with majority of the subjects' duration was between 3 and 5 years and the mean duration was 4.7±2.7 years. For all the CVD patients an echocardiogram was performed and their ejection fraction was recorded and it was correlated with the serum bilirubin levels, authors found a perfect linear correlation between the ejection fraction and serum bilirubin levels, as the ejection fraction decreases the serum bilirubin levels was also decreasing and all the serum bilirubin parameters were found to be very low in patients with ejection fraction <50% when compared to patients with ejection fraction >60% and this association was found to be statistically significant ($p < 0.05$)

Conclusion: This study confirmed a significant inverse association between the reduced serum bilirubin levels and the occurrence of Coronary artery disease. Thus total bilirubin may serve as a protective biomarker of CAD.

Keywords: Coronary artery disease, Risk factor, Serum bilirubin

INTRODUCTION

In recent years, the incidence of cardiovascular disease has increased gradually in developing nations.[1] Coronary artery disease has received most attention from medical workers because of its high fatality rate, especially the acute onset of coronary artery disease. The current scenario necessitates the recognition of novel risk factors and screening of individuals who are at risk of developing CAD.[2] In spite of detailed studies on many established risk factors

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like diabetes mellitus, hypertension, smoking, dyslipidemiaetc, the studies on serum bilirubin and its pre disposition to CAD are worth a consideration. Postulated cardio protective effects of bilirubin are Has antioxidant properties that inhibit oxidation of LDL and lower LDL levels[3] Preserves vascular nitric oxide that maintains vessel wall elasticity Has anti-inflammatory benefits and inhibits platelet activation and aggregation properties that prevent thrombus formation suppresses matrix metalloproteinases and maintains vascular integrity Several studies have concluded inverse correlations between CAD and total serum bilirubin levels.[4] Also inverse correlation between serum bilirubin and smoking, increased LDL cholesterol, diabetes and increased BMI have been documented. Lesser serum bilirubin levels are associated with Protein Kinase C activation, inflammation, and oxidative stress, which are known mediators of endothelial and micro vascular dysfunction. [5] Very few studies in India had been conducted to prove the association between serum bilirubin levels and coronary artery disease and so the present study was undertaken to assess the association between these two variables by comparing it with a control group.

Many factors increase the risk of CAD, including low serum bilirubin level, which is associated with increased risk of CAD.[6]Several studies have shown that bilirubin, the final product of hem metabolismhas potent antioxidant capacity.[7] A study performed on healthy individuals. Dividing them according to serum bilirubin levels into 3 groups of low, intermediate and high, has shown that high bilirubin level prevents coronary flow reserve impairment, microvascular dysfunction and probably coronary atherosclerosis.[8] Epidemiologic studies have indicated that the total bilirubin level is inversely related to diabetes mellitus, hypotension, CAD and metabolic syndrome.[9,10] Atherosclerosis and inflammation are associated with free oxygen and peroxyl radicals' formation.[11,12] Arterial protective responses and adjustment against oxidative stress have important roles in atherosclerosis prevention.[13] Studies have shown that different forms of circulating bilirubin and its precursor, biliverdin, have the ability to remove the reactive forms of oxygen. They also prevent the oxidation of low-density-lipoprotein particles and monocyte chemotaxis all which are considered as stages of atherosclerosis.[14,15] Very few studies in India had been conducted to prove the association between serum bilirubin levels and coronary artery disease and so the present study was undertaken to assess the association between these two variables by comparing it with a control group.

MATERIAL AND METHODS

A cross-sectional study was conducted in the Department of medicine, after taking the approval of the protocol review committee and institutional ethics committee. After taking informed consent detailed history was taken from the patient or the relatives. The technique, risks, benefits, results and associated complications of the procedure were discussed with all patients. Patients with evidence of coronary artery disease by ECG, ECHO were included in this study. Patients with symptoms of congestive cardiac failure, Chronic kidney disease, Chronic liver disease, autoimmune diseases and COPD and malignancy were excluded from the study.

Total of 100 subjects were included in the study with 50 cases and 50 controls. General and systemic examination was conducted on all study subjects including laboratory investigations like complete blood count, renal function test, lipid profile, viral markers such as HBsAG, HCVIgM and liver function test which includes total bilirubin, direct and indirect, liver enzymes, albumin and globulin levels. A 12 lead ECG and a transthoracic echocardiogram was performed for all patients. Total serum bilirubin was measured in the laboratory by spectrophotometry method. In the Jendrassik-Grof allied methods, total bilirubin is reacted with diazotized sulfanilic acid in an acidic medium to form azobilirubin. The absorbance of the azo pigment is then measured as direct bilirubin and the total bilirubin is measured after

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treatment with alkaline tartrated solution, which shifts the maximum absorption of the azo pigment towards longer wavelength.

STATISTICAL ANALYSIS

All the data were entered and analysed using SPSS version 25.0. Mean and standard deviation was derived for all the parametric variables and the parametric variables between the two groups (cases and controls) were compared using unpaired student T test and comparison between the frequencies was done by using chi-square test considering $p \leq 0.05$ as statistically significant

RESULTS

The entire study subjects were divided into two groups of 50 cases (with CVD) and 50 controls. Table 1 shows the mean age and sex distribution of the study subjects. Majority of the patients were in the age group between 50-60 years. The minimum age was 41 and the maximum age was 72 years. The mean age among the cases male and female respectively was 62.6±5.8 and 63.2±7.9 and controls group were 61.9±9.6 and 62.9±7.7 years male and female respectively. 60% were male and 40% female in case group and 62% patients were male and 38% patients were female in control group and So, it shows that the cases and controls did not show any significant difference with respect to age and gender which implies that the controls were age and sex matched.

Table 1: Demographic profile of the patients

Age group	Cases=50		Controls=50	
	Males=30	Females=20	Males=31	Females=19
Mean±SD	62.6±5.8	63.2±7.9	61.9±9.6	62.9±7.7

The most common risk factors for CVD like diabetes, hypertension, smoking, obesity and family history of CVD was found to be slightly higher among the cases than the control groups but it was not found to be statistically significant and it proves that the controls were matched for almost all the risk factors for CVD except for dyslipidemia which was found to be significantly higher among the CVD patients than the controls (Table 2).

Table 2: risk factors for CVD Patients

Risk factors	Cases (n=50)	Controls (n=50)	P value
Diabetes	16 (32%)	14 (28%)	0.33
Hypertension	27 (54%)	21 (42%)	0.15
Smoking	18 (36%)	17 (34%)	0.86
Family history of CVD	21 (42%)	32 (32%)	0.27
Obesity	13 (26%)	10 (20%)	0.18
Dyslipidemia	31 (62%)	21 (42%)	0.003

Table 3: Distribution of the patients based on their duration of CVD.

Duration of CVD	Number of patients =50	%	Mean±SD
Below 3 years	10	20%	
3 - 5 years	25	50%	
5 - 7 years	11	22%	4.7±2.7
Above 7 years	4	8%	

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The duration of CVD among the cases varied from 1 years to 10 years with majority of the subjects' duration was between 3 and 5 years and the mean duration was 4.7±2.7 years. The patients' CVD status was confirmed by history, ECG findings and ECHO reports (Table 3).
The various liver function test parameters were compared between the cases and controls it was found that the serum bilirubin levels which includes total bilirubin, direct bilirubin and indirect bilirubin was found to be lower among the case group compared to the control group and this difference was found to be statistically significant, whereas the other parameters like SGOT, SGPT and GGT levels did not show much difference between the case and control groups and the difference in values were not statistically significant (Table 4).

Table 4: Comparison of the liver function test parameters between the CVD patients and the controls.

LFT	Cases (mean±SD)	Controls (mean±SD)	P value
Total bilirubin	0.89±0.03	1.21±0.22	<0.001
Direct bilirubin	0.23±0.05	0.49±0.15	<0.001
Indirect bilirubin	0.71±0.14	0.88±0.18	<0.001
SGOT (IU/L)	10	17	0.59
SGPT (IU/L)	17	15	0.21
GGT (IU/L)	23	18	0.31

For all the CVD patients an echocardiogram was performed and their ejection fraction was recorded and it was correlated with the serum bilirubin levels, authors found a perfect linear correlation between the ejection fraction and serum bilirubin levels, as the ejection fraction decreases the serum bilirubin levels was also decreasing and all the serum bilirubin parameters were found to be very low in patients with ejection fraction <50% when compared to patients with ejection fraction >60% and this association was found to be statistically significant ($p < 0.05$) (Table 5).

Table 5: Correlation between serum bilirubin levels and the ejection fraction among the CVD patients.

Serum bilirubin	>60 % (n= 12)	50-60 % (n=28)	<50 % (n=10)	P value	r value
Total bilirubin (mean±SD)	1.5±0.25	0.85±0.19	0.73±0.19	<0.001	0.91
Direct bilirubin (mean±SD)	0.41±0.14	0.33±0.16	0.21±0.06	<0.001	0.88
Indirect bilirubin (mean±SD)	0.72±0.23	0.65±0.17	0.59±0.07	<0.001	0.93

DISCUSSION

Atherosclerosis is considered to be the most common underlying cause for the coronary artery disease (CAD), which is the major cause of mortality worldwide both in developed and developing countries. Whereas on the other hand antioxidants are the predominant adaptive responses by the arterial vasculature in response to the oxidative stress thereby preventing the atherosclerosis.[16] Bilirubin, being a toxic waste product formed during heme catabolism is in fact a potent physiological antioxidant that provides important protection against atherosclerosis and inflammation.[17] A particular enzyme namely the hemeoxygenase (HO) is a stress inducible enzyme in the heme catabolism which plays an important role in cell defense mechanism against oxidative injury.

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The products of the catabolic reaction, i.e. bilirubin, carbon monoxide and iron have a protective role. The other important role of bilirubin, the natural antioxidants are the inhibition of vascular cell adhesion molecule VCAM-1 preventing the proliferation of the smooth muscle cells and the transendothelial migration of the leucocytes.[18]

Plasma bilirubin inversely correlated with risk factors of CAD- smoking, diabetes and obesity, thus emphasizing the oxidative stress underlying in them, but in present study authors did not observed such correlation as authors matched most of the risk factors between the cases and controls. Inverse relationship between the presence of CAD and circulatory total bilirubin was first observed by Schwertneret al.[19]

Male gender is one of the most important risk factors for CAD. In this study The mean age among the cases male and female respectively was 62.6±5.8 and 63.2±7.9 and controls group were 61.9±9.6 and 62.9±7.7 years male and female respectively. 60% were male and 40% female in case group and 62% patients were male and 38% patients were female in control group and So, it shows that the cases and controls did not show any significant difference with respect to age and gender which implies that the controls were age and sex matched. We also matched other comorbidities thereby removing the confounding factors responsible for the lowering of bilirubin as a result of the oxidative stress and other mechanisms.[20]

Present study found a significant inverse association between serum bilirubin and CAD in comparison with control, bilirubin levels found to be significantly lower in CAD patients in comparison with the controls ($p < 0.001$) and a similar type of results was also quoted by Taban SM et al. and in their study they had also found a significant association between the bilirubin levels and the severity of CAD by doing an angiogram.[21] So it seems that higher bilirubin level has a protective effect against coronary artery stenosis (CAS).

The present study among 50 CAD patients and 50 healthy controls confirmed the results of several previous epidemiological studies that low serum bilirubin levels were associated with increased risk for coronary events.[22,23,24] A recent study in patients with peripheral arterial disease (PAD) revealed similar results showing a clear association between low bilirubin concentrations and PAD.[25] Present study showed a higher level of mean total bilirubin in males in comparison to females, but the difference was not statistically significant, however lower levels of bilirubin in females may be attributed to the influence of estrogens. This may relate to the increased secretion of bilirubin through the induction of UDP-glucuroniltransferasa enzyme in liver. Estrogens also decrease LDL level, increase HDL level and reduce LDL oxidation.[26]Recently, low serum bilirubin levels have been proposed as a useful biomarker to predict cardiovascular risk and suggests that bilirubin acts as a potent physiologic antioxidant and anti-inflammatory agent. Studies have shown that elevated serum bilirubin concentrations provide important protection against atherosclerotic diseases.[16]Several authors have suggested that bilirubin plays a potential role in inhibition of lipid oxidation.[27] An inverse correlation between the presence of coronary artery disease, peripheral arterial disease, carotid intima-media thickness and bilirubin has been reported in several studies. Subnormal levels of plasma bilirubin are associated with premature coronary artery disease and cardiovascular morbidity.[28] In a previous study, the 3-year incidence of coronary artery disease was significantly lower in patients with Gilbert syndrome.[29] This study showed a significant relation between ejection fraction with total serum bilirubin the ejection fraction showed a descending trend as serum bilirubin level decreased and a similar type of results was also quoted by Taban SM et al.[21]

CONCLUSION

This study confirmed a significant inverse association between the reduced serum bilirubin levels and the occurrence of Coronary artery disease. Thus total bilirubin may serve as a protective biomarker of CAD.

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Original Research Article

Assessment of Thyroid Profile Among Pre and Postmenopausal Women

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Abstract

Background: Thyroid disorders are reported in higher magnitude among women than men. Various reports have shown an increasing trend of thyroid disorders with an increase in age. Occurrence of thyroid disorders such as hypothyroidism, autoimmunity, nodular goiter, and cancer was the most often reported in post-menopausal and elderly women than younger women. **Material & Methods:** 100 post-menopausal women of age group 50-55 years according to inclusion and exclusion criteria and 100 pre-menopausal women of age group 34-49 years according to inclusion and exclusion criteria were enrolled in the present study. Study participants were enrolled by simple random sampling. Clearance from the hospital ethics committee was taken before the start of the study. Written informed consent was taken from each study participant. **Results:** In the present study, out of total study participants, based on the thyroid function test status, the mean value of total T3 among pre-menopausal group was 142.4±10.9 and the mean value of total T3 among post-menopausal group was 169.4±11.8, the mean value of total T4 among pre-menopausal group was 8.1±1.3 and the mean value of total T4 among post-menopausal group was 9.3±1.2, the mean value of TSH among pre-menopausal group was 12.4±4.8 and the mean value of TSH among post-menopausal group was 20.4±5.1, the mean value of free T3 among pre-menopausal group was 286±13.4 and the mean value of free T3 among post-menopausal group was 312±15.6 the mean value of free T4 among pre-menopausal group was 1.23±1.1 and the mean value of free T4 among post-menopausal group was 1.38±1.2. **Conclusion:** We concluded from the present study that thyroid dysfunction suggesting from the thyroid profile in post-menopausal women. We recommend the thyroid profile of all post-menopausal women to diagnose and treat the thyroid dysfunction early.

Keywords: Thyroid dysfunction, post-menopausal women, pre-menopausal women.

Introduction

It is well established in various researches that thyroid hormones function a very important role in the development, regulation of metabolism, protein synthesis, and functioning of other hormones[1]. The thyroid gland is a butterfly-shaped endocrine gland that is situated anatomically in the anterior aspect of the root of the neck and comprises two bulky lateral lobes which are connected by a thin isthmus[2]. The thyroid gland secretes several hormones such as triiodothyronine

(T3), thyroxine (T4), and calcitonin. The prevalence and magnitude of all thyroid disorders are associated and dependent on numerous risk factors and confounding factors[3].

The thyroid hormones control the metabolism of macromolecules, oxygen consumption, and the basal metabolic rate (BMR) of body cells and are essential for normal growth and maturation of the body as well as they are essential for proper development of the peripheral and central nervous system[4]. Peripheral metabolism of thyroid hormones and pituitary-thyroid axis reported to be affected in various diseases and characterized by the Low T3 levels which are followed by subclinical hypothyroidism findings[5].

Thyroid disorders are reported in higher magnitude among the general population, although their prevalence is also high reported among women than men. Various reports have shown an increasing trend of thyroid disorders with the increase in age[6]. Occurrence of thyroid disorders such as hypothyroidism, autoimmunity, nodular goiter, and cancer was the most often reported in post-menopausal and elderly women than younger women[7]. We conduct the present study to assess the thyroid dysfunction among pre-and post-menopausal women at our tertiary care hospital.

Materials and methods

The present cross-sectional, observational study was conducted at the department of general medicine of our tertiary care hospital. The study was an observational study conducted during a period of six months. The study was done at a 90% confidence interval at 10% of maximum allowable error. The sample size of 200 patients was calculated by epi info software. 100 post-menopausal women of age group 50-55 years according to inclusion and exclusion criteria and 100 pre-menopausal women of age group 34-49 years according to inclusion and exclusion criteria were enrolled in the present study. Study participants were enrolled by simple random sampling. Clearance from the hospital ethics committee was taken before the start of the study. Written informed consent was taken from each study participant.

For the study purpose, any woman who had no menstruation for a minimum period of 1-year duration was considered a post-menopausal woman. Previously diagnosed cases of thyroid disorders, diabetes mellitus, hypertension, obesity, and systemic diseases were excluded from the present study. All the study participants were subjected to general physical and clinical examination and detailed history was recorded from all of them. All the study participants were subjected to routine blood investigation for complete blood count and thyroid function tests. All the recorded data was entered in an Excel spreadsheet on Microsoft Excel 2016. The statistical analysis was done using the Statistical software package SPSS v22 and Epi Info v7.2. A p-value <0.05 with 95% confidence intervals was considered statistically significant.

Results

In the present study we enrolled a total of 100 post-menopausal women of age group 50-55 years according to inclusion and exclusion criteria and 100 pre-menopausal women of age group 34-49 years according to inclusion and exclusion criteria were enrolled in the present study. Among the study participants, all the women in the pre-menopausal group were ranged from age 34 to 49 years with a mean age of 42.4 ± 5.6 years. All the women in the post-menopausal group were ranged from age 51 to 55 years with the mean age of 52.9 ± 1.8 years. Out of the total study participants, among all the women in the pre-menopausal group, 8% had hyperthyroidism, 34% had hypothyroidism and 58% had normal thyroid functions. Among all the women in the post-menopausal group, 11% had hyperthyroidism, 39% had hypothyroidism

and 50% had normal thyroid functions. (Table 1)

Table 1: Distribution of study subjects according to the thyroid profile.

Thyroid disorders	post-menopausal group	pre-menopausal group	P value
Hyperthyroid	11%	8%	>0.05
Hypothyroid	39%	34%	
Normal	50%	58%	

In the present study, out of total study participants, based on the thyroid function test status, the mean value of total T3 among the pre-menopausal group was 142.4 ± 10.9 and the mean value of total T3 among the post-menopausal group was 169.4 ± 11.8. the mean value of total T4 among the pre-menopausal group was 8.1 ± 1.3 and the mean value of total T4 among the post-menopausal group was 9.3 ± 1.2. the mean value of TSH among the pre-menopausal group was 12.4 ± 4.8 and the mean value of TSH among the post-menopausal group was 20.4 ± 5.1. the mean value of free T3 among the pre-menopausal group was 286 ± 13.4 and the mean value of free T3 among post-menopausal group was 312 ± 15.6. the mean value of free T4 among pre-menopausal group was 1.23 ± 1.1 and the mean value of free T4 among post-menopausal group was 1.38 ± 1.2. All these differences between both groups were statistically non-significant.(Table 2)

Table 2: Thyroid dysfunction among study participants.

Thyroid function test	post-menopausal group	pre-menopausal group	P value
Total T3	169.4 ± 11.8	142.4 ± 10.9	>0.05
Total T4	09.3 ± 1.2	08.1 ± 1.3	>0.05
TSH	20.4 ± 5.1	12.4 ± 4.8	>0.05
Free T3	312 ± 15.6	286 ± 13.4	>0.05
Free T4	01.38 ± 1.2	01.23 ± 1.1	>0.05

Discussion

In the present study we enrolled a total of 100 post-menopausal women of age group 50-55 years according to inclusion and exclusion criteria and 100 pre-menopausal women of age group 34-49 years according to inclusion and exclusion criteria were enrolled in the present study. Among the study participants, all the women in pre-menopausal group were ranged from age 34 to 49 years with a mean age of 42.4±5.6 years. All the women in post-menopausal group were ranged from age 51 to 55 years with the mean age of 52.9±1.8 years. Similar results were obtained in a study conducted by Shetty AGN et al among 50 post-menopausal women of age group 50-55 years according to inclusion and exclusion criteria and 50 pre-menopausal women of age group 34-49 years. They reported similar findings as to the present study[8]. Similar results were obtained in a study conducted by Kapadia N et al among 50 post-menopausal women of age group 50-55 years according to inclusion and exclusion criteria and 50 pre-menopausal women of age group 34-49 years. They reported similar findings as to the present study[9].

In the present study, based on the thyroid function test status, out of the total study participants, among all the women in pre-menopausal group, 8% had hyperthyroidism, 34% had hypothyroidism and 58% had normal thyroid functions. Among all the women in post-menopausal group, 11% had hyperthyroidism, 39% had hypothyroidism and 50% had normal thyroid functions. Similar results were obtained in a study conducted by G.

Bordoloi et al among 304 post-menopausal women of age group 50-55 years according to inclusion and exclusion criteria and pre-menopausal women of age group 34-49 years. They reported similar findings as the present study[10]. Similar results were obtained in a study conducted by Garg N et al among 100 post-menopausal women of age group 50-55 years according to inclusion and exclusion criteria. They reported similar findings as the present study[11].

In the present study, out of total study participants, based on the thyroid function test status, the mean value of total T3 among pre-menopausal group was 142.4±10.9 and the mean value of total T3 among post-menopausal group was 169.4±11.8, the mean value of total T4 among pre-menopausal group was 8.1±1.3 and the mean value of total T4 among post-menopausal group was 9.3±1.2, the mean value of TSH among the pre-menopausal group was 12.4±4.8 and the mean value of TSH among the post-menopausal group was 20.4±5.1, the mean value of free T3 among the pre-menopausal group was 286±13.4 and the mean value of free T3 among the post-menopausal group was 312±15.6, the mean value of free T4 among the pre-menopausal group was 1.23±1.1 and the mean value of free T4 among the post-menopausal group was 1.38±1.2. All these differences between both groups were statistically non-significant. Similar results were obtained in a study conducted by Chetna P et al among post-menopausal women of age group 50-55 years according to inclusion and exclusion criteria and pre-menopausal women of age group 34-49 years. They reported similar findings as to the present study[12].

Conclusion

We concluded from the present study that thyroid dysfunction suggesting from the thyroid profile in post-menopausal women. We recommend the thyroid profile of all post-menopausal women to diagnose and treat thyroid dysfunction early.

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Original Research Article

Assessment of cases of pulmonary tuberculosis

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Abstract

Background: Tuberculosis (TB) is one of the major infectious disease and health concern in the world. The present study was conducted to assess cases of pulmonary tuberculosis **Materials & Methods:** 238 diagnosed cases of active TB of both genders were included. Contact history, primary disease or recurrence, complaints at admission, Bacillus Calmette-Guerin (BCG) vaccination, clinical findings and involvement sites were recorded. **Results:** Out of 238 patients, males were 138 and females were 100. <25 years had 110 and 25-40 years had 128 patients. Fever was present in 203, fatigue in 156, weight loss in 82, cough in 118 and hemoptysis in 73 patients. Involved area was lymph nodes such as cervical in 30, inguinal in 54, mediastinum in 28, axillary in 52, paratracheal in 22, omentum in 18, peritoneum in 10, vertebra in 6, wrist in 8, skin in 5 and CNS in 5 cases. The difference was significant ($P < 0.05$). **Conclusion:** Maximum cases were seen in males and common site was inguinal lymph node.

Key words: Tuberculosis, inguinal lymph node, hemoptysis

Introduction

Tuberculosis (TB) is one of the major infectious disease and health concern in the world. TB is a bacterial disease caused by Mycobacterium tuberculosis and infrequently by Mycobacterium africanum and Mycobacterium bovis[1]. TB pathogens are slow growing, fastidious, hydrophobic and lipid-rich bacteria that have acid fast rod shape which prevent decolorization with acid alcohol[2]. It is a chronic contagious infection that not only affects humans but a wide range of mammals. The main way of spread occurs by airborne transmission and infectious droplets[3]. A person with TB who is coughing is the key source of infection. The infectiousness of a person with TB disease is directly related to the number of tubercle bacilli that he or she expels into the air. Persons who expel many tubercle bacilli are more infectious than patients who expel few or no bacilli[4].

Mycobacteria invade many organs during primary infection, but these foci remain dormant (without disease development) if the host has an effective immune system. Reactivation is accelerated in patients with latent diseases, under conditions where the immune system is suppressed[5]. The risk of EPTB and mycobacteremia increases with advancing immunosuppression. Extrapulmonary involvement can be seen in >50% of patients with concurrent AIDS and TB. EPTB includes TB of organs other than the lung parenchyma, such as the lymph nodes, pleura, abdomen, genitourinary tract, gastrointestinal tract, skin, joints and bones, or meninges.

The diagnosis of EPTB is more difficult than that of PTB. Its increasing incidence and severe sequelae due to the delay in diagnosis lead to a significant decrease in labor force[6]. The present study was conducted to assess cases of pulmonary tuberculosis.

Materials & Methods

The present study was conducted among 238 diagnosed cases of active TB of both genders. All patients were enrolled with their written consent. Ethical committee approval was obtained from institutional review committee.

Patient data such as name, gender, age, contact history, primary disease or recurrence, complaints at admission, Bacillus Calmette-Guerin (BCG) vaccination, clinical findings and involvement sites were recorded. Active TB was defined as an identification of M. tuberculosis through Ziehl-Neelsen acid-fast stain and culture in Lowenstein Jensen or BACTEC media in a tissue or infected specimen in culture-positive patients. Results of the study was subjected to statistical analysis. P value less than 0.05 was considered significant.

Results

Table 1 Distribution of patients

Total- 238		
Gender	Male	Female
Number	138	100

Table 1 shows that out of 238 patients, males were 138 and females were 100.

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Table II Assessment of parameters

Parameters	Variables	Number	P value
Age group (Years)	<25	110	0.12
	25-40	128	
Clinical features	Fever	203	0.01
	Fatigue	156	
	Weight loss	82	
	Cough	118	
	Hemoptysis	73	
Involved area	Cervical	30	0.04
	Inguinal	54	
	Mediastinum	28	
	Axillary	52	
	Paratracheal	22	
	Omentum	18	
	Peritoneum	10	
	Vertebra	6	
	Wrist	8	
	Skin	5	
	CNS	5	

Table II, graph I shows that <25 years had 110 and 25-40 years had 128 patients. Fever was present in 203, fatigue in 156, weight loss in 82, cough in 118 and hemoptysis in 73 patients. Involved area was lymph nodes such as cervical in 30, inguinal in 54, mediastinum in 28, axillary in 52, paratracheal in 22, omentum in 18, peritoneum in 10, vertebra in 6, wrist in 8, skin in 5 and CNS in 5 cases. The difference was significant (P< 0.05).

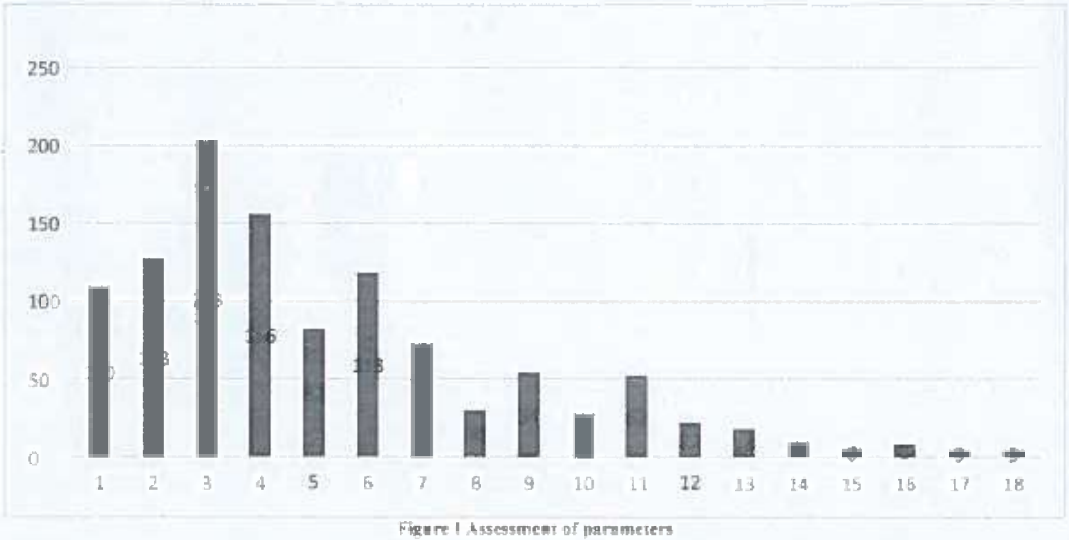

Figure I Assessment of parameters

Discussion

Tuberculosis (TB) is a major global health problem and may appear as a multisystem disease. It is a chronic necrotizing bacterial infection characterized by the presence of granulomatous lesions, caused by the Mycobacterium tuberculosis complex[7]. This includes M. africanum, M. microti, M. tuberculosis, and M. bovis. M. tuberculosis is responsible for 97-99% of disease development. TB has two sequential processes: infection and active disease. Active disease can develop during any period of life in approximately 10% of the subjects who have been infected with the TB bacillus[8]. The disease may involve any or all organs, but the lungs are the most commonly involved (85%), and 50% of untreated patients die within 5 years after the initial infection. Pulmonary Tuberculosis is primarily identified symptomatically using features like cough, fever, sweats, weight loss and hemoptysis and extra-pulmonary lymph node swelling (lymphadenitis)[9]. Also disseminated/miliary TB is characterized by mycobacterial infection apart from lung and lymph node, in any part of the body, including the bone, meninges and kidneys. The probability of developing TB disease is much higher among people living with HIV. It is also higher among people affected by undernutrition, diabetes, smoking and alcohol consumption[10]. The present study was conducted to assess cases of pulmonary tuberculosis.

In present study, out of 238 patients, males were 138 and females were 100. Guler et al[11] evaluated the demographic factors and clinical features of extrapulmonary tuberculosis (EPTB) compared to those of pulmonary tuberculosis (PTB) among adult immunocompetent patients. Among the 427 patients, 55 patients with both PTB and EPTB and who were using steroids or had taken immunosuppressive drugs were excluded from the study. Of the 372 patients, 227 (61%) were males and 168 (45.2%) had EPTB; 204 (54.8%) patients had PTB. The most frequent sites of EPTB were the lymph nodes (n = 45, 12.1%), pleura (n = 40, 10.7%) and brain (n = 7, 1.8%). The most common symptoms were cough (n = 174, 46.7%),

night sweats (n = 127, 34.1%) and fever (n = 123, 33%). Compared to EPTB patients, PTB patients were less likely to have received Bacillus Calmette-Guérin vaccination (odds ratio 0.41, 95% confidence interval 0.2–0.63, p < 0.001). Eighty-one (48.2%) of the EPTB and 146 (71.6%) of the PTB patient.

We observed that <25 years had 110 and 25–40 years had 128 patients. Fever was present in 203, fatigue in 156, weight loss in 82, cough in 118 and hemoptysis in 73 patients. Involved area was lymph nodes such as cervical in 30, inguinal in 54, mediastinum in 28, axillary in 52, paratracheal in 22, omentum in 18, peritoneum in 10, vertebra in 6, wrist in 8, skin in 5 and CNS in 5 cases. Kesete et al[12] assessed the prevalence of tuberculosis disease among patients attending at Nakfa Hospital, Eritrea. A total of 1100 patients were examined for tuberculosis using acid fast staining test. The overall prevalence of smear positive pulmonary TB cases was 7.8% (86 cases out of 1100). Females (8.2%) were more prone to have a positive Tuberculosis smear than males (7.4%). According to severity of infection, 38(3.5%) of subjects were +1 positive, whereas 23(2.1%) and 24(2.2%) of patients were +2 and +3 positives respectively. The highest prevalence of pulmonary TB was observed in the adult age group of 41-60 years (11%) and a comparatively higher number of cases was recorded in age group 21–40 years (8.3%). Adults aged between 41 to 60 had a two times more likelihood to be infected with Tuberculosis than those aged below 20 years old. Moreover, pulmonary tuberculosis was highly prevalent among middle age (20-60) than any other age class in all study years (2014-2019). The pulmonary TB cases were highly predominant during the year 2014 which was 16.8% (19 of 113 subjects) whereas the almost a quarter of it (4.5%) was recorded in following year. Based on locality, the highest rate of infection was observed in Adobha (25%), a town at border of Sudan and Eritrea, in which patients who came from Adobha had 4 times more likelihood to be infected than those from Nakfa town.

Gupta et al[13] evaluated spirometry in cured PTB patients and its association with radiological abnormalities and duration after being cured.75 PTB treated patients (47 males, 28 females) underwent clinico-radiological evaluation, and spirometry [FEV1, FVC, FEV1/FVC ratio]. The patients were further classified into 3 groups according to recent guidelines (ATS/ERS joint statement) i.e mixed, obstructive and restrictive defect. Abnormal PFT was seen in 92% (69/75cases). Mixed pattern was seen in 36%, restrictive defect in 34.7% while obstruction was seen in 21.3% cases. Restrictive abnormality was more commonly seen in females (P=0.030) and old age (P=0.000006) while obstruction in males and young population. Statistically significant direct association of pulmonary impairment was seen with radiological changes (P<0.001) and post treatment duration(P=0.012) but not with age.

Conclusion

Authors found that maximum cases were seen in males and common site was inguinal lymph node.

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Section: Gen. Surgery

Original Article

A Prospective Study on Incidence of Septicaemia in patients in IPD of Medicine Department

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ABSTRACT

Background: *Bloodstream infections are important causes of mortality and morbidity. Rapid empiric antibiotic therapy is often needed. Knowledge of epidemiological data of common pathogens and their antibiotic sensitivity pattern is needed for rapid therapy.*

Methods: *This study was done to analyze the common causes of septicaemia and their antibiotic sensitivity pattern from the Department of General Medicine, Kanachur Institute of Medical Sciences, Natekal, Mangaluru. Isolates were identified using bacteriological and biochemical methods and antibiotic sensitivity was done using the Kirby-Bauer disc diffusion method.*

Results: *This study showed that of the 75 patients examined 22 had septicaemia. 31-45 years age group patients constituted the greatest percentage of infected subjects (n=28) followed by patients aged between 46-60 years (n=17). Gram-positive bacteria were encountered more often than gram negative bacteria. Among the gram positive bacteria, majority isolated were S. epidermidis; followed by S. aureus.*

Conclusion: *Majority of the organism isolated were from Gram positive category, in which S. epidermidis was the most isolated.*

Key words: *Septicaemia, Infection, Emergency coli.*

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INTRODUCTION

Septicaemias are important causes of mortality and morbidity and are among the most common healthcare associated infections.[1] Illnesses associated with bloodstream infections range from self-limiting infections to life threatening sepsis that require rapid and aggressive antimicrobial treatment.[2] A wide spectrum of organisms has been described and this spectrum is subject to geographical alteration. Patients who are granulocytopenic or inappropriately treated may have a mortality rate that approaches 100%.[1]

Moreover, fatalities among patients infected with Gram-negative bacilli are higher than those among patients who have Gram-positive cocci as causative agents of their bacteraemia.[3] Worldwide, emergence of antibiotic resistance in all kinds of pathogenic bacteria is a serious public health issue. It is associated with greater hospital mortality and longer duration of hospital stay, thereby increasing health care costs.[4] Also, colonization and infection with antibiotic-resistant bacteria has made the therapeutic options for infection treatment extremely difficult or virtually impossible in some instances.[5] There are many reasons for this alarming phenomenon, including increasing antibiotic use and misuse in humans, animals and agriculture, clustering and overcrowding and poor infection control.[6]

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Due to the high mortality and mobility associated with septicaemia, antimicrobial therapy in most cases is initiated empirically before the results of blood culture and antimicrobial susceptibility pattern of the isolates are available.[1]

Knowledge of local antimicrobial resistance patterns from accurate bacteriological records of blood culture results is needed to provide guidance towards an empirical therapy before sensitivity patterns are available. Bacteraemia is usually caused by a wide spectrum of bacteria with varying antimicrobial susceptibility pattern. However, there is a paucity of information about the relative contribution of different bacteria to infections in Sub -Saharan Africa and how this varies across the full range age groups.[7] Bacteraemia often require prompt diagnosis and effective treatment to prevent death and complications from septicaemia. Physical signs and symptoms are usually useful in identifying patients with septicaemia and other non-localized infections but these have limited specificity.[8] Bacteriological culture to isolate the offending pathogen and determine its antimicrobial sensitivity pattern has remained the mainstay of definitive diagnosis of septicaemia.[9] In most cases of suspected septicaemia antimicrobial therapy is always initiated empirically because bacteriological culture results take about a week to be available.

Epidemiological data on common blood stream pathogens and their antimicrobial sensitivity pattern is thus very important to make the right choice of empiric therapy.

METHODS

This study was conducted in the Department of General Medicine, Kanachur Institute of Medical Sciences, Natekal, Mangaluru. All the subjects were patients suspected clinically for septicaemia and sent to the bacteriology laboratory for blood culture by physicians. Written informed consent was taken before the study. The blood culture bottles were immediately incubated aerobically at 35°C for 24 hrs.

After 24hrs, bottles were checked for positive cultures (growth on the agar slope and/or turbidity in the broth). Negative cultures were re-incubated and checked daily for up to three weeks unless growth occurred. Before re-incubation, the slope was re-inoculated by tippling the bottle. Antibiotic susceptibility testing was done on MH using the Kirby-Bauer disc diffusion technique.[11] Antibiogram for Streptococcus species was done on blood agar.

RESULTS

Of the 75 patients examined for septicaemia, positive culture was found in 22 (29.33%). Age distribution of the patients is shown in Table 1.

Majority of the infected patients were found in the 31-45 years of age group (n=28) followed by 46-60 age group (n=17) and least in >76 age group. Maximum no. of positive culture was found in 31-45 age group followed by 46-60 years age group.

The type and pattern of bacteria isolates in the various age groups is shown in Table 2. Gram-positive bacteria were encountered more often than gram negative. Among the gram- positive bacteria, Staphylococci constituted most followed by Streptococci species. Among gram-negative bacteria, enterobacteriacea and non-fermenting bacteria were more frequent.

Table 1. Age Distribution of Patients with Septicaemia

Age ranges (years)	No clinically examined	No (%) of positive culture
15-30	14	3
31-45	28	10
46-60	17	6
61-75	12	2
>76	4	1
Total	75	22

Table 2:- The Type and Distribution Of Bacteria Isolates

Bacteria Isolates	Total
S aureus	5
S. epidermidis	6
S. saprophyticus	1
Streptococcus sp	1
S. typhi	1
Salmonella species	2
K. pneumonia	1
E. coli	1
Enterobacter sp	1
Pseudomonas sp	1
Acinetobacter sp	1
Proteus mirabilis	1
Non enterobacteriacaece	1
Gram positive bacilli	1

DISCUSSION

This study is a record of septicaemia in patients attending the Medicine department of Department of Medicine, Kanachur Institute of Medical Sciences. Results showed that septicaemia was present in 29.33% of patients examined. Gram positive bacteria were encountered more than gram-negative bacteria, and the most frequent invasive bacteria were Staphylococcus epiderimidis, S. aureus, Salmonella typhi and Klebsella species.[6]

These results are similar to those obtained in some previous studies[9]. Bacteremia was identified in 552 (45.9%) of 1201 children in Nigeria; 53.4% of the infections were due to gram positive bacteria and 46.6% due to gram negative bacteria. The most frequent isolate was S. aureus (47.7%) followed by coliforms (23.4%), unidentified gram-negative rods (8.0%), Pseudomonas aeruginosa (5.8%), Streptococcal species (4.7%) and Chromobacteria species (4.5%). Hill et al.[7] also reported an incidence of 34% (297) out of 871patients studied. The isolates were dominated by gram-positive bacteria.

Results have also shown a very high incidence of septicaemia among 31-45 age group. It is also in accordance with results from Laos in which 69.2% of Staphylococci were form majority bulk.[12] The rate of isolation also reduced with increasing age as seen in this study.

However, while this study represents real life clinical practice in the hospital in which it was conducted, our approach had some limitations.

The primary reason for requesting the blood culture from patients is still not clear.

CONCLUSION

This study shows that *Staphylococcus epidermidis*, *S. aureus* and *Salmonella typhi* are the living cause of bacteraemia among patients in the locality.

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Section General Medicine

Original Article

Effect of Cigarette Smoking on Male Fertility : A Prospective Hospital Based Study

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ABSTRACT

Background: *World Health Organization (WHO) has reported that smoking is very much prevalent among 30% of all 15 years and older men. Approximately 46% of smokers (men) belong to reproductive age (20 - 39 years of age). A survey from 187 countries reported that the prevalence of smoking in male smokers was decreased from 41.2% in 1980 to 31.1% in 2012. Though, the number of everyday smokers increased from 721 million in 1980 to 967 million in 2012.*

Methods: *Eighty male cases were included in this study. Out of eighty male cases 51 had low sperm count & 29 cases were normal. The study was conducted in Department of General Medicine, Kanachur Institute of Medical Sciences, Natekal.*

Results: *In the present study, low sperm count was occurred in 36.3% and normal sperm count was occurred in 63.7% cases.*

Conclusion: *The results of the present study showed that smoking has severe effects on male fertility. It decreased the sperm motility and sperm count and causes a further decline with continuation of smoking for more than five years.*

Keywords: Sperm motility, Smokers, Non-smokers, Fertility

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INTRODUCTION

It is a well-known fact that smoking has a harmful effect on health in general and on male reproductive system in particular. Despite that it remains a worldwide phenomenon.[1] World Health Organization (WHO) has reported that smoking is very much prevalent among 30% of all 15 years and older men.[2] Approximately 46% of smokers (men) belong to reproductive age (20 - 39 years of age).[3] A survey from 187 countries reported that the prevalence of smoking in male smokers was decreased from 41.2% in 1980 to 31.1% in 2012. Though, the number of everyday smokers increased from 721 million in 1980 to 967 million in 2012.[4]

Semen quality is supposed to be informative about male fertility, that is defined biologic capacity of males for reproduction.[5] Semen analysis is the clinical standard for assessing male fecundity.[6] Apart from this, sperm concentration, motility and morphology are reported to be the key components of classifying men by fertility potential.[7] Infertility is defined as the inability to conceive after twelve months of regular sexual relation without the use of contraception.[8] It poses severe consequences at the cultural, social and emotional levels. It leads to distress, anxiety, blame and sexual problems in married couples' lives.[9]

Tobacco has numerous carcinogens and mutagens which have deadly effects on human beings. One of the most harmful effects of carcinogens has been observed to be more on rapidly dividing cells that include germ cells. It has been

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already reported that the prevalence of smoking is very much high in young adult males in the reproductive period. Despite this, the undesirable effects of smoking are not well recognized and its impact on male fertility and sperm characteristics still remains debatable.

METHODS

Study Population: - Eighty male cases were included in this study. Out of eighty male cases 51 had low sperm count & 29 cases were normal.

Study Area: -The study was conducted in the Department of General Medicine, Kanachur Institute of Medical Sciences, Natekal

Sample Collection: - In this study 13 non-smokers and 67 smokers in the age group between 25 to 40 years attending the primary infertility clinic who smoked a minimum of 10 cigarettes per day. They were categorized on the basis of duration of smoking as those smoking cigarettes for less than 5 years or for more than 5 years

Data analysis:-Data were analyzed by using of Microsoft Excel.

RESULTS

In our study, 80 total numbers of cases were included in this study. Among the 80 cases 13 belongs to non-smoking and 67 were belongs to smoking history. In the present study, low sperm count was occurred in 36.3% and normal sperm count was occurred in 63.7% cases. On the basis of above result the present study is undertaken to observe the effects of smoking on a few selected seminal fluid parameters like sperm count and motility and to compare the results.

Table 1:- Smoking & non-smoking history in all cases

Smoking history	No. of cases	Percentage
Non-smokers	13	16.3%
Less than 5 years	27	33.7%
More than 5 years	40	50%
Total	80	100%

Table 2:- Distribution of cases according to sperm count

Motility	Frequency	Percentage
Normal (greater than 32%)	29	36.3%
Low (Less than 32%)	51	63.7%
Total	80	100%

Table 3:- Comparative study between non-smoker & smoker and sperm motility

Smoking history	Sperm motility greater than 32%		Sperm motility less than 32%		Total
	No of cases	Percentage	No of cases	Percentage	
Non-smokers	10	76.9%	3	23.1%	13
Smokers less than 5 years	12	44.5%	15	55.6%	27
Smokers greater than 5 years	7	17.5%	33	82.5%	40

DISCUSSION

It has been observed in many studies that the effects of cigarette smoking on all the seminal parameters are detrimental. Though, its effect on the individual parameters is yet to be established. Due to smoking, there is an increase in the concentrations of reactive oxygen species and cadmium which affect sperm quality.[10] A good primary testicular function may compensate the free radical injuries. As, this is known that sperm count is used to measure the effectiveness of spermatogenesis. Epididymal maturation and sperm functional capability are indicated by sperm motility.[11] Sperm motility is attributed to its tail which is composed of flagella. The mid piece provides the required energy for the movement which is rich in mitochondria.[12] Motility is important for the normal functioning of sperm, as it is not only helpful in transportation but also in penetrating the outer layers of ovum for fertilization.[13] Hence, the sperm motility can be considered as the most important factor that influences fertility.

It has been revealed in the previous researches that mammalian sperm remain motile in the female genital tract and free energy released from the hydrolysis of ATP that is required for this movement.[14] Zavos et al., have reported that abnormalities in the ultrastructure of the flagellum and the axonemal structures of the sperm tail are related with reductions in sperm motility.[15] Garrett et al., have observed in their study that superior sperm morphology and motility increased the pregnancy rates.[16]

The present study results found decreased sperm motility and sperm count in cigarette smokers with a smoking history of more than 5 years. Out of the 80 subjects, 51 subjects had low sperm count. It showed that the sperm count was less affected than the sperm motility. Zakarya Bani Meri et al., revealed in one of their study that sperm concentration was less among heavy smokers as compared to the light smokers. They concluded that, cigarette smoking has a harmful effect on some of the seminal fluid parameters like motility, morphology and leukocyte count that result in male subfertility.[17] Farkhunda Nadeem et al., found the potential dangerous chemicals present in cigarette smoke which may affect chromosomes and lead to sperm abnormality. They also reported that smoking can decrease the sperm motility and percentage of normal sperm cells that results male infertility. It is also correlated with the number of cigarettes smoked per day.[18] These results supports our study and many other studies also (Shaaraway M et al., Vytas Kaulikauskas et al., Vogt et al., Hughes ED et al, Vine MF et al., Alexander E et al., Al Bader A et al., S. Sinclaire, Arabi M and Somwanshi et al.).[19–28] Azar Aghamohammadi et al. revealed some contradictory results to our study that there was no significant difference in sperm quality in smokers except for semen volume and total sperm count. Though, they also concluded that quitting smoking is beneficial for enhancing general health. So, more research is necessary to evaluate its role in male fertility.[29]

CONCLUSION

The results of the present study showed that smoking has severe effects on male fertility. It decreased the sperm motility and sperm count and causes a further decline with continuation of smoking for more than five years.

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ORIGINAL ARTICLE

A retrospective study of central venous catheters GCRI experience

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ABSTRACT

Background: The use of central venous catheters (CVCs) has greatly improved the quality-of-care in cancer patients, yet these catheters may cause serious infectious and thrombotic complications. The aim of this retrospective study was to study the various types of CVCs and their complications. **Materials and Methods:** We studied retrospectively 213 cases of CVCs in our institute with their indications, type and complications from August 2010 to July 2011. **Results:** A total of 213 CVCs were inserted in patients with hematological (62%) and solid organ malignancies (38%). Ninety-eight patients (46%) had peripheral inserted central catheter (PICC), 90 (42%) patients had Hickman catheters and 25 (12%) had a port. The median duration of retention of Hickman catheters was 104 days (3-365 days), for the peripherally inserted central catheters was 59 days (3-100 days) and for the port it was 280 days (45-365 days). Non-infective complications were more than infective (12% vs. 7%). The most common complication was non-infective occlusion and thrombophlebitis. In one patient with PICC thrombosis occurred in the cephalic, radial and ulnar vein and in one patient with port thrombosis occurred in the superior vena cava. Organisms were isolated in 80% (12 out of 20) of cultures. Common organisms isolated were *Pseudomonas aeruginosa* in 5 (42%), *Staphylococcus aureus* in 2 (16%), *Escherichia coli* in 2 (16%) and *Aspergillus* in 3 (25%) patients. 7 out of 12 infected patients had negative blood cultures within 7 days of antibiotic treatment. 5 patients remained positive for more than 7 days with antibiotics. In 165 patients (73%), the desired treatment protocol was completed and at present there are still 28 patients (13%) with catheters. 5 patients (2.3%) died of febrile neutropenia and septicemia with multi-organ failure. In 5 patients (2.3%), the catheters (1 Port, 1 Hickman and 3 PICC) were prematurely removed because of thrombosis. **Conclusion:** CVCs are better options to facilitate the long-term vascular access provided infection is prevented with meticulous care and treated promptly with proper antibiotics. Most CVCs is acceptable to patients.

Key words: *Central venous catheter, chemo port, Hickman central venous catheter, peripheral inserted central catheter*

INTRODUCTION

Cancer patients require frequent intravenous administration of chemotherapy, antibiotics, blood components, etc., for a considerable period of time. Repeated venipunctures are poorly tolerated by these patients. The introduction of central venous catheters (CVCs) in the 1980s significantly improved the quality-of-life of oncology patients.[1,2] However, the use of these CVCs has been associated with mechanical, infectious and thrombotic complications.

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Central venous devices are of various types like open-ended tunnelled catheters, tunnelled valve catheters and implanted subcutaneous ports, non-tunneled external catheters (CVCs and peripheral inserted central catheters (PICCs)).

Relative contraindications are bleeding disorders, anticoagulation or thrombolytic therapy, combative patients, distorted local anatomy, cellulitis, burns, severe dermatitis and vasculitis.

Selection of the device is based on the number of factors such as disease, number and type of solutions, osmolality,

flow required and duration of use- days versus months, preference of physician and patient and cost of the device.

Complications are acute or delayed. Acute are: (1) procedure related; Dysrhythmias, catheter knotting or malposition, nerve injury, pneumothorax, hemothorax, hydrothorax, hemomediastinum; (2) vascular: Air embolus, arterial puncture, arteriovenous fistula, hematoma, blood clot; (3) infectious: sepsis, cellulitis, osteomyelitis, septic arthritis. Delayed like postinsertion phlebitis, extrinsic compression, i.e., pinch off, kink, catheter occlusion by precipitate, thrombus, fragmentation and infection.

AIMS AND OBJECTIVES

Aims

To study the profile of patients with CVCs and types of CVCs with respect to their complications.

Objectives

- Indications for various types of CVCs.
- Complications and their management overview.

MATERIALS AND METHODS

A retrospective study of function and complication rates of CVCs ($n = 213$) placed in children (112) and adults (101) at our institute over a 1 year period (August 2010 till July 2011) was done. We retrieved case files from the medical record department and reviewed for demographic profile, indication of insertion, any immediate, acute and late-onset complications. Indications of removal of catheter such as infection, occlusion and completion of treatment were noted.

Study population

Patients who were admitted to medical and pediatric oncology department underwent catheterization for various purposes were studied. The CVCs used were peripherally PICC, Hickman CVC (HC) or a chemo port (CP). A total of 458 CVCs were inserted. Patients with short-term catheter cavafix and subclavian/internal jugular vein (IJV) certofix (145) were excluded from the study. Patient with incomplete data (101) regarding CVC removal, lost to follow-up and catheter insertion outside the Gujarat Cancer Research Institute (GCRI) were also excluded from the study.

RESULTS AND ANALYSIS

In our study, median age of pediatric patients was 4 year (6 month to 14 year) and for adults 40 years (>14-65 year). The 112 (52.6%) CVCs were inserted in pediatric patients and 101 (47.4%) were in adult patients. Hickman was preferred in pediatric group, out of 112 CVCs, 68 (61%) were Hickman, 32 (28%) were PICC and 12 (11%) were port. Although in adults PICC was commonly used. Out of 101 CVCs, 66 (65%) were PICC, 22 (22%) were Hickman and 13 (13%) were port [Figures 1, 2, and Table 1].

Overall 62% CVCs were used in hematological malignancies and 38% were used in solid malignancies. In pediatric patients, acute lymphoblastic leukemia was most common indication others were Ewing sarcoma, rhabdomyosarcoma, retinoblastoma, hepatoblastoma, neuroblastoma, wilms' tumor and germ cell tumor. In adults most common indication was acute myeloblastic leukemia, others were breast cancer, colorectal cancer, head and neck cancer and non-Hodgkin's lymphoma.

Overall median duration of CVCs was 89 days, for PICC 59 days, Hickman catheter 104 days and for port it was 280 days.

Catheter related complications were seen in 40 (19%) CVCs. Non-infective complications (12%) such as thrombophlebitis, malposition, swelling and occlusion were more common than infective (7%).

Blood cultures and/or catheter tip cultures were send in 20 cases. Organisms were cultured in 12 (60%) specimens. Most common organism was *Pseudomonas* (five cases) while *Aspergillus* (3), *Staphylococcus aureus* (2) and *Escherichia coli* (2) were found in others. 7 out of 12 infected patients had negative blood cultures within 7 days of antibiotic treatment while 5 patients remained positive. In 155 patients (73%), the desired treatment protocol was completed and at present there are still 28 patients (13%) with catheters. 5 patients (2.3%) died of febrile neutropenia and septicemia with multi-organ failure. In 5 patients (2.3%), the catheters (1 Port, 1 Hickman and 3 PICC) were prematurely removed because of thrombosis.

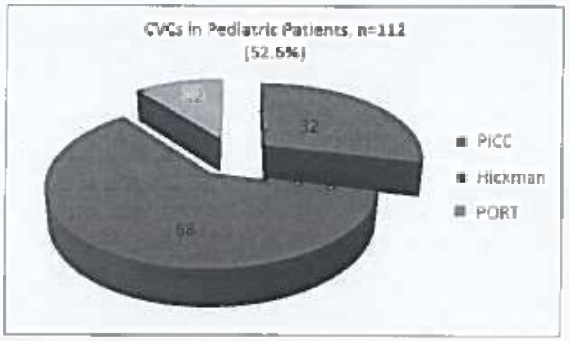

Figure 1: Number of pediatric patients with different central venous catheters

DISCUSSION

CVCs have a paramount role throughout the management of cancer patients, as they are needed in the initial phases for surgery or chemotherapy, in the advanced stage for chronic treatment and in the last stage for palliative measures. Central venous access is commonly attempted in the IJV, subclavian vein, femoral vein or arm veins.[3]

Physicians must determine the individualized catheter type by considering various factors such as catheter duration, technique, compliance, complications, cost and efficacy. CVCs are classified by tip position, technical features or materials. They can be classified in terms of short-term, medium-term or long-term access. Because superior vena cavas (SVCs) are a non-tunneled catheter, the expected duration was generally short and they have a known disadvantage of infection. The PICC is also a non-tunneled catheter and is useful for a relatively longer duration. The CP is a tunneled catheter and is useful for the long term. Tunneled catheters and PICCs[4,5] and are held to have lower infection rates, but no randomized controlled trials have demonstrated this contention to date.[6] Additionally, thrombosis occurs more often with a PICCs than other catheters due to the influence of multifactorial phenomenon.[7]

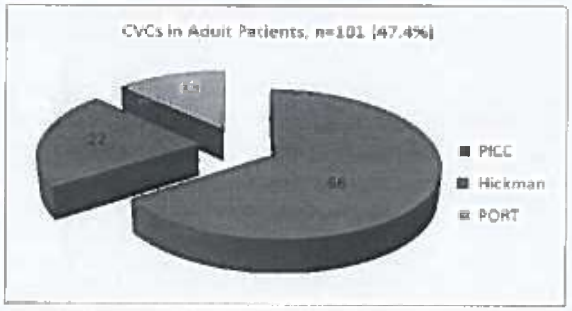

Figure 2: Number of adult patients with different central venous catheters

Table 1: Patient data

Total no. of patient	213
Median age	
Pediatric	4 years (6 months to 14 years)
Adult	40 years (>14-65 years)
Indication (%)	
Solid malignancy	81 (38)
Hematological malignancy	132 (62)

Table 2: Median duration of different devices

Median duration		
Types	Range (days)	Median (days)
PICC	3-200	59
Hickman	3-365	104
Port	45-365	280
All	3-365	89

PICC - Peripheral inserted central catheter

The incidence of catheter related complication was 19% in our study with 12% non-infected such as occlusion, malposition and swelling while 7% infected. In the study by Kim,[8] they had 18.3% non-infected complication like malposition, thrombosis, bleeding and 12.8% infected complications. In a prospective study by Nirni,[9] infection was found in 30% of cases with 26% culture positive, mainly for *S. aureus*. Jain *et al*.[10] found infection in 16% cases. In the study by Winter *et al*.[11] 13% had a non-infective complication while only 1% had infective complication. The incidence of documented thrombosis was 2.3% in our study, which was relatively low despite not using prophylactic anticoagulation. One patient with acute myeloid leukemia (AML) developed thrombosis in the cephalic, radial and ulnar vein (PICC). Other two patients with PICC thrombosis were AML induction (1) and acute lymphocytic leukemia (ALL) consolidation (1). While one patient with ca breast on adjuvant chemotherapy developed thrombosis in SVC (Port) and another patient with ALL consolidation developed thrombosis in HC. The thrombosis incidence rate tended to be more frequent (three cases) in patients with PICCs than Hickman and CPs. Nirni and Kim *et al.* noticed 2% and 4.5% incidence of thrombosis in their studies respectively. In our study incidence of complications are less, probably secondary to proper counselling, strict aseptic precautions and proper cath flush. Furthermore, we have separate CVC care service and dedicated nursing staff.

We found one catheter-related immediate-onset complication in AML induction patient in the form of hemothorax after IJV insertion, that patient also had PICC related thrombosis and pulmonary embolism and was expired. No other immediate complication like pneumothorax, except bleeding was found. Most cases were performed by an expert anesthetist or by expert oncology resident. Majority of PICC insertion were without using ultrasound (USG) or fluoroscopic guidance. A study has also reported that USG is not beneficial for reducing catheter-related complication.[12] However, it is optimal to insert catheters using USG or fluoroscopic guidance if facility available to reduce the immediate-onset complication rate.

The median PICC life span was 59 days (3-100 days), for Hickman 104 days (3-365 days) and for port 280 days (45-365 days). Overall median duration was 89 days until study completed. In addition, a longer-term use of catheters occurred in patients with a solid malignancy than hematologic malignancy. Patients with a solid malignancy underwent a CP rather than another catheter type due to scheduled, intermittent long-term chemotherapy. Therefore, the CP was considered an

Table 3: Comparison of different studies

Author	Median duration (days)	Non-infected %	Thrombosis %	Infection %	Culture positivity %	Organism
Nirni *et al.* (*n*=50)	84	11	1	30	26	*S. aureus*
Jatin *et al.* (*n*=52)	90	5.6	NA	16	NA	*S. aureus*
Winter *et al.* (*n*=43)	153	13	NA	1	NA	NA
Kim *et al.* (*n*=219)	46	18.3	4.5	32.8	NA	NA
Present study (GCRI) (*n*=213)	89	12	2.3	7	40	*Pseudomonas*

S. aureus=*Staphylococcus aureus*; GCRI=Gujarat Cancer Research Institute

effective tool for long-term use in patients with cancer. In Kim study, the median catheter life span was 46 days and the CP was useful for the long term (median 269 days); however, the median life span of the PICC was 37 days. In studies by Nirni, Jatin *et al.* and Winter *et al.* had median duration of 84 days, 90 days and 153 days respectively.

CONCLUSION

CVCs are better options to facilitate the long term vascular access provided infection is prevented with meticulous care and treated promptly with proper antibiotics. Most CVCs are acceptable to patients.

The major problems related to CVCs were thrombosis, malposition or migration of the tip and infection. Port is an effective tool for long-term use in patients with cancer, while Hickman and PICC are feasible for few months. In addition, the insertion of CVCs with the image guidance is advisable and the fixation of the tip is important for the management of PICC.

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A Prospective Study on Serum Uric Acid Level in Predicting Outcome in Acute Myocardial Infarction

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DOI: https://doi.org/10.21276/iabcr.2019.5.4.13

Keywords: Acute myocardial infraction, Uric acid, STEMI

Abstract

Background: *Higher levels of SUA are also associated with hypertension and renal disease. It is observed in >75% of patients with malignant hypertension. This elevation has been reported as a result of decreased renal blood flow and resultant increased urate reabsorption. It has been further reported that a 1 mg/dL increase in SUA levels was associated with a 26% increase in mortality.*

Methods: *. The duration of study was over a period of two year. Total 204 cases were included with acute myocardial infraction. This study was conducted in the Department of Medicine.*

Results: *In this study 204 cases of acute myocardial infraction were included. Among all cases 132 were male & 72 were female. Prevalence of uric acid level in acute MI cases were 4.1-5.5 mg/dl seen in 28.4% followed by >7.0 mg/dl in 27.4%, <4 mg/dl in 22.5% & 5.6-7.0 mg/dl in 21.5%.*

Conclusions: This study concludes that serum uric acid is a cheap and effective prognostic indicator of AMI.

Downloads

Download data is not yet available.

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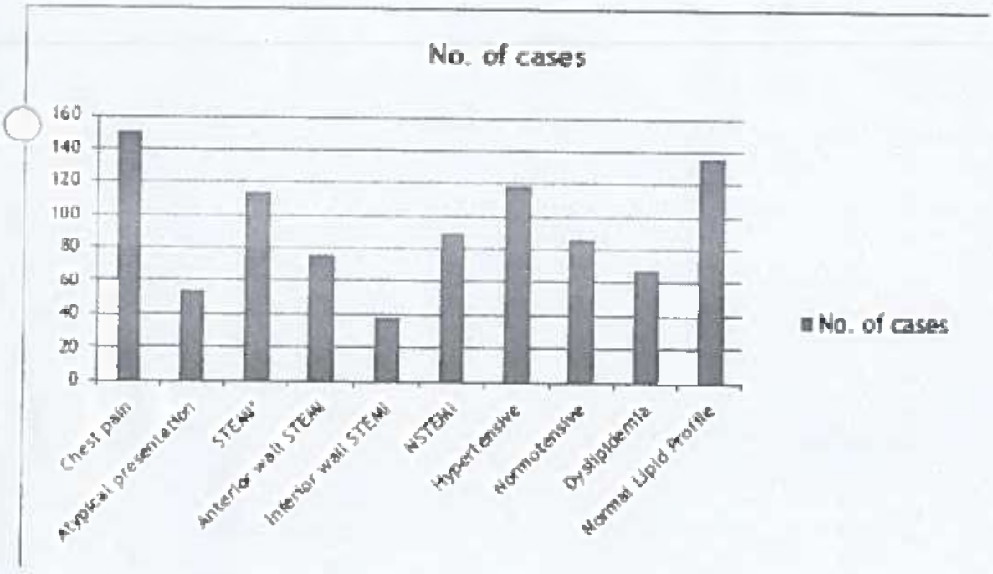

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Section General Medicine

Original Article

Incidence of Ventilator Associated Pneumonia in a Tertiary Care Teaching Hospital

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ABSTRACT

Background: *The present study was attempted for multivariate analysis through principal component analysis for carotid intima medial thickness (CIMT) as dependent variable compared to different independent variables used as parameters in diabetes and dyslipidaemia. Invasive mechanical ventilation (MV) should have to be used commonly to stabilize and treat critically ill patients in an ICU. Iatrogenic lung damages, including VAP, have been reported as some hazards of MV. These hazards are affected by the severity of illness, duration of MV, immunity and physiological reserve of the individual.*

Methods: *The biochemical and obese data of total 75 patients were taken from earlier study. The data of six biochemical markers of DM and dyslipidaemia along with one obese marker and CIMT were analysed. Data were analysed for Pearson's-Spearman correlation coefficients matrix for the relationships between CIMT and parameters of DM as well as dyslipidaemia. Principal component analysis (PCA) was performed to reduce the variables into a smaller number of uncorrelated predictor variables. Individual PC scores were generated from their risk factors loadings for DM and dyslipidaemia separately. The duration of study was over a period of one year. This study was conducted in the Department of Medicine. The study was over a period of one year and it was separated into a 6 month for pre-implementation period throughout which standard care used for mechanically ventilated cases and a for the post-implementation period also 6 months included throughout which a VAP care bundle was affected.*

Results: *In our study 323 & 306 cases were required >48 hrs during Pre-implementation period & during Post-implementation period respectively. Different types of microorganism we isolated from all cases.*

Conclusions: *It can be concluding that constant compliance with quality improvement practices would reduce the incidence of VAP shortly.*

Keywords: *VAP, Micro-Organisms, Nosocomial pneumonia*

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INTRODUCTION

Nosocomial pneumonia is one of the most acquired infections in the intensive care unit (ICU). In a number of cases, the patient's critical condition and causal disease need invasive procedures and diagnostics, which may instigate the risk of colonization by the exogenous microbes.[1-3] Endotracheal intubation is one of the most used invasive procedures. An artificial respiratory tract eliminates the physiological functions like heating, humidification and purification of the upper respiratory mucosa and increase the risk of ventilator-associated PNEU (VAP).[4-7] The microorganisms of VAP and their varied drug resistance among different hospitals wards[8] incite a need for local surveillance data that is extremely essential in starting local procedures for PNEU prevention.[1,9,10] Though the lower respiratory tract samples are the best to diagnose causative microorganism of VAP, the invasive sampling is not possible, every time.

Invasive mechanical ventilation (MV) should have to be used commonly to stabilize and treat critically ill patients in an ICU.

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Iatrogenic lung damages, including VAP, have been reported as some hazards of MV. These hazards are affected by the severity of illness, duration of MV, immunity and physiological reserve of the individual.[11,12] Patients diagnosed with VAP have been found to have a longer ICU stay,[13] higher mortality rates[14] and excessively inflated costs of treatment.[15]

It has been reported that the mortality rates in intubated ICU patients were higher than the patients who do not need ventilator support . It has been reported that in ICU patients, VAP developed 2–3 days after the endotracheal intubation. To diagnose VAP earliest, ICU care specialists should be alarmed for infection alerts (e.g. fever, white blood cell count change) and at new or progressive radiological infiltrate, altered sputum characters and isolation of a causative organism.[15]

METHODS

Study duration: - The duration of study was over a period of one year.

Study Area:-This study was conducted in the Department of Medicine.

Data Collection:-

The study was over a period of one year and it was separated into a 6 month for pre-implementation period throughout which standard care used for mechanically ventilated cases and a for the post-implementation period also 6 month included throughout which a VAP care bundle was effected. All adult patients were recruited in the study. In our study we were included who were above 18 years of age, intubated and mechanically ventilated cases. Those cases intubated prior to admission to the ICU, ICU length of stay less than 48 hours, and tracheostomies cases were excluded in this study.

Data Analysis:- Data were analyzed by using Microsoft excel.

RESULTS

In our study 739 & 649 cases included during mechanically ventilated cases during Pre-implementation period & mechanically ventilated cases during Post-implementation period respectively. Among all 323 & 306 cases were required >48 hrs during Pre-implementation period & during Post-implementation period respectively. In Pre-implementation cases 59% male & 41% were female. While 63% cases were male during Pre-implementation & 37% were female during post implementation period. 29 VAP cases pre-implementation cases & 12 post-implementation cases were microbiologically confirmed. Different types of microorganism were isolated which showed in table 6.

Table 1: Distribution of cases according to implementation period

Mechanically ventilated cases during Pre-implementation period	>48hrs required in ICU	Mechanically ventilated cases during Post-implementation period	>48hrs required in ICU
734	323	649	306

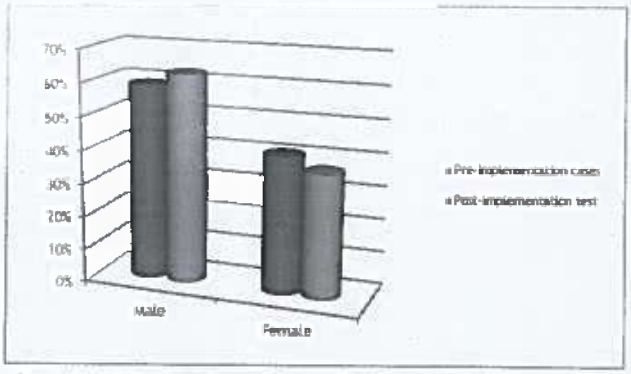

Chart: 1 Distribution of cases according to gender

Table 2: Distribution of cases according to Clinical VAP

Clinical VAP in Pre-implementation cases	Clinical VAP in Post-implementation cases
15%	9%

Table 3: Distribution of cases according to Microbiological confirmation

Microbiological confirmed VAP in Pre-implementation cases	Microbiological confirmed VAP in Post-implementation cases
(29)9%	(12)4%

Table 4: Distribution of cases according to diagnosis of bronco alveolar lavage

Diagnosed by bronco alveolar lavage in Pre-implementation cases	Diagnosed by bronco alveolar lavage in Post-implementation cases
19%	17%

Table 5: Distribution of cases according to microorganisms

Microorganisms	Pre-implementation cases	Post-implementation cases
Gram positive bacteria	10	1
Gram negative bacteria	16	9
Fungal infection	3	2
Total	29	12

Table 6: Distribution of cases according to Microbiological profile

Microbiological profile	Pre-implementation cases	Post-implementation cases
Staphylococcus aureus	9	2
CONS	1	0
Acinetobacter spp	2	1
Citrobacter spp	2	1
Enterobacter spp	3	2
Escherichia coli	2	1
Klebsiella pneumoniae	3	0
Pseudomonas spp	4	3
Fungal	3	2
Total	29	12

DISCUSSION

It has been reported in various studies that several studies have shown that the involvement of a multidisciplinary team led to a decrease in nosocomial infections and VAP.[16,17] In the present study, a VAP prevention bundle containing five elements; 30° head-up position, daily mouth wash with chlorhexidine gel (2%), continuous aspiration of subglottic secretions, daily sedation review, and daily assessment for weaning and extubation was used. This bundle was first described by the Scottish Intensive Care Society Audit Group for the Scottish Patient Safety Programme.[18] It was found in the present study that the use of a VAP prevention bundle caused a substantial decrease in the incidence of VAP. Findings of Wip and Napolitano[19] study supported the findings of the present study.

In the present study, peptic ulcer prophylaxis or DVT prophylaxis was not included in the VAP bundle as these were part of our standard regimen for critically ill patients' management. It has been reported in a couple of studies that the gastric reflux and aspiration of the gastric contents were commonly seen in supine patients while receiving enteral nutrition.[20,21] This was prevented with a semi-upright position of patients on mechanical ventilation.[22-24] This has been reported earlier that the patients in a 30° head-up position have fewer chances of developing VAP in comparison to patients positioned at less than 30°.[25,26] A decrease in the incidence of early VAP has been reported by using a subglottic secretion ETT 31 and the CASS endotracheal tube.[27,28]

It has been found that the excessive use of sedation in the ICU resulted in various side effects such as gastrointestinal motility disturbances and difficult weaning from the MV. On the contrary, it has been found in another study that the use of the least amount of sedation decreased the number of ventilated days and ICU mortality and early extubation associated with shorter duration of MV. Therefore, daily sedation interruptions of all the intubated patients have been suggested previously, if their clinical condition allows.[29-31] Prolonged intubations have been further reported to increase the chances of infection, micro-aspiration, gastrointestinal motility, and microcirculatory disturbances.[32,33] A shortened time of MV and reduced duration of ETT exposure has been reported to decrease the chances of aspiration of contaminated secretions and the risk of developing VAP.[34]

CONCLUSION

With the help of the findings of the present study, it can be suggested that the use of a VAP care bundle was an effective regimen for lowering the VAP incidence in different ICUs. It can be further stated that constant compliance with quality improvement practices would reduce the incidence of VAP shortly.

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Original Research Article

Prevalence of Septicaemia in Patients Admitted in Medicine Department Of a Tertiary Care Hospital

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ABSTRACT

Background: Bloodstream infections are important causes of mortality and morbidity. Rapid empiric antibiotic therapy is often needed. Knowledge of epidemiological data of common pathogens and their antibiotic sensitivity pattern is needed for rapid therapy.

Methods: This study was done to analyze the common causes of septicaemia and their antibiotic sensitivity pattern from the Department of Medicine, Ananta Institute of Medical Science and Research Center, Rajsamand. Isolates were identified using bacteriological and biochemical methods and antibiotic sensitivity was done using the Kirby-Bauer disc diffusion method.

Results: This study showed that of the 145 patients examined 40 (27.58%) had septicaemia. 31-45 years age group patients constituted the greatest percentage of infected subjects (n=55) followed by patients aged between 46-60 years (n=38). Gram-positive bacteria were encountered more often than gram negative bacteria. Among the gram-positive bacteria, majority isolated were *S. epidermidis*; followed by *S. aureus*.

Conclusion: Majority of the organism isolated were from Gram positive category, in which *S. epidermidis* was the most isolated.

Keywords: Septicaemia, Infection, Emergency.

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INTRODUCTION

Septicaemias are important causes of mortality and morbidity and are among the most common healthcare associated infections.[1] Illnesses associated with bloodstream infections range from self-limiting infections to life threatening sepsis that require rapid and aggressive antimicrobial treatment.[2] A wide spectrum of organisms has been described and this spectrum is subject to geographical alteration. Patients who are granulocytopenic or inappropriately treated may have a mortality rate that approaches 100%.[1] Moreover, fatalities among patients infected with Gram-negative bacilli are higher than those among patients who have Gram-positive cocci as causative agents of their bacteraemia.[3] Worldwide, emergence of antibiotic resistance in all kinds of pathogenic bacteria is a serious public health issue. It is associated with greater hospital mortality and longer duration of hospital stay, thereby increasing health care costs.[4] Also, colonization and infection with antibiotic-resistant bacteria has made the therapeutic options for infection treatment extremely difficult or virtually impossible in some instances.[5] There are many reasons for this alarming phenomenon, including increasing antibiotic use and misuse in humans, animals and agriculture, clustering and overcrowding and poor infection control.[6]

Due to the high mortality and mobility associated with septicaemia, antimicrobial therapy in most cases is initiated empirically before the results of blood culture and antimicrobial susceptibility pattern of the isolates are available.[1]

Knowledge of local antimicrobial resistance patterns from accurate bacteriological records of blood culture results is needed to provide guidance towards an empirical therapy before sensitivity patterns are available. Bacteraemia is usually caused by a wide spectrum of bacteria with varying antimicrobial susceptibility pattern.[7]

Bacteraemia often require prompt diagnosis and effective treatment to prevent death and complications from septicaemia. Physical signs and symptoms are usually useful in identifying patients with septicaemia and other non-localized infections but these have limited specificity.[8]

Bacteriological culture to isolate the offending pathogen and determine its antimicrobial sensitivity pattern has remained the mainstay of definitive diagnosis of septicaemia.[8] In most cases of suspected septicaemia antimicrobial therapy is always initiated empirically because bacteriological culture results take about a week to be available.

Epidemiological data on common blood stream pathogens and their antimicrobial sensitivity pattern is thus very important to make the right choice of empiric therapy.

MATERIALS AND METHODS

This study was conducted in the Department of Medicine, Ananta Institute of Medical Science and Research Center, Rajsamand. All the subjects were patients suspected clinically for septicaemia and sent to the bacteriology laboratory for blood culture by physicians. Written informed consent was taken before the study. The blood culture bottles were immediately incubated aerobically at 35°c for 24 hrs.

After 24hrs. bottles were checked for positive cultures (growth on the agar slope and/or turbidity in the broth). Negative cultures were reincubated and checked daily for up to three weeks unless growth occurred. Before re-incubation, the slope was re-inoculated by tippling the bottle.

Antibiotic susceptibility testing was done on MH using the Kirby-Bauer disc diffusion technique.[11] Antibiogram for Streptococcus species was done on blood agar.

Table 1: Age Distribution of Patients with Septicaemia

Age ranges (years)	No clinically examined	No (%) of positive culture
15-30	22	6
31-45	55	16
46-60	38	12
61-75	25	5
>76	5	1
Total	145	40

Table 2: The Type and Distribution Of Bacteria Isolates

Bacteria Isolates	Total
S.aureus	10
S. epidermidis	12
S. sapropihyticus	1
Streptococcus sp.	2
S. typhi	2
Salmonella species	2
K. pneumonia	2
E. coli	1
Enterobacter sp.	2
Pseudomonas sp.	1
Acinectobacter sp.	1
Proteus mirabilis	1
Non enterobacteriacaece	1
Gram positive bacilli	1
Klebsellla oxytoca	1
Total	40

RESULTS

Of the 145 patients examined for septicaemia, positive culture was found in 40 (27.58%). Age distribution of the patients is shown in Table 1.

Majority of the infected patients were found in the 31-45 years of age group (n=55) followed by 46-60 age group (n=38) and least in >76 age group. Maximum no. of positive culture was found in 31-45 age group followed by 46-60 years age group.

The type and pattern of bacteria isolates in the various age groups is shown in **Table 2**. Gram-positive bacteria were encountered more often than gram negative. Among the gram- positive bacteria, Staphylococci constituted most followed by Streptococci species. Among gram-negative bacteria, enterobacteriacea and non-fermenting bacteria were more frequent.

DISCUSSION

This study is a record of septicaemia in patients attending the Medicine department of Department of Medicine, Ananta Institute of Medical Science and Research Center, Rajsamand. Results showed that septicaemia was present in 27.58% of patients examined. Gram positive bacteria were encountered more than gram-negative bacteria, and the most frequent invasive bacteria were Staphylococcus epidermidis, S. aureus, Salmonella typhi and Klebsella species.[6]

These results are similar to those obtained in some previous studies[5]: Bacteremia was identified in 552 (45.9%) of 1201 children in Nigeria; 53.4% of the infections were due to gram positive bacteria and 46.6% due to gram negative bacteria. The most frequent isolate was S. aureus (47.7%) followed by coliforms (23.4%), unidentified gram-negative rods (8.0%), Pseudomonas aeruginosa (5.8%), Streptococcal species (4.7%) and Chromobacteria species (4.5%). Hill et al.[7] also reported an incidence of 34% (297) out of 871patients studied. The isolates were dominated by gram-positive bacteria.

Results have also shown a very high incidence of septicaemia among 31-45 age group. It is also in accordance with results from Laos in which 89.2% of Staphylococci were form majority bulk.[12] The rate of isolation also reduced with increasing age as seen in this study. However, while this study represents real life clinical practice in the hospital in which it was conducted, our approach had some limitations. The primary reason for requesting the blood culture from patients is still not clear.

CONCLUSION

This study shows that *Staphylococcus epidermidis*, *S. aureus* and *Salmonella typhi* are the living cause of bacteraemia among patients in the locality.

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Original Research Article

Use of Antihypertensive Drugs in Type 2 Diabetic Patients: A Hospital Based Study

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ABSTRACT

Background: Patients with diabetes has 2 fold higher chances of suffering from hypertension. Hypertension is risk factor for development of diabetes as well for complications like nephropathy, CAD and neuropathy etc. Hypertension control is vital to prevent and retard progression of microvascular and macrovascular complications. Therefore, we undertook this study to evaluate treatment patterns in diabetic patients with hypertension, those are being followed at our institute.

Methods: This study was conducted on diabetic patients who had hypertension as well. Prescribing Pattern of Antihypertensive drugs was analysed on all diabetic patients reporting to medicine OPD at Department of Medicine, Ananta Institute of Medical Science and Research Center, Rajsamand were screened.

Results: Out of n=220 patients, 120 were males and 100 were females. Mean age of group was 46.75 years. 46.18% patients were on monotherapy and remaining patients were on combination antihypertensive drugs. There were total 486 antihypertensive drug exposures. Patient needed mean antihypertensive drug of 1.98. Angiotensin receptor blockers were the most commonly prescribed drugs. Angiotensin inhibitors (angiotensin receptor blockers and ACE inhibitors) were utilized in 71 % patients. Hypertension control was achieved in 37.66% patients. About 81.2%) aware about disease.

Conclusion: Our study showed that majority of diabetic hypertensive patients needed multiple drug therapy to control hypertension. Most of the patients were on ARBs/ACE inhibitors. This was according to recommendation by ADA or JNC8.

Keywords: Diabetes, Hypertension, Antihypertensive Drugs, Angiotensin Receptor Blocker.

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INTRODUCTION

Hypertension and Diabetes are life style disease and are the major burden of global Health due to complications. India currently has 40.9 million diabetic patients and it is expected to rise to is expected to rise to 69.9 million by 2025 unless urgent and effective preventive steps are taken.[1]

One and half billion people will suffer from hypertension[2] and 300 million will suffer from diabetes by 2025.[3] Prevalence of hypertension is 60% in type 2 DM.[4] Patients with T2DM has two fold higher chances of suffering from hypertension in comparison to age match subjects without diabetes.[5] Hypertension has been shown as a major risk factor not only for the development of diabetes but also for the development of micro and macro vascular complications like neuropathy, nephropathy, retinopathy, coronary artery disease, stroke, Peripheral Vascular Disease (PVD) in diabetic patients. The benefits of Blood Pressure (BP) control in diabetic patients exceed the benefits of tight glycemic control and vital to the prevent and retard progression of both microvascular and macrovascular complications of hyperglycemias.[6]

Therefore, all of the hypertension management guidelines, that is, eighth report of Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure-2013 (JNC-8),[7] American Diabetes association (ADA) 2014[8] and European Society of Hypertension (ESH 2013)[9] focused aggressively on Blood Pressure (BP) control in diabetic patient to below 140/80-90 mmHg.

JNC 8 recommended target of diastolic BP <90 mmHg and ESC 2013 recommended <85 mmHg. But ADA recommended target of DBP <80 mmHg. There are limited data from India regarding physician's choices of anti-hypertensive therapies for a patient with diabetes in single- and multiple-drug based regimens. Therefore, we undertook this study to evaluate treatment patterns in diabetic patients with hypertension, those are being followed at our institute.

Our objectives were.

1. To evaluate the utilization of ACEI or Angiotensin Receptor Blockers (ARBs) and other preferred anti-hypertensive therapies based on the JNC VIII guidelines as agents to treat diabetic hypertension.
2. To compare utilization of different types of antihypertensive therapies in other comorbid conditions
3. To assess BP control in this population.
4. To assess awareness about hypertension in the study group.

METHODS

This study was conducted on diabetic patients who had hypertension as well. Prescribing Pattern of Antihypertensive drugs was analysed on all diabetic patients reporting to Department of Medicine, Ananta Institute of Medical Science and Research Center, Rajsamand, at our institute were screened. Around n=220 patients were recruited on the basis of inclusion and exclusion criteria.

Patients with advance renal failure (serum creatinine >3.5 mg %) and patients with malignant hypertension were excluded. Patients were diagnosed hypertensive if they had at least 2 visits with diagnosis of hypertension or they had prescription of antihypertensive drug with one recording of elevated BP or they had elevated BP on two visits. Elevated BP was defined as systolic BP >139 mmHg and Diastolic BP (DBP) >89 mmHg.[7] Patients were diagnosed as diabetic if they had two visits with diagnosed of diabetes or they had prescription of antidiabetic drugs or insulin or raised glycosylated haemoglobin.

Patients were diagnosed with CAD if they had symptoms suggestive of CAD with ECG evidence or echocardiographic evidence or positive treadmill test or evidence in coronary arteriography. Data of antihypertensive drugs was recorded and grouped according to class of drug. Antihypertensive drugs were grouped in to seven groups - Calcium channel blockers, beta blockers, diuretics, Alfa blockers, Angiotensin Convertase Enzyme Inhibitors (ACEI), Angiotensin Receptor Blockers (ARB), centrally acting drugs. Data for antihypertensive drugs was recorded in form of need of monotherapy, two drugs or three drugs therapy. Data for non-pharmacological therapy was also recorded like salt restriction, loss of weight or exercise.

Table 1: Showing epidemiology data.

Age (years)	Number	Monotherapy	Dual Therapy	Triple Therapy	Quadruple Therapy
<35	26	24	26	6	0
35-50	84	82	52	26	6
50-75	90	80	56	38	8
>75	20	20	12	8	2
Total	220	206	146	78	16

Table 2: Showing utilization of various drugs.

Drug	No. of patients
Angiotensin receptor blocker	100
Calcium channel blocker	86
Diuretic	78
ACE inhibitor	28
Beta blocker	58
Alfa blocker	13
Central agonist	7

Table 3: Description of combination utilization (Dual drug)

Drug Combination	Number	Percentage
ARB+D	22	30.13
CCB+BB	14	20.55
ARB+CCB	14	19.17
ACEI+D	12	16.43
ACEI+BB	10	13.69
Total	72	100

RESULTS

There were 220 patients in this study. Our study group comprised of n=120 males and n = 100 females. Demographic data of patients has been described in Table 1. 46.18% were on monotherapy and remaining patients were on combination antihypertensive drugs. There were total n=486 antihypertensive drug exposures Table 2. Patient needed mean antihypertensive drug of 1.98.

Number of drugs - Monotherapy was needed in 42.58% patients and dual therapy was required in 36.42% patients. 19.75% were on triple drug therapy and 6.25% were on quadruple drug therapy.

Type of drug - Angiotensin receptor blockers were the most commonly prescribed drugs. Angiotensin inhibitors (angiotensin receptor blockers and ACE inhibitors) were utilized in 71% patients. These were followed by calcium channel blockers, diuretics, and beta blockers Table 2.

Combination Utilization pattern - Angiotensin receptor blocker with diuretics was the most commonly used dual drug combination strategy in our study. It was followed by combination of beta blocker with calcium channel blocker, calcium channel blocker with angiotensin receptor blocker, ACE inhibitor with diuretic and ACE inhibitor with beta blocker. Combination utilization pattern has been shown in Table 3. Combination of Beta blocker with calcium channel blocker and diuretic was most commonly (51.28%) used in patients on triple drug combination. Combination of ARB, diuretic with CCB was used in 33.3% and combination of Alfa blocker, BB and diuretic was used in 10.24%. Combination of ACEI, CCB with diuretic was used in 5.12% patients. Combination of ACEI/ARB, diuretic with centrally acting drugs was used in 15.9% patients. Majority patients (50%) on quadruple therapy were on combination of Alfa blocker, diuretic, ACE inhibitor and central agonist. Combination of Alfa blocker, diuretic, central agonist with CCB or ARB was used in remaining 50% patients.

DISCUSSION

Our study tried to find utilization of various antihypertensive drugs in diabetic hypertensive patients and awareness about hypertension. A prescription based study is an effective way to assess and evaluate prescribing attitude of physicians.[10] Majority of patients in our study were on multidrug regimens. Only 42.58% patients were on single drug therapy. It is consistent with other studies.[11,12]

Berlowitz et al.[13] have shown worse BP control in patients with diabetes and less intensive anti-hypertensive medication therapy. ARB was the most common drug prescribed in 44.39% patients either alone or in combination. ACEI/ARB were used in 158 (71%) patients either alone or in combination. Most of the patients (76.6%) on single drug were receiving either ACEI or ARB. There is suggestion that ARBs should be a regular component of combination treatment and preferred drug in patients on monotherapy in diabetics.[14] It has been described that initial monotherapy ACE inhibitors may be superior to dihydropyridine CCB in reducing cardiovascular events.[15,16]

Calcium channel blockers were used in 37.66% patients either in combination or as monotherapy. JNC 8 also recommends calcium channel blockers as first line drug in diabetic hypertensive patient.[7] CCBs ranked second followed by diuretics when considering overall utilization pattern of various anti-hypertensive drugs but Johnson et al found thiazide was second most frequently prescribed drug followed by CCBs and beta blocker. CCBs ranked second followed by diuretics when considering overall utilization pattern of various anti-hypertensive drugs in Indian study.[17] Diuretics were used in 34% patients either as single or combination therapy. Diuretic use ranked third after CCBs and these were more commonly used as part of multidrug regimen. Dhanraj et al. described same pattern in their study on diabetic hypertensives.[18] Beta Blockers were used in 26% patients. Usage of BB was significantly higher in patients with CAD in our study. BB has protective effect in CAD and other studies[19,20] also found higher use of BB in patients with CAD.

ARB/ACEI with diuretic was the most commonly used combination therapy. It is consistent with other study. Patients with nephropathy needed higher no of antihypertensive drugs. Use of ACEI/ARB was higher in patients with nephropathy than without nephropathy. Shah et al.[15] also found similar pattern in their patients. Use of ACEI and ARB has been recommended by ADA9 also. Blood pressure control was achieved in 37.66% patients. Our control rates are better than other studies[19,22] with control rate of 25-32%. Which may be due to difference in sample size. Patients with nephropathy had lesser percentage of patients with control of hypertension than patients without nephropathy. Shah et al[18] also described similar pattern. Awareness about hypertension was found in 81% patients. Asfaq et al. also found awareness in 80% patients attending tertiary care hospital.[22]

CONCLUSION

Our study showed that majority of diabetic hypertensive patients needed multiple drug therapy to control hypertension. Most of the patients were on ARBs/ACE inhibitors. This was according to recommendation by ADA or JNC8. Patients with diabetes had lesser chance of control of hypertension. Hypertension control was achieved in 39% patients. We found awareness rate of 81% in our study group. Still there is room for better control of hypertension and optimization of antihypertensive therapy.

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Association of Anemia with Cerebral Venous Thrombosis in Puerperium and its Pattern of Recovery

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Keywords: cerebral venous thrombosis (CVT), anemia, IDA, neurological deficit

Abstract

Background: Anemia is often considered to be a risk factor for cerebral venous thrombosis (CVT). We investigated the association between anemia and CVT. **Methods**: 42 postpartum /puerperal females were studied retrospectively for various factors like anemia, conscious level at admission, place of delivery (home or hospital) and their neurological sequel was measured at the time of discharge.

Platelets counts were also noted (to rule out thrombocytosis). Anemia was defined according to World Health Organization criteria: non- pregnant women hemoglobin < 7.5 gm/dl, pregnant women < 6.9gm/dl. Modified Rankin Score (mRS) was taken as a scale for recovery. **Results**: *Patients with CVT were younger (mean age 28). Anemia was more frequent in 32.7%. Hemoglobin as a continuous variable was inversely associated with CVT. Platelets counts, BT CT were normal hence no thrombocytosis was seen. No gross increase in WBC count was noted indicating absence of sepsis (puerperal). Outcome was favorable in 83% patients. N=4 (7%) patients died.* **Conclusions**: *We concluded that there is a positive correlation with increased levels of HbA1c and FBS ($p<0.001$) in diabetic postmenopausal women and knee osteoarthritis. we found a significant association of severe anemia and CVT in patients of CVT of non-infectious origin, although the exact mechanism leading to hypercoagulability remains unclear and had poor prognosis.*

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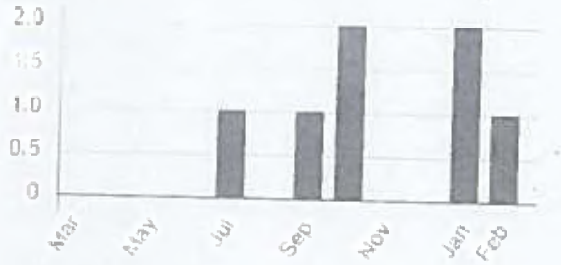

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Left Ventricular Diastolic Dysfunction (LVDD) Whether more in Hypertension or Diabetes Mellitus? An Echocardiographic Study

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Keywords: Echocardiography, Diabetes, Left Ventricular dysfunction

Abstract

Background: *To assess the effect of Hypertension and Diabetes on Left Ventricular Diastolic Function.* **Methods**: *2D Echocardiography was performed in 295 subjects. Subjects were divided into two groups – Group 1 having hypertension (HTN) and Group 2 having diabetes mellitus only (DM). Patients with cardiac illness like heart failure, myocardial infarction, arrhythmias were excluded from the study. The procedure was explained and consent was obtained from the patients. All the subjects underwent detail clinical examination. Height, weight, blood pressure, blood sugar, lipid profile, ECG was done. Early peak Diastolic (E) and late peak diastolic (A) transmitral flow were recorded. E/A was calculated. Data are presented as Mean ± Standard Deviation for continuous variables and as proportions for categorical variables. The X^2 test was used to test differences between proportion. Multiple linear*

regressions were performed to assess the independent association of hypertension and diabetes with Diastolic function parameters. Differences between Hypertension and Diabetes group were assessed by one way analysis of variance. (Performed using STATA). **Results:** *Correlation of hypertension and diabetes with Diastolic function parameters. Diabetes subjects had significantly higher A wave (P<0.05) and lower E/A ratio. No significant differences were observed between hypertension and diabetes groups in any of the Diastolic function parameters.* **Conclusions:** *Prevalence of Diastolic dysfunction of any grade in both subjects were 58.2% (62.2in Hypertension and 54.3% in Diabetes).*

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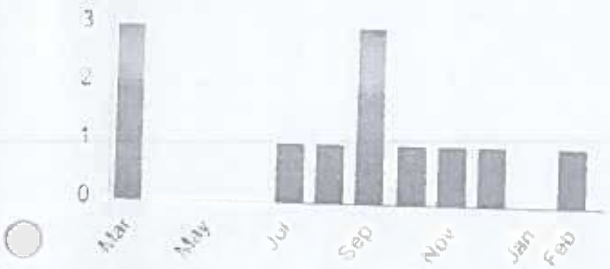

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Research Article

PREVALENCE AND DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS (GDM) AND FETOMATERNAL OUTCOME IN WOMEN WITH GDM

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Gestational Diabetes, perinatal, glucose challenge, macrosomia

ABSTRACT

Objective: the study was conducted to diagnose the gestational diabetes mellitus (GDM) in early pregnancy using glucose challenge test (GCT) and glucose tolerance test (GTT) and to find out the prevalence of GDM in southern part of Rajasthan and fetomaternal outcome in those GDM patients.

Material and Methods: It was a prospective study carried out in the department of Gynaecology and Obstetrics of a tertiary healthcare centre during the period of 2 years from January 2017 to January 2019. 700 random pregnant women with 18-28 week of gestation were subjected to 50 gram GCT. Women with abnormal GCT were then subjected to 75 gram 2 hour GTT test. Patients were followed up till delivery and perinatal and maternal status were recorded.

Results: The age of the study participants ranges from 18 to 36 years with the mean age of 24±3 years while the mean age of GDM diagnosed women was 28.3±2 years. Out of 700 pregnant women included in the study, 67 women were found to have abnormal GCT and 27 women (3.8%) out of these 67 were found to have abnormal OGTT and were diagnosed with GDM. Most of the GDM patients were having plasma glucose level between 166-175mg/dl (33.33%) followed by 155—165mg/dl (29.62%). There was no fetal loss, no congenital abnormalities; no birth asphyxia in any of the newborns of GDM diagnosed women. 4 out of 27 newborns had macrosomia (weight >4kgs) and 3 newborns had IUGR (weight < 2.5kgs). Mean birth weight was 2.67 kgs.

Conclusion: prevalence of GDM in present study was 3.8%. Routine screening of pregnant women before 28 week of gestation with GCT and GTT should be performed because it is an easy, economical and patient friendly test. Prompt diagnosis and early management can improve maternal and perinatal outcome.

INTRODUCTION

Gestational Diabetes Mellitus (GDM) is defined as any degree of glucose intolerance with the onset of pregnancy or first recognized during pregnancy. [1] Women with history of GDM are at an increased risk of adverse fetomaternal outcome and also at increased risk of future diabetes, predominantly type II including their children. [2] Therefore it is important to diagnose the GDM as early as possible to prevent adverse fetomaternal outcome and complications.

There are many controversies regarding methods of screening and diagnosis of GDM and their cost-effectiveness. Precise level of glucose intolerance which characterizes GDM has also been controversial over past few decades. In 1964, O'Sullivan and Mahan performed study on 752 pregnant women and suggested the use of glucose values in diagnosis of GDM after 3 hour 100 gram oral glucose tolerance test (OGTT).[3]

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This diagnostic criteria was further modified by National Diabetes Data Group Criteria (NDDG) in 1979 by adjusting diagnostic thresholds upward.[4] This NDDG thresholds were adopted and recommended by American Diabetes Association (ADA) as diagnostic cut-off points for GDM until 1999.[5]

In 2000, ADA revised the recommendation for GDM diagnostic criteria and proposed adoption of Coustan and Carpenter Criteria (CCC) thresholds instead of NDDG thresholds.[6]

The International Association of Diabetes and Pregnancy Study Groups (IADPSG) in 2010 decided to use mean values of fasting, 1 hour and 2 hour blood glucose of all pregnant females as reference and chose to use odds ratio of 1.75 to define the diagnostic cut-offs for GDM, which led to the development of the widely used and accepted IADPSG criteria. [7]

Still there are some controversies regarding screening of pregnant women for GDM. The ADA recommends selective screening for GDM in pregnant women who are at high risk,

while other guidelines, including those of American College of Obstetrics and Gynecologists (ACOG), support screening of all pregnant women for GDM.[8, 9] The present study used the IADPSG criteria (2010) for diagnosing GDM in which fasting OGTT was performed with 75 gram glucose and if fasting plasma glucose (FPG) is ≥126 mg/dl, overt diabetes is diagnosed and if FPG is < 126 mg/dl, then GDM is diagnosed if any one of the values exceeds the threshold shown below:

	Fasting	1 hour	2 hour
Plasma Glucose (mg/dl)	≥92	≥180	≥153

The variation in prevalence of GDM worldwide depends on various screening and diagnostic methods used as well as on age and ethnicity of the pregnant women of the particular region.[10-16] The OGTT is usually performed between the 24th and 28th week of gestation; however, in women with associated risk factors like previous gestational diabetes or family history of diabetes, OGTT should be performed earliest soon after diagnosis of pregnancy.[16] Early screening can avoid serious complications in women with GDM.[17]

The present study is aimed to find out the prevalence and diagnosis of GDM in southern part of Rajasthan with the use of GCT and OGTT and fetomaternal outcome in the patients of GDM.

MATERIAL AND METHODS

The present study was a prospective study carried out in the department of Gynaecology and Obstetrics, Ananta institute of medical sciences, Rajsamand during the period of 2 years from January 2017 to January 2019.

700 pregnant women with gestation of 18-28 week were randomly recruited from the antenatal clinic of our institute. All the 700 women were given 50 gram glucose load for glucose challenge test (GCT) without regard to the time of last meal and the venous blood samples were collected after 1 hour for estimating plasma glucose. GCT was marked abnormal if 1 hour plasma glucose was > 140 mg/dl (7.77 mmol/L).

All the women with abnormal results were then subjected to 2 hour 75 gram oral glucose tolerance test (OGTT) for confirmation. In OGTT, initial blood sample was taken after overnight fasting and the patient was then asked to drink solution of 75 gram glucose in 200 ml water. If fasting plasma glucose (FPG) was ≥126 mg/dl, overt diabetes was diagnosed and if FPG was < 126 mg/dl, then GDM was diagnosed if any one of the values exceeds the threshold as shown below:

	Fasting	1 hour	2 hour
Plasma Glucose (mg/dl)	≥92	≥180	≥153

Patients were followed up till delivery and maternal and perinatal status was recorded.

RESULTS

The age of the study participants ranges from 18 to 36 years with the mean age of 24±3 years.

Out of 700 pregnant women included in the study, 67 women were found to have abnormal GCT and these 67 women were then subjected to 2 hour, 75 gram OGTT. 27 women (3.8%) out of 67 were found to have abnormal OGTT and were diagnosed with GDM. The mean age of the GDM diagnosed women was 28.3±2 years.

Most of the GDM patients were having 2 hour plasma glucose level between 166-175mg/dl (33.33%) followed by 155—165mg/dl (29.62%). (Table 1)

Table 1 Range of plasma sugar level in GDM patients

Plasma sugar level (mg/dl)	Number of patients	Percentage
155-165	8	29.62
166-175	9	33.33
176-185	7	25.92
>185	3	11.11
Total	27	100%

There was no fetal loss, no congenital abnormalities; no birth asphyxia in any of the newborns of GDM diagnosed women. 4 out of 27 newborns had macrosomia (weight >4kgs) and 3 newborns had IUGR (weight < 2.5kgs). Mean birth weight was 2.67 kgs.

DISCUSSION

The worldwide prevalence of gestational diabetes ranges from 1-14%. [18, 19]

In India, prevalence rates reported to be between 4.6% and 14% in urban areas, and 1.7% and 13.2% in rural areas. [20] In present study, the overall prevalence of GDM was 3.8%. The figure was comparable to the studies done in the past by Indian workers like Maheshwari *et al* and Kumar *et al* with the prevalence of GDM 4.9% and 5.5% respectively. [21, 22]

The mean age of all study participants in present study was 24±3 years while the mean age of GDM diagnosed women was 28.3±2 years. Similar results were obtained in the study by Ismail NA *et al* who reported the mean age of 27.9 years in GDM patients. [23] Hence increasing age of patient was significantly associated with GDM.

High perinatal mortality rate in uncontrolled GDM patients has been reported by O'Sullivan JB *et al* in 1973. [24] Similarly, Fareed P *et al* showed 9% perinatal mortality in GDM patients compared to 1% in control group. [25] The results were in contrary to the results of present study. In present study, there was no perinatal mortality and no congenital malformation was there. Mean birth weight of the newborns was 2.67 kgs. This could be made possible because of early screening for GDM and management of the patients.

4 out of 27 newborns (14.81%) had macrosomia (weight >4kgs) and 3 newborns (11.11%) had IUGR (weight < 2.5kgs). This observation was comparable to past studies done by Fareed P *et al*, Wahi P *et al* and Bener AB *et al* where macrosomia was found 17%, 16.2% and 10.3% respectively. [25, 26, 27]

CONCLUSION

The study concluded that the prevalence of GDM is 3.8% in southern area of Rajasthan. Increasing age of pregnancy is significantly associated with GDM. We advocate the routine screening of pregnant women before 28 week of gestation with 50 gram GCT, because it is an easy, economical and patient friendly test as patient need not to come fasting for this test. Patients who have abnormal value in GCT should be subjected to GTT for confirmation of GDM. Prompt diagnosis and early management can improve maternal and perinatal outcome.

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A Prospective Study on Type 2 Diabetic Patients having Cutaneous Manifestations in a Tertiary Care Hospital in Rajsamand

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Keywords: Diabetes mellitus, skin lesions, Diabetes complications

Abstract

Background: *Diabetes mellitus is now affecting individuals of all age group and socioeconomic status. Besides other complications of the diabetes mellitus, skin is affected by the acute metabolic derangements as well as by chronic degenerative complications of diabetes. To evaluate the prevalence of skin manifestations in patients with diabetes mellitus. To analyze the prevalence and pattern of skin disorders among diabetic patients in North part of Uttar Pradesh.*

Methods: *This Prospective study was conducted on 40 diagnosed Type 2 diabetic patients having skin lesions attending the Department of Medicine, Ananta Institute of Medical Sciences & Research Center, Rajsamand, Rajasthan were included in our study on the basis of inclusion and exclusion criteria. Out*

of 40 patients, only 25 patients were completed the whole study done during the duration of 3 months (March 2016 to May 2016.

Results: *The common skin disorders were: diabetic dermopathy (44%), Xerosis (36%), skin tags (32%), cutaneous infections (31%), and seborrheic keratosis (30%).*

Conclusions: *Skin is involved in diabetes quite often and the manifestations are numerous. Most of the patients were affected from Diabetic dermopathy.*

Downloads

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Use of Antihypertensive Drugs in Type 2 Diabetic Patients - A Hospital Based Study in Rajsamand

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Keywords: Diabetes, Hypertension, Antihypertensive drugs, Angiotensin receptor blocker.

Abstract

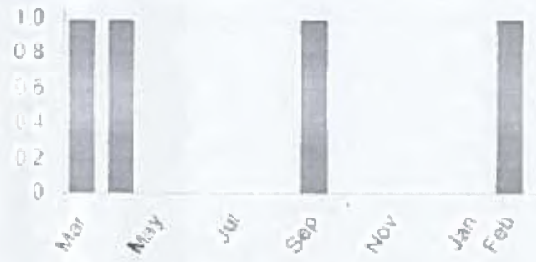
Introduction: *Diabetes Mellitus has been closely associated with Hypertension. Hypertension is major risk factor for development of diabetes as well for complications like nephropathy, CAD and neuropathy etc. Therefore, controlling Hypertension is vital to prevent and retard progression of microvascular and macrovascular complications. Therefore, we undertook this study to evaluate treatment patterns in diabetic patients with hypertension, those are being followed at our institute.*

Materials and Methods: *This study was conducted on diabetic patients who had hypertension as well attending Medicine department of Ananta Institute of Medical Sciences & Research Center, Rajsamand, Rajasthan. Antihypertensive drugs were analysed on all diabetic patients reporting to medicine OPD from February 2016 to April 2016 at our institute were screened.*

Results: *Around 145 patients were included in our study. Out of 145 patients, only n=112 patients completed our study. Out of n=112 patients, 62 were males and 50 were females. Mean age of group was 52.5 years. N=33 patients were on monotherapy and remaining patients were on combination antihypertensive drugs. There were total 331 antihypertensive drug exposures. Angiotensin receptor blockers were the most commonly prescribed drugs. Angiotensin inhibitors (angiotensin receptor blockers and ACE inhibitors) were utilized in n=150 patients.*

Conclusion: *Our study showed that majority of diabetic hypertensive patients needed multiple drug therapy to control hypertension. Most of the patients were on ARBs/ACE inhibitors. This was according to recommendation by ADA or JNC8.*

Downloads



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Original Research Article

Prevalence of Thyroid Disorders in Pregnancy

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ABSTRACT

Objective: The present study was carried out to find out the prevalence of various thyroid disorders among pregnant women in their first trimester in the southern area of Rajasthan.
Material & Methods: The study was conducted during the period of 1year from July 2017 to July 2018. 200 pregnant women attending antenatal clinic for their routine antenatal visit in first trimester were included in the study. Routine blood and urine investigations along with serum TSH, FT3 and FT4 were done in all the study participants.
Results: Age of the patient's ranged from 19 to 38 with the mean age of 25.66±3.90 years. Mean gestational age of study population was 8.12±1.63 weeks. The mean TSH, FT3 and FT4 values were 1.499, 2.386 and 1.410 respectively. Thyroid disorders were found in 14%patients out of 200 study participants. 86% patients were euthyroid among the study participants. 7% patients were found to be having subclinical hypothyroidism. 4% were having overt hypothyroidism and 3% were having subclinical hyperthyroidism.
Conclusion: The study revealed high prevalence of thyroid disorders (14%) among pregnant women in their first trimester specially hypothyroidism (11%). Routine antenatal thyroid screening should be performed in all pregnant women.

Keywords: Hypothyroidism, antenatal, hyperthyroidism, eclampsia

INTRODUCTION

Normal thyroid hormone levels are necessary in maintaining pregnancy and in development of fetus. Thyroid dysfunctions are more common in female than in male. Maternal thyroid functions changes during pregnancy and leads to thyroid disorders in absence of adaptation to these changes. Thyroid disorders during pregnancy can result in substantial adverse fetomaternal outcomes. Furthermore, thyroid dysfunction can be readily diagnosed with simple and reliable blood tests and easily corrected with economical and easily available treatments. [1]

Worldwide, thyroid disorders are common in women of child-bearing age. [2] During pregnancy, demands on the hypothalamic-pituitary-thyroid axis increases which commonly leads to borderline thyroid abnormalities. Both hyper and hypo-thyroidism types of thyroid disorders can occur during pregnancy and correction of these disorders dramatically reduces the risk of adverse fetomaternal outcomes like foetal loss, preterm birth, pre-eclampsia and eclampsia and maternal morbidity. [3,4]

According to the western literature, the prevalence of hypothyroidism in pregnancy is around 2.5%. The prevalence of gestational diabetes is around 0.1–0.4% and that of thyroid autoimmunity (TAI) is around 5-10%. [5]

There are very few data from India about the prevalence of thyroid dysfunction in pregnancy especially in the southern Rajasthan. With this background, the present study aims to find the prevalence of thyroid disorders including hyperthyroidism, hypothyroidism and Subclinical Hypo and hyper- thyroidism during pregnancy in southern part of Rajasthan.

MATERIALS AND METHODS

The present study was a prospective study carried out in the department of Gynaecology and Obstetrics, Ananta institute of medical sciences, Rajsamand during the period of 1 year from July 2017 to July 2018.

200 patients attending OPD in their first trimester for routine antenatal check up were randomly selected and included in the study.

Inclusion criteria:

1. ≤ 12 week gestation
2. Singleton pregnancy
3. Primi/ multigravidae

Exclusion criteria:

1. Patients who were not willing to give consent.

Procedure:

Detailed history of all the patients was taken regarding symptoms of thyroid disorders, past medical and obstetric history, family history and personal history. Complete general and systemic examination was done in all the patients. Per abdominal and per vaginal examination were also done and findings were recorded.

Routine blood and urine investigations along with serum TSH, FT3 and FT4 were done in all the study participants. Pregnancy ≤12 week was confirmed by clinical examination, pregnancy test and ultrasonography. The reference ranges of the test values used in this study were as per the Guidelines of American Thyroid Association (ATA) for the diagnosis and management of thyroid disease during pregnancy and postpartum. As per regulation 14.2 of ATA Guidelines, if trimester specific ranges for TSH are not available in the laboratory, the following normal reference ranges are recommended: 1st trimester - 0.1 to 2.5 m IU/L, 2nd trimester - 0.2 to 3.0 m IU/L and 3rd trimester - 0.3 to 3.0 m IU/L. Normal free T4 level is 0.7 to1.8 ng/ml and free T3 level is 1.7 to 4.2 pg/ml.

Ethical consideration: Permission was taken from institutional ethical committee and written consent was taken from all the study participants.

RESULTS

200 pregnant women in their first trimester were included in present study. Age of the patients ranged from 19 to 38 with the mean age of 25.66±3.90 years. Mean gestational age of study population was 8.12±1.63 weeks.

The mean TSH, FT3 and FT4 values were 1.499, 2.386 and 1.410 respectively. (Table 1)

Table.1 Baseline parameters of the study participants

S.No.	Parameters	Value (Mean ±SD)
1	Age	25.66±3.90 years
2	Gestational Age	8.12±1.63 weeks
3	TSH	1.499±0.324 IU/L
4	FT3	2.386±0.537 ng/ml
5	FT4	1.410±0.461 pg/ml

Thyroid disorders were found in 28 cases (14%) out of 200 study participants. Table 2 illustrates variety of thyroid disorders in the study population. 86% patients were euthyroid among the study participants. 7% patients were found to be having subclinical hypothyroidism. 4% were having overt hypothyroidism and 3% were having subclinical hyperthyroidism.

Table 2. Percentage of thyroid disorders in study participants

S.No.	Type	Number	Percentage
1	Euthyroid	172	86
2	Overt Hypothyroidism	8	4
3	Subclinical hyperthyroidism	6	3
4	Subclinical hypothyroidism	14	7
5	Overt Hyperthyroidism	0	0
6	Total	200	100

DISCUSSION

The present prospective study was conducted in a tertiary healthcare centre of southern Rajasthan. 200 pregnant women

with ≤12 weeks of gestation, who met the inclusion criteria, were included in the study.

The prevalence of thyroid disorders was 14% in present study. Many studies done in the past had similar results. Taghavi et al found 14.6% prevalence of thyroid disorders in their study. [6] Ajmani et al found 13.25% cases of thyroid disorders in their study. [7] Similarly, Weiwei Wang et al (10.2%), Sahu et al (12.7%) and Dhanwal DK et al (14.3%) had comparable results in their studies. [8-10]

The prevalence of thyroid disorder was very less (5%) in a study conducted by Thanuja PM et al [11], while the prevalence was very high (26.5%) in a study by Rajput et al [12], hence the results of these studies were in contrary with present study.

The prevalence of subclinical hypothyroidism in present study was 7%. In a study done by Sangeeta Pahwa et al, the prevalence of subclinical hypothyroidism was 6%. [13] Similarly, in a study by Sahu MT et al, the prevalence was 6.47% which is also comparable to our study. [9]

All women who have been diagnosed subclinical hypothyroidism during pregnancy should be tested for antithyroid antibodies because it can be associated with other autoimmune disorders like type I diabetes and can have adverse fetomaternal outcome. [14,15] ATA updated its guidelines in 2017 for the management of thyroid disorders in pregnancy. They suggested that Thyroxine should be started if antithyroid antibodies are present and initial level of TSH is 2.5- 4 mIU/L. If initial TSH level is > 4mIU/L, then Thyroxine should be started irrespective of the status of antithyroid antibodies. Usually the Thyroxine is started in the dose of 50 microgram per day to treat subclinical hypothyroidism and thyroid function tests are repeated after 4 weeks of starting treatment. [16, 17]

The prevalence of overt hypothyroidism in present study was 2%, which was consistent with the results obtained by Saraladevi et al with the prevalence of 2.8% [18] and partly consistent with the results obtained by Sahu MT et al, in which the prevalence was 4.58%. [9]

In present study, prevalence of subclinical hyperthyroidism and overt hyperthyroidism were 3% and 0% respectively. The prevalence of subclinical and overt hyperthyroidism was 0.5 and 0.4% respectively in the study done by Stagnaro Green A. [17] Similarly in the study done by Saraladevi et al the prevalance were 1.8% and 0.6% respectively. [18]

Our study had few limitations that fetomaternal outcomes were not included in the study. The sample size was also small. Hence, further researches with large sample size are advisable.

CONCLUSION

The study revealed high prevalence of thyroid disorders (14%) among pregnant women in their first trimester specially hypothyroidism (11%). Hyperthyroid disorders are rare in pregnant women. Due to immense impact of thyroid disorders on the fetomaternal outcome, we advocate the routine antenatal thyroid screening.

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ASSESSMENT OF CLINICAL PROFILE OF DENGUE FEVER

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ABSTRACT

Background: World health organization also reported that as the high prevalence of dengue infection seen worldwide it requires immediate action and planning to combat the situation. It is reported that globally more than 2.5 billion of population living in the areas which are endemic for dengue viral infection. Approximately near about 50 million new dengue infections reported each year. **Material & Methods:** The present cross-sectional study includes 100 Patients who had dengue IgM antibody positive were enrolled from outdoor and from ward by simple random sampling. Clearance from Institutional Ethics Committee was taken before start of study. Written informed consent was taken from each study participant. **Results:** 92 % patients had myalgia which was followed by headache in 86% patients, 84% patients had retro-orbital pain and 83% patients had vomiting. Out of the total pain abdomen was present among 72% patients, bleeding tendencies were found among 21% patients, petechiae/purpura was present in 13% patients. Oliguria was found among 2% patients, 1% patient had altered sensorium and convulsions was present among 1% patient. **Conclusion:** The common presenting symptoms of dengue viral infections were fever, headache, myalgia, retro orbital pain, vomiting, pain abdomen, purpura and bleeding tendencies. The most common presenting sign was skin rash followed by ascites and splenomegaly. The most common presented complication was hepatic dysfunction.

Key words: Dengue fever, Clinical profile, Complications.

INTRODUCTION

The prevalence of dengue viral infection has tended to rise globally in the recent decades (1). According to the World Health Organization about forty percent of the world's population reported that in current scenario is at risk for encountering dengue viral infection (2). Dengue is an emerging epidemic disease and several outbreaks among every state of India is being reported from time to time (3). In India the burden and prevalence of dengue viral infection is increasing as trends reported globally. Hence, along with global pandemic concern dengue has become major public health concern in India.

The etiology behind dengue is reported as vector borne viral diseases which is transferred to humans by the bite of the infected Aedes mosquito. It was also reported that the number of dengue vector (Aedes mosquito) also increased which is also contributing in the high prevalence of dengue viral infections (4).

Due to its high incidence and prevalence rates of dengue viral infections in India, national vector borne diseases control program is initiated for integrated management of vector, surveillance and monitoring and diseases prevention along with

patients which was followed by ascites among 28% patients. Hepatomegaly was found among 24% patients and splenomegaly was found among 9% patients. Positive tourniquet test was reported among 13% patients. (Table 2)

Table 2: distribution of study subjects based on signs

Signs	Number of Patients
Skin rash	56%
Ascites	28%
Hepatomegaly	24%
Tourniquet test (positive)	13%
Splenomegaly	9%

In the present study, out of total 100 study participants, on the assessment of complications of dengue fever it was found that, hepatic dysfunction was the most common presented complication which was present among 36% patients which was followed by shock reported among 3% of patients. pleural effusion was reported among 2% patients and acute renal failure was reported among 2% cases. Severe hemorrhage and encephalitis were present among 1% patients respectively. (Table 3)

Table 3: distribution of study subjects based on complications of dengue fever.

Complications	Number of patients
Hepatic dysfunction	36%
Shock	3%
Pleural effusion	2%
Renal failure	2%
Severe hemorrhage	1%
Encephalitis	1%

DISCUSSION

Dengue is an emerging epidemic disease and several outbreaks among every state of India is being reported from time to time (3). In Inia the burden and prevalence of dengue viral infection is increasing as trends reported globally. Hence, along with global pandemic concern dengue has become major public health concern in India. The etiology behind dengue is reported as vector borne viral diseases which is transferred to humans by the bite of the infected Aedes mosquito. It was also reported that the number of dengue vector (Aedes mosquito) also increased which is also contributing in the high prevalence of dengue viral infections (4). In the present study we enrolled 50 patients who were aged from 18 to 71 years. The mean age of the enrolled patient was 42.36 ± 5.19 years. There was no patient in the present study who aged less than 15 years of age. Out of total patients diagnosed dengue IgM antibody positive 58% were male and 42% were females. All of these patients with dengue viral fever were subjected for routine blood investigation for complete blood count and liver function test and ELISA for dengue serology. Similar results were obtained in a study conducted by Aggarwal A et al among patients of dengue viral fever and found similar results with present study (9).

Out of the total study participants, all of them were presented with fever. 92 % patients had myalgia which was followed by headache in 86% patients. 84% patients had retro-orbital pain and 83% patients had vomiting. Out of the total pain abdomen was present among 72% patients. bleeding tendencies were found among 21% patients, petechiae/purpura was present in 13% patients. Oliguria was found among 2% patients. 1% patient had altered sensorium and convulsions was present among 1% patient. Similar results were obtained in a study conducted by Chandralekha et al among patients of dengue viral fever and found similar clinical profile patterns among study participants (10). Similar results were obtained in a study conducted by Selvan T et al among patients of dengue viral fever and found fever was the most common symptom which was followed by myalgia and retroorbital pain, vomiting and convulsions and altered sensorium (11).

In the present study, out of total 100 study participants, on the assessment of signs of dengue fever it was found that, skin rash was the most common presenting sign reported among 56% patients which was followed by ascites among 28% patients. Hepatomegaly was found among 24% patients and splenomegaly was found among 9% patients. Positive tourniquet test was reported among

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ROLE OF SERUM LIPID PROFILE IN OCCURRENCE OF DIABETIC NEPHROPATHY?

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ABSTRACT

Background: The prevalence of non-communicable diseases is increasing compared to communicable diseases. Among the non-communicable diseases, diabetes mellitus is rapidly increasing globally and affecting all the age groups. Diabetes is a chronic disease in etiology and occurs when the pancreas does not produce enough amount of insulin or when there is resistance towards its action on the body. **Material & Methods:** In the present study a total 200 patients with type 2 diabetes mellitus and confirmed with laboratory investigations were enrolled from outdoor and from ward by simple random sampling. Clearance from Institutional Ethics Committee was taken before start of study. Written informed consent was taken from each study participant. **Results:** The mean value of total cholesterol among study participants was 194.2 ± 36.4 mg/dl, mean value of HDL- cholesterol was 32.4 ± 6.2 mg/dl, mean value of LDL- cholesterol was 112.8± 42.5 mg/dl and mean value of Serum triglycerides was 201.6 ± 58.7 mg/dl. 32 (16%) diabetes patients had diabetic Nephropathy. On the estimation of GFR, it was found that Out of total diabetic patients, 168 (84%) diabetic patients had GFR > 90 ml/min/1.73 m2, 30 (15%) diabetic patients had GFR of 60-90 ml/min/1.73m2 and 02 (1%) diabetic patients had GFR < 60 ml/min/1.73 m2. There was a significant association found between High LDL-cholesterol, High serum triglycerides and High total cholesterol levels. (p value < 0.05). **Conclusion:** We concluded from the present study that there was a significant association was found between dyslipidemia and diabetic nephropathy in patients with type 2 diabetes mellitus. Hence, serum lipid profile should be investigated annually among all the patients of diabetes.

Key words: Diabetes mellitus, Diabetic nephropathy, Dyslipidemia.

INTRODUCTION

The prevalence of non-communicable diseases is increasing compared to communicable diseases. Among the non-communicable diseases, diabetes mellitus is rapidly increasing globally and affecting all the age groups. Diabetes is a chronic disease in etiology and occurs when the pancreas does not produce enough amount of insulin or when there is resistance towards its action on the body. In 2014, WHO reports that 8.5% of adults who aged 18 years or above had diagnosed with diabetes. In 2016, WHO reports that diabetes was the directly responsible for 1.6 million mortality occurred worldwide. It was estimated that by the year 2030 diabetes will became seventh leading cause of mortality worldwide (1).

In India, the prevalence of diabetes is increasing and imposing challenges on health care infrastructure of the country. The overall prevalence of diabetes reported by WHO was 8.7% among the age group of 20 and 70 years. This rising prevalence depends on

various factors such as, sedentary lifestyles, rapid urbanization, unhealthy diets and substance use/abuse along with increasing life expectancy. Obesity and overweight are also the most important associated risk factors. The onset of diabetes can be prevented or delayed by life style and behavioral changes by taking healthy diet and routine physical activity (2).

The diabetes has several microvascular and macrovascular complications which are responsible for several serious complications. Dyslipidemia in diabetes characterized by abnormalities in patient's lipid profile associated with changes in quantity and quality of serum lipoproteins. These changes in serum lipoproteins leads to vascular complications such as coronary heart disease, atherosclerosis and several other macrovascular complications. Diabetes mellitus is most common leading cause of end stage renal disease. Diabetic nephropathy is accounts for mortality and morbidity among more than 20% of patients with diabetes mellitus (3). Hence, the association of dyslipidemia in macro vascular complications has been well studied. Therefore, we conducted the present study to elaborate and find the role of serum lipid profile among the cases of diabetic nephropathy.

MATERIALS & METHODS

The present prospective study was conducted at department of general medicine of Pacific Medical College & Hospital, Udaipur. The study duration was of one year from Oct. 2016 to Nov. 2017. A sample size of 200 was calculated at 95% confidence interval at 10% acceptable margin of error by epi info software version 7.2. Patients who were presenting with type 2 diabetes mellitus and confirmed with laboratory investigations were enrolled from outdoor and from ward by simple random sampling. Clearance from Institutional Ethics Committee was taken before start of study. Written informed consent was taken from each study participant.

The data were collected by detailed history, general physical and clinical examination from each patient after taking the written consent. The hematological investigation was done for fasting and post prandial blood sugar, glycosylated hemoglobin (HbA1c), fasting lipid profile, 24 hour urine protein, serum creatinine levels, spot urine albumin levels and spot urine albumin creatinine ratio. Dyslipidemia was considered if the values of, TG≥150 mg/dl, S. LDL≥ 100mg/dl, S. HDL value ≤40 mg/dl (male) and ≤50 mg/dl (female) and TC more than 200 mg/dl (4). GFR estimation was done by using Crockroft-Gault equation. Patients who had hypertension, patients taking drugs for lipid lowering or drugs which can alter lipid profile and BMI> 30 kg/m2 were excluded from the present study. Data analysis was carried out using SPSS v22. All tests were done at alpha (level significance) of 5%; means a significant association present if p value was less than 0.05.

RESULTS

In the present study we enrolled 200 patients of diabetes mellitus who were aged from 28 to 60 years. The mean age of the enrolled patients was 38.91 ± 7.56 years. Out of total patients diagnosed with diabetes mellitus 116 (58%) patients were male and 84 (42%) patients were females. On the detailed history and laboratory investigation it was found that mean duration of diabetes mellitus was 5.64 ± 4.23 years. Mean level of HbA1C was 8.45 ± 1.69. We found the mean fasting blood sugar was 167.6 ± 21.2 mg/dl and mean post prandial blood sugar was 265.7 ± 32.6 mg/dl. The dyslipidemia was found among 114 (57%) patients in our study and it was found that 32 out of 116 males and 25 out of 84 females were diagnosed with dyslipidemia, i.e. the prevalence of dyslipidemia among males was 27.6% whereas among females was 29.8%. (Table 1)

Table No.-1: Distribution of patients according to study parameters.

Study parameters	No. of Patients (%)
Male	116 (58%)
Female	84 (42%)
Mean age	38.91 ± 7.56 years
Mean duration of diabetes mellitus	5.64 ± 4.23 years
Mean HbA1C	8.45 ± 1.69
Mean fasting blood sugar	167.6 ± 21.2 mg/dl
Mean post prandial blood sugar	265.7 ± 32.6 mg/dl
Prevalence of dyslipidemia	114 (57%)

In the present study, combined serum lipid profile abnormalities were found among majority of

cholesterolemia patients. Among the patients with combined dyslipidemia, we found raised serum triglycerides and low HDL- cholesterol levels in higher frequencies among both males and females. This abnormality in serum lipid profile is followed by isolated dyslipidemia associated with decreased levels of HDL- cholesterol among both males and females. The mean value of total cholesterol among study participants was 194.2 ± 36.4 mg/dl, mean value of HDL- cholesterol was 32.4 ± 6.2 mg/dl, mean value of LDL- cholesterol was 112.8± 42.5 mg/dl and mean value of Serum triglycerides was 201.6 ± 58.7 mg/dl. We found a statistically significant association control (p value < 0.05) with dyslipidemia and HbA1C more than 7(poorly controlled diabetes mellitus). (Table 2)

Table No.-2: Mean values of serum lipid profile in our study.

Lipid parameter	Mean +SD
Total cholesterol	194.2 ± 36.4 mg/dl
HDL- cholesterol	32.4 ± 6.2 mg/dl
LDL- cholesterol	112.8± 42.5 mg/dl
Serum triglycerides	201.6 ± 58.7 mg/dl

In present study, out of total two hundred enrolled study participants, 32 (16%) diabetes patients had Diabetic Nephropathy. Out of these 32 (16%) diabetic nephropathy patients 28 (14%) presented with micro albuminuria and 04 (2%) presented with macro albuminuria. On the estimation of GFR, it was found that Out of total diabetic patients, 168 (84%) diabetic patients had GFR > 90 ml/min/1.73 m2. 30 (15%) diabetic patients had GFR of 60-90 ml/min/1.73m2 and 02 (1%) diabetic patients had GFR < 60 ml/min/1.73 m2. There was a significant association found between High LDL-cholesterol, High serum triglycerides and High total cholesterol levels (p value < 0.05) (Table 3)

Table No.-3: Distribution of patients according to study parameters.

Study parameters	No. of Patients (%)
Diabetic Nephropathy	32 (16%)
micro albuminuria	28 (14%)
macro albuminuria	04 (2%)
GFR > 90 ml/min/1.73 m2	168 (84%)
GFR - 60-90 ml/min/1.73m2	30 (15%)
GFR < 60 ml/min/1.73 m2	02 (1%)

DISCUSSION

In the present study we enrolled 200 patients of diabetes mellitus who were aged from 28 to 60 years. The mean age of the enrolled patients was 38.91 ± 7.56 years. Out of total patients diagnosed with diabetes mellitus 116 (58%) patients were male and 84 (42%) patients were females. On the detailed history and laboratory investigation it was found that mean duration of diabetes mellitus was 5.64 ± 4.23 years. Mean level of HbA1C was 8.15 ± 1.69. We found the mean fasting blood sugar was 167.6 ± 21.2 mg/dl and mean post prandial blood sugar was 265.7 ± 32.5 mg/dl. The dyslipidemia was found among 114 (57%) patients in our study and it was found that 22 out of 116 males and 25 out of 84 females were diagnosed with dyslipidemia. I.e. the prevalence of dyslipidemia among males was 19.6% whereas among females it was 29.8%. Similar results to the present study was found in a study conducted by yadav SK et al among patients of type 2 diabetes mellitus to found the association between serum dyslipidemia and diabetic nephropathy and they found the overall prevalence of serum dyslipidemia was 70% (5). Similar results to the present study was found in a study conducted by Hetal Pandya et al et al among patients of type 2 diabetes mellitus to found the association between serum dyslipidemia and diabetic nephropathy and they found the overall prevalence of serum dyslipidemia was 72% (6).

In the present study, combined serum lipid profile abnormalities were found among majority of dyslipidemia patients. Among the patients with combined dyslipidemia, we found raised serum triglycerides and low HDL- cholesterol levels in higher frequencies among both males and females. This abnormality in serum lipid profile is followed by

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isolated dyslipidemia associated with decreased levels of HDL- cholesterol among both males and females. The mean value of total cholesterol among study participants was 194.2 ± 36.4 mg/dl, mean value of HDL- cholesterol was 32.4 ± 6.2 mg/dl, mean value of LDL- cholesterol was 112.8± 42.5 mg/dl and

mean value of Serum triglycerides was 201.6 ± 58.7 mg/dl. We found a statistically significant association control (p value < 0.05) with dyslipidemia and HbA1C more than 7 (poorly controlled diabetes mellitus). Similar results to the present study was found in a study conducted by Daniel Nii Aryee Tagoe et al et al among patients of type 2 diabetes mellitus to found that the overall prevalence of serum dyslipidemia was 93%. They found raised serum triglycerides and low HDL- cholesterol levels in higher frequencies among both males and females (7). Similar results to the present study was found in a study conducted by Jayarama N et al et al among patients of type 2 diabetes mellitus to found that combined serum lipid profile abnormalities among majority of patients (8).

In present study, out of total two hundred enrolled study participants, 32 (16%) diabetes patients had diabetic Nephropathy. Out of these 32 (16%) diabetic nephropathy patients 28 (14%) presented with micro albuminuria and 04 (2%) presented with macro albuminuria. On the estimation of GFR, it was found that Out of total diabetic patients, 168 (84%) diabetic patients had GFR > 90 ml/min/1.73 m2, 30 (15%) diabetic patients had GFR of 60-90 ml/min/1.73m2 and 02 (1%) diabetic patients had GFR < 60 ml/min/1.73 m2. There was a significant association found between High LDL-cholesterol, High serum triglycerides and High total cholesterol levels. (p value < 0.05). Similar results to the present study was found in a study conducted by Vinod M R et al et al among patients of type 2 diabetes mellitus (9). Similar results to the present study was also found in a study conducted by Prashant Tayde et al et al among patients of type 2 diabetes mellitus (10). Similar results to the present study was also found in a study conducted by Kanakamani J et al et al among patients of type 2 diabetes mellitus and found that microalbuminuria among 24 % diabetic patients and macroproteinuria among 6% diabetic patients (11). Similar results to the present study was also found in a study conducted by Macisaac RJ and Jerums G among patients of type 2 diabetes mellitus and found that 20 % patients have GFR <60ml/min/1.73m2 (12). Similar results to the present study was also found in a study conducted by Toth PP among patients of type 2 diabetes mellitus and found that dyslipidemia is significantly associated with diabetic nephropathy (13).

CONCLUSION

We concluded from the present study that there was a significant association was found between dyslipidemia and diabetic nephropathy in patients with type 2 diabetes mellitus. Hence, serum lipid profile should be assessed annually among all the patients of diabetes. Screening for Diabetic Nephropathy done by estimation of urinary albumin and creatinine.

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ASSESSMENT OF CLINICAL PROFILE OF PATIENTS WITH ALCOHOLIC LIVER DISEASE

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Abstract

Background: Alcohol consumption affects both mental and physical function of the body and hence called as "dual disease" because it has mentioned in etiology of morbidity in both the components of the body. According to the reports of World Health Organization there were more than 150 million people worldwide has indulged with alcoholism.

Material & Methods: The present prospective study was conducted at department of general medicine of our tertiary care hospital. 100 Patients who were diagnosed as acute onset alcoholic liver disease were enrolled from outdoor and from ward by simple random sampling.

Results: The most common clinical feature recorded among study participants was of nausea and vomiting seen in 46 (92%) of patients, which was followed by jaundice reported among 43 (86%) of patients. Hepatomegaly was reported among 37 (74%) of patients, which was followed by signs of liver failure reported among 30 (60%) patients, followed by anorexia reported among 29 (58%) of patients. Splenomegaly was reported among 17 (34%) of patients, fever was reported among 13 (26%) of patients, abdominal pain was reported among 12 (24%) of cases and ascites was reported among 8 (16%) study participants.

Conclusion: We concluded from the present study that larger quantities of alcohol consumption for a longer duration of time result in high morbidity and mortalities. Alcoholic liver disease is not only a medical burden but also a social burden which leads to frequent hospitalization and unwanted out of pocket expenditure.

Key words: alcoholic liver disease, liver cirrhosis, hepatomegaly.

Introduction:

Alcohol consumption affects both mental and physical function of the body and hence called as "dual disease" because it has mentioned in etiology of morbidity in both the components of the body. According to the reports of World Health Organization there were more than 150 million people worldwide has indulge with alcoholism (1). Several studies had reported that alcoholism affect the biological mechanisms which involves in equilibrium of multiple organs of human body along with this it directly have adverse effect on social environment of the person involving family life, mental health and also the vocational capabilities (2). Alcohol act as central nervous system depressant in higher blood concentration, however in low doses it act as central nervous system behavioral stimulant (3). Alcoholism is reported to be significantly associated with high mortality and morbidity rates, which accounts for more than 4% of the mortality reported worldwide and also for near about 5% of the DALYs lost worldwide (4).

Alcoholic liver disease has reported to have group of diseases disease ranging from mild liver steatosis to severe liver cirrhosis. The most common etiology behind this ranging disease spectrum reported was chronic and excessive alcohol consumption (5). In India also alcoholism is reported for the most prevalent cause of acute and chronic liver diseases (6). Alcoholic liver disease ranges from mild fatty liver, alcoholic hepatitis and alcoholic cirrhosis. Among them alcoholic hepatitis and severe liver cirrhosis are life threatening conditions and sometimes fatal (7). However, many other factors are also associated in the outcome of the alcoholic liver diseases like, amount and duration of alcohol content, nutritional deficiency, iron overload, viral hepatitis and several genetic factors (8). Hence, we conducted present study to assess the clinical profile of alcoholic live disease.

MATERIALS & METHODS

The present prospective study was conducted at department of general medicine of our tertiary care hospital. The study duration was of six months from July 2018 to December 2018. A sample size of 50 was calculated at 95% confidence interval at 10% acceptable margin of error by epi info software version 7.2. Patients who were diagnosed as acute onset alcoholic liver disease were enrolled from outdoor and from ward by simple random sampling. Clearance from Institutional Ethics Committee was taken before start of study. Written informed consent was taken from each study participant.

The data were collected by detailed history, general physical and clinical examination from each patient after taking the written consent. The hematological investigation was done for routine blood investigation and liver function test. Patients who had chronic diseases such as cardiac diseases, renal diseases, hypertension and cancer were excluded from the study. Data analysis was carried out using SPSS v22. All tests were done at alpha (level significance) of 5%; means a significant association present if p value was less than 0.05.

RESULTS

In the present study we enrolled 50 patients who were aged from 21 to 59 years. The mean age of the enrolled patient with alcoholic liver disease was 36.42 ± 4.78 years. There was no patient in the present study who aged less than 18 years of age. Out of total patients diagnosed with alcoholic liver disease 94% were male and 6% were females. In the present study, majority of the patients were in the age group of 31-40 years (52%) which is followed by 24% of the patients were in the age group of 21- 30 years followed by 14% of the patients were in the age group of 41-50 years and 10% of patients were in the age group of 51-60 years. In our study majority of patients were farmers which is followed by employed at private service and daily wages workers. In the present study, according to the of alcohol consumption majority of the patients were consumed alcohol intake more than 60 gm which is followed by patients who were consuming alcohol 50 - 60 gm in 24 hours and lastly patients who had history of alcohol consumption of less than 50 gm in 24 hours. On the basis of consumption, majority of the patients had alcohol consumption of more than five years which is followed by alcohol consumption for past 3-4 years, which is followed by alcohol consumption for past 2-3 years and at last patients who had history of alcohol consumption from past 1-2 years. (Table 1)

Table 1: Age and gender wise distribution of study participants.

Variables		No. of cases
Age (years)	21-30 years	12 (24%)
	31-40 years	26 (52%)
	41-50 years	7 (14%)
	51-60 years	5 (10%)
Gender	Male	47 (94%)
	Female	3 (6%)

In the present study, the most common clinical feature recorded among study participants was of nausea and vomiting seen in 46 (92%) of patients, which was followed by jaundice reported among 43 (86%) of patients. Hepatomegaly was reported among 37 (74%) of patients, which was followed by signs of liver failure reported among 30 (60%) patients, followed by anorexia reported among 29 (58%) of patients. Splenomegaly was reported among 17 (34%) of patients, fever was reported among 13 (26%) of patients, abdominal pain was reported among 12 (24%) of cases and ascites was reported among 8 (16%) study participants. (Table 3)

Table 2: Distribution of study participants based upon clinical features.

Clinical features	No. of cases
Nausea and vomiting	46 (92%)
Jaundice	43 (86%)
Hepatomegaly	37 (74%)
Signs of liver failure	30 (60%)
Anorexia	29 (58%)
Splenomegaly	17 (34%)
Fever	13 (26%)
Abdominal pain	12 (24%)
Ascites	8 (16%)

DISCUSSION

In the present study we enrolled 50 patients who were aged from 21 to 59 years. The mean age of the enrolled patient with alcoholic liver disease was 36.42 ± 4.78 years. There was no patient in the present study who aged less than 18 years of age. Out of total patients diagnosed with alcoholic liver disease 94% were male and 6% were females. In the present

study, majority of the patients were in the age group of 31-40 years (52%) which is followed by 24% of the patients were in the age group of 21- 30 years followed by 14% of the patients were in the age group of 41-50 years and 10% of patients were in the age group of 51-60 years. Similar results were obtained in a study conducted by Chavan et al among patients of alcoholic liver disease and found that majority of the patients with alcoholic liver disease were in the age group of 30-40 years (9). Similar results were obtained in a study conducted by Nand et al among patients of alcoholic liver disease and found that male preponderance was highly prevalent. They reported similar mean age finding to the present study (10).

In our study majority of patients were farmers which is followed by employed at private service and daily wages workers. In the present study, according to the of alconol consumption majority of the patients were consumed alcohol intake more than 60 gm which is followed by patients who were consuming alcohol 50 - 60 gm in 24 hours and lastly patients who had history of alcohol consumption of less than 50 gm in 24 hours. On the basis of consumption, majority of the patients had alcohol consumption of more than five years which is followed by alcohol consumption for past 3-4 years, which is followed by alcohol consumption for past 2-3 years and at last patients who had history of alcohol consumption from past 1-2 years. Similar results were obtained in a study conducted by Pathak et al among patients of alcoholic liver disease and found that male preponderance was highly prevalent and majority of patients were farmers which is followed by employed at private service and daily wages workers (11). Similar results were obtained in a study conducted by Ray et al among patients of alcoholic liver disease and found that majority of the patients had alcohol consumption of more than 80 grams per day and also consumed poor quality of liquor for a mean duration 9 years and more (12).

In the present study, the most common clinical feature recorded among study participants was of nausea and vomiting seen in 46 (92%) of patients, which was followed by jaundice reported among 43 (86%) of patients. Hepatomegaly was reported among 37 (74%) of patients, which was followed by signs of liver failure reported among 30 (60%) patients, followed by anorexia reported among 29 (58%) of patients. Splenomegaly was reported among 17 (34%) of patients, fever was reported among 13 (26%) of patients, abdominal pain was reported among 12 (24%) of cases and ascites was reported among 8 (16%) study participants. Similar results were obtained in a study conducted by Mitra et al among patients of alcoholic liver disease and found that ascites was the most common finding followed by hepatic encephalopathy and upper gastrointestinal bleed (13). Similar results were obtained in a study conducted by Mendenhall et al among patients of alcoholic liver disease and found that in majority of patients ascites was the most common finding (14). Similar results were obtained in a study conducted by Khatroth S et al among patients of alcoholic liver disease and found that in majority of patients nausea and vomiting and jaundice, hepatomegaly, loss of appetite or anorexia and palpable splenomegaly are the most common findings (15).

CONCLUSION

We concluded from the present study that larger quantities of alcohol consumption for a longer duration of time result in high morbidity and mortalities. Alcoholic liver disease is not only a medical burden but also a social burden which leads to frequent hospitalization and unwanted out of pocket expenditure.

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ASSESSMENT OF THYROID FUNCTION AMONG DIABETES MELLITUS PATIENTS

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Abstract

Background: Thyroid disorders are reported in higher magnitude among general population, although its prevalence is not as high as prevalence of diabetes mellitus. Thyroid disorders are endocrine in nature as diabetes mellitus and various studies were conducted to find out correlation between both the disorders.

Material & Methods: Patients who were presenting with type 2 diabetes mellitus and confirmed with laboratory investigations and healthy controls were enrolled from outdoor and from ward by simple random sampling. Clearance from Institutional Ethics Committee was taken before start of study. Written informed consent was taken from each study participant.

Conclusion: We concluded from the present study that the patients of diabetes mellites had higher prevalence of thyroid dysfunction in comparison to the healthy controls enrolled in the study. We found suoclinical hypothyroidism was more common than clinical hypothyroidism.

Key words: thyroid dysfunction, diabetes mellitus, hypothyroidism, hyperthyroidism.

INTRODUCTION

Diabetes is a chronic disease in etiology and occurs when the pancreas does not produce enough amount of insulin or when there is resistance towards its action on the body (1). In 2014, WHO reports that 8.5% of adults who aged 18 years or above had diagnosed with diabetes. In 2016, WHO reports that diabetes was the directly responsible for 1.6 million mortality occurred worldwide. It was estimated that by the year 2030 diabetes will became seventh leading cause of mortality worldwide (2). The prevalence of non-communicable diseases is increasing compared to communicable diseases. Among the non-communicable diseases, diabetes mellitus is rapidly increasing globally and affecting all the age groups. (3). In India, the prevalence of diabetes is increasing and imposing challenges on health care infrastructure of the country (4).

The overall prevalence of diabetes reported by WHO was 8.7% among the age group of 20 and 70 years. This rising prevalence depends on various factors such as, sedentary lifestyles, rapid urbanization, unhealthy diets and substance use/abuse along with increasing life expectancy (5). Obesity and overweight are also the most important associated risk factors. The onset of diabetes can be prevented or delayed by life style and behavioral changes by taking healthy diet and routine physical activity (6). Thyroid disorders are reported in higher magnitude among general population, although its prevalence is not as high as prevalence of diabetes mellitus. Thyroid disorders are endocrine in nature as diabetes mellitus and various studies were conducted to find out correlation between both the disorders (7). Hence, we conducted present study to find out association between the thyroid disorders and type 2 diabetes mellitus.

MATERIALS & METHODS

The present prospective study was conducted at department of general medicine of our tertiary care hospital. The study duration was of one year from January 2018 to December 2018. A sample size of 200 was calculated at 95% confidence interval at 10%

acceptable margin of error by epi info software version 7.2. Patients who were presenting with type 2 diabetes mellitus and confirmed with laboratory investigations and healthy controls were enrolled from outdoor and from ward by simple random sampling. Clearance from Institutional Ethics Committee was taken before start of study. Written informed consent was taken from each study participant.

The data were collected by detailed history, general physical and clinical examination from each patient after taking the written consent. The hematological investigation was done for fasting and post prandial blood sugar, glycosylated hemoglobin (HbA1c) and thyroid profile. Patients who had chronic diseases such as cardiac diseases, liver and renal diseases, hypertension and cancer were excluded from the study. Data analysis was carried out using SPSS v22. All tests were done at alpha (level significance) of 5%, means a significant association present if p value was less than 0.05.

RESULTS

In the present study we enrolled 100 patients of diabetes mellitus who were aged from 27 to 58 years. The mean age of the enrolled patients was 42±5.6 years. In the present study we enrolled 100 healthy controls who were aged from 24 to 55 years. The mean age of the enrolled controls was 37±6.8 years. Out of total patients diagnosed with diabetes mellitus 59% patients were male and 41% patients were females. Out of total healthy controls 56% were male and 44% were females. On the assessment of BMI it was found that patients diagnosed with diabetes mellitus had mean BMI of 29.1±2.4 and controls had mean BMI of 28.5±3.1. On the assessment of TSH it was found that patients diagnosed with diabetes mellitus had mean TSH levels of 3.3±2.6 and controls had mean TSH levels of 3.2±1.8. On the assessment of FT4 levels it was found that patients diagnosed with diabetes mellitus had mean FT4 levels of 1.4±1.1 and controls had mean FT4 levels of 1.5±0.7. (Table 1)

Table 1: Demographic variables of study participants

Parameters	Diabetes group	Control group
Age (Mean ± SD)	42±5.6	37±6.8
Male	59 %	56 %
Female	41 %	44 %
BMI (Kg/m2)	29.1±2.4	28.5±3.1

In the present study, among total study participants it was found that, the prevalence of thyroid dysfunction among the type II diabetes group was 28% and among the control group was 16%. The prevalence of subclinical hypothyroidism among the among the type II diabetes group was 17% and control group was 11% (p>0.05). The prevalence of Clinical Hypothyroidism among the among the type II diabetes group was 8% and control group was 4% (p>0.05). The prevalence of subclinical hyperthyroidism among the among the type II diabetes group was 2% and control group was 1% (p>0.05). The prevalence of Clinical hyperthyroidism among diabetes group was 1% (>0.05) (Table 2).

Table 2: Distribution of types of Thyroid disorders among the study participants

Type of thyroid disorder	Diabetes group	Control group	p value
Subclinical hypothyroidism	17%	11%	>0.05
Clinical Hypothyroidism	8%	4%	>0.05
Subclinical hyperthyroidism	2%	1 %	>0.05
Clinical Hyperthyroidism	1%	0 %	>0.05
Total	28%	16%	

DISCUSSION

Diabetes is a chronic disease in etiology and occurs when the pancreas does not produce enough amount of insulin or when there is resistance towards its action on the body. Among the non-communicable diseases, diabetes mellitus is rapidly increasing globally and affecting all the age groups. Thyroid disorders are reported in higher magnitude among general population, although its prevalence is not as high as prevalence of diabetes mellitus. Thyroid disorders are endocrine in nature as diabetes mellitus

and various studies were conducted to find out correlation between both the disorders (8).

In the present study we enrolled 100 patients of diabetes mellitus who were aged from 27 to 58 years. The mean age of the enrolled patients was 42±5.6 years. In the present study we enrolled 100 healthy controls who were aged from 24 to 55 years. The mean age of the enrolled controls was 37±6.8 years. Out of total patients diagnosed with diabetes mellitus 59% patients were male and 41% patients were females. Out of total healthy controls 56% were male and 44% were females. Similar results were obtained in a study conducted by Palma et al among diabetes mellitus patients and found that the prevalence of thyroid dysfunction was reported to be 15%. However, majority of cases they found were of subclinical hypothyroidism which is followed by clinical hypothyroidism (9). Similar results were obtained in a study conducted by Fremantle et al among diabetes mellitus patients and found that the prevalence of thyroid dysfunction was reported to be 9%. Majority of cases they found were of subclinical hypothyroidism which is followed by clinical hypothyroidism (10). Similar results were obtained in a study conducted by Chuet cols et al among diabetes mellitus patients and found that the prevalence of thyroid dysfunction was reported to be 9%. Majority of cases they found were of subclinical hypothyroidism which is followed by clinical hypothyroidism (11).

In the present study, on the assessment of BMI it was found that patients diagnosed with diabetes mellitus had mean BMI of 29.1±2.4 and controls had mean BMI of 28.5±3.1. On the assessment of TSH it was found that patients diagnosed with diabetes mellitus had mean TSH levels of 3.3±2.6 and controls had mean TSH levels of 3.2±1.8. On the assessment of FT4 levels it was found that patients diagnosed with diabetes mellitus had mean FT4 levels of 1.4±1.1 and controls had mean FT4 levels of 1.5±0.7. Similar results were obtained in a study conducted by NHANES study among diabetes mellitus patients and found similar values of TSH and FT4 levels among diabetic patients (12). Similar results were obtained in a study conducted by Ramos AJS et al study among diabetes mellitus patients and found that the prevalence of thyroid dysfunction was reported to be 20%. Majority of cases they found were of subclinical hypothyroidism which is followed by clinical hypothyroidism (13).

In the present study, among total study participants it was found that, the prevalence of thyroid dysfunction among the type II diabetes group was 28% and among the control group was 16%. The prevalence of subclinical hypothyroidism among the among the type II diabetes group was 17% and control group was 11% (p>0.05). The prevalence of Clinical Hypothyroidism among the among the type II diabetes group was 8% and control group was 4% (p>0.05). The prevalence of subclinical hyperthyroidism among the among the type II diabetes group was 2% and control group was 1% (p>0.05). The prevalence of Clinical hyperthyroidism among diabetes group was 1% (>0.05). Similar results were obtained in a study conducted by Souza et al study among diabetes mellitus patients and found that the prevalence of thyroid dysfunction was reported to be 14%. Majority of cases they found were of subclinical hypothyroidism which is followed by clinical hypothyroidism (14).

CONCLUSION

We concluded from the present study that the patients of diabetes mellites had higher prevalence of thyroid dysfunction in comparison to the healthy controls enrolled in the study. We found subclinical hypothyroidism was more common than clinical hypothyroidism; however this difference was statistically non-significant. Since present study had small sample size, therefore, further large studies required for generalization of study results.

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Dear Authors, Rajiv Kumar Saxena, Hemendra Bamaniya (Corresponding author), H.S. Bhuie

We are pleased to inform you that your Original Research Article (Title: Role of Nasal Douching in Chronic Allergic Rhinitis) has been accepted for publication in Tropical Journal of Ophthalmology and Otolaryngology.

We are planning to finalize and publish your article in the issue of April June 2019 (in Volume- 4, Issue 2 of 2019 will be published in next 2-3 weeks) of our Tropical Journal of Ophthalmology and Otolaryngology. We may ask you for any minor corrections if we found anything at drafting and finalizing the article.

We shall send Galley proof of article before publication. Kindly see the attachments for further processing.

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Acceptance Letter for Publication of Research Article

To,

1. Rajiv Kumar Saxena, Associate Professor, Department of ENT, Ananta Institute of Medical Sciences, Rajsamand
2. Hemendra Bamaniya, Associate Professor, Department of ENT, Ananta Institute of Medical Sciences, Rajsamand
3. H.S. Bhuie, Professor, Department of ENT, Ananta Institute of Medical Sciences, Rajsamand

Sub: Acceptance of Original Research Article for Publication in Print Journal- International Journal of Research and Review

Dear Sir,
We are pleased to inform you that your article entitled **"Serum Vitamin D levels in chronic Allergic Rhinitis"** has been accepted for publication under *Original Research Article* category in Vol.6; Issue 6; June 2019 Issue of International Journal of Research and Review. The article is contributed by Rajiv Kumar Saxena, Hemendra Bamaniya and H.S. Bhuie.
Corresponding author is Dr. Hemendra Bamaniya.

Best wishes to all authors/coauthors!

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ORIGINAL ARTICLE

Comparison between Voice Handicap Index and Voice Symptom Scale by Subjective Analysis of Voice Disorders

[1]Hemendra Samariya, [2]Alok K Vaishnav, [3]Shashank Joshi, [4]Harbinder S Bhuie, [5]Rajiv K Saxena

ABSTRACT

Objective: Purpose of the present study was to use and compare two patient-derived scales voice handicap index (VHI) and voice symptom scale (VoiSS) for the assessment of the quality of life in patients of voice disorders and to assess their response to treatment.

Design: Longitudinal, cohort comparison study.

Setting: Department of Otorhinolaryngology, Maharana Bhupal Government Hospital, Udaipur, Rajasthan.

Participants: Fifty patients with a complaint of change in voice attended ear, nose and throat outpatient department at Maharana Bhupal Government Hospital and Rabindranath Tagore Medical College, Udaipur from 7th July 2010 to 30th June 2011.

Materials and methods: Two self-reported patients derived scale VHI and VoiSS were applied to all 50 patients of voice disorders both before as well as after treatment and compared the effect sizes of both the scales.

Result: Out of 50 cases, predominant cases included in the study were of malignant growth larynx (30%) followed by vocal nodule (18%). A total of 60% were male, and 40% were female. Maximum cases were of 41 to 60 years of age group (48%). Both the patient-derived scales VHI and VoiSS were found equally useful in assessing the quality of life in patients of voice disorders. Outcomes were similar in both the scales. The mean scores in both the scales before treatment were reduced to almost half after the respective treatment.

Conclusion: The result suggested that both the scales (VHI and VoiSS) are equally important as the results were highly correlated and no strong evidence was found to favor either of the scales. These scales are very useful in the assessment of the impact of voice disorders on patient's life and improvement in the quality of life after respective treatment as well as in assessing response to treatment.

Keywords: Dysphonia, Quality of life, Voice handicap index (VHI), Voice disorders, Voice symptom scale (VoiSS).

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INTRODUCTION

Voice is a complex phenomenon that is produced by interaction among the respiratory, laryngeal and resonance sub-systems.[1]

The phonation or voice is produced when the air is expelled from the lungs through the glottis, creating a pressure drop across the larynx. The oscillations of vocal cords modulate the pressure and flow of the air through the larynx, and this modulated airflow is the main component of the sound of most voiced phones.

Describing the vocal function and evaluating the voice problems are, likewise, complex tasks.

Voice measurement can improve our understanding of voice production, helps us to identify links between laryngeal disorders and voice production, and document change with interventions. It is also an important part of all phonatory surgery.[2]

Voice measures are divided into three categories:

1. Patient scales
2. Perceptual evaluation
3. Measures

Patient Scales

- VHI
- VoiSS
- Voice Related Quality of Life (V-RQOL)
- Voice activity and participation profile (VAPP)
- Reflux symptom scale (RSI)
- Patient questionnaire of vocal performance (VPQ)
- Voice outcome survey (VOS)

Perceptual Evaluation

- Auditory perceptual scale
  - Grade, roughness, breathiness, asthenia, and strain (GRBAS)

b. Consensus auditory perceptual evaluation-voice (CAPE-V),
c. Vocal profile analysis (VPA)
- Visual perceptual scale
- Tactile perceptual evaluation

Measures

Measuring voice is accomplished using:
- Acoustic analysis,
- Aerodynamic assessment, and
- Source measures.

Dysphonia can be defined as an impairment of the speaking or singing voice. It arises from an abnormality of the structures and or functions of the voice production system and can cause bodily pain, personal communication disability or an occupational or social handicap. The etiology of dysphonia is multifactorial. Genetic and psychological factors may predispose an individual to voice disorders.[2]

There are so many acute and chronic variables which can precipitate dysphonia. These include occupational vocal demands, trauma, environment, medications, health problems and lifestyle choices. Dysphonia is as disruptive to quality of life as any other chronic disease like angina, sciatica and chronic sinusitis.[3] The communicative issues associated to dysphonia can lead to depression, social withdrawal, and occupational handicap.[4]

OBJECTIVE

The objective of the present study is to use and compare VHI and VoiSS for the assessment of the quality of life in patients with voice disorders and their response to treatment.

Voice Handicap Index

It is a voice-specific outcome, measures patients' disability from voice disorders.

The index consists of a 30-item questionnaire, and each statement is noted from 0 (never) to 4 (always) composing a total score from 0 to 120, the higher the standard score, the higher the VHI (Table 1).

Voice Symptom Scale

This scale is yet in progress.

VoiSS consists of 43 items on a five-point equal appearing interval scale that reflects the frequency of occurrence. The total score is 0 to 172 (Table 2).

The questions in VoiSS represent five aspects (or domains) of voice pathology-communication problems, throat infection, psychosocial distress, voice sound, and variability and phlegm.

MATERIALS AND METHODS

This study was carried out on 50 patients that came to Otorhinolaryngology OPD at Maharana Bhopal (M.B.) Hospital and R.N.T. Medical College, Udaipur from 7th July 2010 to 30th June 2011 with a clinical diagnosis of dysphonia.

All patients then underwent thorough history-taking, general physical examination, and uniformly documented detailed local examination.

The routine laboratory tests, viz. blood for Hb, TLC, DLC, ESR, urinalysis, sklagram soft-tissue neck lateral view, sklagram chest PA view were done in all cases.

An indirect laryngoscopic evaluation was performed in all cases. Direct laryngoscopy and histopathological examination were done in required cases.

Thus the clinical diagnosis was made of all the cases with voice problems. Then the 43-item questionnaire of VoiSS and 30-item questionnaire of VHI were applied to all patients. The results and scores of both the voice analysis tools (VoiSS and VHI) were then compared to each other.

All the patients under study were kept under follow up until the proper treatment of voice disorder was carried out. The follow-up period for the different patient was different as the treatment duration for all diseases is not the same.

The patients were assessed thoroughly again, and both the VHI and VoiSS questionnaire were reapplied to all the patients after treatment.

Only those patients who were able to complete the posttreatment questionnaire were included in the study. Laryngectomized and tracheostomized patients were excluded from the study.

The comparisons between pre and post-intervention VHI scores and pre- and post-intervention VoiSS scores as well as between VHI and VoiSS scores were carried out to assess the role of these scores in deciding treatment pattern for the voice disorders as well as in assessing the quality of life of patients of voice disorders.

The improvement in the quality of life following treatment of voice disorder was assessed using the difference between pre and post VHI and VoiSS score.

RESULTS

The maximum number of cases of dysphonia, we encountered was of malignant growth larynx followed by a vocal nodule, globus and so on, as plotted on the following table (Table 3).

Since the cases included in the present study were only those, who were able to complete our questionnaire

Table 1: Voice handicap index

S.No	Questionnaire	Score				
	Part I-F	0	1	2	3	4
1.	My voice makes it difficult for people to hear me.					
2.	People have difficulty understanding me in a noisy room.					
3.	My family has difficulty hearing me when I call them throughout the house.					
4.	I use the phone less often than I would like to.					
5.	I tend to avoid groups of people because of my voice.					
6.	I speak with friends, neighbors, or relatives less often because of my voice.					
7.	People ask me to repeat myself when speaking face-to-face.					
8.	My voice difficulties restrict my personal and social life.					
9.	I feel left out of conversations because of my voice.					
10.	My voice problem causes me to lose income.					
	SUBTOTAL _____					
	Part II-P					
1.	I run out of air when I talk.					
2.	The sound of my voice varies throughout the day.					
3.	People ask, "What's wrong with your voice?"					
4.	My voice sounds creaky and dry.					
5.	I feel as though I have to strain to produce voice.					
6.	The clarity of my voice is unpredictable.					
7.	I try to change my voice to sound different.					
8.	I use a great deal of effort to speak.					
9.	My voice is worse in the evening.					
10.	My voice "gives out" on me in the middle of speaking.					
	SUBTOTAL _____					
	Part II-E					
1.	I am tense when talking to others because of my voice.					
2.	People seem irritated with my voice.					
3.	I find other people don't understand my voice problem.					
4.	My voice problem upsets me.					
5.	I am less outgoing because of my voice problem.					
6.	My voice makes me feels handicapped.					
7.	I feel annoyed when people ask me to repeat.					
8.	I feel embarrassed when people ask me to repeat.					
9.	My voice makes me feel incompetent.					
10.	I am ashamed of my voice problem.					
	Subtotal _____					
	Total _____					

0 = Never, 1 = Almost Never, 2 = Sometimes, 3 = Almost always, 4 = Always

of VHI and VoSS and were supposed to come for the follow up till the intervention for their voice disorder completed, so the data of prevalence of voice disorders may be different than in present study.

In the present study, the prevalence of voice disorders was found to be more in male (60%) patients as compared to female (40%) patient.

Also, the prevalence of cancer larynx and laryngopharynx was found to be more in male and prevalence of globus was more in female patients.

Globus pharyngis, in most cases, is caused by inflammation of one or more parts of the throat, such as the larynx and/or hypopharynx, gastroesophageal reflux disorder, due to cricopharyngeal spasm, laryngo-pharyngeal reflux or oesophageal versatility.[7]

In a few cases, the cause of globus is unknown, and the symptoms may be attributed to a psychogenic cause, i.e., a somatoform or anxiety disorder. It has also been recognized as a symptom of depression, that responds to antidepressive treatment.[8]

Table 2: Voice symptom scale

S.No	Questionnaire	0	1	2	3	4
1.	Do you have difficulty attracting attention?					
2.	Do you get frustrated by your voice problem?					
3.	Do you have problems singing?					
4.	Do people ignore you?					
5.	Is your throat sore?					
6.	Are you able to shout?					
7.	Is your voice hoarse?					
8.	When talking in company do people fail to hear you?					
9.	Do you lose your voice?					
10.	Does your voice problem reduce your social life?					
11.	Are you able to read aloud?					
12.	How often do you worry about catching a throat infection?					
13.	Do you cough or clear your throat?					
14.	Do you have pains in the chest?					
15.	Do you have a weak voice?					
16.	Do you have problems talking on the telephone?					
17.	Do you feel miserable or depressed because of your voice problem?					
18.	Does it feel as if there is something stuck in your throat?					
19.	Do you have swollen glands?					
20.	Do you talk less than you normally would?					
21.	Are you embarrassed by your voice problem?					
22.	Do you find the effort of speaking tiring?					
23.	Does your voice problem make you feel stressed and nervous?					
24.	Do you have difficulty competing against background noise?					
25.	Are you unable to shout or raise your voice?					
26.	Are you able to ask for things in shops?					
27.	Does your voice problem put a strain on your family and friends?					
28.	Do you have a lot of phlegm in your throat?					
29.	Do you run out of air when you talk?					
30.	Does the sound of your voice vary throughout the day?					
31.	Do people seem irritated by your voice?					
32.	Do you have a blocked nose?					
33.	Do people ask what is wrong with your voice?					
34.	Does your voice sound creaky and dry?					
35.	Do you feel you have to strain to produce voice?					
36.	Do you find other people do not understand your voice problem?					
37.	Do you try to change your voice to sound different?					
38.	How often do you get throat infections?					
39.	Is your voice worse in the evening?					
40.	Does your voice 'give out' in the middle of speaking?					
41.	Do you feel annoyed when people ask you to repeat?					
42.	Does your voice make you feel incompetent?					
43.	Are you ashamed of your voice problem?					
	Total					

0 = Never, 1 = Occasionally, 2 = Some of the time, 3 = Most of the time, 4 = All of the time

A total of 44% of cases examined in the present study were having a history of smoking or alcohol intake.

Moreover, all case of cancer laryux and laryngopharynx were having a history of smoking or alcohol intake or both which significantly proves cigarette smoking and alcohol intake as the important risk factor of cancer larynx and laryngopharynx.[7]

A total of 24% of all cases in the present study were having a history of vocal abuse either due to occupation or due to habit.

All cases of the vocal nodule, vocal cord papilloma, and vocal polyp were having a history of vocal abuse, which is showing the relationship between vocal abuse and development of vocal nodule or polyp.[8] Though vocal cord papilloma is a viral disease and is not associated with vocal abuse, in our case there was a coincidental history of vocal abuse.

Majority of the cases (48%) included in this study were of the age group of 41 to 60 years and the rests were as shown in Table 4.

Table 3: Clinical diagnosis of patients with voice disorders

No.	Diagnosis	No. of cases	Percentage
1.	M.G. larynx	15	30%
2.	Vocal nodule	9	18%
3.	Globus pharyngis	6	12%
4.	M.G. pharynx	5	10%
5.	Laryngitis	5	10%
6.	Pharyngitis	3	6%
7.	Vocal cord palsy	2	4%
8.	Vocal cord polyp	1	2%
9.	Vocal cord papilloma	1	2%
10.	Puberphonia	1	2%
11.	Goitre	1	2%
12.	Acute bronchial Asthma	1	2%
	Total	50	100%

Table 5: Presenting complaints of the patients

S.No.	Presenting complaints	No. of cases	Percentage
1.	Change in voice	35	70
2.	Difficulty in breathing	03	06
3.	Difficulty in swallowing	05	10
4.	Stridor	04	08
5.	Neck swelling	03	06
6.	Total	50	100

The presenting complaint of most of (70%) patients included in the present study, was the change in voice. The change in voice varied from simple harshness in laryngitis to hoarseness in carcinoma larynx. Six percent of the patient came with the complaint of neck swelling associated with dysphonia. 10% of patient were having to present complains of difficulty in swallowing, 8% were having stridor, and 6% patients came with complaints of difficulty in breathing (Table 5).

VHI scores of all the patients both before and after treatment were noted, and also the differe nce between them was calculated (Table 6 and Fig. 1).

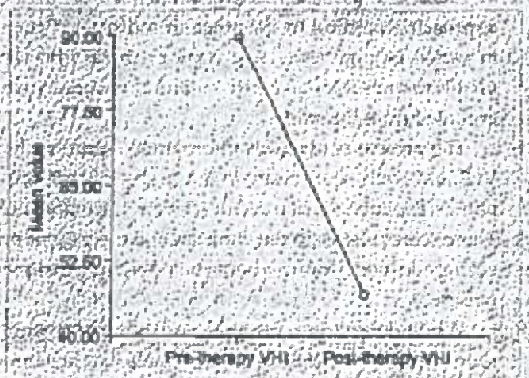

Fig. 1: Plot of mean sections of pre- and post-therapy VHI score

Table 4: Age wise distribution of patients

S. No.	Age-group	No of cases	Percentage
1.	11–20	5	10
2.	21–30	5	10
3.	31–40	8	16
4.	41–50	12	24
5.	51–60	12	24
6.	61–70	07	14
7.	71–80	01	02
	Total	50	100

Table 6: Pre- and post-treatment VHI score

	Pre-treatment VHI score			Post-treatment VHI score			
Total count	Mean	Standard deviation	Standard error	Mean	Standard deviation	Standard error	Mean of difference
50	89.7	26.54	3.75	49.96	29.315	4.14	42.14

Table 7: Pre- and post-treatment VoiSS score

	Pre-treatment VoiSS score			Post-treatment VoiSS score			
Total count	Mean	Standard deviation	Standard error	Mean	Standard deviation	Standard error	Mean of difference
50	119.28	37.98	5.37	83.16	35.32	4.99	58.12

A significant difference between pre- and post-treatment VHI score was found which shows the improvement in the quality of life of the patient after treatment of voice disorder.

Similarly, scores of VoiSS both before and after treatment were also noted and statistical analysis was done (Table 7 and Fig. 2).

In case of VoiSS questionnaire also, a similar type of scores found showed improvement in the quality of life of the patient after treatment of the voice disorder.

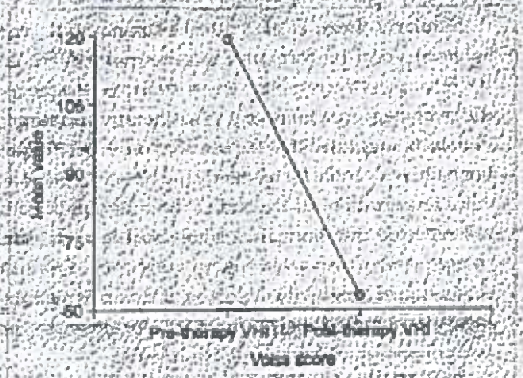

Fig. 2: Plot of mean sections of pre and post therapy VoiSS score

VoiSS score; more is the improvement in the quality of life of the patient.

CONCLUSION

In the present study, the results of both VHI and VoiSS were similar and highly correlated, and the comparative study did not favor any of the scale more for the evaluation purpose.

Thus the study showed that both VHI and VoiSS are important tools to assess the disability caused by voice disorders and also very useful to measure the functional outcomes of medical, behavioral and surgical treatment of voice disorders. These scores help the clinician and the patient to compare various treatment options. The improvement in the quality of life of the patient as well as the effectiveness of various voice intervention can be assessed using these scales.

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Original Research Article

A Study of Surgical Outcomes of Tympanoplasties with and without Cortical Mastoidectomy

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ABSTRACT

Background: Tympanoplasty, also called eardrum repair, refers to surgery performed to reconstruct a perforated tympanic membrane (eardrum) or the small bones of the middle ear. Eardrum perforation may result from chronic infection or, less commonly, from trauma to the eardrum.

Objective: The Objective of the study is to evaluate the surgical outcomes of tympanoplasties with and without mastoidectomies in terms of graft uptake and hearing improvement.

Methods: A total of 58 patients undergoing tympanoplasties with and without mastoidectomy were included and followed up for a period of one year.

Results: There was no significant difference in the surgical outcomes of both the surgeries in terms of graft uptake and hearing improvement. In inlaid technique Ballast Rule of 3 thumb application enables the actual hearing benefit of the patient.

Conclusion: There is no difference in related to outcome. The addition of cortical mastoidectomy to tympanoplasty did not improve the outcome of surgeries done for mucosal type of chronic suppurative otitis media.

KEY WORDS: Cortical Mastoidectomy, Tympanoplasty, Ballast Rule.

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INTRODUCTION

Tympanoplasty, also called eardrum repair, refers to surgery performed to reconstruct a perforated tympanic membrane (eardrum) or the small bones of the middle ear. Eardrum perforation may result from chronic infection or, less commonly, from trauma to the eardrum.

The tympanic membrane of the ear is a three-layer structure. The outer and inner layers consist of epithelium cells. Perforations occur as a result of defects in the middle layer, which contains elastic collagen fibers. Small perforations usually heal spontaneously. However, if the defect is relatively large, or if there is a poor blood supply or an infection during the healing process, spontaneous repair may be hindered. Eardrums may also be perforated as a result of trauma, such as an object in the ear, a slap on the ear, or an explosion [1]. The purpose of tympanoplasty is to repair the perforated eardrum, and sometimes the middle ear bones that consist of the incus, malleus, and stapes. Tympanic membrane grafting may be required. If needed, grafts are usually taken from a vein,

or fascia (muscle sheath) tissue on the lobe of the ear [2]. Synthetic materials may be used if patients have had previous surgeries and have limited graft availability. The mastoid is a honeycomb cavity in the temporal bone, which lies directly behind the ear and is connected to the middle ear space. When a hole arises in the eardrum due to previous injury or infection, or when a long-standing infection persists with tissue in the middle ear or mastoid, mastoid surgery often becomes necessary to alleviate this infection. This part of the procedure is called mastoidectomy. Surgery for tubotympanic type of chronic suppurative otitis media is the commonest otological surgical procedure in our country [3].

This study discusses the various pre-operative factors which play a major role in the post-operative success of two various surgeries – myringoplasty and cortical mastoidectomy with type 1 tympanoplasty. The hearing benefit is determined by Air bone gap closure and also subjective evaluation of hearing is done by applying Belfast rule of thumb.

MATERIALS AND METHODS

This Prospective study was conducted at RNT medical college and attached M B hospital, Udaipur, Rajasthan from Dec 2009 to Dec 2011. Study involves total 56 patients attending ENT OPD with mucosal disease at Our hospital for a period of one year and the patients were followed up for a period of one year. Among them, 6 patients did not turn up for follow up and they were excluded from the study.

Inclusion criteria: Patients between 15 to 50 years of both sexes, after elimination of focal sepsis, having either wet or dry ears and pure tone audiometry showing conductive hearing loss.

Exclusion Criteria: Patients with congenital or acquired abnormalities of ear, unsafe ear, undergone ear surgeries previously and with pure tone audiometry showing mixed and sensorineural hearing loss were excluded from the study.

Methodology: Minimum duration of discharge for the patients under study was 1year and maximum was 15 years. Minimum duration of hearing impairment was 6 months and maximum was 10 years. For all patients, under study with wet ears, ear swabs were taken from middle ear and for patients with culture positive results, treated with specific antibiotics prior to surgery.

All cases were admitted, pre-operative examination done under microscopy, subjected to endoscopic eustachian tube evaluation (those with normally looking pharyngeal end of eustachian tube orifice were taken up for study) and hearing assessment done with tuning fork tests and pure tone audiogram. All patients were informed about their need for a follow up period of one year. Informed written consent to undergo surgery was obtained from all patients. Mastoid shaving and local preparation was done in the ward prior to surgery. All cases were done under GA. Premedication and local infiltration was done for all cases.

Group A: About 25 patients with dry ear for more than 6 weeks and with only conductive hearing loss, were subjected to myringoplasty and considered as Group A. About 13 patients with unilateral disease and 12 patients with bilateral disease were taken up for study. For patients with bilateral disease, worse ear was taken up for surgery. All patients were taken up for surgery under GA. Trans canal approach was followed in 21 cases and in 4 cases with narrow external auditory canal, post aural approach was followed. 4 quadrant local infiltration was given with 2% xylocaine with adrenaline premixed solution. Temporalis fascia graft harvested by a separate incision over supra auricular region for patients done through trans-canal approach & in patients done through post aural approach, graft was harvested via the same incision. Temporalis fascia graft kept by underlay technique. All cases were followed up for 3,6 months and one year for graft uptake and postoperative hearing evaluations done at 3,6 months and one year. Results of hearing benefit, compared with pre-op and post-op air bone gap and for unilateral disease Belfast rule of thumb applied.

Group B: About 25 patients with wet ear and with no active infection as per microbiological report & with conductive hearing loss were subjected to cortical mastoidectomy with type 1

tympanoplasty and considered as Group B. About 15 patients with unilateral disease and 10 patients with bilateral disease were taken up for study. For patients with bilateral disease, worse ear was taken up for surgery.

All patients were taken up for surgery under GA. Post-aural approach was followed in all cases. Post aural incision made, temporalis fascia graft harvested through the superior aspect of the incision as the first step, incision deepened and mastoid cortex exposed. Pinna retracted anteriorly, incision made in the posterior canal wall skin from 6 o'clock to 12 o'clock position and tympanomeatal flap was elevated. Granulations if present in the tympanum were removed, mobility of ossicular chain were checked. Mastoid cortex was drilled out in all cases, patency established. For, about 21 patients granulations noted in antrum removed and in 4 patients antrum found free of disease. For all patients, temporalis fascia graft kept by underlay technique, tympanomeatal flap repositioned and post-aural wound closed in layers. All cases were followed up for 2, 6 months and 1 year for graft uptake and post-operative hearing evaluations done at 3, 6 months and 1 year. Results of hearing benefit, compared with pre-op and post-op air bone gap and for unilateral disease, Belfast rule of thumb applied.

Even though socio-economic status does influence the disease, all the patients attending RNT Medical College and M B Hospital Hospital belongs to lower, socio-economic group. Hence this parameter is not included in this study.

RESULTS

Total number of cases registered in this study was 56 patients, who came to the ENT Department with Mucosal disease. Among them 6 patients did not turn up for follow up and hence they were not included in the study.

The overall graft take up rate in both the surgeries was 88.33%. The overall hearing benefit was 90%, excellent with < 10dB ABG in 51.67% and Good with < 20dB in 38.33%. There was no postoperative complications, deterioration in hearing or sensorineural hearing loss in all 50 patients.

In Group A ,15 were females & 10 were males, 13 patients had unilateral and 12 had bilateral disease, 20 had medium sized central perforation and 05 had subtotal perforation. 10 had good pre-op Air bone gap of 10 to 20 dBHL 15 patients had a fair pre-op Air bone gap of 20 to 30 dBHL.

1. Overall graft take up rate was 86.6%.

2. Otoscopic evaluation of 20 patients with medium sized perforation at the end of 2 months, revealed 15 to be intact, 5 residual perforation in the antero - inferior quadrant. In 5 patients with subtotal perforation 3 were intact, 1 with residual perforation & 1 grafts got rejected because of post-op wound infection. Otoscopic examination at the end of 6months & 1 year revealed – for all 20 patients with medium size perforation, tympanic membrane was intact and out of 5 patients with subtotal 2 were with residual perforation & 1 with rejection of graft. Hence the size of the perforation does have a role in graft take upirate. This is statistically significant by applying chi square test with p value < 0.05.

3. In 10 patients with good pre-op ABG, the post-op ABG was excellent. In 15 patients with fair pre-op ABG, the post-op ABG results were, excellent in 9, good in 8 and fair in 3 patients accounting for 46.66% in excellent, 40% in good and 13% in fair groups. By applying Chi square test, these results are statistically significant. Hence, for the patients with lesser pre-operative Air bone gap have a better post-operative hearing.

4. When Belfast rule of thumb was applied to 13 patients with unilateral disease, 10 of them with medium sized perforation, felt subjectively better and out of 3 of them with subtotal perforation, 2 felt better & 1 patient felt hearing same as the pre operative status. These results are statistically significant with p value<0.05, implies that Belfast rule of thumb interpret the post-operative hearing benefit in a better way than the Air-bone gap ,which tells about only the technical success.

5. The correlation coefficient between the duration of discharge and the pre-op ABG is 0.4172 and that between the duration of hearing impairment with pre-op ABG is 0.3821 and is statistically significant. The correlation coeffi-

-ent between the duration of discharge and the post-op ABG is 0.4544 and that between the duration of hearing impairment with post-op ABG is 0.4489 and is statistically significant, implies that the patients with lesser duration of discharge and hearing impairment had better post-operative hearing than the patients with longer duration of disease and hearing impairment.

6. The other parameters, such as age, sex, weight does not have influence on the outcome of results in this study.

7. The type of approach does not have a significant p value with graft intake in this study. Applying chi square test, the Pearson value is 0.

In Group B, 17 were females & 8 were males, 15 patients had unilateral and 10 had bilateral disease. 18 had medium central perforation and 07 had subtotal perforation, 08 had good pre-op Air bone gap of 10 to 20 dBHL, 17 patients had a fair pre-op Air bone gap of 20 to 30 dBHL.

1. Overall graft take up rate was 96%.

2. The relationship between graft take up rate and size of the perforation is statistically significant by applying chi square test with person value of 0.02535.

Otoscopic evaluation of 15 patients with medium sized perforation at the end of 2 months, revealed 14 to be intact, 1 residual perforation in the antero-inferior quadrant. In 07 patients with subtotal perforation, 05 were intact, 2 with residual perforation. Otoscopic examination at the end of 6 months & 1 year revealed – for all 18 patients with medium size perforation, tympanic membrane was intact and out of 07 patients with subtotal 3 were with residual perforation. Hence the size of the perforation do have a role in graft take up rate even when cortical mastoidectomy is done along with repair of tympanic membrane.

3. In this study, out of 18 patients with medium sized perforation, 8 had a good & 17 had fair pre-op ABG. Out of 07 patients with subtotal perforation, 6 patient had good & 01 had fair pre-op ABG, implies that 85.71 % of the patients with subtotal perforation had pre-op ABG of 20 to 30 dB.

4. Out of 25 patients included in this procedure -re, 50% had excellent, 50% had good &10% had fair post-op ABG. Those with medium sized perforation had better results than those with subtotal perforation.

5. On comparison of pre-op ABG & post-op ABG, all 8 patients with good pre-op ABG improved to excellent, out of 17 with fair ABG, 3 were excellent, 12 were good and 2 were fair post-operatively. This result is highly statistically significant with pearson value of 0.00006

6. Graft intake in 4 patients with disease free antrum mucosa is 100%.

7. Out of 25 patients, 21 patients had disease in the antrum & 4 had a healthy antrum. 77.85% of the patients with healthy antrum and 9.5% of the patients with diseased antrum had good pre-op Air bone gap 30.5% with diseased and 22.2% with healthy antrum had fair preop Air bone gap.

8. In patients with healthy antrum, the post-op ABG was excellent in 88.9% and 66.7% of the patients

with diseased antrum had a good ABG post-operatively.

9. On applying Rellfast rule of thumb to 15 patients with unilateral disease, 83.3% had better hearing, implies the post-operative hearing benefit better than assessment with Air bone gap.

10. The correlation coefficient between the duration of discharge and the pre-op ABG is 0.3803 and that between the duration of hearing impairment with pre-op ABG is 0.3776. The correlation coefficient between the duration of discharge and the post-op ABG is 0.3794 and that between the duration of hearing impairment with pre-op ABG is 0.3729 and are statistically significant, implies that the patients with lesser duration of discharge and hearing impairment had better post-operative hearing than the patients with longer duration of disease and hearing impairment.

11. The other parameters, such as age, sex, weight does not have influence on the outcome of results in this study.

DISCUSSION

Analysis of 50 cases undergone surgery for [illegible]

same is compared with similar and related studies available in literature.

1. Graft Take Up Rate: The overall graft take up rate in Myringoplasty in this study was 86.6%, which is within the range to the studies available. The graft take up rate in various studies were [Table 1].

Table 1: Graft take up rate [1].

Study	No of cases	year	Graft take up rate
Gibb, Cleary R.M [5]	345	1982	91.60%
Black, PJ Wormald [3]	261	1995	78%
Raj A Vidit [2]	50	1999	84%
Kotecha et al [7]	107	1999	82.20%
Tseng, Mishira et al [1]	104	2001	94.60%
Kageyama et al [6]	190	2001	82.30%
Alberra et al [2]	85	2008	86%

The graft take up rate in Cortical mastoidectomy with type 1 tympanoplasty is 90% which is also within the range to the studies available in literature [Table 2].

Table 2: Graft take up rate [2].

Studies	No of cases	Graft take up rate
Tseng, Mishira et al [1]	147	94.20%
Adnan, saleem et al [2]	85	92.95 %
Alberra et al [2]	100	91%
Rabi CM et al [2]	135	90.40%

2. Graft Failure Rate: Graft failure rate in various studies were [Table 3].

Table 3: Re-perforation Rate % [1].

Studies	Re-perforation Rate %
Alberra et al [2]	7 to 21
Vartiainen et al [14]	10.6
Adnan, saleem et al [2]	7.05

In this study, in myringoplasty series the rate of residual perforation is 5.7% and the rate of rejection of graft is 6.7%. The probable cause of residual perforation is the slippage of the graft from its position and the cause for rejection is the post operative infection of the operated site, which is same as the reason cited by the study of Vartiainen et al and Kotecha et al [7,14] Study of Alberra et al also includes the efficiency of the surgeon and the surgical techniques [2].

3. Pre-operative Hearing: In this study the pre operative pure tone average in Myringoplasty series was between 30 to 40 dB with average type 1 tympanoplasty series between 30 to 55 dB with average being 42.16 dB. As the perforation size increases, the preoperative hearing threshold also increases – this is consistent with the study conducted by Mehta et al, Bhusal et al Nepal A Bhandary et al, Kageyama et al, Alberra et al and Saeed et al [1,2]

4. Post Operative Hearing Benefit: Hearing improvement in various studies quoted in literature were [Table 4];

Table 4: Hearing Improvement [2,3].

Study	Hearing improvement
Adnan et al [2]	85.88%
Khan et al [1,2]	84.90%
Raj A Vidit et al [2]	68%
Kotecha et al [7]	67%

In this study, the overall post operative hearing benefit based on Air bone gap was 90% with <10 Db in 51.67% and <20db in 38.33%. As hearing benefit is better assessed with the subjective evaluation, in this study we have applied Belfast rule of thumb in patients with unilateral disease. In 23 patients with unilateral disease in Myringoplasty series, 95.7% felt significant improvement in hearing and 4.3% felt no improvement. In 18 patients with unilateral disease in Mastoidectomy with type 1 tympanoplasty series, 83.3% felt significant improvement in hearing and 16.7% felt no improvement.

CONCLUSION

From Our study we Would like to conclude that the success of Myringoplasty in terms of graft uptake and hearing improvement is better in patients with lesser duration of disease, less preoperative Air bone gap and with medium sized perforations when compared to subtotal perforations. The success of Cortical mastoidectomy with type tympanoplasty in terms of graft uptake and hearing improvement is better in patients with lesser duration of disease and less pre-operative Air bone gap.

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Original Research Article

Aerobic Bacteriology of Chronic Suppurative Otitis Media in Rajsamand District of Rajasthan

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ABSTRACT

Objectives: The objective of our study was to examine the aerobic bacteriological profile and antibiotic sensitivity pattern to locally available antibiotics in chronic suppurative otitis media (CSOM) in Rajsamand district of Rajasthan state in India.

Materials and methods: This prospective study was conducted in the department of otorhinolaryngology, Aranya Institute of Medical Sciences, Rajsamand for a period of one year from February 2017 to February 2018. Aural swabs were taken on the first day of attendance of the patients to ENT OPD before any local medication was given to the patient, using sterile cotton wool swabs and sterile ear specula and sent for culture and sensitivity.

Results: A total of 150 cases of CSOM were selected for the study out of which 109 cases were of unilateral CSOM and 41 cases were having bilateral disease. Thus, a total of 191 swabs were taken for analysis. Out of 191 swabs processed, microbial growth was seen in 176 samples while 15 samples showed no growth. 121 (68.75%) samples showed mono-microbial growth while 55 (31.25%) samples showed poly-microbial growth. The peak incidence of CSOM was found in the age group 31-45 years (34.66%) followed by age group 16-30 years (27.33%). Females (62%) were more commonly affected than males (38%) and the female: male ratio was 1.6:1. *Pseudomonas aeruginosa (38.63%) was the most commonly isolated bacterial pathogen followed by staphylococcus aureus (35.22%) and Klebsiella sp. (10.22%).*

Conclusion: A thorough and precise knowledge of the etiological agents causing CSOM and their antimicrobial susceptibility is of essential importance for an effective and efficient treatment and thus in further prevention of both complications and development of antibiotic resistance which is becoming more common now a days.

Keywords: Chronic suppurative otitis media, antibiotic resistance, staphylococcus aureus, Amikacin

INTRODUCTION

Chronic suppurative otitis media (CSOM) is a major problem globally since prehistoric times with higher incidence in developing countries because of poor socio-economic status and lack of health education.[1]

CSOM is a long standing infection of a part or whole of the middle ear cleft. Clinically, CSOM is divided into two major types: Tubotympanic CSOM i.e. 'Safe' or 'Benign' type of CSOM and Atticoantral i.e. 'unsafe' or 'dangerous' type of CSOM.[2]

CSOM is found to be the single major cause for conductive deafness (66.3%) and it is also responsible for 1.5% of speech disorders.[3]

The indiscriminate, haphazard and half hearted use of antibiotics and poor follow up of the patients have resulted in

persistent changes in the bacteriological pattern of the disease, the advent of new antimicrobials, anti-inflammatory and anti-histamine agents make an evaluation of bacterial flora of CSOM important. [4]

The objective of our study was to examine the bacteriological profile and antibiotic sensitivity pattern to locally available antibiotics in CSOM.

MATERIALS AND METHODS

This prospective study was conducted in the department of otorhinolaryngology, Ananta Institute of Medical Sciences, Rajsamand for a period of one year from February 2017 to February 2018.

Aural swabs were taken on the first day of attendance of the patients to ENT OPD before any local medication was given to the patient, using sterile cotton wool swabs and sterile ear speculs. The collected samples were enclosed in airtight plastic tubing and then transported to the microbiology test laboratory. The samples were always taken before cleaning/suctioning the ear canals of the excess purulent exudates. Samples from bilaterally discharging ears were collected separately. The material was inoculated on Sheep Blood agar, Mac Conkey's agar, Chocolate agar, Robertson's Cooked meat broth for aerobic and anaerobic bacteria. The swabs were incubated for 48 hr and 72hr. Organisms were identified using standard procedures. [5] Antimicrobial sensitivity testing for aerobic isolates was carried out by Kirby Bauer disc diffusion method on Muller Hinton agar. Results were interpreted in accordance with central laboratory standards institute guide-lines. [6]

RESULTS

A total of 150 cases of CSOM were selected for the study out of which 109 cases were of unilateral CSOM and 41 cases were having bilateral disease. Thus, a total of 191 swabs were taken for analysis.

Out of 191 swabs processed, microbial growth was seen in 176 samples while 15 samples showed no growth. 121 (68.75%) samples showed mono-microbial growth while 55 (31.25%) samples showed poly-microbial growth.

In present study, age of the patients ranges from 10 months to 73 years. The peak incidence of CSOM was found in the age group 31-45 years (34.66%) followed by age group 16-30 years (27.33%). Females (62%) were more commonly affected than males (38%) and the female: male ratio was 1.6:1. (table.1)

Microbiological profile of isolates from patients of CSOM and their antibiotic sensitivity pattern is depicted in table.2 and table.3 respectively.

Table.1 Age wise distribution of patients with CSOM.

S.No.	Age group (years)	Number	Unilateral	Bilateral	Mono-microbial	Poly-microbial	Sterile	Total
1.	10-15	23	11	12	22	9	4	35
2.	16-30	41	34	7	33	12	3	48
3.	31-45	52	44	8	38	17	5	60
4.	46-60	20	12	8	11	13	4	28
5.	61-75	14	8	6	4	4	2	20
	Total	150	109	41	121	55	15	191

Table.2 microbiological profile of aerobic isolates from patients of CSOM.

S.No.	Type of organism	Number of samples	Percentage
1.	Pseudomonas aeruginosa	68	38.63
2.	Staphylococcus aureus	62	35.22
3.	Klebsiella sp.	18	10.22
4.	Proteus mirabilis	17	09.65
5.	E.coli	8	04.54
6.	Enterococcus faecalis	3	01.70
	Total	176	100

Table 3 Antibiotic sensitivity pattern of organism isolated in present study

S.No.	Antibiotic	Pseudomonas sp.	Staph. Aureus	Klebsiella sp.	Proteus mirabilis	E. coli	Enterococcus faecalis
1.	Ampicillin	0	11 (17.74%)	0	0	0	0
2.	Cloxacillin	0	18 (27.41%)	0	0	0	0
3.	Ampicillin + clavulanate	0	48 (77.41%)	0	0	0	0
4.	Amikacin	59 (86.76%)	38 (61.29%)	8 (44.44%)	7 (41.17%)	4(36%)	0
5.	Gentamicin	47 (69.11%)	39 (62.90%)	2 (11.11%)	3 (17.64%)	0	0
6.	Netilmicin	48 (70.58%)	42 (67.74%)	0	3 (17.64%)	2 (22%)	0
7.	Vancomycin	64 (94.11%)	47 (75.80%)	0	0	0	0
8.	Ciprofloxacin	38 (55.88%)	22 (35.48%)	6 (33.33%)	3 (17.64%)	3(31.3%)	1 (33.3%)
9.	Levofloxacin	36 (44.11%)	15 (24.19%)	4 (22.22%)	2 (11.76%)	1(12.5%)	1 (33.3%)
10.	Ceftriaxone	4 (60.29%)	44 (70.96%)	2 (11.11%)	3 (17.64%)	4(50%)	0 (66.66%)
11.	Cefotaxime	27 (39.70%)	28 (41.93%)	1(5.55%)	3 (17.64%)	3(37.5%)	0
12.	Ceftazidime	5 (7.3%)	44 (70.96%)	1(5.55%)	9 (52.94%)	0	0
13.	Piperacillin+ Tazobactam	51(75%)	53 (85.50%)	6 (33.33%)	6 (35.29%)	3(41.3%)	1 (33.3%)

DISCUSSION

CSOM is a long standing infection of a part or whole of the middle ear cleft. Clinically, CSOM is divided into two major types: Tubotympanic CSOM i.e. 'Safe' or 'Benign' type of CSOM and Atticoantral i.e. 'unsafe' or 'dangerous' type of CSOM. [2]

The definitive treatment of CSOM is by surgery (tympanoplasty and/or mastoidectomy), nevertheless, initial treatment by ear toilet and ototopical agents is necessary to prepare the ear for surgery. The selection of local or systemic antibiotic for therapy depends greatly on the type of the organism isolated in such cases.

In present study, microbial growth was seen in 176 (92.14%) samples out of 191 swabs used. 15 samples (7.8%) showed no growth. The culture results are found correlated with previous studies. [7-11] Negative cultures can be attributed to Non-bacterial growth, Anaerobic growth, Prior-antibiotic therapy and/ or Presence of antimicrobial enzymes i.e. lysozyme alone or in combination with immunoglobulins that suppress the bacterial growth. [4,10]

121 (68.75%) samples showed mono-microbial growth while 55 (31.25%) samples showed poly-microbial growth. Our study is correlated with Rama Rao et al. (1980) [9] found equal incidence of mixed and pure culture and Barnak et al. (1972) [12] found predominance of mixed culture.

In present study, most commonly affected age group was 31-45 years (34.66%) followed by age group 16-30 years (27.33%). In most of the earlier studies, the most commonly affected age group is 0-30 years. [13-16] The reason for high prevalence in higher age group in present study may be because of low socioeconomic status and poor awareness of the patients in villages near the hospital.

In the present study, Pseudomonas aeruginosa (38.63%) was the most commonly isolated bacterial pathogen followed by staphylococcus aureus (35.22%) and klebsiella sp. (10.22%).

Pseudomonas is the predominant cause of CSOM in tropical region does not usually inhabit the upper respiratory tract, its presence in the middle-ear cannot be ascribed to an invasion through eustachian tube and it should be considered as secondary invader gaining access to the middle-ear via tympanic membrane perforation. [17] Proteus mirabilis was seen in 9.65%% of the cases and Escherichia coli were isolated from 4.5% cases, and these findings were similar to the reports in earlier studies. [14,16]

In the present study the most effective antibiotic against Pseudomonas aeruginosa was found to be Vancomycin (94.11%) followed by amikacin (86.76%), piperacillin+Tazobactam, ceftazidime, netilmicin, Gentamicin, ceftriaxone and ciprofloxacin. This finding was corroborated by studies of numerous other authors. [13,18,19]

Staphylococcus aureus was found to be the second most common organism in the present study. The antimicrobial susceptibility pattern of Staphylococcus

aureus revealed highest sensitivity to piperacillin+tazobactam (88.70%) followed by amoxicillin+ clavulanate (77.41%), Vancomycin (75.80%), ceftriaxone & ceftazidime (70.96%), Netilmicin (67.74%) and Amikacin (61.29%) and least sensitivity to quinolones. In case of Klebsiella sp, Proteus, E.coli and Enterococcus faecalis-ceftriaxone, Amikacin and piperacillin with Tazobactam were found to be equally effective. These findings are in accordance with previous study done by Gulati et al (1997). [9]

CONCLUSION

A thorough and precise knowledge of the etiological agents causing CSOM and their antimicrobial susceptibility is of essential importance for an effective and efficient treatment and also in further prevention of both complications and development of antibiotic resistance which is becoming more common now a days.

Conflict of interest:

No conflicts of interest exist for these authors. No relevant financial relationship exists between the authors and procedures or products used in this manuscript.

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2	HUGE VULVAL ELEPHANTIASIS OF UNKNOWN AETIOLOGY	**DR. ANJALI SETHI** & DR. DEEPAK SETHI	Anjali Sethi, Deepak Sethi ."Huge Vulval Elephantiasis of Unknown Aetiology". Journal of Evolution of Medical and Dental Sciences 2014 ; Vol . 3 , Issue 1 3 , March 31 ; Page: 3324 -3329,DOI: 10.14260/jemds/2014/2288	EISSN :2278-480 PISSN :2278-474
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DEPARTMENT OF SURGERY

List of Publications

9	A STUDY ON RELATION THYROID STIMULATING HORMONE LEVEL WITH SKELETAL METASTASIS IN CARCINOMA PROSTATE PATIENTS	DR. MINAXI MISHRA, DR. KRISHNA GOPAL SHARMA, DR.DEEPAK SETHI, DR RAJVEER SINGH, **DR. ANJALI SETHI**	Sharma KG, Sharma M, Sethi D. et.al. A study on dysphagia due to benign oesophageal strictures.J. Evolution Med. Dent. Sci. 2017;6(73):5225-5231, DOI:10.14260/jemds/2017/1135	EISSN :2278-4802 PISSN :2278-4748
10	A STUDY OF DYSPHAGIA DUE TO BENIGN OESOPHAGEAL STRICTURES	DR. KRISHNA GOPAL SHARMA, DR. JMINAXI SHARMA, DR. DEEPAK SETHI, DR. RAJVEER SINGH, **DR, ANJALI SETHI**	Sharma KG, Sharma M, Sethi D. et.al. A study on dysphagia due to benign oesophageal strictures.J. Evolution Med. Dent. Sci. 2017;6(73):5225-5231, DOI:10.14260/jemds/2017/1135	EISSN :2278-4802 PISSN :2278-4748
11	POST MASTECTOMY UPPER LIMB LYMPHOEDEMA: A TERTIARY CARE HOSPITAL EXPERIENCE	DR. MUKTA SUKHADIA, DR. DEEPAK SETHI , **DR. ANJALI SETHI**	Sukhadia M, Sethi D, Sethi A, et.al. post mastectomy upper limb lymphoedema : A tretiary hospital experience.Scj.J.App.Med. Sci., Feb 2018; 6(2);696-701 DOI: 1021276/sjams.2018.6.2.44	EISSN :2320-6691 PISSN :2347-9547
12	LYMPHOEDEMA:NON-OPERATIVE MANAGEMENT	DR.MUKTA SUKHADIA, DR, DRRPAK SETHI, **DR. ANJALI SETHI**	Sukhadia M, Sethi D, Sethi A. Lymphoedema : non- operative management. Int. Surg J 2018;5:1067-71	EISSN :2349-3305 PISSN :2349-2902
13	PERIPHERAL VASCULAR TRAUMA-A LIMB MAY BE SAVED	DR. HEMLATA VERMA, DR. RAM SWAROOP SAIN, DR. DEEPAK SETHI, **DR. ANJALI SETHI**	Verma H, Sain RS, Sethi D, et al. Peripheral Vascular Trauma-a limb may be saved.J. Evolution Med. Dent. Sci. 2018;7 (14):1732-1736, Doi: 10.14260/jemds/2018/391	EISSN :2278-4802 PISSN:2278-4748

9	Sharma M, Sharma KG, Sethi D, et al. A study on relation of thyroid stimulating hormone level with skeletal metastasis in carcinoma prostrate patients. J. Evolution Med. Dent. Sci. 2017;6 (79):5619-5625, DOI:10.14260/jemds/2017/1219
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12	Sukhadia M, Sethi D, Sethi A. Lymphoedema : non- operative management. Int. Surg J 2018;5:1067-71
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14	Sharma A, Sethi D, Sethi A.Laparoscopy : A tool for undiagnosed pain abdomen iNt Surg J 2018;3350-5
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16	Prem Shankar Meena, Atul Ameta, Deepak Sethi, Anjali Sethi. A study of locally advanced breast cancer management in patients with rural background. Int J Surg Sci 2019;3(4):400-404. DOI: https://doi.org/10.33545/surgery.2019.v3.i4g.278
17	Sain RS, Verma H, Sethi D, Sethi A Vascular Trauma: Our Experience at Tertiary Level Hospital. IJSS Journal of Surgery 2020;6(1) : 7-12

Paper Publications - Dr. Anjali Sethi,
Professor, Department of Surgery,
Ananta Institute of Medical Sciences & Research Center

Sr. No.	Title of Paper	Journal	Month of Publication
1	Recurrent Marjolin's Ulcer with Regional Lymph Node Metastasis	Journal of Evolution of Medical and Dental Sciences	Nov-12
2	Huge vulval elephantiasis of unknown aetiology	Journal of Evolution of Medical and Dental Sciences	Mar-14
3	Penile cutaneous horn - a rare case	International Journal of Medical Research and Review	Oct-15
4	Breast cancer: is obesity a risk factor?	Journal of Evolution of Medical and Dental Sciences	Nov-15
5	Triple Testes - A rare case	International Journal of Health Sciences & Research	Nov-15
6	Correlation of breast cancer and serum high density lipoprotein cholesterol level: a single center study	Journal of Evolution of Medical and Dental Sciences	Dec-15
7	Isolated corpus spongiosum and urethral injury during sexual intercourse - a rare case	International Journal of Innovations in Medical Education and Research	Jan-16
8	Primary Grynfeltt's Lumbar Hernia - An Uncommon Occurrence	Journal of Evolution of General Surgery and Laparoscopy	Jun-17
9	A study on relation of thyroid stimulating hormone level with skeletal metastasis in carcinoma prostate patients	Journal of Evolution of Medical and Dental Sciences	Sep-17
10	A Study on Dysphagia due to Benign Oesophageal Strictures	Journal of Evolution of Medical and Dental Sciences	Sep-17
11	Post Mastectomy Upper Limb Lymphoedema: A tertiary care hospital Experience	Scholars Journal of Applied Medical Sciences (Surgery)	Feb-18
12	Lymphoedema: non-operative management	International Surgery Journal	Mar-18
13	Peripheral Vascular Trauma - A limb may be saved	Journal of Evolution of Medical and Dental Sciences	Apr-18
14	Laparoscopy: a tool for undiagnosed pain abdomen	International Surgery Journal	Oct-18
15	The benefits of protective defunctioning ileostomy in ileal perforation surgery	International Surgery Journal	Jul-19
16	A study of Locally advanced breast cancer management in patients with rural background	International Journal of Surgery Science	Sep-19
17	Vascular Trauma: Our Experience at Tertiary Level Hospital	IJSS Journal of Surgery	Feb-20

CASE REPORT

RECURRENT MARJOLIN'S ULCER WITH REGIONAL LYMPH NODE METASTASIS

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ABSTRACT: Marjolin's ulcer is a malignant tumour developing in a chronic skin lesion (burn scar, vaccination scar, non-healing wound etc.). The majority of cases reported are squamous cell carcinoma. Surgery remains the first treatment of choice (resection with 2cms. safety margin of healthy skin for primary squamous cell carcinoma Marjolin ulcers and 2.5cms. safety margin for recurrent cases). Recurrence after surgery and regional lymph node metastasis are not uncommon (17% & 30% respectively).We presents a case report and literature review of Recurrent Marjolin's Ulcer with regional Lymph Node Metastasis. Marjolin's ulcer should be considered as a significant post-burn complication; it should be treated with full emphasis on adequate local clearance and regular follow up for many years; if not treated adequately, it may lead to complicated recurrence.

KEY WORDS: Marjolin's Ulcer, Recurrent, Lymph Node Metastasis.

INTRODUCTION: Marjolin's ulcer is a malignant tumour developing in a chronic skin lesion (burn scar, vaccination scar, non-healing wound etc.).[1] The majority of cases reported are squamous cell carcinoma but other type of malignancy such as basal cell carcinoma, malignant melanoma, liposarcoma, osteosarcoma, and fibrosarcoma can also be seen although rare.[2] The incidence of burn scar undergoing malignant transformation has been reported to be 0.77-2 %.[3]

CASE REPORT: A 22 year old male was presented to our surgical department with exophytic ulcerated growth of size 7x7 cm. near angle of right scapula. He had a past history of burn over anterior chest wall, back and left arm 12 years ago that healed completely by conservative management. Approx. 11 years after initial insult, the patient developed an ulcer on the back over burn scar. It gradually increased in size to become exophytic growth of size 12x12cms. No regional lymph node enlargement was noted at that time. Whole of the ulcer with a 2 cm. margin of healthy skin was excised. The defect in skin was closed by partial thickness skin graft. Histopathological examination of the excised tissue was suggestive of poorly differentiated squamous cell carcinoma.

8 months after surgery & skin grafting, the patient came with exophytic ulcerated growth of size 7x7 cm. near angle of right scapula. It was fixed to underlying muscles of back.

Patient was also having another fungating growth in left axilla which was 6x6 cms. in size, fixed to underlying structures causing restriction of movements at shoulder. Serous discharge was present from axillary growth. There was no vascular or neurological impairment present in left upper limb. Biopsy from axillary growth was positive for squamous cell carcinoma.

LITERATURE REVIEW: The eponym "Marjolin's ulcer" was derived from French surgeon Jean Nicholas Marjolin in 1828 who observed and classified cellular change in burn skin and coined the term "ulcere cancroide".[4] The skin lesion underlying development is predominantly burn scar (75%), traumatic non healing wound (8%), venous stasis ulcer (6%), pressure ulcer (3%) and other e.g. Frost bite, vaccination scar .[1]

The latency period is inversely proportional to patient's age at the time of skin injury. In chronic Marjolin's ulcer it ranges from 20-40 year as transformation from non-healing wound to malignant disease is slow. The average time lag between the burns and subsequent malignant ulceration is 19 years. [5] In acute Marjolin's ulcer it occurs within few weeks to one year.[1] Average age at diagnosis of Marjolin's ulcer is in 5th decade of life with a range of 18-84 years.[2] It is seen more frequently in males as compare to females with ratio of 3:1.[2] Most commonly it is located on lower extremities (53%), upper extremities (18%), trunk (12%), face and nape (5%), scalp (9%).[4]

Aetiology of Marjolin's ulcer is not yet clear. Many hypotheses have been suggested. Slow healing and scar instability characterized by chronic irritation and the induction of constantly proliferating epidermal unit have been blamed. Repeated cycle of healing and breakdown, wound that never healed and application of irritant medication are all result in reduced ability to withstand carcinogens.[6] As a result of constant breakdown of ulcer, a nutritional deficiency develops, owing to release of toxins by autolysis and heterolysis of scar. This yields an epithelium that is unable to withstand the carcinogens produced by skin because of excessive heat and radiation. [7] Ultraviolet rays are also found to be associated with Marjolin's ulcer. On histological examination of sun damaged skin, dyskeratosis and vacuolated keratinocytes known as sun burn cell are seen. Marjolin's ulcer least frequently founds on trunk which is not frequently exposed to sunlight. [8] It has also been suggested that relatively avascular scar tissue act as immune privileged site that allows the tumour to resist body defences against foreign cell.[6]

Scar tissue acts as a barrier for the tumours, if we release this barrier, the virulent spread of the tumour will be permitted.[8] Regional lymph node metastasis and recurrence after surgery is not uncommon. Metastasis to regional lymph nodes is seen in 30% of cases and local recurrence occurs in 17% of patients. The median interval to recurrence after surgery is 15 months. Locoregional recurrence is more common in female patients and those with high-grade tumours.[9] Poorly differentiated squamous cell carcinomas have a tendency to spread to lymph nodes earlier. Squamous cell carcinomas resulting from the Marjolin's ulcer have a much greater tendency to metastasize than squamous cell carcinomas resulting from the other causes [10].

Various studies suggested that all chronic wound should be closed surgically either by skin graft or skin muscle flap. Large wound should not be left for secondary intention healing. Burn scar from childhood should be carefully monitored; biopsy of any suspected lesion should not be delayed. At present no standard treatment for Marjolin's ulcer is suggested. Surgery remains the first treatment of choice. Marjolin's ulcer should be excised with a 2 cm. margin of normal healthy tissue, which may necessitate amputation with lesion involving joint space or deep local extensive invasion. Although classically 2cm safety margin is still widely used for resection of primary squamous cell carcinoma Marjolin ulcers, 2.5cm safety margin is better for

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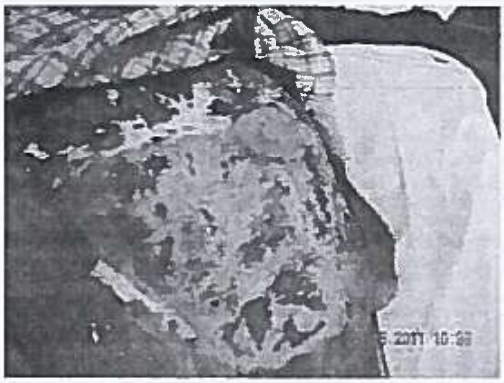

Figure 1: Marjolin's Ulcer arising in a Burn Scar

Figure 2: Exophytic Marjolin's Ulcer

Figure 3 : Marjolin's Ulcer on back

Figure 4: Regional Lymph Node Metastasis in case of Recurrent Marjolin's Ulcer on back

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CASE REPORT

HUGE VULVAL ELEPHANTIASIS OF UNKNOWN AETIOLOGY

Anjali Sethi[1], Deepak Sethi[2]

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Anjali Sethi, Deepak Sethi. "Huge Vulval Elephantiasis of Unknown Aetiology". Journal of Evolution of Medical and Dental Sciences 2014; Vol. 3, Issue 13, March 31; Page: 3324-3329, DOI: 10.14260/jemds/2014/2288

ABSTRACT: Genital Elephantiasis is an important medical problem in the tropics; usually affects young and productive age group and is associated with physical disability and mental anguish. It is one of the bizarre & nipping diseases and has a long history of worldwide distribution. Most of the reported cases occur as an end result of lymphatic obstruction due to various diseases like Filariasis, sexually transmitted diseases (LGV & Donovanosis) as well as malignancies. Few cases may remain of unknown etiology. We are reporting a case of huge vulval elephantiasis, etiology of which remained unknown.

KEYWORDS: Elephantiasis, Lymphatic Obstruction, Vulval.

INTRODUCTION: The word 'Elephantiasis' was originally used to describe elephant like appearance of legs. The term was subsequently used to describe the similar enlargement of arm, chest, breast, vulva, penis & scrotum.

Genital Elephantiasis is an important medical problem in the tropics; usually affects young and productive age group and is associated with physical disability and mental anguish. It is one of the bizarre & nipping diseases and has a long history of worldwide distribution. Most of the reported cases occur as an end result of lymphatic obstruction due to various diseases like Filariasis, sexually transmitted diseases (LGV & Donovanosis) as well as malignancies.[1]

CASE REPORT: A 35 years old female was presented with a huge mass arising from right labium majus for 2 years. She noticed a small swelling over her vulva at right labium majus 2 years back. The swelling gradually increased in size over period of 2 years to reach the size of approximately 60*60 centimetres. (Figures No. 1, 2, 3). The whole mass hanged from labium to reach up to knees.

The history did not reveal any symptoms related to Filariasis, sexually transmitted disease or any other disease. She had a history of surgery for excision of similar but small swelling from the same labia 5 years ago. No documental record related to previous surgery was present with patient.

The mass was non-tender, firm in consistency and had rugosities all over its surface with ulcerations at some places. The skin over supra – pubic region was also involved. The other labium was normal. Both lower limbs were normal. Inguinal Lymph nodes were not palpable. General Physical examination revealed anemia and otherwise normal.

Pre-operative investigations showed mild anemia and FNAC from the mass showed chronic non-specific inflammation. Examination of nocturnal skin prick blood sample for microfilariae was negative, Mantoux test was negative and Complete Blood Counts did not show any Eosinophilia or Lymphocythemia. After full investigations, patient was posted for operation.

After spinal anesthesia patient was placed in lithotomy position. Whole of the mass from vulva & also from supra – pubic region was excised (total weight of the mass was approx. 8 kilograms) (Figure No. 5). The vulva was reconstructed and wound was primarily closed over a

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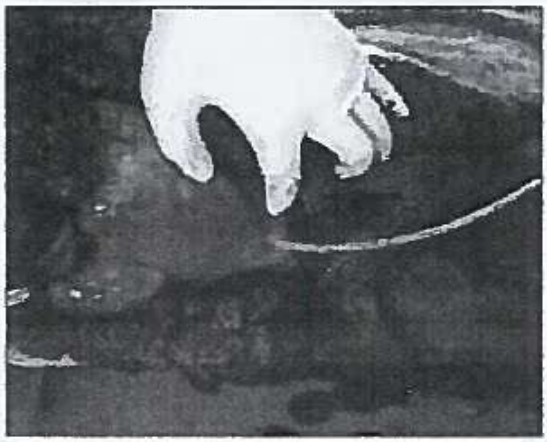

Fig. 3 : Left Labium Majus is Normal

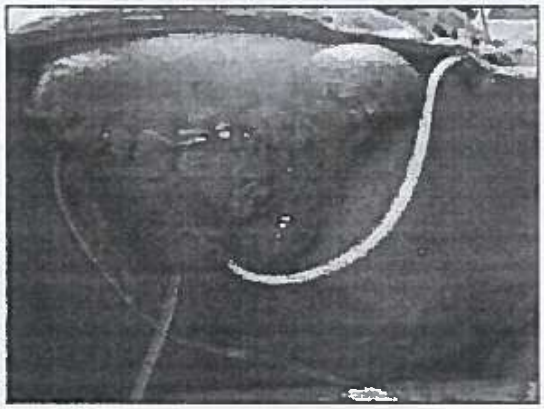

Fig. 4: Immediate Post-Operative photograph

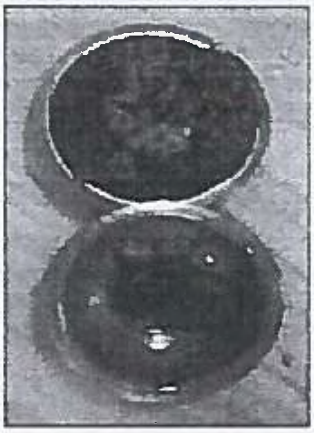

Fig. 5: Resected Elephantiasis Tissue specimen weighing approx. 8 kilograms

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edema, sclerosing fibrosis of subcutaneous tissue, elephantiasis and chronic genital ulceration. It is often associated with ano-rectal complications including fistulae & strictures both in men & women.

Donovanosis is chronic progressive destructive, granulomatous infection of superficial tissue of the genital region, caused by Calymmatobacterium granulomatis. Lymphedema of genital region is one of the long term complications. Clinically Donovanosis induced elephantiasis is characterized by firm, pedunculated, lobular swelling. It affects predominantly the labia majora & the clitoris.

Various treatment modalities have been described for genital elephantiasis which includes compression therapy, drugs & surgery. Basic principle of the treatment is complete removal of all affected tissue by surgery, and drugs for causative organism.[6]

Compression therapy is not practical for lymphedema of genitalia; but minor swelling can be treated by support hosiery.

Drugs:

LGV– Doxycycline 100 mg. twice daily for prolonged period of approx.13 months.

Donovanosis– Azithromycin 1 gm on first day followed by 500 mg once daily or Co-trimoxazol (Trimethoprim 80 mg & Sulphamethaxazol 400 mg) two tablets twice daily for 10-14 days.

Filariasis– Diethyl Carbazine is the drug of choice.

Bypass procedures include omentum pedicle, Skin Bridge anastomosing lymph nodes to vein; and most recently lympho-venous anastomosis with aid of microscope. However, long term results of all these techniques are poor.

Reduction procedures include removal of subcutaneous elephantoid tissue and closure of wound either by preservation of overlying skin flaps or by free skin graft or rotational flaps. Labial reduction is easily achieved by wide elliptical excision with single suture line.[6]

CONCLUSION: Genital elephantiasis is a significant medical problem and persons affected may become a major burden to their families & community. At present surgery is only effective option for patients in whom the disorder is disabling, persistent and psychological devastating.

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Penile cutaneous horn-a rare case

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Abstract

Penile cutaneous horn is a horn like hyper-keratotic lesion over penis which is an unusual site and a rare case. We report a case of cutaneous horn of penis in age of 20 years which is also a rare presentation in this age group.

Key words: Cutaneous Horn, Penile Cutaneous Horn, Penile Horn

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Introduction

Cutaneous horns are also known as cornucutaneum, which are unusual keratinous skin tumors with the appearance of horn. This is clinically appears as conical projection above the surface of the skin [1]. Although the cutaneous horn may develop over a normal skin, these more often develop over some pre-existing skin conditions like warts, keratosis, nevi, trauma, burns, lupus vulgaris, and even on an epithelioma[2]. Cornucutaneum (cutaneous horn) is a well-defined cone-shaped lesion with hyper-keratotic features. This type of lesion mostly found on exposed skin [3]. Cutaneous horns occur rarely on the penis. The incidence of the lesion is very low, with only 30 cases reported in 25 years [4]. Disease may be benign in 42%-56%, premalignant in 22%-37%, or frankly malignant in 20%-22% of patients [5].

Case Report

BREAST CANCER: IS OBESITY A RISK FACTOR?

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ABSTRACT

Most epidemiological studies established obesity as an important risk factor for breast cancer. It is one of the few risk factors that women can modify. Now-a-days breast cancer is considered to be a life-style disease. The relation of obesity to breast cancer is complex one. Obesity is found to be associated with increased risk of cancer in post-menopausal women, but relation is reverse in pre-menopausal women. In these patients, obesity increases risk due to enhanced oestrogenic activity in obese females. Apart from it, other factors like Insulin-like Growth Factor (IGF-1), Leptin has also been involved. Due to big breasts in obese females there is delay in seeking medical attention, delay in diagnosis, poor response to surgery, chemotherapy, radiotherapy and associated complication during treatment. We study the effect of obesity (Weight, BMI, WHR) as a risk factor in occurrence of breast cancer in local population of Southern part of Rajasthan in India. We found no significant association between obesity and increased risk of breast cancer in local population of this region where women are multiparous, physically active and usually do not use exogenous hormones.

KEYWORDS

Obesity, Breast Cancer, Risk Factor, Body Mass Index, Waist-to-Hip Ratio, Body Weight.

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INTRODUCTION

Breast cancer is a malignancy of breast that is common in women and rare in men. Because breast is a superficial organ, it can be easily accessed by both patients and doctors. As the incidence of breast cancer increases, significant advances have been made in development of early detection method, less radical primary therapy, use of radiation and chemotherapy which have saved significant number of lives.

The quality of life in India is improving with improvements of socio-economic status. As the life expectancy increases, the cancer burden to society also increases. Apart from curative modalities, we must also think about preventive policies as an essential step. Definitive etiology of breast cancer has eluded the researchers. Breast cancer is now considered as a lifestyle disease. Lots of factors such as nutrition, lifestyle, high fat intake, age of menarche, age of first pregnancy, being overweight, use of HRT, age of menopause have been incriminated.

Breast cancer is considered to be a consequence of affluence and being overweight. Excess of adipose tissue leads to increased circulating oestrogen.

ABBREVIATIONS

BMI- Body Mass Index.
WHR- Waist-to-Hip Ratio.
HRT- Hormone Replacement Therapy.
CL- Confidence Limit.
IGF- Insulin-like Growth Factor.
Kg- Kilogram.
Mt- Metre.

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Obesity may further add insult to injury because lipid is more prone to oxidative damage as compared to protein and carbohydrate. In present study, we planned to find out association between obesity and breast cancer in local population of Southern part of Rajasthan in India.

INCIDENCE

Breast cancer is a global disease. Incidence of breast cancer is continuously rising in last few decades. It accounts for 33% of all female cancer and is responsible for 20% cancer related death in women. It also shows a widespread geographical distribution. There is many fold variation in incidence and mortality among different countries. In UK incidence was 74.4/1,00,000 in 2003, where as in South Korea it was 2.6/1,00,000 (Cancer Statistics 2003). In USA 2,11,300 new cases were diagnosed in 2003 with mortality of 39,800, which were raised to 2,32,000 new cases with mortality of 44,000 in 2012.

In India it has now become the first most common cancer in women population, way ahead of cervical cancer. It accounted for 25.9% of all female cancer in 2008; figure was raised to 27% in 2012. In India 1,15,000 new cases were diagnosed in 2008 with a mortality of 5,300, which raises to 1,45,000 new cases and mortality of 70,000 in 2012.[1] For the year 2015, there would be an estimated 1,55,000 new cases of female breast cancer and about 76,000 women in India are expected to die due to disease.[2]

METHODS AND MATERIAL

In present study, we studied 50 clinico-pathologically diagnosed patients of breast cancer. Diagnosis was based on detailed history, clinical examination, diagnostic modalities like mammography, USG and confirmed by FNAC and Tru-Cut Biopsy. Obesity was measured by body weight (Kg), Body Mass Index (BMI-Weight/Height.^{2} Kg/mt.^{2}) and Waist-to-Hip Ratio (WHR-Waist circumference-to-hip circumference ratio WC/HC). Waist circumference was measured just above the level of lateral iliac crest below lowest rib, and hip circumference under inferior rim of pubic symphysis in midline.

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Menopausal Status	Cases		Controls	
	N	%	N	%
Pre-menopausal	24	48.00	23	46.00
Post-menopausal	26	52.00	27	54.00
Total	50	100.00	50	100.00

Table 1: Menopausal Status of Breast Cancer Patients and Controls

Age	Cases (n = 50)		Controls (n = 50)	
	N	%	N	%
<30	3	6.00	0	0.00
31-40	12	24.00	11	22.00
41-50	18	36.00	21	42.00
51-60	11	22.00	11	22.00
>60	6	12.00	7	14.00
Total	50	100.00	50	100.00

Table 2: Age of Breast Cancer Patients and Controls

Stage	Pre-menopausal (n=24)		Post-menopausal (n=26)		Total	
	N	%	N	%	N	%
Stage I (n = 0)	0	0	0	0	0	0
Stage II (n=22)	7	29.1	15	57.1	22	44.0
Stage III (n=16)	10	41.6	6	23.0	16	32.0
Stage IV (n=15)	7	29.1	5	19.8	12	24.0
Total	24	100.0	26	100.0	50	100.00

Table 3: Staging of Breast Cancer V/s Menopausal Status

Weight (Kg)	Pre-menopausal				Post-menopausal			
	Early Stage	Advanced Stage	Total		Early Stage	Advanced Stage	Total	
			N	%			N	%
<=40	1	4	5	20.83	3	2	5	19.23
41-50	3	8	11	45.83	3	3	6	23.08
51-60	3	3	6	25.00	4	4	8	30.77
61-70	0	1	1	4.17	3	1	4	15.38
>70	0	1	1	4.17	2	1	3	11.54
Total	7	17	24	100.00	15	11	26	100.00

Table 4: Weight V/s Staging in Pre- and Post-menopausal Women

Weight (Kg)	Pre-menopausal		Post-menopausal		Total	
	N	%	N	%	N	%
<=40	5	21.74	3	11.11	8	16.00
41-50	9	39.13	6	22.22	15	30.00
51-60	6	26.09	8	29.63	14	28.00
61-70	3	13.04	5	18.52	8	16.00
>70	0	0.00	5	18.52	5	10.00
Total	23	100	27	100	50	100.00

Table 5: Weight of Controls

Height (cm)	Pre-menopausal				Post-menopausal			
	Early Stage	Advanced Stage	Total		Early Stage	Advanced Stage	Total	
			N	%			N	%
<=130	0	0	0	0.00	2	0	2	7.69
131-140	0	0	0	0.00	0	2	2	7.69
141-150	3	6	9	37.5	5	3	8	30.77
151-160	3	10	13	54.17	7	5	12	46.15
>160	1	1	2	8.33	1	1	2	7.69
Total	7	17	24	100.00	15	11	26	100.00

Table 6: Height V/s Staging in Pre- and Post-menopausal Breast Cancer Patients

Height (cms)	Pre-menopausal		Post-menopausal		Total	
	N	%	N	%	N	%
<=130	0	0.00	1	3.70	1	2.00
131-140	0	0.00	0	0.00	0	0.00
141-150	9	39.13	6	22.22	15	30.00
151-160	13	56.52	19	70.37	32	64.00
>160	1	4.35	1	3.70	2	4.00
Total	23	100	27	100	50	100.00

Table 7: Height of Controls

WHR	Pre-menopausal				Post-menopausal			
	Early Stage	Advanced Stage	Total		Early Stage	Advanced Stage	Total	
			N	%			N	%
<=0.75	0	4	4	16.67	1	0	1	3.85
0.75-0.80	2	4	6	25.00	8	2	10	38.48
0.80-0.85	3	5	8	33.3	3	6	9	54.46
0.85-0.90	1	3	4	16.67	1	2	3	11.54
>0.90	1	1	2	8.33	2	1	3	11.54
Total	7	17	24	100.00	15	11	26	100.00

Table 8: WHR Ratio V/s Staging in Pre- and Post-menopausal Breast Cancer Patients

WHR	Pre-menopausal		Post-menopausal		Total	
	N	%	N	%	N	%
<=0.75	2	8.70	0	0.00	2	4.00
0.75-0.80	3	13.04	4	14.81	7	14.00
0.80-0.85	6	26.09	12	44.44	18	36.00
0.85-0.90	9	39.13	10	37.04	19	38.00
>0.90	3	13.04	1	3.70	4	8.00
Total	23	100	27	100	50	100.00

Table 9: WHR of Controls

BMI	Pre-menopausal				Post-menopausal			
	Early Stage	Advanced Stage	Total		Early Stage	Advanced Stage	Total	
			N	%			N	%
<=15 (Underweight)	0	0	0	0.00	2	0	2	7.69
16-20 (Underweight)	0	0	0	0.00	0	2	2	7.69
21-25 (Desirable)	3	6	9	37.5	5	3	8	30.77
151-160 (Over weight)	3	10	13	54.17	7	5	12	46.15
>160 (Obese)	1	1	2	8.33	1	1	2	7.69
Total	7	17	24	100.00	15	11	26	100.00

Table 10: BMI V/s Staging in Pre- and Post-menopausal Breast Cancer Patients

BMI	Pre-menopausal		Post-menopausal		Total	
	N	%	N	%	N	%
<=15	1	4.35	0	0.00	1	2.00
16-20	10	43.48	4	14.81	14	28.00
21-25	8	34.78	8	29.63	16	32.00
26-30	4	17.39	9	33.33	13	26.00
>30	0	0.00	6	22.22	6	12.00
Total	23	100	27	100	50	100.00

Table 11: BMI of Controls

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Case Report

Triple Testes - A Rare Case

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ABSTRACT

Polyorchidism is a very rare congenital anomaly, less than 200 cases reported in literature. Triorchidism is commoner in polyorchidism, mostly extra testes found in left side. We report a case of 47 year old patient with incidental finding of third testis during inguinal hernia operation.

Key words: Polyorchidism, Polyorchism, Triple Testes, Orchiectomy, Rare.

INTRODUCTION

Polyorchidism is an uncommon congenital anomaly that is defines by presence of more than two testes in a man. The supernumerary testes may be present in scrotum or in inguinal canal or even intra-abdominally. It is a very rare congenital disorder, with fewer than 200 cases reported in medical literature (Bergholz R *et al.*; 2009). Polyorchidism is frequently associated with additional urological pathologies such as undescended testis, inguinal hernia, testicular torsion, hydrocoele, malignancy and infertility (O'Sullivan DC*et al.*; 1995), (Spranger R*et al.*; 2002).

CASE REPORT

We report a case of triple testes, an incidental finding during left inguinal hernia operation. A 47 year old male patient came to hospital with complaint of swelling in left inguinal region. Patient was diagnosed as a case of left indirect inguinal hernia. On clinical examination of scrotum both testes were present but left testis was smaller than right. After investigations, patient was posted for surgery under spinal anaesthesia. Intra-operatively it was found that spermatic cord contained two separate vas deferenses, one was connected to testis in scrotum and the other testis present in the inguinal canal (Figure-3). Orchiectomy was done of inguinal testes. Hernioplasty was done for inguinal hernia. Later on, ultra-sonic examination of right side showed presence of single testis on right side.

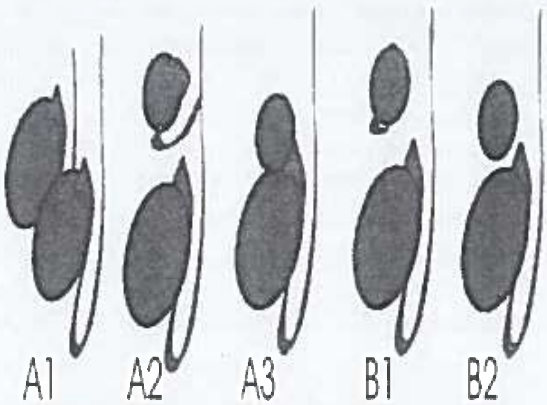


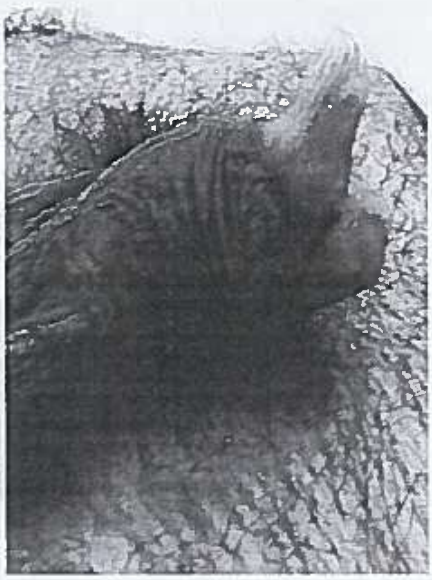
Figure 1- Classification (Dr. Matt A. Morgan *et al.*).

penile cutaneous horns are associated with an underlying malignancy[8,9].

Recently, several studies indicated that immune-histochemical expression of p16ink4a may be used not only as a marker of high-risk HPV infection, but also on differential diagnosis of penile epithelial abnormalities and precancerous lesions. Earlier data showed strong association of HPV with high-grade squamous cell carcinoma, whereas well-differentiated SCC subtypes were not HPVrelated. Chaux et al. Have published a study designed to seek an immune-histochemical profile that can be helpful in the classification and differential diagnosis of penile epithelial abnormalities and precancerous lesions[10].

Conclusion

Penile cutaneous horn is a rare case.Penile cutaneoushorn is a clinical diagnosis which is made on the basis of morphological appearance. Horn can be associated with benign or malignant condition. True diagnosis is proved after histopathological examination of tissue. We report this case of penile cutaneous horn with benign histopathology.



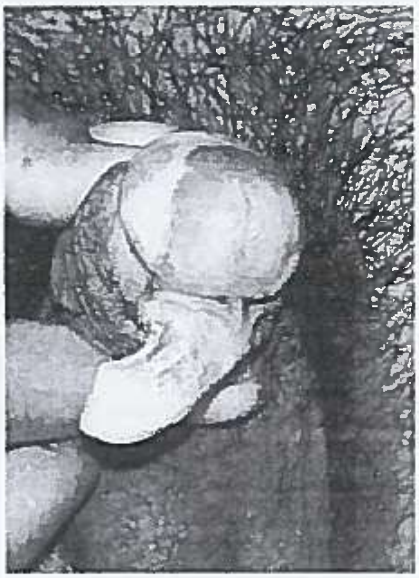


Fig 1 and 2: showing penile cutaneous horn around 3 cm in length

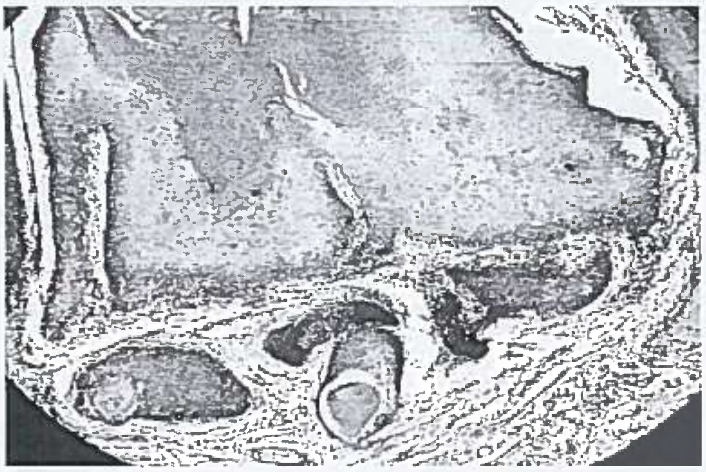


Fig 3: Histopathological slide at base of penile cutaneous horn-showing hyperplastic squamous epithelium. keratin pearl with chronic inflammatory infiltration.(10X)

Case Report

Penile cutaneous horn-a rare case

Barolia DK[1*], Sethi D[2], Sethi A[3],Ram J[4],Meena S[5], Rachhoya P[6]

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Abstract

Penile cutaneous horn is a horn like hyper-keratotic lesion over penis which is an unusual site and a rare case. We report a case of cutaneous horn of penis in age of 20 years which is also a rare presentation in this age group.

Key words: Cutaneous Horn, Penile Cutaneous Horn, Penile Horn.

Introduction

Cutaneous horns are also known as cornucutaneum, which are unusual keratinous skin tumors with the appearance of horn. This is clinically appears as conical projection above the surface of the skin [1]. Although the cutaneous horn may develop over a normal skin, these more often develop over some pre-existing skin conditions like warts, keratosis, nevi, trauma, burns, lupus vulgaris, and even on an epithelioma[2]. Cornucutaneum (cutaneous horn) is a well-defined cone-shaped lesion with hyper-keratotic features. This type of lesion mostly found on exposed skin [3]. Cutaneous horns occur rarely on the penis. The incidence of the lesion is very low, with only 30 cases reported in 25 years [4]. Disease may be benign in 42%-56%, premalignant in 22%-37%, or frankly malignant in 20%-22% of patients [5].

Case Report

We report a case of cutaneous horn at unusual site over penis. A twenty one year old male presented in hospital with conical shape hard swelling over ventral surface of penis. He noticed the lesion one year back. Before one year he was having the complaint of phimosis. Therefore he was operated circumcision. After two months of circumcision he develops the lesion. The lesion was gradually increased in size. When he came to hospital, lesion was conical in shape, hard in consistency, over ventral surface of penis and near about three centimeter in size. Horn was surgically excised with free margine. Histopathology of tissue at base of cutaneous horn shows hyperplastic squamous epithelium with marked hyper keratosis. There was no evidence of malignancy. This patient discharged without any complication with satisfactory result. In follow up patient was satisfied with surgery and having no complain.

Discussion

Cutaneous horn (synonyms: Cornucutaneum; Cornuhumanum) is a conical, hyper-keratotic protrusion that often resembles like an animal horn. The term "cutaneous horn" is not a true diagnosis. It is named after morphologic appearance like animal horn. To this date just >150 cases have been reported in the literature [4].The factor which leads to these patients developing penile horn is unclear. The roles of chronic irritation, phimosis, surgical trauma and radiotherapy that have been implicated in penile horn formation have also been found to predispose to carcinoma penis [1,6]. Cutaneous horn may be benign, premalignant or malignant. The etiology of penile cutaneous horn remains uncertain. The earliest documented case of cutaneous horn, or cornucutaneum, of an elderly Welsh woman in London who was displayed commercially as an anomaly of nature in 1588 [6]. The first case report of penile cutaneous horn was published in 1854[7]. The European Association of Urology guidelines on penile cancer they consider penile cutaneous horn as a premalignant lesion and approximately one-third of

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This variant results from incomplete longitudinal division of the genital ridge and the proximal portion of the mesonephric duct. In type D, complete longitudinal duplication of the genital ridge and mesonephric duct occurs, with resultant complete duplication of testes, epididymides, and vas deferens. This type may be associated with an ipsilateral duplicated ureter and is the least common (John B. Amodio *et al.;* 2004).

It is believed to result embryologically from an abnormal division of the genital ridge (Woodward PJ *et al.;* 2003).Embryological theories responsible for polyorchidism include

i. degeneration of parts of the mesonephric components;
ii. duplication of the genital ridge; or
iii. division of the genital ridge.

There is an increased risk of malignancy if supernumerary testicles are detected (Ahlfeld F *et al.;* 1880).

Differential diagnosis: Possible differential considerations include scrotal hernia, bilobed testicle, crossed testicular ectopia, testicular tumour (Dr. Matt A. Morgan *et al.*).

Management: Because polyorchidism is very uncommon, there is no standard treatment for the condition. Prior to advances in ultrasound technology, it was common practice to remove the supernumerary testicle (Leung, A. K.; 1988). Several cases have been described where routine follow-up examinations conducted over a period of years showed that the supernumerary testicle was stable (Bergholz R *et al.*; 2009).

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CORRELATION OF BREAST CANCER AND SERUM HIGH DENSITY LIPOPROTEIN CHOLESTEROL LEVEL: A SINGLE CENTRE STUDY

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ABSTRACT

Breast cancer is the most common site specific cancer in women. Lots of etiological factors have been suggested regarding its causation. The risk is influenced by obesity, parity, exogenous and endogenous hormones, exposure to chemicals and radiation and many more. Various studies suggest that as HDL-C seems to be cardio protective, it is also protective for breast cancer. Serum HDL-C levels are found to be low in breast cancer patients. We studied this hypothesis in local population of Southern Rajasthan and nearby region to see if low serum HDL-C is associated with increased risk of breast cancer. We studied serum HDL-C level in 50 female patients of breast cancer along with their menopausal status and compared it to their respective controls. We found that breast cancer patients had significantly low level of serum HDL-C and presented in advanced stage of cancer. It supports that low serum HDL-C level is associated with increased risk of breast cancer. So one should think about those dietary and lifestyle measures, which maintain high serum HDL-C level so that it might become preventive measure for breast cancer.

KEYWORDS

Breast Cancer, High Density Lipoprotein Cholesterol, Risk Factors, Pre-menopausal, Post-menopausal.

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INTRODUCTION

Breast Cancer is the most common site specific cancer in women and a leading cause of death due to cancer between 40-45 years of age. It has now become a global disease. It accounts for 33% of all female cancer and 20% of cancer related death in women.

The exact cause of breast cancer is not known but sex hormones, both endogenous and exogenous play an important role. Exposure to radiation and chemicals can also stimulate the onset of disease.[1] The risk of breast cancer is also influenced by dietary fat intake, obesity, parity, duration of breast feeding, family history and socio-economic status.[2] Breast cancer is considered to be consequences of high fat consumption.

There may be chemical carcinogen in fatty fried diet and altered bacterial flora in intestine leads to increased production of carcinogenic substances. Serum lipid profile is an important marker of dietary fat intake.[2] Various studies indicate that plasma triglycerides and LDL-C levels were found to be significantly elevated among breast cancer patients.,[3] but HDL-C level were observed to be significantly low as compared to control.[1,4,5] It raises a question that HDL-C seems to be protective in breast carcinogenesis.

Serum HDL-C levels are found to be low in breast cancer patients. We studied this hypothesis to see if low serum HDL-C is associated with increased risk of breast cancer.

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DOI:10.14260/jemds/2015/2388

We studied the correlation between serum HDL-C (HDL) level and female breast cancer and clinical staging in local population of Southern Rajasthan and nearby region in the patients who consulted to our Tertiary Care Level Hospital.

ABBREVIATIONS

HDL-C (HDL)–High Density Lipoprotein Cholesterol
LDL–Low Density Lipoprotein
VLDL–Very Low Density Lipoprotein
USG–Ultrasonography
FNAC–Fine Needle Aspiration Cytology
CL–Confidence Limit
SR-BI–Scavenger receptor class B type I.

METHOD AND MATERIAL

We studied 50 patients of breast cancer. Patients were diagnosed on basis of detailed history, clinical examination, mammography, USG, FNAC, and Tru-Cut biopsy. Lifestyle parameters like socio-economic status, age of menarche, menopausal status, use of oral contraceptives, hormone replacement therapy, etc., were also evaluated.

HDL (HDL-C) was estimated in venous blood samples of patients. Blood sample of 50 controls were also analyzed for HDL-C. Controls were those females who were not suffering from breast cancer, but fell in same age group. HDL-C was detected in lab by direct homogenous assay method.

Females who presented in stage I and II were included in early stage and those in stage III and IV were included in advanced stage.

Expected Normal Range

Adult Male–54.5±12.9mg/dl
Adult Female–61.2±12.3mg/dl

Staging of Breast Cancer v/s Menopausal Status						
Stage	Pre-menopausal (n=24)		Post-menopausal (n=26)		Total	
	N	%	N	%	N	%
Stage I (n = 0)	0	0	0	0	0	0
Stage II (n=22)	7	29.1	15	57.1	22	44.0
Stage III (n=16)	10	41.6	6	23.0	16	32.0
Stage IV (n=15)	7	29.1	5	19.8	12	24.0
Total	24	100.0	26	100.0	50	100.00

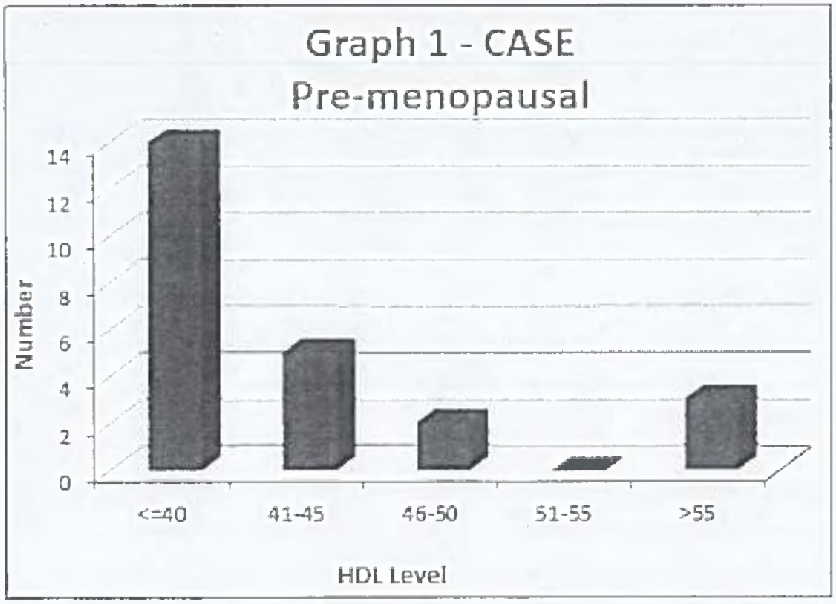
Table 3

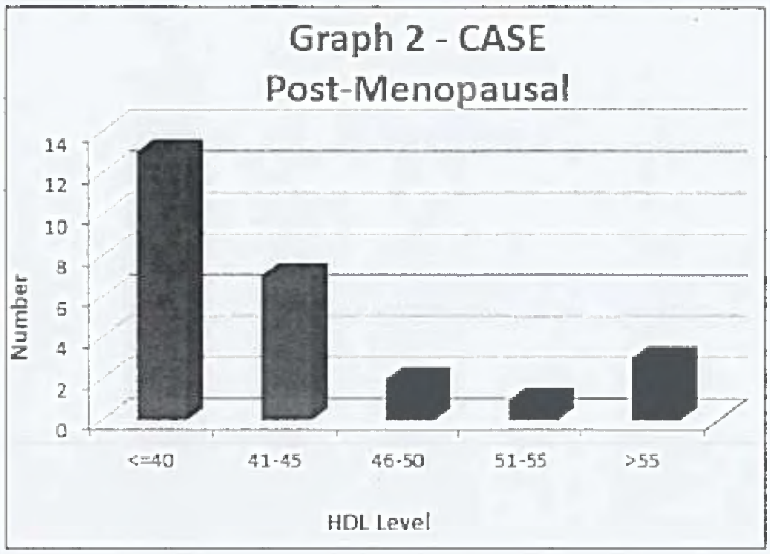
HDL Level V/s Staging in Pre- and Post-menopausal Breast Cancer Patients								
	Pre-menopausal				Post-Menopausal			
HDL Level	Early Stage	Advance Stage	Total		Early Stage	Advance Stage	Total	
			N	%			N	%
<=40	3	11	14	58.30	7	6	13	50.0
41-45	3	2	5	20.80	6	1	7	26.92
46-50	0	2	2	8.33	0	2	2	7.69
51-55	0	0	0	0.00	0	1	1	3.85
>55	1	2	3	12.50	2	1	3	11.54
Total	7	17	24	100.00	15	11	26	100.00

Table 4

HDL Level of Controls						
HDL	Pre-menopausal		Post-menopausal		Total	
	N	%	N	%	N	%
<=40	7	30.43	6	22.22	13	26.00
41-45	2	8.70	4	14.81	6	12.00
46-50	6	26.09	4	14.81	10	20.00
51-55	5	21.74	9	33.33	14	28.00
>55	3	13.04	4	14.81	7	14.00
Total	23	100	27	100	50	100.00

Table 5

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Post-Menopausal
Number
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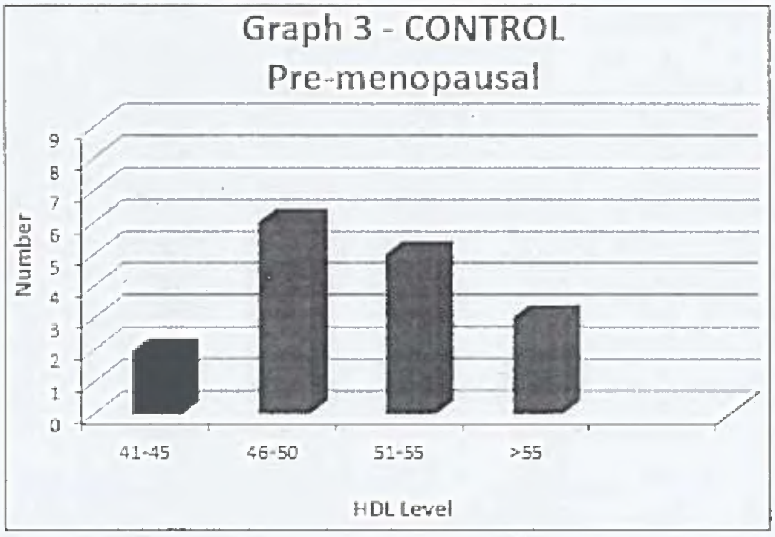
12
10
8
6
4
2
0
<=40
41-45
46-50
51-55
>55
HDL Level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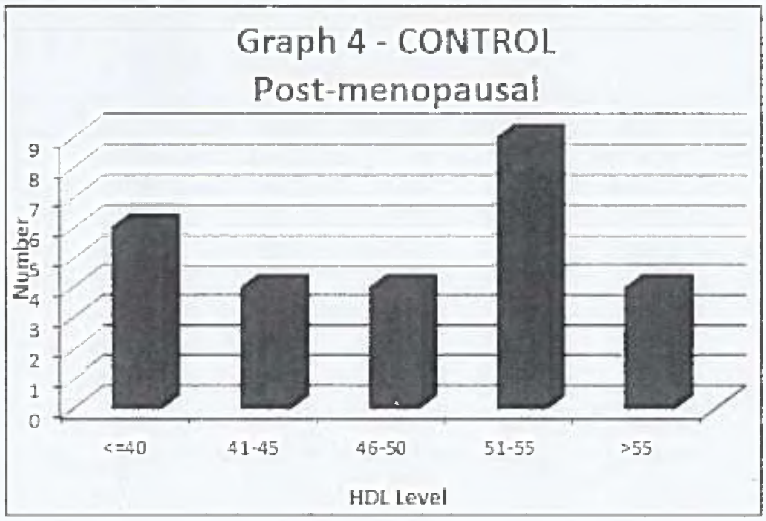
Pre-menopausal
Number
9
8
7
6
5
4
3
2
1
0
41-45
46-50
51-55
>55
HDL Level


Graph 4 - CONTROL
Post-menopausal
Number
9
8
7
6
5
4
3
2
1
0
<=40
41-45
46-50
51-55
>55
HDL Level

Case Report

Isolated corpus spongiosum and urethral injury during sexual intercourse—a rare case

Dinesh Kumar Barolia[1], Deepak Sethi[1], Vinesh Kumar Rana[1], Anjali Sethi[2], Pinky Rachhoya[3]

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Abstract

Penile fracture is a rare surgical emergency. Penile fracture involved the rupture of corpus cavernosum and may be associated with rupture of corpus spongiosum or urethra. We report a case of a 22-year old man presenting with penile swelling and pain, with retention of urine after getting a trauma during sexual intercourse. After exploration in emergency, we found that there was isolated rupture of corpus spongiosum with urethra, both corpus cavernosum were intact. We did repair of the ruptured urethra and corpus spongiosum. In follow-up, the patient did not present any complications such as distortion of penis and erectile dysfunction.

KEY WORDS: Penile fracture, penis, corpus spongiosum, urethra, urethral injury

Introduction

Penile fracture is an uncommon urological emergency.[1] Penile fracture is a disordering of the tunica albuginea of one or both corpus cavernosum owing to blunt damage to the erect penis.[2] There is immediate loss of erection state, with large hematoma and deformation. There may be microscopic hematuria and urethral bleeding when corpus spongiosum ruptured along with urethra. This occurs in 10%–20% of cases.[3,4] Penile fractures typically present with a "cracking" sound, rapid detumescence of the penis and often pain, swelling, and ecchymosis.[5]

Case Report

We report a case of a 22-year old man who came to emergency with complaint of penile swelling with pain and per urethral bleeding. He gave history that, during sexual intercourse, he got trauma, then rapid loss of erection, penis became flaccid, penile pain, and bleeding per urethra. On physical examination, patient built was good. There was penile discoloration, swelling of penis and scrotum, and bleeding per urethra. Penis was tender, flaccid, and edematous. Patient was operated in emergency operation theater under anesthesia. Subcoronal circumferential degloving incision was given, and hematoma was drained. There was isolated rupture of corpus spongiosum along with urethra. After per urethral catheterization, urethra was repaired; then ruptured corpus spongiosum was repaired. Edematous foreskin was excised, and wound approximation was done. Patient was treated with broad spectrum antibiotics. Patient was discharged without any complication. In follow-up, Foleys Catheter was removed after third postoperative week. On last follow-up, he had normal erectile function, but he developed stricture urethra. He advised and explained intermittent self-urethral dilation.

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Discussion

Penile fracture is the rupture of one or both of the tunica albuginea, the fibrous coverings that envelope the penile corpora cavernosa. It is caused by rapid blunt force to an erect penis, usually during vaginal intercourse or aggressive masturbation.[6] It sometimes also involves partial or complete rupture of the urethra or injury to the dorsal nerves, veins, and arteries.[7] Penile fractures account for approximately one case in 175,000 emergencies in emergency department visits.[8] There are 1,642 published cases in the literature.[1]

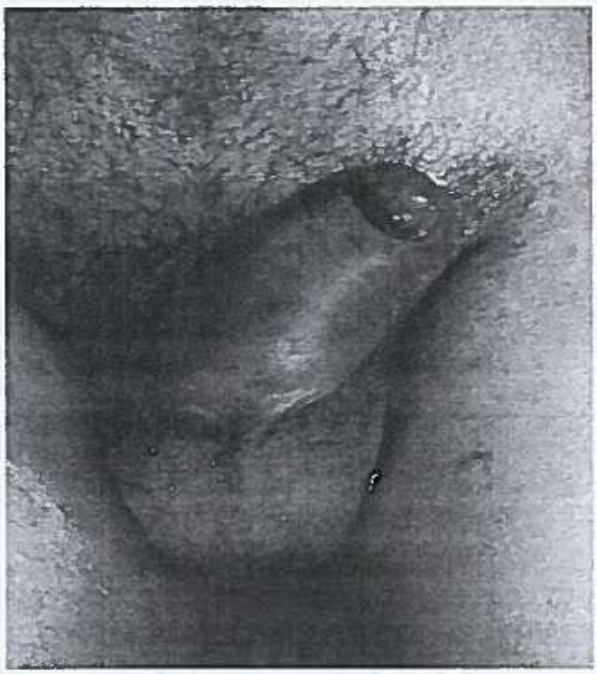

Figure 1: Fracture penis at the time of admission.

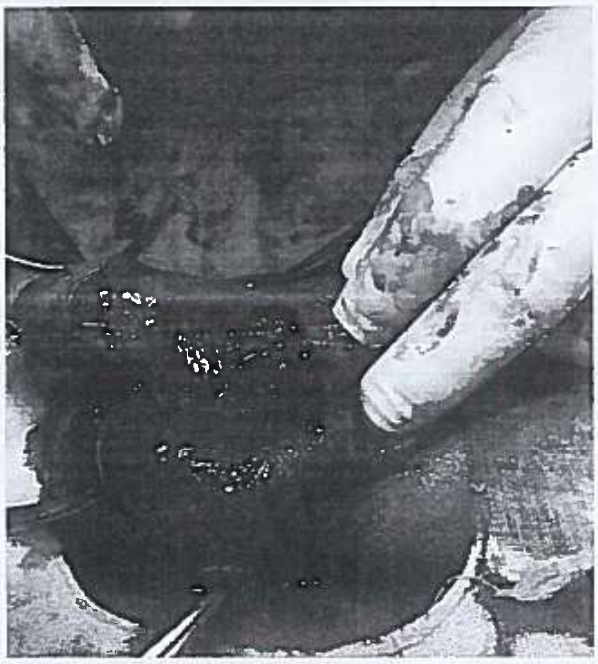

Figure 2: Drainage of hematoma.

Figure 3: Visible Foleys catheter through ruptured corpus spongiosum and urethra.

A 2014 study of accident and emergency records at three hospitals in Campinas, Brazil, showed that woman on top positions caused the greatest risk with the missionary position being the safest. The research conjectured that, when a woman is on top, she usually controls the movement, and her entire body weight lands on the erect penis. She is not able to interrupt movement when the penis suffers a misaligned penetration. Conversely, when the man is controlling the movement, he has better chances of stopping the penetration thrusts in response to pain, minimizing harm to himself.[9]

Early conservative treatment with cold applications, pressure dressings, catheterization, anti-inflammatory drugs, antibiotics, and erection suppressing drugs is now replaced with immediate surgical repair. Surgical repair of penile fracture was first described by Fetter and Gartman in 1936.[8] Since the early surgical repair reduces the complication of fracture, it is now the gold standard for treatment of penile fractures.[2-10]

Conclusion

Penile fracture is a rare surgical emergency. Isolated corpus spongiosum rupture along with urethra is a very rare condition. A complete physical examination and clinical history

required to diagnose penile fracture because patient present with different history. Early diagnosis and surgical intervention reduces the complication and increases the chances of full recovery.

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PRIMARY GRYNFELTT'S LUMBAR HERNIA- AN UNCOMMON OCCURRENCE

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ABSTRACT

BACKGROUND

Lumbar Hernia is an uncommon occurrence. It may occur through superior or inferior lumbar triangle. Hernia through superior lumbar triangle is more common. Treatment of lumbar hernia is essentially surgical with mesh repair, which may be done by open or laparoscopic techniques. Surgical management requires skill and expertise. We report a case of Lumbar Hernia through superior triangle (Grynfeltt's). A 57 years old lean and thin patient presented with swelling in left loin on coughing. Diagnosis was confirmed by ultrasonography. Hernia was repaired by on-lay application of polypropylene mesh. Patient was asymptomatic at follow-ups.

KEYWORDS

Lumbar Hernia, Grynfeltt's Hernia, Superior Lumbar Triangle, Inferior Lumbar Triangle, Mesh Repair.

HOW TO CITE THIS ARTICLE: Sethi D, Sethi A. Primary Grynfeltt's lumbar hernia- an uncommon occurrence. Journal of Evolution of General Surgery and Laparoscopy 2017; Vol. 3, Issue 1, Jan-June 2017; Page: 1-3

BACKGROUND

Lumbar Hernia is an uncommon occurrence. A surgeon may come across with these hernias on a very few occasions in his life time. Lumbar Hernias account for approximately 2% of all abdominal wall hernias. Lumbar Herniation may occur through superior lumbar triangle (Grynfeltt's Hernia) or inferior Lumbar Hernia (Petit's Hernia). Lumbar Hernias may be congenital or acquired. Acquired hernias may be primary or secondary. We present a case of Primary Lumbar Hernia through superficial lumbar triangle.

CASE REPORT

A 57-year-old lean and thin male patient was presented to surgical outdoor with history of swelling on left side of his back for last 1 year. Swelling appeared while coughing or straining only and disappears after coughing. Swelling was smaller and asymptomatic initially. It gradually increased in size. He had no history of trauma or any surgical intervention at and around the local area.

On physical local examination, patient had slight retraction over left loin and a globular swelling appeared just below twelfth rib while coughing. On deep respiration, there was further retraction at loin and then a swelling measuring approximately 6 cm × 8 cm appeared on coughing. Swelling disappeared a few moments after coughing (Fig. 1).

Vital parameters and General Physical Examination were within normal limits except that patient was lean and thin with poor built and muscle mass. On ultrasonography, a defect of approximately 2 cm × 4 cm was observed in the muscular planes of left lumbar region below the twelfth rib. Rest of the examination was within normal limits. All routine investigations were within normal limits. So, decision of patient to be post for open hernioplasty was taken.

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After informed risk consent, patient was given general anaesthesia and placed in right lateral position. Transverse incision was given below twelfth rib over the defect. After dissection of subcutaneous tissue, a defect of size approximately 2 cm × 4 cm was found in the muscular planes of superior lumbar triangle (Fig. 2). On exploration of the defect, a hernial sac was found. Hernial sac was reduced and defect in the muscular planes was closed with silk suture. A large on-lay polypropylene mesh was placed over muscles and was fixed on to the periosteum of twelfth rib superiorly, iliac crest inferiorly and to the muscles on medially and laterally and thus tension free mesh repair was done (Fig. 3). Post-operative period was uneventful. Suture removal was done on eighth post-operative day. Patient was asymptomatic at follow-ups.

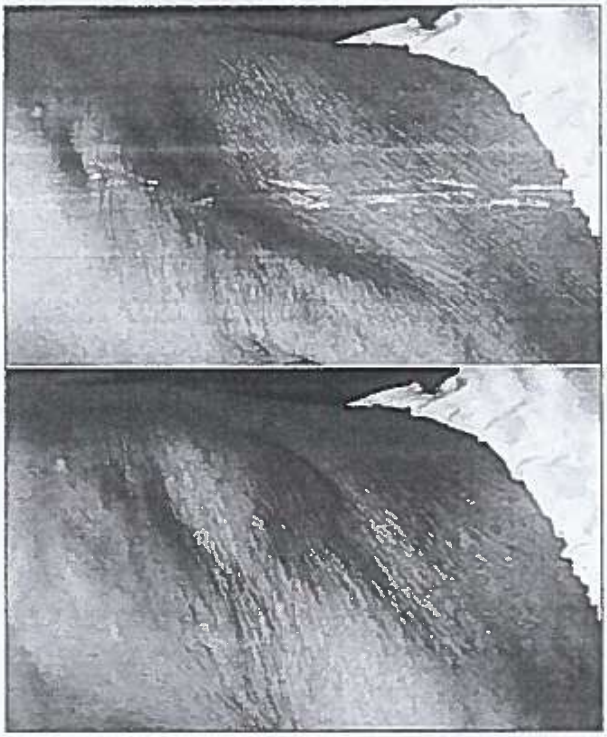

Figure 1. Lumbar Hernia showing Impulse on Coughing

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A STUDY ON RELATION OF THYROID STIMULATING HORMONE LEVEL WITH SKELETAL METASTASIS IN CARCINOMA PROSTATE PATIENTS

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ABSTRACT

BACKGROUND

Prostate, a genital organ, secretes fluid, seminal plasma, the possible function of which is to provide nutrition to the sperms and serve as their vehicle during ejaculation. Prostate is of great clinical importance because of its affinity for inflammatory, congestive, hyperplastic and neoplastic diseases. Majority of instances of prostatic pathology are manifested by derangement of urination owing to the intimate anatomical relationship between urinary bladder and prostate. We studied serum TSH Levels in patients of BPH and CA prostate and its relation with skeletal metastasis.

This descriptive study was aimed to study any correlation between Serum TSH level and bone metastasis in patients with Prostate carcinoma.

MATERIALS AND METHODS

This descriptive study was conducted at Rabindranath Tagore Medical College and Maharana Bhupal Government Hospital, Udaipur, Rajasthan in the Department of Surgery. A non-statistical sample size of 50 patients suffering from benign prostatic hyperplasia or prostate cancer was taken as per convenience. The patients were divided into 2 groups, 25 patients of BPH based on serum PSA estimation (control) and 25 patients of prostate cancer based on serum PSA estimation (test). Preoperative estimation of serum TSH and serum PSA was done in all the patients. All the patients were operated (TURP or palliative TURP). The results of serum TSH, serum PSA, and Gleason score were then analysed and a relation between increasing levels of serum TSH, serum PSA, and Gleason grade was sought based on exploratory data analysis (EDA).

RESULTS

Serum PSA level in most of the BPH patients was found to be within normal limit and serum TSH level in all of the BPH patients was found to be within normal limits. Only in 8% cases of Prostate carcinoma patients had very high PSA level (>100 ng/mL) as well as increased serum TSH level and it was associated with Gleason score 8 (high-grade tumour) and skeletal metastases. Further statistical/epidemiological studies are required for confirmation of these findings.

CONCLUSION

Only in 8% cases of Prostate carcinoma patients had a very high PSA level (>100 ng/mL) as well as increased serum TSH level, and it was associated with Gleason score 8 (high-grade tumour) and skeletal metastases. Further statistical/epidemiological studies are required for confirmation of these findings.

KEYWORDS

Prostate Carcinoma, Serum PSA, Serum TSH, Benign Prostatic Hyperplasia (BPH).

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BACKGROUND

Prostate, a genital organ, secretes fluid, seminal plasma, the possible function of which is to provide nutrition to the sperms and serve as their vehicle during ejaculation.

Prostate is of great clinical importance because of its affinity for inflammatory, congestive, hyperplastic and neoplastic diseases.

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Majority of instances of prostatic pathology are manifested by derangement of urination owing to the intimate anatomical relationship between urinary bladder and prostate.

Prostate specific antigen (PSA) is a glycoprotein that is a serine protease. Its function may be to facilitate liquefaction of semen, but it is a marker for prostatic disease. It is measured by an immunoassay. The normal upper limit of PSA is about 4 ng/mL. Men with locally confined prostate cancer usually have serum PSA levels < 15 ng/mL. Its level in men with metastatic prostate cancer usually increased to > 30 ng/mL.

Human TSH on the other hand is a glycoprotein that contains 211 amino acids residue, plus hexoses, hexosamines and sialic acid. The biologic half-life of human TSH is about 60 min. The normal secretion rate is about 110 µg/day. The average plasma level is about 2 µIU/mL, which is produced

We studied serum TSH Levels in patients of BPH and CA prostate and its relation with skeletal metastasis.

Aims and Objectives

This descriptive study was aimed to study any correlation between Serum TSH level and bone metastasis in patients with Prostate carcinoma.

MATERIALS AND METHODS

This descriptive study was conducted at Rabindranath Tagore Medical College and Maharana Bhupal Government Hospital, Udaipur, Rajasthan in the Department of Surgery.

A non-statistical sample size of 50 patients suffering from benign prostatic hyperplasia or prostate cancer was taken as per convenience.

The diagnosis was made by a combination of history, detailed clinical examination including digital rectal examination (DRE) and lymph node examination, radiological films of chest and pelvis and serum PSA levels. Serum TSH was estimated in all the patients.

The Patients were divided into 2-Groups of 25 each-

- Group A: 25 patients of BPH based on serum PSA estimation (control)
- Group B: 25 patients of prostate cancer based on serum PSA estimation (test).

Preoperative estimation of serum TSH and serum PSA was done in all the patients. All the patients were operated (TURP or palliative TURP). Postoperatively tissue biopsy was histopathologically examined in all the cases and grading was done based on the Gleason Scoring System.

The resultant data of serum TSH, serum PSA, and Gleason score were then analysed and a relation between increasing levels of serum TSH, serum PSA, and Gleason grade was sought based on exploratory data analysis (EDA).

RESULTS

A Total of 50 patients were studied, of which 25 were BPH Patients and 25 were CA Prostate. Age distribution of our patients was as per Table 1.

Most of the cases of BPH patients belonged to rural population i.e., 64% and 36% belonged to urban population. Most of the cases of Prostate carcinoma patients belonged to rural population i.e., 76% and 24% belonged to urban population.

In BPH, all of the patients had complaints of sensation of incomplete emptying of urinary bladder, weak urinary stream and hesitancy (100%) followed by frequency, intermittency and nocturia (92%), urgency (88%), dysuria (76%), burning micturition (40%), retention of urine (28%) and haematuria in 16% cases.

In Prostate carcinoma, all of the patients had complaints of sensation of incomplete emptying of urinary bladder, weak urinary stream and hesitancy (100%) followed by frequency and nocturia (96%), intermittency and urgency (92%), dysuria (88%), burning micturition (76%), haematuria (20%) and retention of urine in 16% cases.

AUA score of patients of BPH and CA-prostate are shown in Table 2 and Table 3.

Other associated symptoms in cases of BPH/Prostate carcinoma are given in Table 4.

Blood Urea and Serum Creatinine levels of the patients were as per Table 5 and Table 6 respectively.

In BPH, 84% cases were vegetarians and 48% were smokers and 12% were alcoholics.

In Prostate carcinoma, 72% cases were vegetarians, 64% were smokers and 28% were alcoholics.

Findings of DRE were as per Table 7.

Findings of cystoscopy were as per Table 8.

USG findings of the patients were as per Table 9.

X-ray KUB findings in cases of BPH and CA-prostate patients is as per Table 10.

X-ray KUB finding in BPH patients were normal KUB in most of the cases of BPH i.e., 23 cases (92%). In only 2 cases i.e., 8% cases, there was left ureteric stone present.

X-ray KUB finding in Prostate carcinoma patients- normal KUB was found in most of the Prostate carcinoma cases i.e., 84% (21 cases). There was left ureteric stone in 4% cases and left renal stone in 4% cases. In 8% cases, osteoblastic secondaries were seen in iliac bone.

Serum PSA level, in BPH patients was found to be normal in 10 cases i.e. 40% and was found to be between 5-10 ng/mL in 15 cases i.e. 60%. Serum PSA level, in Prostate carcinoma patients was found to be between 21-40 ng/mL in 8 cases i.e. 32%. Serum PSA level was found to be between 5-20 ng/mL in 6 cases i.e. 24%; was found to be between 41-60 ng/mL in 5 cases i.e. 20%; was found to be between 81-100 ng/mL in 3 cases i.e. 12%; was found to be > 100 ng/mL in 2 cases i.e. 8% and between 61-80 ng/mL in 1 case i.e. 4%. (Table 11).

Serum TSH level in all the BPH patients was found to be within normal limits. It was found to be between 1.0-3.0 µIU/mL in 24 cases i.e. 96% and was found to be between 0.3 to 0.9 µIU/mL in 1 case i.e. 4%. (Table 12).

Serum TSH level in Prostate carcinoma patients: it was found to be within normal limits in most of the cases. It was found to be between 1.0-3.0 µIU/mL in 22 cases i.e. 88% and was found to be between 0.3 to 0.9 µIU/mL in 1 case i.e., 4%. It was found to be increased i.e. >5.0 µIU/mL in only 2 cases (8%) and serum PSA level was >100 ng/mL. (Table 12). These two cases were associated with osteoblastic secondaries in iliac bone and histopathologically was found to be high-grade tumour with Gleason score 8.

In CA prostate patients, histopathological findings showed well-differentiated tumour in 17 cases (68%), intermediate-grade tumour in 6 cases (24%) and high-grade tumour in 2 cases (8%). (Table 13).

Gleason score, in Prostate carcinoma patients was found to be between 2 to 4 in 17 cases (68%) and to be between 5 to 7 in 6 cases (24%) and between 8 to 10 in 2 cases (8%). (Table 14).

Sl. No.	Age (years)	BPH		Ca-Prostate	
		No. of Cases	Percent	No. of Cases	Percent
1.	< 50	1	4	Nil	0
2.	51 – 60	7	28	3	12
3.	61 – 70	7	28	13	52
4.	71 – 80	9	36	6	24
5.	> 80	1	4	3	12

Table 1. Distribution of Patients According to their Age Groups

Findings of DRE were as per Table 7.

Prostate cancer spread has predictable patterns, known to affect the prostatic contours. Of the asymmetrical contours, 55 (34%) were caused by cancer, and of the cancer foci, 55 (20%) generated asymmetrical contours.[9]

One of the physical sign of a malignant prostate is asymmetry of gland. The finding of a patient with a relatively early prostate cancer is suggested by a firm nodule in one of the prostate lobes. As it enlarges, it may occupy the whole of one lobe and/or extend posteriorly to invade one or both of the seminal vesicles, giving extension shaped like horns of a bull. The central sulcus may be distorted or lost altogether and the rectal mucosa may become fixed to the gland. As the disease becomes more extensive, it may also invade both prostatic lobes and be felt as a hard, irregular, nodular structure with extensions of tumour laterally to the pelvic walls and these fixed the position of gland within the pelvis.

Bone survey films (skeletal radiography) are insensitive as a method to screen for the presence of bone metastasis. Lentle and co-workers (1974) demonstrated that 50% of the bone density must be replaced by tumour before standard radiographic imaging method identifies distant spread. Skeletal radiography is recommended only for confirmation of a positive bone scan in men in whom bony metastasis are not suspected at initial evaluation.[10]

Many of the men presenting with prostate cancer may have metastasis at time of diagnosis, the commonest site for these being in the bones. The lumbar spine is often affected and deposits of metastatic tissue may invade or compress the spinal cord and give rise to lower limb neurological signs. Other physical signs that may be associated with a diagnosis of advanced prostate cancer include a hydronephrotic kidney due to unilateral or bilateral ureteric obstruction and signs of renal impairment.

As general guidelines, the majority of men (70-80%) with PSA values less than 4.0 ng/mL have pathologically organ-confined disease, more than 50% of men with PSA levels greater than 10.0 ng/mL already have established capsular penetration and more men (75%) with serum PSA levels greater than 50 ng/mL have positive pelvic lymph node.[11]

Although the overall positive predictive value of the DRE was poor, most patients diagnosed with prostate cancer had an abnormality on the DRE that corresponded either to the location of cancer detected on biopsy or had cancer volumes on prostatectomy specimens large enough to be palpable. Higher serum PSA levels even if less than 4.0 ng/mL were associated with dramatic increases in prostate cancer detection.[12]

High serum TSH levels in men with Gleason 8 prostate cancer is a result of the elaboration of TSH by cancer cells. Bone mineral density in the face of normal levels of thyroid hormone depends on an intact response to TSH, which ordinarily suppresses both osteoblast and osteoclast differentiation, thereby exerting control over bone remodelling. However, with abnormally high TSH levels this process may become deranged, promoting the development of bone metastases. If TSH production by prostate cancer cells could be suppressed, the incidence of bone metastases might be reduced.[13]

In a study by Sawin CT et al, done in 344 relatively healthy persons older than 60 years, 22 (5-9%) had a clearly elevated level of serum thyrotropin (TSH) (greater than 10 μIU/mL), a finding more common in women than in men. A further 14.4% had a slightly elevated level of serum TSH (> 5 and ≤ 10 μIU/mL). The study did not find any correlation between elevated serum TSH and prostatic malignancy.[13]

In a prospective study, Phadke MA et al estimated serum prolactin, TSH, LH, FSH and inhibin level using radioimmunoassay, in normal subjects and in patients with benign prostatic hyperplasia (BPH), before and after tumour resection. In cases of benign prostatic hyperplasia, no significant changes in the level of TSH were noted after surgery.[14]

In another prospective study by Salminen et al (2004), levels of serum thyroid stimulating hormones (TSH), free thyroxine (fT_4) and thyroid binding globulin concentrations were measured in prostate cancer patients treated with either radiotherapy and androgen deprivation for 12 months (AD) or radical radiotherapy alone. The study concluded that prolonged use of AD hampers the interpretation of thyroid test results by causing a significant decline in fT_4 at 6 and 12 months.[15]

A study by Frokovic et al (1994) reported development of TSH-secreting small cell prostate cancer (SCPC) from high-grade adenocarcinoma (Gleason score 8) with an elevated number of chromogranin A positive cells located in benign structures adjacent to the cancer. Conversion to SCPC was followed up during 4 years. The study concluded (i) extremely poor prognosis associated with high grade adenocarcinomas that demonstrate stronger immunohistochemical positivity for prostatic acid phosphatase (PAP) than for PSA, (ii) chromogranin A positive cells in benign structures adjacent to the cancer as a possible paracrine promoter of SCPC from poorly differentiated adenocarcinoma.[16]

In yet another study, Aprikian et al (1994) attempted to determine the correlation of neuroendocrine differentiation and deoxyribonucleic acid content in lymph node and skeletal metastasis. They immunohistochemically examined 62 metastatic lesions (41 pelvic lymph nodes and 21 bone metastases) for the presence of chromogranin-A expressing tumour cells. Of 41 lymph nodes and 21 bone metastases, 19 (46%) and 11 (52%) respectively contained chromogranin-A immunoreactive cells. Peptide hormone immunocytochemistry in 19 cases (12 lymph nodes and 7 bone metastases) demonstrated neuroendocrine cells containing TSH in 17 (89%) cases.[17]

Abbreviations

TSH – Thyroid Stimulating Hormone
PSA – Prostate Specific Antigen
BPH – Benign Prostatic Hyperplasia
CA Prostate – Prostate carcinoma
DRE – Digital Rectal Examination
TURP – Trans-urethral Resection of Prostate
EDA – Exploratory data analysis
AUA – American Urology Association
X-ray KUB – X-ray of Kidney, Ureter and Bladder Region.

CONCLUSION

Serum PSA level in most of the BPH patients was found to be within normal limits and serum TSH level in all of the BPH patients was found to be within normal limits.

Serum PSA level in all the Prostate carcinoma patients was found to be increased and it was found to be >100 ng/mL in only 8% cases of Prostate carcinoma. Serum TSH level in most of the Prostate carcinoma patients was found to be within normal limits and it was found to be increased only in 8% cases of Prostate carcinoma. Histopathology in Prostate carcinoma patients was found to be well differentiated with tumour with Gleason score 2 to 4 in 68% cases followed by intermediate-grade tumour with Gleason score 5 to 6 in 24% cases followed by high-grade tumour with Gleason score 8 in only 8% cases and in these 8% cases there was associated skeletal metastases (osteoblastic secondaries in iliac bone).

By this study, it is hereby concluded that only in 8% cases of Prostate carcinoma, patients had very high PSA level (>100 ng/mL) as well as increased serum TSH level and these cases were associated with Gleason score 8 (high-grade tumour) and skeletal metastases.

Further statistical/epidemiological studies are required for confirmation of these findings.

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A STUDY ON DYSPHAGIA DUE TO BENIGN OESOPHAGEAL STRICTURES

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ABSTRACT

BACKGROUND

Gastroesophageal reflux disease, alkali or acid ingestion, achalasia due to unknown aetiology are considered as main causative factors in the genesis of benign oesophageal strictures. The two types of treatment modalities are used including conservative dilatation and surgical approach according to aetiology and site of involvement. Our study attempts to understand the various aetiopathogenesis and epidemiological features of this problem and their clinical presentation; so that early detection maybe planned and various treatment modalities for achalasia cardia, peptic stricture, corrosive stricture and their results are evaluated.
The aim of the study is to study various-

1. Aetiological factors of stricture oesophagus (benign).
2. Features and clinical presentation of stricture oesophagus, so that early detection maybe planned.
3. Treatment methods of management of benign oesophageal strictures.

MATERIALS AND METHODS

This is a descriptive study of dysphagia due to benign oesophageal strictures. Cases presenting in the surgical outdoor with symptoms suggestive of oesophageal stricture and admitted in different surgical and gastroenterology units were included in the study. A detailed history and examination was done in these patients. Management was done by endoscopic or manual dilatation with bougies and/or surgical operation. Surgical management consisted of Heller's cardiomyotomy or oesophagoplasty.

RESULTS

Total number of 40 patients of dysphagia due to benign oesophageal strictures were studied out of which 16 (40%) patients were of corrosive strictures, 14 (35%) having achalasia cardia and 10 (25%) of peptic strictures. The male-to-female ratio was 1.35:1. The mean age was 42.62 years. Strictures due to corrosive were more common in younger age groups while 20170912mthe peptic stricture occurred later in life. The incidence of various symptoms were dysphagia 100%, regurgitation 45%, epigastric or substernal pain 35%, weight loss 25% and cough in 12% cases. Patients with GERD or achalasia cardia had more dysphagia to liquid/semi-solids, while patients with corrosive ingestion (alkali/acid) had more dysphagia to solids. The most common site affected was lower third of oesophagus in 55% of cases, followed by middle third (40%) and upper third (5%). In present study, out of 40 patients, 25 patients were treated conservatively in form of dilatation and operative intervention was done in 15 patients. All of the patients of stricture due to GERD were treated by conservative management. Most of the patients with corrosive ingestion/unknown aetiology were treated by conservative management. All of the patients with achalasia cardia were treated by operative management. One patient out of 25 managed with conservative treatment developed complication in the form of oesophageal perforation. Out of 15 patients that were managed by operative treatment, 5 developed pulmonary complications and 5 developed wound infections. Out of 4 patients who had undergone oesophagoplasty, 2 suffered with minor anastomotic leaks. In our study, after treatment (surgery/dilatation), 85% of patients were able to swallow most of solids and liquids, 10% of patients could swallow only solids and 5% of patients could swallow only liquids or semisolids.

CONCLUSION

It can be concluded that dysphagia due to benign oesophageal stricture maybe because of post-corrosive stricture, peptic stricture, achalasia cardia, etc. Conservative treatment in the form of dilatation gives excellent results in management of dysphagia. The surgery should be offered to the patients who are otherwise fit and dilatation cannot be done due to very narrow stricture. In operative patients, results of Heller's cardiomyotomy and esophagoplasties are excellent.

KEYWORDS

Oesophageal Stricture, Corrosive Ingestion, Achalasia Cardia, Peptic Stricture.

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BACKGROUND

Oesophagus is "the organ about which so little is known" and even today unfortunately, the oesophagus remains a no man's land, into whose top end, the ENT surgeons make light reconnaissance's and whose bottom end is often attacked by abdominal surgeons under cover of the diaphragm.

Physicians (from their greater elevation) still like to drop consignments of antacids down it, but these do not alter its abnormal configuration.

Other causes include aggressive treatments for Barrett oesophagus (such as photodynamic therapy) and nasogastric tube injury.[2]

Out of 40 patients of benign dysphagia, 23 (57.50%) patients were male and rest 17 (42.50%) were female. The male-to-female ratio was 1.35:1 (Table 1).

In the present series, most of patients were between 15-45 years, i.e. 62% of patients. The youngest patient of benign dysphagia (corrosive) was 18 years and oldest was of 80 years. The mean age was 42.62 years (Table 2).

69% of corrosive stricture patients were under the age of 30 years and 60% of peptic stricture patients were between 61-75 years (Table 2).

In present series, most of patients were between 15-45 years, i.e. 62% of patients. The youngest patient of benign dysphagia (corrosive) was 18 years and oldest was of 80 years. Strictures due to corrosive were more common in younger age groups while the peptic stricture occurred later in life. It may be due to more incidence of either accidental or suicidal ingestion of corrosive in younger age group with early development of stricture post ingestion. Peptic strictures develop in later age after longstanding peptic disease.

The median age of patients of dysphagia due to benign oesophageal lesions as reported by various authors was-

Median age of corrosive patients were 40 years (range 8-80 years) and 35.7 years (range 15-68 years) in study by Huang MH[3] (1989) and Stoica AL[4] (2004), respectively. In a study by Arevalo Silva C[5] (2006), a biphasic distribution of the patients was noted, half were children under 5 years old and the remainder were adults more than 35 years. The most frequent cause for ingestion was accidental (67%) as opposed to attempt suicide (33%). All cases of attempted suicide occurred in adults. Most of them reported ingestion of large amounts of caustic substance.

Median age of achalasia patients were 36.5 ± 14.6 years, 44 years, 44.5 ± 14 years (range 16-76), 41.42 ± 18.07 years and 40 years in Ghoshal[6] (2004), Harold KL[7] (2004), Onopriev VI[8] (2005), Boztas G[9] (2005) and Kennedy (2010)[10], respectively.

In peptic stricture, patients were of 61.1 ± 16.3 years and 56.1 years (range 32-82 years) in Mazzadi SA[11] (2004) and Chiu YC[12] (2004), respectively.

In the present study, 25% of patients had history of GERD, but in Said A[13] (2003) study, the incidence was 77 (Table 3).

In the present study, 15 (37%) cases had history of alkali ingestion. This was similar to that of Huang MH[3] (1989) and Arevalo Silva C[5] (2006) who reported the incidence of 38% and 42%, respectively (Table 3).

In our study, acid ingestion induced strictures were 2.5% while in study by Arevalo Silva C[5] (2006), it was 32% (Table 3).

Unknown aetiology and achalasia were presented in 35% of cases in our study (Table 3).

Patti MG[14] (2005) reported 77% of achalasia cases and Arevalo Silva C[5] (2006) reported 32% of acid ingestion, which produce benign dysphagia.

This variation in aetiological factors and age maybe due to difference in cultural and dietary habits in Indians from other countries.

Initially, sign and symptoms due to benign oesophageal stricture are minimal and nonspecific for a long duration. Often patients do not seek medical advice until the appearance of clear-cut symptoms of dysphagia and/or regurgitation appear (Table 4).

The first and the most important symptom was progressive dysphagia, which was present in 100% of cases in our study. Unfortunately, dysphagia is not an earlier manifestation of the disease, because it manifests only after reduction of 60% of oesophageal luminal diameter occurs.

Functional Grading of Dysphagia[15]

Grade I- Eating normally.
Grade II- Requires liquids with meal.
Grade III- Able to take semisolids, but unable to take any solid food.
Grade IV- Able to take liquid only.
Grade V- Unable to take liquid, but able to swallow saliva.
Grade VI- Unable to swallow saliva.

The incidence of various symptoms were dysphagia 100%, regurgitation 45%, epigastric or substernal pain 35%, weight loss 25% and cough in 12% cases, which are comparable with study of Mazzadi SA[11] (2004) in which dysphagia (100%), regurgitation (40%) and epigastric pain (30%). Similar results were found in study of Ghoshal UC[6] (2004) with dysphagia (100%), regurgitation (48%), epigastric pain (17%), weight loss (26%) and pulmonary symptoms occurred in 18% cases.

One significant observation that emerged from this study was that 50% of patients presented with dysphagia for liquids or semi solids, 35% were only for solid and remaining 15% patients were having dysphagia for both solids and liquids. Patients with GERD or achalasia cardia had more dysphagia to liquid/semi-solids, while patients with corrosive ingestion (alkali/acid) had more dysphagia to solids (Table 5).

The relationship between symptoms and severity of injury is uncertain. Stridor and drooling were considered 100% specific for significant oesophageal injury, but no single symptom or symptom cluster can predict the degree of oesophageal damage.[16]

In present series, majority of patients, i.e. 40% presented with <3 months' duration followed by 30% with 3-6 months' dysphagia, 15% with 6-9 months' dysphagia and only 5% of patients presented after 1 year of dysphagia.

Barium swallow reports were available for 30 patients. Oesophageal lesion with stricture and hold up of contrast with proximal dilatation were present in 55% patients, in 20% patients, the barium swallow was normal, which were later on proved to have the oesophageal stricture on endoscopy. Remaining 10 patients had peptic strictures and this investigation was not called for (Table 6).

In the present study, the most common site affected was lower third of oesophagus, in 55% of cases, followed by middle third (40%) and upper third (5%) (Table 7).

Dascalescu C[17] (2005) reported that corrosive poisons produced the lesion in 62% cases in oesophagus followed by 26% at oesophagogastric junction. The study of Mazzadi SA[11] (2004) on peptic stricture shows 97% of stricture present in lower one third of oesophagus.

Chiu YC et al (2013) reported that, of the 18 patients with oesophageal stricture alone, 6 had orifices of strictures located in the upper third of the oesophagus, 6 in the middle third and 6 in the lower third.[18]

Tharavej C et al (2017) reported that, 8 out of 55 patients (14.5%) had perforations.[28]

In their study, Hsieh KH et al (2017) reported that 1 oesophageal perforation developed after balloon dilatation (1/63).[27]

Aghaji MA[32] (1993) reported that major postoperative complications were proximal anastomotic leaks 49%, wound sepsis 25%, pulmonary complications 27% and colon graft necrosis 4% of cases.

In our study, after treatment (surgery/dilatation), 85% of patients were able to swallow most of solids and liquids, 10% of patients could swallow only solids and 5% of patients could swallow only liquids or semisolids (Table 14).

In our study, 60% of patients were discharged within 3 days of admission (which were treated conservatively), 90% discharged within 9 days of admission. Only 10% patients were discharged after 9 or more days, which suffered from wound infections or other operative complications.

CONCLUSION

It can be concluded that dysphagia due to benign oesophageal stricture maybe because of post-corrosive stricture, peptic stricture, achalasia cardia, etc. Conservative treatment in the form of dilatation gives excellent results in management of dysphagia. The surgery should be offered to the patients who are otherwise fit and dilatation cannot be done due to very narrow stricture. In operative patients, results of Heller's cardiomyotomy and esophagoplasties are excellent.

Sl. No.	Lesion	No. of Cases			%
		Male	Female	Total	
1.	Achalasia cardia/unknown aetiology	9	5	14	35%
2.	Corrosive stricture	9	7	16	40%
3.	Peptic stricture	5	5	10	25%
	Total	23	17	40	100%

Table 1. Gender Wise Distribution of Oesophageal Stricture Cases

Age	Achalasia Cardia/ Unknown Aetiology	Corrosive Stricture	Peptic Stricture	Total	
	No. of Cases	No. of Cases	No. of Cases	No. of Cases	%
15-30	4	11	1	16	40%
31-45	3	4	2	9	22%
46-60	2	-	-	2	5%
61-75	3	1	6	10	25%
76-90	2	-	1	3	8%
	14	16	10	40	100%

Table 2. Age Wise Distribution of Oesophageal Stricture Cases

Sl. No.	Aetiological Factors	No. of Cases	Percentage
1.	GERD/Acid peptic disease	10	25%
2.	Alkali ingestion	15	37.50%
3.	Acid ingestion	1	2.50%
4.	Achalasia cardia	10	25%
5.	Unknown aetiology	4	10%
	Total	40	100%

Table 3. Aetiological Factor Wise Distribution of Oesophageal Stricture

Sl. No.	Symptoms	No. of Cases	Percentage
1.	Dysphagia	40	100%
2.	Regurgitation/vomiting	18	45%
3.	Substernal/epigastric pain	14	35%
4.	Weight loss	10	25%
5.	Cough	5	12%

Table 4. Symptoms of Oesophageal Stricture

Sl. No.	Aetiology	Type of Dysphagia		
		Solid	Liquid/Semi-Solid	Total
1.	GERD	2	8	-
2.	Corrosives (alkali/acid)	10	-	6
3.	Achalasia/unknown	2	12	-
	Total	14	20	6

Table 5. Type of Dysphagia

Sl. No.	Barium Swallow Finding	No. of Cases	Percentage
1.	Oesophageal stricture	12	30%
2.	Hold up with dilatation	10	25%
3.	Normal	8	20%
4.	Not available	10	25%

Table 6. Various Radiological Sign As Seen On Barium Oesophagogram

Sl. No.	Site	No. of Cases	Percentage
1.	Upper one third (15-23 cm)	2	5%
2.	Middle one third (24-31 cm)	16	40%
3.	Lower one third (32-40 cm)	22	55%

Table 7. Level of Oesophageal Stricture According to Esophagoscopy

Sl. No.	Extent of Stricture	No. of Cases	Percentage
1.	0-3 cm	19	47%
2.	3-6 cm	15	37%
3.	6-9 cm	5	13%
4.	>9 cm	1	3%

Table 8. Extent of Stricture as Seen on Esophagoscopy

Sl. No.	Treatment	No. of Cases	Percentage
1.	Conservative	25	62.50%
2.	Operative	14	35%
3.	Both	1	2.50%

Table 9. Management of Dysphagia

Sl. No.	Aetiology	No. of Patients	Conservative	Operative
1.	GERD	10	10	-
2.	Corrosive ingestion	16	12	4
3.	Achalasia	10	-	10
4.	Unknown	4	3	1
	Total	40	25	15

Table 10. Distribution of Cases According to Type of Management

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Surgery

Post Mastectomy Upper Limb Lymphoedema: A Tertiary Care Hospital Experience

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Abstract: It is known that breast cancer is most common cancer in women of developed countries and is on rise in developing countries. Besides recurrence, one of the major complications is lymphoedema. This study was done on women who presented with lymphoedema after primary surgical treatment of breast cancer. A detail history was recorded with special emphasis on irradiation to axilla, chemotherapy and hormonal therapy. They were specifically asked regarding the mode of onset of lymphoedema. A detailed physical examination was done with special emphasis on diagnosis of lymphoedema. The data were then analyzed based on Exploratory Data Analysis. Out of 1047 patients who underwent surgical intervention, the occurrence of lymphoedema is 6.017% with maximum occurrence in age group 56-65 years (8.3%) with maximumoccurrence of lymphoedema observed in 2nd year after primary surgical treatment. Maximum occurrence of lymphoedema was observed in T2 subgroup (8.15%), N1 subgroup (7.33%), and in MRM subgroup (6.67%). Patients who were irradiated after surgery showed higher occurrence of lymphoedema (13.64%). Maximum occurrence of lymphoedema was seen within 1-2-year post mastectomy (47.62%) and in patient with T2, N1 stage. There was consistent increase in occurrence of lymphoedema with increase in BMI & patient with history of radiation post mastectomy.

Keywords: Mastectomy, Lymphoedema, Breast Cancer, Post Mastectomy Lymphoedema.

INTRODUCTION

Breast cancer is the most common cancer in women of developed countries and is on rise in developing countries [1]. Besides recurrence, one of the major complications is lymphoedema.

Lymphoedema can cause severe physical and psychological morbidity in breast cancer survivors and measurable reduction in quality of life in respect to functional, emotional, physical and social wellbeing. Studies have shown that women who develop lymphoedema exhibit higher levels of psychological, social, sexual and functional morbidity than those who do not develop this complication. Keeping this in mind I would like to throw some light on this clinical entity.

It is not a new topic of consideration for practitioners and researchers concerned with skin and wound care. In 1587, the noted Ming Dynasty Physician Gong Tingxian described 'phlegm-damp'accumulation and treatment. More recently King and DiFalco [2] discussed the rise of lymphoedema in an ageing population. They highlighted the array of skin problems associated with lymphoedema and noted that such conditions lead to cellulitis which further damages the lymphatic system. They state that "... most lymphoedema is the result of surgical treatment of malignant disease. Because malignancy is increasingly curable, the latent potential for developing lymphoedema is growing medical problem."

Lymphoedema following breast cancer treatment is traditionally attributed to lymphatic obstruction with venous obstruction as an infrequent complicating factor. The lymphatic system also known as 'Third Circulation' consists of thin walled, low pressure vessels, nodes that occur along the course of lymphatic vessels. By regulating fluid absorption from the interstitium, the lymphatic system maintains plasma drainage routes by surgery, radiotherapy, and disturbances in Starling forces in the skin and

Table-1: Distribution of all post-surgical patients and patients with lymphoedema in different age group

Age in Years	Total Post-Surgical Patients	%	Patients with Lymphoedema	Lymphoedema Occurrence
≤ 35	159	15.2%	0	0%
36-45	316	30.18%	18	5.70%
46-55	297	28.41%	23	7.74%
56-65	191	18.28%	16	8.3%
> 65	84	7.93%	6	7.14%
Total	1047	100	63	6.017%

Table No 2: Distribution of all post-surgical patients and patient with lymphoedema according to Tumor Size

Tumor Size	Total Post-Surgical Patients	%	Patients with Lymphoedema	Lymphoedema Occurrence
T_{IS}	81	7.7%	0	0%
T_1	46	4.4%	2	4.3%
T_2	417	39.87%	34	8.15%
T_3	401	38.32%	26	6.48%
T_4	89	8.59%	0	0%
T_X	13	1.1%	1	7.69%
Total	1047	100%	63	6.017%

Table-3: Distribution of all post-surgical patients and patients with lymphoedema according to Nodal Status

Nodal Size	Total Post-Surgical Patients	%	Patients with Lymphoedema	Lymphoedema Occurrence
N_0	489	46.7%	26	5.31%
N_1	472	45.15%	32	6.78%
N_2	63	7.05%	4	6.35%
N_3	11	1.1%	0	0
N_X	13	1.1%	1	7.69%
Total	1047	100%	63	6.017%

Table-4: Distribution of all post-surgical patients and patients with lymphoedema according to type of surgery performed

Type of Surgery	Total Post-Surgical Patients	Patients with Lymphoedema	Lymphoedema Occurrence
MRM	854	57	6.67
BCT + Simple mastectomy with ALND + Salvage mastectomy	193	6	3.11
Total	1047	63	6.017%

Table-5: Distribution of all post-surgical patients and patients with lymphoedema according to Radiotherapy

Radiotherapy	Total Post-Surgical Patients	Patients with Lymphoedema	Lymphoedema Occurrence
Yes	242	33	13.64%
No	805	30	3.72%
Total	1047	63	6.017%

Table-6: Distribution of all postsurgical patients and patients with lymphoedema according to Body Mass Index

BMI	Total Post-Surgical Patients	Patients with Lymphoedema	Lymphoedema Occurrence
<25	501	23	4.59%
25-30	483	31	6.42%
>30	63	9	17.46%
Total	1047	63	6.017%

duration of lymphoedema, Body Mass Index, mastectomy, and past history of cellulitis [13], though obesity is not directly related to breast cancer [14]. Helyer L K et al. (San Francisco) performed a study on "obesity a risk factor developing post-operative lymphoedema". The study of BMI by multivariate analysis revealed that patients with BMI >30 had an odd ratio of 2.93 with those of BMI <25 of having lymphedema [15]. Edward TL reported that body weight or BMI are important factor that increase the risk of lymphedema [16]. In present study there was consistent trend of increase in occurrence of lymphoedema with increase in BMI, in subgroups of <25, 25-30, >30.

Edwards found that the number of lymph nodes removed was not correlated with lymphoedema[16]. Roses et al. stated that the number of removed lymph nodes was not a risk factor in multivariate analysis, but in univariate analysis it increased the risk [17]. In present series patients were assigned into three categories with respect to number of lymph nodes removed i.e. <15, 15-25, and >25. Out of 63 patients 42 patients (66.07%) belong to the group where the number of removed lymph nodes were between 16-25, 19 patients (30.16%) rest in group where number of removed lymph nodes were <15.

Nikanen's study supports an increase in incidence of edema in patients irradiated post operatively [11]. A study conducted by Schuemann (San Diego, US) showed the highest incidence of edema was among patients who had received radiotherapy in high doses with few fractions to the axilla (60%) [18]. Radiologyinfo.org reviewed that radiation therapy given to the axillary lymph nodes can increase the risk of patients developing arm swelling ("lymphoedema") following axillary (armpit) dissection [19].

In present study occurrence of lymphoedema was higher in the patients who were irradiated (13.64%) as compared to those who didn't receive radiotherapy (3.72%). Out of 63 patients who developed lymphoedema, 33 patients were given postoperative radiotherapy.

CONCLUSION

- The occurrence of lymphoedema in patients registered in breast clinic was found to be 6.017%.
- Maximum occurrence of lymphoedema was seen within 1-2 years i.e. 47.62% after primary surgical treatment followed by 23.80% seen between 2-3 years. Then there was decrease in occurrence of lymphoedema with increase in duration after surgery.
- Patients, who received radiotherapy where axillary dissection was performed, had increased risk of lymphoedema (13.64%).
- 53.96% of patients having lymphoedema were having tumor size ranging from 2-5 cm with overall incidence of 8.15%.
- 57.14% of patients having lymphoedema were node positive, with maximum incidence of lymphoedema.
- There was consistent increase in occurrence of lymphoedema with increase in BMI. The occurrence of lymphoedema was 4.59%, 6.42% and 17.46% in BMI categories < 25, 25-30 and > 30 respectively.

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Original Research Article

Lymphoedema: non-operative management

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ABSTRACT

Background: Lymphoedema is one of the most undesirable complication that is anticipated in patients of cancer breast post mastectomy. A comprehensive care of patient of lymphoedema is required which includes, prevention, early diagnosis and treatment. In the study conducted, efficacy of non-operative management of lymphoedema is observed.
Methods: A descriptive study was conducted on women who presented with lymphoedema post-mastectomy. Thirty-three patients were studied for non-operative management. Treatment of patients was carried out with physiotherapy, massage, compression bandages and stockings and Intermittent pneumatic compression by pneumatic compression pump.
Results: Patients were categorized according to the grades, duration of lymphoedema, type of treatment they received and effect of the treatment.
Conclusions: Lymphoedema being dreaded complication, much attention needs to be given on its prevention post mastectomy. But in country like India, compliance and regular follow up is not possible for every patient, especially for the patients of the rural background. The same pattern of dearth in compliance follows in management of lymphoedema. Non-operative management is an effective mode of treatment in cases of post-mastectomy lymphoedema.

Keywords: Lymphoedema, Non-operative management, Post-mastectomy

INTRODUCTION

Lymphoedema is one of the most undesirable complication that is anticipated in patients of cancer breast post mastectomy. Carcinoma breast being common disease and a great deal of improvement in management of patients lead us to give more emphasis on quality of life and long-term post treatment sequalae.

There is expectation on the part of patient, their family, and care givers that the patient should lead a near normal life. Lymphoedema being chronic debilitating disease results in significant swelling of limb, disfiguring body image and may lead to functional disability. So postmastectomy upper limb lymphoedema may be said to be the paradigm for discussion of follow up care.

Clinically, lymphoedema results from abnormal accumulation of protein in the interstitial space causing interruption of normal lymphatic drainage channels. Initial swelling is due to excess fluid collections in subcutaneous tissue resulting in pitting oedema. This is the initial fluid phase of lymphoedema. Longstanding lymphoedema leads to chronic accumulation of inflammatory fluid with fibrocyte and adipocyte resulting in deposition of fats in subcutaneous tissue with resultant non-pitting oedema. This is known as solid phase of lymphoedema.[1,2] Axillary lymph node dissection may further alter the lymph node transfer capacity.

lymphoedema after mastectomy (Table 2). Distribution of patients according to the severity of lymphoedema (Table 3).

Low grade lymphoedema responded to physiotherapy and massage; moderate grade lymphoedema needed compression bandage and/or pneumatic compression; severe grade lymphoedema needed all the four modalities. Distribution of patients according to the treatment they received (Table 4). Mode of treatment according to the severity of lymphoedema (Table 5).

Two thirds of the patients who received physiotherapy and massage only responded well with reduction in lymphoedema. Moderate grade lymphoedema responded well (76.4%) to physiotherapy and massage along with compression bandage. Moderate to severe grade lymphoedema also needed intermittent pneumatic compression and responded well to these modalities (83.3%). Most of the patients with various grades of lymphoedema responded well to non-conservative treatment with reduction in their lymphoedema. Efficacy of non-operative treatment in patients of lymphoedema (Table 6).

Table 6: Efficacy of treatment in patients of lymphoedema.

Treatment given	No. of patients	Reduction	Static	Progression
PT+Msg	33	22(66.6%)	7(21.1%)	4(12.1%)
PT+ Msg+ CB	17	13(76.4%)	3(17.6%)	1(5.8%)
PT+ Msg+ CB + IPC	6	5(83.3%)	1(16.6%)	0

DISCUSSION

Lymphoedema being dreaded complication, much attention needs to be given on its prevention post mastectomy. But in country like India, compliance and regular follow up is not possible for every patient, especially for the patients of the rural background. The same pattern of dearth in compliance follows in management of lymphoedema.

In the study done, patients were subjected to non-operative management which includes; physiotherapy and massage, compression bandages and intermittent pneumatic compressions.

These treatment methods were studied based on their synergistic effectiveness on lymphoedema.

Kuno et al, (US) made an investigation of lymphoedema and function of the arm in 1,115 patients after mastectomy. Slight edema was present in 26.7%, moderate lymphoedema was observed in 3.9% and severe in 0.9%.[5]

Lymphoedema was dependent on extensiveness of surgical operation. Three stages of lymphoedema have been described in CMAJ 2001. Stage 1 presents with pitting and is considered as reversible; stage II presents brawny, fibrotic, non-pitting and is irreversible; stage III presents as advanced lymphoedema in which cartilaginous hardening occurs with papillomatous outgrowths and hyperkeratosis of skin.[6,7]

In present study 31 patients (prevalence=2.96%) were of grade I lymphoedema, 14 patients (prevalence=2.87%) belongs to category of grade II lymphoedema, 2 patients had grade III lymphoedema.

Dennis (US) reported only 9 patients but observed a large variability in the time between surgery and onset of lymphoedema i.e. between 2 months and 3 years.[8]

In present series maximum number of patients i.e. 30 patients (47.62%) developed lymphoedema between 1 to 2 years after surgery followed by 15 patients (23.81%) who developed lymphoedema between 2-3 years.

In present study patients were categorized according to grades of lymphoedema. Out of 33 patients who were treated for lymphoedema, 17 patients had mild lymphoedema. Moderate lymphoedema was present in 14 patients and severe lymphoedema was seen in 2 patients.

Johansson et al (US) examined the effects of low stretch compression bandaging (CB) or in combination with manual lymph drainage (MLD) in 38 female patients with arm lymphoedema after treatment for breast cancer. After CB therapy for 2 weeks, the patients were allocated to either CB or CB +MLD for 1 week. Arm volume and subjective assessment of pain, heaviness, and tension were measured. The mean volume of reduction for total group during part I was 26% and during part II in CB+MLD group was 11% and in CB group it was 4% which was significantly different($p=0.04$).[9]

In present series MLD was offered to 17 the patients of mild lymphoedema along with regular physiotherapy. There was considerable reduction in arm swelling along with relief in pain and heaviness in 9 patients. There was mild reduction or swelling remained static in 4 patients. Progression of disease was seen in 2 patients who were inconsistent with treatment. Two patients with mild lymphoedema were lost to follow up.

There were 9 patients of moderate lymphoedema who were offered compression bandages and stockings along with massage and physiotherapy. There was reduction in

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PERIPHERAL VASCULAR TRAUMA- A LIMB MAY BE SAVED

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ABSTRACT

BACKGROUND

The incidence of vascular trauma has increased considerably during the past 40 years. Although, they represent less than 3% of all injuries, they deserve special attention because of complications and limb loss.

MATERIALS AND METHODS

This was a descriptive study. Over a period of one year, 98 patients were operated for peripheral vascular injuries. Physical examination was used for diagnosis with the use of duplex ultrasonography/ CT angiography where needed. Vascular repair was carried out in terms of primary repair or interposition vein graft and fasciotomy was considered as and when required. Patients with non-salvageable extremity requiring primary amputation were excluded from the study.

RESULTS

Most of the patients were male. Most common cause was road traffic accidents. Occurrence of concomitant orthopaedic injuries was very high in this study. The commonly injured artery was popliteal artery (38.7%) and brachial artery (27.5%). Surgical procedures performed were interposition vein grafts in 54% cases, whereas end-to-end repair in 20.4% cases. The limb salvage rate was 76.53%.

CONCLUSION

Early diagnosis and treatment of vascular injury is important for limb salvage. Patients should be surgically intervened even after golden period has passed, because with limb or without limb matters a lot.

KEYWORDS

Vascular Trauma, Interposition Vein Graft, Limb Salvage, Vascular Repair, Road Traffic Accidents.

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BACKGROUND

Vascular trauma is a fast growing emergency for vascular surgeons. The incidence of vascular trauma has increased considerably during the past 40 years. Vascular injuries comprise of 3% of all civilian traumas and continue to have significant associated morbidity and mortality in the 21st century.[1] Although, they represent only 3% of all injuries, they deserve special attention because of complications and limb loss.

Various common mechanism of injury seems to differ in different parts of the world[2,4] and include blunt and penetrating trauma, stab wound, gunshot wound and RTA with later being the most common cause in majority of cases.[4] In view of urgent need of intervention, usually physical examination is used for diagnosis with the use of duplex ultrasonography/ CT angiography where critically indicated. CTA provides accurate and timely diagnosis of peripheral vascular injuries and challenges the gold standard of arteriogram.[5]

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In the past attempts to control arterial bleeding were by means of cauterisation method, manual compression and pouring boiling liquid materials on the wounds. Ambroise Pare initially used the ligation method during XVI century.[4] While first and second world wars gave knowledge of diagnosis and treatment of vascular injuries, vascular reconstructive methods were mainly introduced during the Korean and Vietnamese wars with a tremendous progress[3,4] and a dramatic decrease in amputation rate.[2,3,6,7] Successful treatment of major arterial injuries is life-saving and allows limb salvage with restoration of function[6]; however, return of function also depends on concomitant nerve injury.[7]

Vascular trauma is associated with major morbidity and mortality, but little is known about its incidence or nature in our region. This study was done in 98 patients who underwent operative intervention for vascular trauma. This report presents the different mechanisms of vascular trauma, arteries involved, associated bone or nerve injuries and types of vascular intervention done and specially limb salvage rate at our centre. Injury to major peripheral artery causes limb ischaemia and if not repaired at proper time then can lead to loss of limb. That is why vascular trauma should be dealt within 6 hrs. of injury, which is called as golden period. But at our centre most of the patients present after passing of these golden hours because of delay in diagnosis or transportation. Still we moved on to repair these limb-threatening arterial injuries and got good limb saving results. We excluded crushed injuries, badly infected wound, limb with gangrenous changes and injuries presented after 100 hrs.

due to delayed presentation and infection (1), while 1 case underwent toes amputation. Overall limb salvage rate was 76.53%.

Artery	No. of Cases	Percentage
Axillary	2	2.08
Brachial	26	26.53
Radial	7	7.14
Ulnar	4	4.08
Femoral	18	18.36
Popliteal	37	37.75
Posterior tibial	4	4.08
Total	**98**	**100**

Table 1. Artery Involved

Time (Hours.)	No. of Cases	Percentage
0 – 6	19	19.38
7 – 12	40	40.82
13 – 19	5	5.10
20 – 25	10	10.20
26 – 30	4	4.09
31 – 40	1	1.02
41 – 50	7	7.15
51 – 60	2	2.04
61 – 70	0	0
71 – 80	5	5.10
81 – 90	2	2.04
91 – 100	3	3.06
Total	**98**	**100**

Table 2. Time of Presentation

Injury	No. of Cases	Percentage
Contusion	48	48.97
Spasm	10	10.20
Partial transection	7	7.14
Complete transection	29	29.59
Multiple sites	3	3.06
AV fistula	1	1.02
Total	**98**	**100**

Table 3. Arterial Injury

Repair	No. of Cases	Percentage
No intervention	2	2.04
Embolectomy	10	10.20
Lateral sutures	4	4.08
End-to-end repair	20	20.40
Vein graft	53	54.08
PTFE graft	3	3.06
Ligation	6	6.12
Total	**98**	**100**

Table 4. Arterial Repair

Result	No. of Cases	Percentage
Warm limb	84	85.71
Pulse present	63	64.28
Pulse absent	21	21.42
Cold limb	14	14.28
Total	**98**	**100**

Table 5. Result of Vascular Repair

Complication	No. of Cases	Percentage
Bleeding	3	3.06
Infection	10	10.20
Amputation	23	23.46
Death	2	2.04

Table 6. Complication

Limb Condition	No. of Cases	Percentage
Cold limb	14	14.28
Warm limb	9	9.18
Total Amputation	**23**	**23.46**

Table 7. Amputation

DISCUSSION

Despite modern surgical interventions, vascular injuries can still cause extremity loss and even death. According to some authors, amputation rates can even reach 78%.[8] In our study amputation rate was 23%, while it was 6%,[9,10] 7.7%,[11] 14.6%[7] and 17.24%[12] in other studies. The extremity salvage in our study was 76.53%, while it was 84%,[7,9,11] 94%[10] and 95%[13] in others. Cause of less percentage of limb salvage may be due to delayed presentation.

Successful outcome in vascular trauma depends on early diagnosis and intervention. In our set-up, majority of the patients presented beyond what is considered as the "Golden Period."

In this study Road traffic injury was the commonest cause (60%), mainly in male patients. This may be due to population and road discrepancy. Also women usually do not prefer driving in our region. Vascular injuries are frequent among young male population,[7,9,10,14] and in this study male patients composed of 93% of the cases with lower limb involvement (60.20%), more common than upper limb (39.79%).

Vessels, nerves and bones may be injured together due to their close relation anatomically.[15,16]

In our study, popliteal artery was the most commonly injured artery (37.75%) followed by brachial artery (26.53%).

Bone fractures and nerve lesions in this study involved 65% and 12% of cases respectively. The patients with bone fracture, nerve injury and severe soft tissue injuries were assessed by related disciplines and appropriate intervention was done. In our patients with fractures external fixation was more preferred because of easier application and low infection risk.

Peripheral angiography in vascular injuries is controversial. Some authors are suggesting angiography to every pre-operative patient.[8,17,18,19] Many clinicians report their successful vascular injury results without angiography.[7,14,20,21] We followed only clinical diagnostic method for early intervention and peripheral angiography was only done in cases with multilevel vascular and orthopaedic injuries. In all the patients with associated orthopaedic injuries, the orthopaedic surgeon performed reduction and fixation of fracture and/ or dislocation prior to the vascular repair. In one study, end-to-end repair was done in 26.75%, vein graft in 21%, PTFE graft in 1.9% and ligation in 8.9% cases.[7]

Reversed saphenous vein interposition graft in this study was used most commonly to repair the artery (53%) with end-to-end repair done in 20% cases and PTFE graft was used in 3% cases, while in another study primary repair in 55.5% cases and vein graft 35.2% cases.[10] Ligation was done in 6 cases.

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Original Research Article

Laparoscopy: a tool for undiagnosed pain abdomen

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ABSTRACT

Background: Diagnostic laparoscopy has been in the armamentarium of the surgeon and gynaecologist for many years as a useful technique for evaluating pelvic pathology and it is now one of the most frequently performed laparoscopic procedures. The purpose of this study is to evaluate the role of diagnostic laparoscopy in undiagnosed pain abdomen. The Objectives of this study is to evaluate laparoscopy as a diagnostic tool in cases of undiagnosed abdominal pain where clinical symptoms and investigations are not conclusive and to evaluate benefits and complications of diagnostic laparoscopy.

Methods: The study was done in 60 patients, presenting with chronic undiagnosed pain abdomen to a tertiary care hospital. All the patients were operated under general anesthesia in supine position. Diagnostic laparoscopy was done using 3 ports, one umbilical 10 mm, other two depending upon possible pathology. After the study, the data was analyzed to evaluate the role of laparoscopy in undiagnosed abdominal pain.

Results: Out of 60 patients, 44 were female and 16 males. On diagnostic laparoscopy, findings were- chronic appendicitis - 31, chronic appendicitis with left ovarian cyst - 1, endometriosis with adhesions - 3, PID - 5, PID with adhesions - 3, suspected TB (GI/Genital) - 4, adhesions - 12, negative diagnostic lap - 1. So it may be concluded that diagnostic laparoscopy is a very useful tool to establish diagnosis in patients with undiagnosed abdominal pain with the following benefits are, superior diagnostic ability, better visualization of the abdominal cavity including the paracolic gutters and the pelvis, able to pin point the sites of adhesions with adhesiolysis during the same procedure, retrieval of specimen for histopathological examination, management of the pathology during the same procedure, avoiding unnecessary laparotomy, low complication rate.

Conclusions: Laparoscopy is an efficient tool in the armamentarium of the surgeon to diagnose the patients of undiagnosed pain abdomen with numerous benefits and minimal complications.

Keywords: Adhesiolysis, Diagnostic, Laparoscopy, Laparoscopic appendicectomy, Undiagnosed pain abdomen

INTRODUCTION

The term laparoscopy has been derived from a Greek word 'lapara' which means 'body wall' or 'flank' and 'skopein' which means 'to examine'. The terms 'laparoscopy' and 'peritoneoscopy' are interchangeable, however, peritoneoscopy is the preferred term as the purpose is to examine the contents of peritoneal cavity and not the abdominal wall.[1]

Chronic abdominal conditions represent a major group of cases for a general surgeon. In the majority of cases, diagnosis can be made by clinical examination and sometimes with the help of basic and advanced

RESULTS

A total of 60 patients with undiagnosed abdominal pain underwent diagnostic laparoscopy after thorough clinical examination and a battery of selected laboratory tests. Imaging techniques like X-ray and abdominal ultrasound were helpful in some but not in all the cases.

The procedure was evaluated as a positive outcome when one of the following were seen or done.

- Positive pathologic findings correlated with clinical and ultrasound examination.
- Positive pathologic findings not correlated with clinical and ultrasound examination or a new diagnosis was established.
- Therapeutic procedure done to relieve the obvious pathology encountered inside the abdominal cavity.

However, in certain instances, conversion to laparotomy was done, when the surgery was not proceeding further as desired.

Age and sex wise distribution of patients

Out of 60 cases, the maximum number of patients 31.6% was in the age group between 31-35 years, followed by age group 21-25 years and 26-30 years (Figure1). Female patients outnumbered the male patients by a ratio of 44:16 (Figure2).

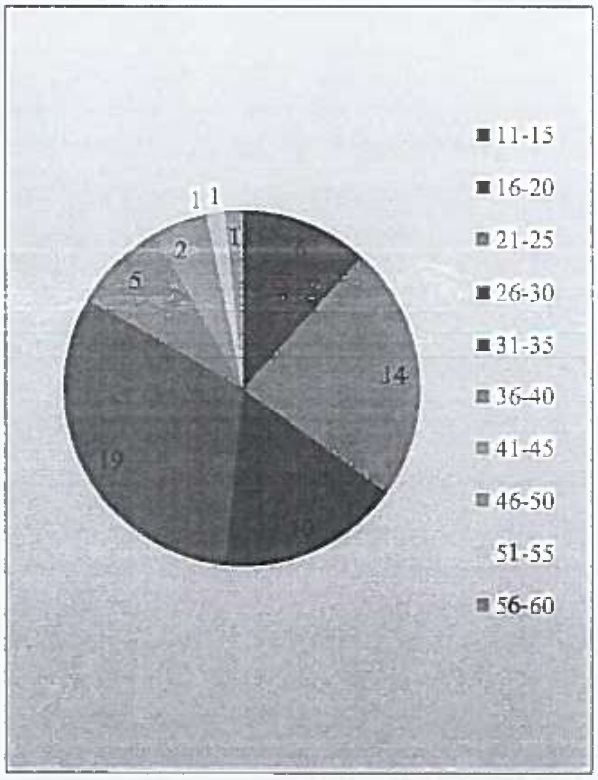

Figure1: Age wise distribution of patients.

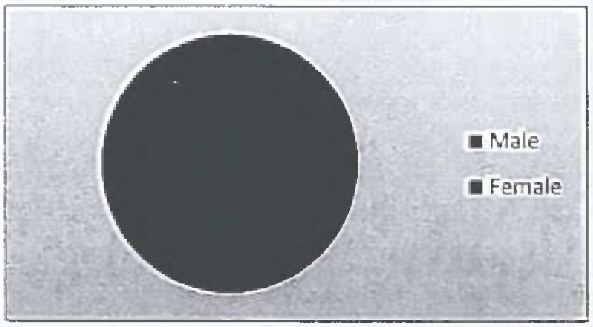

Figure 2: Sex wise distribution of patients.

Site

Most common primary site of occurrence of pain/tenderness in the abdomen was the right iliac fossa (60%), followed by around the umbilicus in 20% and the hypogastrium in 15%. Sites such as epigastrium and right hypochondrium were present in remaining 5%.

Bar

Associated complaints

The most common associated complaint was vomiting in 9 patients, followed by Diarrhoea and constipation 6, Dysuria 4, Abdominal Distention 3 and Discharge Per Vaginum 3.

Past surgical history (Other than normal vaginal delivery)

The most common significant past history was of abdominal sterilization that was present in 6 out 44 female patients (14%), followed by 9 cases each of LSCS and TAH/SOO. Out of 44 females, 27 patients had no significant past history. Male patients had no significant past history (Table 1).

Table 1: Previous medical or surgical history in females.

Past history	No. of cases	% (out of 44)
Sterilization (Abdominal tubal ligation)	6	14
LSCS	4	9
TAH/ SOO	4	9
Tuberculosis	3	7
Insignificant	27	61
Total	44	100

Ultrasonography

In most of the cases (47) USG was normal study. Six patients showed chronic Appendicitis in their USG. In 3 patients, USG showed small Renal calculi, but site of their pain was not corresponding to their USG findings.

DISCUSSION

In surgical practice pain in the abdomen is a frequent complaint in both the sexes and may present as an acute or chronic condition. A patient with abdominal pain, acute or chronic, almost always poses a diagnostic challenge for a surgeon. Hospitalizing the patient and performing frequent examinations when they present with atypical signs employ a "wait-and-watch" approach while some are scheduled for elective or emergency exploratory laparotomy. Diagnostic laparoscopy is a worthy alternative to laparotomy which may be even more informative than former with the added advantage of performing multiple therapeutic procedures.

Diagnostic laparoscopy is a minimally invasive surgical procedure that allows the visual examination of intra-abdominal organs in order to detect pathology.

Diagnostic laparoscopy has been embraced by the surgeon for the diagnosis of a wide range of abdominal diseases and the application of laparoscopic technique for the treatment of many of these diseases have accelerated its use as a diagnostic tool. In the present study, the average age was 30.83 years (range 11-59 years) which was comparable with the other study by Al-Bareeq et al having average age 31 years (16-62 years).[6] The sex ratio in present study was Female: Male 2.75:1 which was comparable to that of Easter et al and Lavonius et al.[7,8]

The primary site of pain/tenderness in present study was right iliac fossa (60%) followed by umbilicus (20%) and hypogastrium (15%) which was comparable to the series of the study conducted by Klingensmith et al who reported the reproducible tenderness to be close to 50%.[9]

History of previous surgery

A history of previous surgery was present in 23% of the cases in the present study (all patients were female). The history of previous surgery should be a relative contraindication to laparoscopic examination and that laparoscopy in patients with multiple previous abdominal operations is not entirely safe.

With the advent of open technique for creation of pneumoperitoneum this no longer holds true.[9,10] Diagnostic laparoscopy should be performed in patients who have chronic abdominal pain, especially if they have had previous surgery or pelvic inflammatory disease because a laparotomy causes formation of newer adhesions while laparoscopy is associated with a low frequency of post-operative adhesion formation.[8]

Findings in diagnostic laparoscopy

In the present study, the most common finding based on gross morphology during laparoscopy was appendicitis (chronic) seen in 32 patients (53.3%), followed by PID in 8 cases. In study by Onders et al, appendicular pathology was found in only 16% cases while in study by Al-Bareeq et al, it was 73%.[11,6]

Intra peritoneal adhesions were present in 18 cases (30%) while in the study of Arya et al, it was in 8% cases only. Adhesions are common source of pain especially in the patients who have undergone some elective abdominal procedure in the past.

One of the major benefits of diagnostic laparoscopy is that we can, not only accurately pin point sites of adhesions but also perform adhesiolysis in the same operative session thus relieving the patient of adhesion induced pain in a majority of circumstances.[12] Diagnostic laparoscopy facilitates the retrieval of histopathologic specimen without sacrificing on the patient comfort and cosmetic issues.

In the present series, the final outcome based on histopathology ha not deviated much for the gross diagnoses made during surgery mainly due to the panoramic view, brilliant illumination and extensive examination of the abdominal cavity done during diagnostic laparoscopy.

Establishment of accurate diagnosis by laparoscopy in chronic abdominal pain

Establishment of accurate diagnosis was achieved in 98.3%of the cases in our study. In previous years, diagnostic accuracy by laparoscopy was only 47% while in the current years diagnostic accuracy has raised to 99 - 100%.[7,6,11,13] Hence it may be considered a useful tool in the diagnosis of undiagnosed pain abdomen.

Laparotomy avoided

In our study using laparoscopy 58 cases (96.6%) were saved from undergoing laparotomy, similar results were observed by Schrenk et al (94%) and Onders et al (100%).[14,11]

Complications of diagnostic laparoscopy

In our study, minor complications were observed in 1 case (1.6%). In other studies, also, complication rate was found to be quite low as in the study by Udwadia (0.09%).[15]

The low incidence of complications during laparoscopy can be explained on the basis of the availability of better instruments, for example, the use of Hasson's cannula for creation of pneumoperitoneum by open technique in patients with previous history of abdominal surgery, and due to availability of a better expertise and training to the laparoscopic surgeon.[16]

So, it may be concluded that diagnostic laparoscopy is a very useful tool to establish diagnosis in patients with undiagnosed abdominal pain with the following benefits:

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Original Research Article

The benefits of protective defunctioning ileostomy in ileal perforation surgery

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ABSTRACT

Background: Perforation of bowel, particularly ileal perforation, is a significant emergency surgical problem in developing and underdeveloped nations and usually associated with high morbidity and mortality. The study is focussed on evaluating the impact of protective ileostomy in ileal perforation and to compare its outcome in term of post operative complication, hospital stay, psychological impact and mortality with primary surgery without ileostomy and observe its effect on prognosis of patient as a whole. Aim of the study we compared two modalities of treatment, primary surgery without ileostomy v/s primary surgery with protective defunctioning ileostomy with respect to post operative complications, duration of hospital stay, morbidity, mortality and psychological impact.

Methods: We studied 50 patients of ileal perforation (diagnosed per-operatively) admitted to tertiary level hospital and operated upon for laparotomy. Patients were divided in 2 groups: Group A = Protective defunctioning ileostomy along with primary surgery, and Group B = Primary surgery alone. Primary surgery includes primary closure of perforation or resection and end to end anastomosis.

Results: The commonest cause of non-traumatic ileal perforation was typhoid (52%) followed by non specific, tuberculosis and diverticulitis. Different types of operative procedures were performed. In Group A, total no. of dreaded complications like faecal fistula was 1 while in Group B, 10 patients developed faecal fistula. Other complications like wound infection and wound dehiscence were 28% in Group A while 96% in Group B. Overall mortality rate was 24% with 12% mortality in group A and 36% in group B. Mean hospital stay in Group A patient was 12.640±5.75 days (1-23 days) and those of group B was 23.760±16.04 days (5-59 days).

Conclusions: Construction of protective defunctioning ileostomy in case of distal ileal perforation repair or anastomosis greatly reduces the dreaded complication and mortality in comparison to perforation repair or anastomosis without protective ileostomy. Although it is associated with ileostomy related complications, but they are only temporary and obviously no more than the price of life saved.

Keywords: Defunctioning ileostomy, Faecal fistula, Ileal perforation, Protective ileostomy

INTRODUCTION

Perforation of bowel, particularly ileal perforation, is a significant emergency surgical problem in developing and underdeveloped nations and usually associated with high morbidity and mortality. Most common cause of ileal perforation is typhoid; other may be tuberculosis, trauma and non specific enteritis. Patients usually present with abdominal pain and tenderness with signs of peritonitis like abdominal guarding and rigidity etc. Late cases may present with severe toxic state. Surgical intervention is the definite treatment for it. Various

There was male preponderance in this study with male to female ratio of 3.5:1 (Table 2).

Most of patient presented with symptoms and signs of peritonitis. The commonest symptoms were pain abdomen, fever, vomiting. The common sign were abdominal tenderness, guarding and rigidity, absent bowel sounds, abdominal distension and obliteration of liver dullness. Gas under right dome of diaphragm was found in 89% of the patients.

Table 1: Age incidence.

Age (years)	Number of cases	Percentage (%)
≤20	5	10
21-30	14	28
31-40	13	26
41-50	8	16
51-60	5	10
61-70	5	10
Total	50	100

Table 2: Sex incidence.

	Group A		Group B		Total	
Sex	No. of cases	%	No. of cases	%	No. of cases	%
Male	19	76	20	80	39	78
Female	6	24	5	20	11	22
Total	25	100	25	100	50	100

The commonest cause of non-traumatic ileal perforation was typhoid (52%) followed by non specific, tuberculosis and diverticulitis. Widal was done in all patients in whom ileal perforation was diagnosed per-operatively. Widal test for typhoid was positive in 52% of patients. Histopathological evidence of typhoid found in 7 cases out of 26 cases of typhoid. Diagnosis of tuberculosis was made in 5 cases and diverticulitis in one case. Rest of cases showed features of non specific inflammation with no definitive aetiology (Table 3).

Table 3: Aetiology of Ileal Perforation.

Diagnosis	Total cases	Percentage (%)
Typhoid	26	52
Non-specific	18	36
Tuberculosis	5	10
Diverticulitis	1	2
Total	50	100

During laparotomy feculent peritonitis was seen in 44% of cases and purulent peritonitis on 56% cases. 74% of patient had single perforation, 16% had two perforations and 10% have three or more perforations. 74% patient had associated ileitis adjacent to perforation, only 26% had healthy bowel.

Different types of operative procedures were performed. Out of 25 patients in Group A; in 19 cases, primary closure of perforation(s) with proximal loop ileostomy and in 6 cases, resection anastomosis of ileum with proximal loop ileostomy was done. Out of 25 patients in Group B; in 20 cases, primary closure of perforation(s) and in 5 cases, resection anastomosis of ileum was done (Table 4).

Table 4: Operative procedures.

Group A		Group B	
Procedure	Number	Procedure	Number
Primary closure of perforation(s) with proximal loop ileostomy	19	Primary closure of perforation(s)	20
Resection anastomosis of ileum with proximal loop ileostomy	6	Resection anastomosis of ileum	5
Total	25	Total	25

Post operative complications were encountered in varying proportions in both groups. Faecal fistula was most dreaded fatal complication. In Group A, total no. of dreaded complications like faecal fistula was 1 while in Group B, 10 patients developed faecal fistula. Other complications like wound infection and wound dehiscence were 28% in Group A while 96% in Group B. In Group A, Ileostomy related complications like Skin excoriation, Ileostomy prolapse, Ileostomy retraction, etc. were also present. Overall mortality rate was 24% with 12% mortality in group A and 36% in group B (Table 5).

Table 5: Post-operative complications (n=25) in each group.

Complications	Group A		Group B	
	No. of patients	%	No. of patients	%
Wound Infection	5	20	14	56
Wound Dehiscence	2	8	10	40
Skin Excoriation	18	72	0	0
Ileostomy Prolapse	1	4	0	0
Ileostomy Retraction	5	20	0	0
Electrolyte Imbalance	4	16	1	4
Faecal Fistula	1	4	10	40
Psychological Symptoms	7	28	8	32
Death	3	12	9	36

certainly better when a protective defunctioning Ileostomy is formed to protect the distal anastomosis or perforation closure. Ileostomy specific complications however increase the post-op morbidity. These complications can be reduced, if not out-right eliminated, by proper fashioning of stoma. It is of paramount importance that ileostomies are properly sited and constructed. A stoma should be formed by surgeon who is not only technically skilled but also understands the potential metabolic and mechanical problems associated with ileostomy. Morbidity, mortality and thus, the economic burden was significantly high in group B patients.

Protective ileostomy greatly reduced the occurrence of faecal fistula in patients there by reducing the mortality, although was associated with stoma related complication. Though bothersome, ileostomy is still a life saving and damage control surgical procedure. It should be recommended that ileostomy in these cases is only temporary and extra cost of management is not more than price of life saved.

Table 6: Outcome of study (n=25) in each group.

Complications	Group A	Group B	P value	Statistical significance
Hospital stay (days)	12.64	23.76	0.000	Highly significant
Wound infection	20%	56%	0.009	Significant
Wound dehiscence	8%	40%	0.008	Significant
Skin excoriation	72%	0	0.000	-
Ileostomy prolapse	4%	0	0.312	-
Ileostomy retraction	20%	0	0.018	-
Electrolyte imbalance	16%	4%	0.157	Insignificant
Faecal fistula	4%	40%	0.002	Significant
Psychological symptoms	28%	32%	0.758	Insignificant
Death	12%	36%	0.040	Significant

CONCLUSION

Construction of protective defunctioning ileostomy in case of distal ileal perforation repair or anastomosis greatly reduces the dreaded complication and mortality in comparison to perforation repair or anastomosis without protective ileostomy. Although it is associated with ileostomy related complications, but they are only temporary and obviously no more than the price of life saved. However, further controlled trials may be needed for more details on the matter.

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A study of locally advanced breast cancer management in patients with rural background

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Abstract
Introduction: Breast cancer is the most common of the types of cancer occurring in India, followed by lung cancer and cervical cancer. Breast cancer is categorized into operable and advanced breast cancer for the management purpose. While early detection is the key for successful breast cancer treatment, one in three women in rural India had not even heard of the deadly disease. Due to lack of awareness most of women from rural background reach hospitals with advanced disease. This study was done to determine how different modalities of treatment affect the outcome in advanced breast cancer patients with rural background.
Aims and Objectives: To evaluate cases of advanced breast cancer clinically and by relevant investigations in rural population. To evaluate the role of surgery either in the first presentation of patient or after chemotherapy.
Materials and Methods: This study was conducted in Rabindranath Tagore Medical College, Udaipur (Rajasthan). A total of 40 patients with locally advanced breast cancer were evaluated.
Conclusion: In the patients of locally advanced carcinoma breast with rural background, surgery with adjuvant chemotherapy is a better option in comparison to neoadjuvant chemotherapy followed by surgery. The reason is that many of patients do not return for surgery after neoadjuvant chemotherapy.

Keywords: breast cancer, locally advanced breast cancer, rural background, modified radical mastectomy

1. Introduction

Breast cancer is the most common of the types of cancer occurring in India, followed by lung cancer and cervical cancer. Breast is the most commonly diagnosed cancer among women in the Western world accounting for 1/5th (18%) of all cancers in women. Every year about one million women and several thousand men are diagnosed with breast cancer worldwide and approximately 60,000 die from it (Parkin DM *et al.* 2005) [1]. Breast cancer is the most common site specific cancer in women and a leading cause of death due to cancer between 40-45 years of age (Sethi A Sethi D 2015) [2]. In India, it is the most common cancer in females with 75,000 new cases occurring every year as per the cancer registries in the country in urban females. Breast cancer is categorized into operable and advanced breast cancer for the management purpose. Advanced breast cancer is either locally advanced or metastatic disease. Locally advanced breast cancer (LABC) is characterized by varying clinical presentations such as presence of a large primary tumour (>5 cm), associated with or without skin or chest-wall involvement or with fixed (matted) axillary lymph nodes or with disease spread to the ipsilateral internal mammary or supraclavicular nodes in the absence of any evidence of distant metastases (Valero V 1996) [3]. These cancers are classified as stage IIB, IIIA, IIIB or IV breast cancer according to the American Joint Committee for Cancer Staging and End Results Reporting (5th Ed. 1997) [4]. Locally advanced breast cancer is a very common clinical scenario especially in developing countries (30-60%) possibly due to various factors like lack of education and poor socio-economic status. With this wide spectrum of presentation, management of LABC is a challenge for the surgeon. Treatment of LABC has evolved from single modality treatment, consisting of radical mutilating surgery or higher doses of radiotherapy in inoperable disease to multimodality management consisting of surgery, radiation therapy (RT), chemotherapy with or without hormonal therapy and others.

While early detection is the key for successful breast cancer treatment, one in three women in rural India had not even heard of the deadly disease. Due to lack of awareness most of women

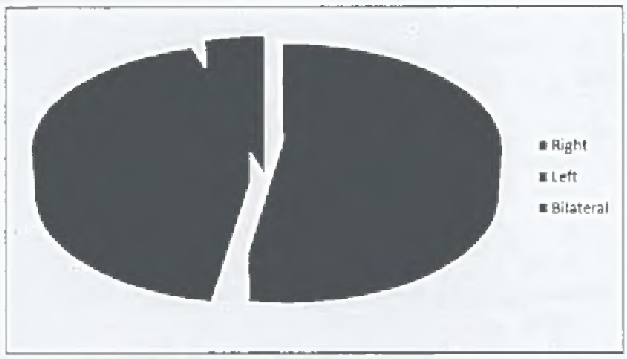

Fig 4: Distribution of breast cancer patients according to side involvement (n=40)

Figure 4 shows that 52.5% cases had right side breast involvement only while 42.5% had left side involvement only and 2 cases (5%) were having involvement of both breasts.

Table 1: Distribution of cases according to location of tumour (quadrant) (n=40)

S. No.	Location	No. of patients	Percentage
1.	Upper outer quadrant	13	32.5
2.	Upper inner quadrant	4	10.0
3.	Lower outer quadrant	2	5.0
4.	Lower inner quadrant	1	2.5
5.	Central	2	5.0
6.	More than one quadrant	18	45.0

Table 1 show that maximum cases (45%) had tumour localized in more than one quadrant, 32.5% presented with tumour in upper outer quadrant, 10% in upper inner quadrant and 5% in lower outer quadrant and 2.5% cases had in lower inner quadrant.

Table 2: Family history of cancer among breast cancer cases (n=40)

S.No.	Family history of cancer	No. of patients	Percentage
1.	Family h/o breast cancer	2	5.0
2.	Family h/o other cancer	4	10.0
3.	No family h/o cancer	34	85.0
	Total	40	100

Table 2 shows that 15% patients of breast cancer had family history of cancer. Out of these, only 5% had family history of breast cancer and 10% had cancer other than breast.

Table 3: Distribution of cases according to tumour size (based on TNM staging) (n=40)

S. No.	TNM staging	No. of patients	Percentage
1.	T_X	-	-
2.	T_1	-	-
3.	T_2	-	-
4.	T_3	34	85.0
5.	T_4	6	15.0
	Total	40	100

Table 3 shows that majority of patients (85%) presented in stage T3 and 15% in stage T4.

Table 4: Distribution of breast cancer cases according to lymph nodes status (clinical assessment based on TNM staging) (n=40)

S. No.	Lymph node status	No. of patients	Percentage
1.	N_0	-	-
2.	N_1	33	82.5
3.	N_2	6	15.0
4.	N_3	1	2.5
	Total	40	100

Table 4 show that 33 patients (82.5%) presented with N_1 stage node involvement while one case (2.5%) had N_3 involvement and in 6 patients (15%) had N_2 involvement.

Table 5: Distribution of breast cancer cases according to histopathological types and their grading (n=40)

S. No.	Histopathological type	No. of patients	%	Grade I		Grade II		Grade III	
				No.	%	No.	%	No.	%
1.	Ductal carcinoma	33	82.5	25	75.75	5	15.15	3	9.09
2.	Medullary carcinoma	6	15.0	5	83.33	1	16.67	-	-
3.	Lobular carcinoma	1	2.5	1	100	-	-	-	-
	Total	40	100	31	77.5	6	15.0	3	7.5

Table 5 shows in infiltrating ductal carcinoma (75.75%) cases were grade I and 15.15% cases were grade II and only 9.09% were grade III. In medullary carcinoma 83.33% were grade I and 16.67% were grade II. In lobular carcinoma, only 1 one case (100%) was grade I. Overall grade I, II and III were 77.5%, 15.0% and 7.5%, respectively.

Table 6: Distribution of breast cancer cases according to metastasic status in follow up (n=40)

S. No.	Metastasis	No. of patients	Percentage
1.	Metastasis developed during follow up	4	10
2.	No metastasis during follow up	32	80
3.	Lost in follow up	4	10
	Total	40	100

Table 6 shows that 4 patient (10%) developed metastasis during follow up and no metastasis is seen in rest of patients.

Table 7: Status of the patients at the time of presentation in breast cancer patients

S. No.	Patients presenting with	No. of patients	Percentage
1.	Locoregional recurrence	3	7.5
2.	Presenting first time to hospital	37	92.5
	Total	40	100

Table 7 shows that 3 patients (7.5%) who were operated elsewhere presented to us with locoregional recurrence. The remaining cases presented first time to the hospital.

background, surgery with adjuvant chemotherapy is a better option in comparison to neoadjuvant chemotherapy followed by surgery. The reason is that many of patients do not return for surgery after neoadjuvant chemotherapy.

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Original Article

Vascular Trauma: Our Experience at Tertiary Level Hospital

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Abstract

Introduction: Vascular injuries of extremities are a very important cause of morbidity and mortality in the society. The incidence of vascular trauma has increased considerably during the past few decades.

Materials and Methods: This study was conducted at a tertiary level hospital over a period of 6 years. A total number of 690 patients presented with extremity vascular trauma that underwent the operative procedure. Patients with isolated venous trauma, unsalvageable extremity injury requiring primary amputation, trauma with severe multiple system involvement, and patients presenting more than 100 h after injury were excluded from the study. This study was done to evaluate the mode and type of injuries, arteries involved and methods to re-establish vascular continuity, and end result of the vascular intervention.

Results: Six hundred ninety patients, including 660 (95.6%) men and 30 (4.3%) women, were operated. Most of the patients (55.4%) were between 20 and 40 years old. The most common cause of vascular injury was road traffic accidents (93%). The most common artery involved was popliteal artery and contusion was the most common pattern of injury. Interposition vein graft was the most common mode of repair. Over all limb salvage rate was 79%.

Conclusion: Vascular injury to extremity requires prompt recognition and referral to a vascular center. Immediate revascularization has excellent results and less morbidity.

Key words: Arterial repair, Road traffic accident, Save limb, Vascular injury to limb, Vascular trauma to extremity

INTRODUCTION

Vascular injuries of extremities are a very important cause of morbidity and mortality in the society. The incidence of vascular trauma has increased considerably during the past few decades. The great majority of these injuries are due to road traffic accidents (RTA), penetrating trauma with sharp objects, and gunshot wounds.[1] Despite modern surgical interventions, vascular injuries can still cause extremity loss and even death.[2] Timely intervention to re-establish vascular supply to the affected limb is very crucial; otherwise, it may result into limb loss or mortality due to bleeding, ischemia, renal failure, and secondary complications like – infection. Vascular reconstruction leads to a dramatic decrease in amputation rate.[3] Successful treatment of major arterial injuries may be lifesaving as well as allowing limb salvage and restoration of function.[4] Return of function is often related to the presence of concomitant injury to peripheral nerves and bones.[5]

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Our center is a tertiary care center and largest hospital of state. It drains nearby states also. Although delay occurs because of transportation or diagnostic delay, still our aim is to provide vascular continuity as early as possible with simultaneous treatment for nerves, bones, and other injuries.

This retrospective study was done in 690 patients who underwent an operative procedure for vascular trauma in the past 6 years to evaluate the mode and type of injuries, arteries involved and methods to re-establish vascular continuity, and end result of the vascular intervention.

MATERIALS AND METHODS

This retrospective observational analytic study was conducted at our center Sawai ManSingh Medical College,

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most common vascular injury in upper extremity was brachial artery injury in 169 patients (24.5%) followed by ulnar/radial artery injury in 66 (9.6%) cases. In the lower extremity, the popliteal artery was the most frequently affected artery as it was injured in 276 (40%) cases followed by femoral artery in 141 (20.4%) cases [Table 5].

Vascular injury was more often associated with orthopedic injuries, as both occurred in 528 patients, mostly in the form of fracture or dislocation. The concomitant vein or nerve injury occurred in 85 patients [Table 6]. The arterial repair was performed after orthopedic intervention for bone injuries.

Contusion was the most common pattern of arterial injury (51.9%) followed by complete transection (31.3%) [Table 7].

The most common mode of repair was by use of reversed saphenous vein interposition graft to repair the artery (52%) followed by end-to-end repair in 30% cases. Ligation (anterior or posterior tibial artery) was done in 2.4% cases. No intervention was done in 10 cases because after exposing the artery, pulsations were present with no visible vascular injury. This may be due to angulation of artery by corner of fractured or dislocated bone which relieved after manipulation [Table 8].

In the upper extremity, the most common type of reconstruction was end to end anastomosis followed by inter-position vein grafting while in lower extremity it was inter-position vein grafting followed by an end to end anastomosis. A balloon embolectomy catheter was used to remove thrombus and to confirm the patency of the artery proximally and distally.

Table 5: Artery involved

Artery	No. of cases	Percentage
Subclavian	2	0.3
Axillary	12	1.7
Brachial	169	24.5
Radial/ulnar	66	9.6
Femoral	141	20.4
Popliteal	276	40.0
Anterior tibial/posterior tibial	24	3.5
Total	690	100

Table 6: Associated injury

Injury	No. of cases	Percentage
Bone	528	76.5
Major nerve injury	27	3.9
Major vein injury	58	8.4

A repair of major venous injury was performed in 58 cases. Nerve repair was done in 27 cases. Fasciotomy was performed in 110 patients, mostly (103 cases) in the lower extremities and only in seven cases in the upper extremity.

In spite of the presentation after 6 h, the results of the repair were extremely good. Of 138 patients who presented within 6 h, 130 achieved warm limb with a palpable distal pulse. In 552 cases of delayed presentation, we were able to save limb in 427 cases. In 125 cases of vascular repair, limb remained cold, mainly in patients who presented after 24 h [Table 9].

Post-operative complications in the form of infection were seen in 61 (8.8%) cases, secondary hemorrhage in 20 (2.9%). A total of 145 (21%) patients end up with amputation of limb (125 due to cold limb postoperatively and 20 due to infection or secondary bleeding). A total of 13 patients (1.9%) expired [Table 10].

Overall limb salvage rate was 79%.

The mean duration of hospitalization was 10 ± 5 days (range 5–30 days). The duration of hospitalization was significantly longer in lower extremity injuries compared to upper extremity injuries.

Table 7: Pattern of arterial injury

Injury	No. of cases	Percentage
Contusion	358	51.9
Spasm/angulation	25	3.6
Partial transection	69	10.0
Complete transection	216	31.3
Multiple site	22	3.2
Total	690	100

Table 8: Type of arterial repair/operation

Repair	No. of cases	Percentage
Embolectomy only	10	1.4
Lateral sutures	74	10.7
End to end repair	207	30
Vein graft	359	52
PTFE graft	13	1.88
Ligation	17	2.4
No intervention	10	1.5
Total	690	100

Table 9: Result of vascular repair/operation

Presentation	Total number	Warm limb and pulse, both present	Warm limb only, no pulse	Cold limb
Early (within 6 h)	138	130	8	0
Late (after 6 h)	552	232	195	125
Total	690	362	203	125

exploration, proximal and distal arterial control must be established before a repair is attempted; and vascular reconstruction is preferable to ligation.

A well-stabilized skeleton is essential before definitive arterial repair.[27] However, Hunt and Kingsley suggested that arterial revascularization should be followed by skeleton stabilization and nerve and tendon repair.[28] In this study, skeleton fixation was done before vascular repair.

In arterial injuries, successful results were obtained in arterial reconstruction procedures, which were held within 6–8 h after the event. Almost all of the amputations performed in our study were late cases that were revascularized after 8 h of injury. Infection is also a major factor, which increases the amputation rate after a successful vascular surgery. For this reason, vigorous and appropriate tissue debridement is important before and after the revascularization procedure.[29] In our study, 61 (8.84%) patients developed infection, which was treated with good antibiotic coverage, debridement of wound, and regular dressing of the wound. Of 61 infected cases we were able to save limb in 48 patients and amputation was done in 13 cases.

This study is limited by its retrospective nature and by reflecting experience at one tertiary center only. Further studies are warranted to confirm the hypotheses raised by the observations described.

CONCLUSION

The vascular injury requires prompt recognition and referral to a vascular center. Early diagnosis and immediate treatment of vascular injury are necessary to reduce morbidity and mortality. Patients should be surgically intervened even after the golden period has passed because with a limb or without limb matters a lot.

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DEPARTMENT OF SURGERY

List of Publications

DR. RAJIV JAIN				
1	DIAGNOSIS OF ABDOMINAL TUBERCULOSIS IN CHRONIC ABDOMINAL PAIN: LAPAROSCOPY AS AN EFFECTIVE DIAGNOSTIC TOOL	DR.RAJIV JAIN, DR.RAVI DOSI	Journal of Evolution of Medical and Dental Sciences/ Volume 2/ Issue 16/ April 22, 2013 Page-2756 -2762	
2	CERVICAL TUBERCULAR LYMPHADENITIS:EVALUATION OF DIAGNOSTIC MODALITIES	DR.RAJIV JAIN, DR.RAVI DOSI	Journal of Evolution of Medical and Dental Sciences/ Volume 2/ Issue 16/ April 22, 2013 Page-2688-2693	
3	AN OBSERVATIONAL STUDY OF AETIOPATHOGENESIS, CLINICAL PROFILES AND MANAGEMENT OF NEONATAL NECROTISING ENTEROCOLITIS	DR.RAJIV JAIN, DR. ABHISHEK KANSAL DR. SURAJ JAIN & DR.RISHIKANT VASHISHTHA	Kansal A, Jain R, Jain S, et al. An observational study of aetiopathogenesis, clinical profiles and management of neonatal necrotising enterocolitis. J. Evolution Med. Dent. Sci. 2016;5(100):7388-7393, DOI: 10.14260/jemds/2016/1672	
4	MANAGEMENT OF VARIOUS RARE AND ATYPICAL HERNIAS : EXPERIENCE AT A TERTIARY CARE CENTRE IN CENTRAL INDIA	DR. RAJIV JAIN & DR.KOLLA VENKATESH	Jain R, Venkatesh K. Management of various rare and atypical hernias: experience at a tertiary care centre in central India. Int Surg J 2016;3:146-52.	

ORIGINAL ARTICLE

DIAGNOSIS OF ABDOMINAL TUBERCULOSIS IN CHRONIC ABDOMINAL PAIN: LAPAROSCOPY AS AN EFFECTIVE DIAGNOSTIC TOOL

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ABSTRACT: Chronic abdominal pain is a FREQUENTLY ENCOUNTERED problem and abdominal tuberculosis is a very common cause of the same. Diagnostic laparoscopy is a highly sensitive, specific, and safe procedure for the early diagnosis of abdominal tuberculosis. The procedure is beneficial because it is minimally invasive and provides diagnostic benefit in terms of both visual appearances and tissue yield for histopathological and cytological confirmation. We have performed an extensive retrospective study with 250 subjects and were able to justify the safety, sensitivity & early selection of laparoscopy as a procedure of choice to confirm tuberculosis in chronic abdominal pain.

INTRODUCTION: Chronic abdominal pain is a very frequent problem putting a heavy burden on the limited health resources in a developing country like India. Often the clinical presentation is vague and nonspecific and the available diagnostic modalities fail to pinpoint the underlying pathology.

Histopathological confirmation of abdominal Tuberculosis is difficult due to suboptimal noninvasive access to the pathology.

Tuberculosis (TB) remains a major global health problem. It causes ill-health among millions of people each year and ranks as the second leading cause of death from an infectious disease worldwide, after the human immunodeficiency virus (HIV).The latest estimates report that there were almost 9 million new cases in 2011 and 1.4 million TB deaths (990 000 among HIV negative people and 430 000 HIV-associated TB deaths). [1]

AIMS AND OBJECTIVES: To evaluate the role of laparoscopy as a confirmatory diagnostic tool in diagnosing abdominal Tuberculosis as a leading cause of chronic abdominal pain.

MATERIAL AND METHODS: We performed a retrospective evaluation of patients presented for evaluation of chronic abdominal pain over the last three years in SAIMS medical college and hospital, Indore.

The duration of the study was 3 years and the total study subjects were 250.

Patients presenting with vague abdominal pain and other gastrointestinal complaints of three months or more duration with no conclusive diagnosis despite many investigations were included.

Follow up study of these patients were performed on basis of available contact details and data stored in the medical record department & out patient department.

Out of all the laparoscopies conducted in 212 patients, 9 were converted into formal laparotomies because of intraoperative problems like difficult access, dense adhesions, and poor visualization. so the identification of anatomical details of intraabdominal structures was not possible. These 9 cases were converted to laparotomies for diagnostic purposes only. and in these 9 conversion, after opening the abdomen by laparotomy, the intraabdominal contents were explored, the visual findings were noted and the biopsies were taken from representative tissues and the biopsy specimens were sent for histopathology.

Histopathological report of biopsy established the diagnosis of abdominal tuberculosis in 123 patients (58%). All patients were started on antitubercular therapy and they showed good

Clinical response-

Diagnosis	Percentage
Tuberculosis	58%
Malignancy	11%
Post operative adhesions	8%
Pelvic inflammatory disease	7%
Recurrent appendicitis	6%
Ovarian cyst, fimbrial cyst	3%
Cirrhosis liver	2%
Others	5%

The prominent laparoscopic findings noted were the following,

MALIGNANCY
Intestinal mass lesions
Omental mass
Diffuse carcinomatosis
Malignant ascites
abdominal lymphadenopathy

PELVIC INFLAMMATORY DISEASE
Fluid in pouch of Douglas
Adnexal pathology

Abdominal tuberculosis	
Stalactic bands	
Multiple white tubercles /nodules	DSC00022.JPG
Omental thickening	DSC00017.JPG
Hyperemic edematous bowel	
Dense inter bowel loop adhesions	
Mesenteric lymphadenopathy	
Straw colored ascites	

High correlation with Bhargava et al [3]

Post operative adhesions

Earlier Laparotomy was the only definitive diagnostic approach. Though it yields correct diagnosis but at the cost of significant morbidity. Laparoscopy provides minimally invasive access to the peritoneum, thus reducing morbidity without compromising the diagnostic yield.
During laparoscopy , abdominal tuberculosis is suggested by macroscopic signs like tubercles/nodules over the peritoneal surfaces, thickening and hyperemia of omentum, inflammatory adhesions and a long fibrous band extending from the parietal to visceral peritoneum called *'Stalactic band'* which is quite characteristic of abdominal tuberculosis.[8]
Analysis of macroscopic findings during laparoscopy in 123 histopathological confirmed cases of abdominal tuberculosis.

In our study, small white tubercles over peritoneal surfaces were found in 106 patients (86%)
Omental thickening was found in 101 patients (82%).

Stalactic band which is the best macroscopic confirmatory feature was found in 110 cases [89%].

There were no complications or mortality in any of the laparoscopic surgery.

In 9 cases intraoperative decision for conversion of Laparotomy was taken due to difficult access, dense adhesions, inadequate exposure and poor identification of anatomical details.

The biopsy tissues obtained during laparoscopy were sent for histopathological examination.

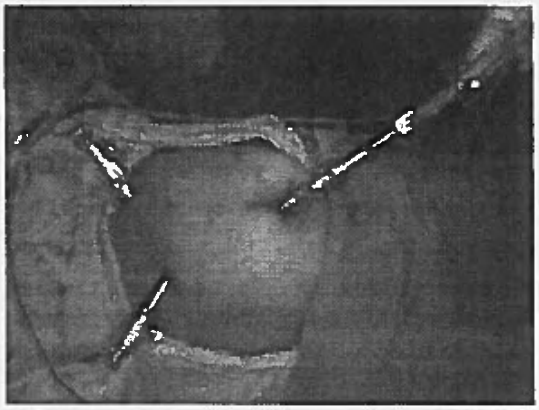
In all the patients in whom histopathological confirmation of abdominal tuberculosis was obtained, antitubercular treatment was started promptly and the patients improved symptomatically very soon.
Several authors confirm the role of laparoscopy in diagnosing abdominal tuberculosis,

Author	Study Subjects	Sensitivity
Bhargava et al [3]	87	95%
Rai & Thomas et al [4]	36	100%
Ibrahullah et al [5]	23	87%
Razi hospital , Iran [6]	29	98%
Our Study ,SAIMS	212	58%

The beneficial aspects of diagnostic laparoscopy were

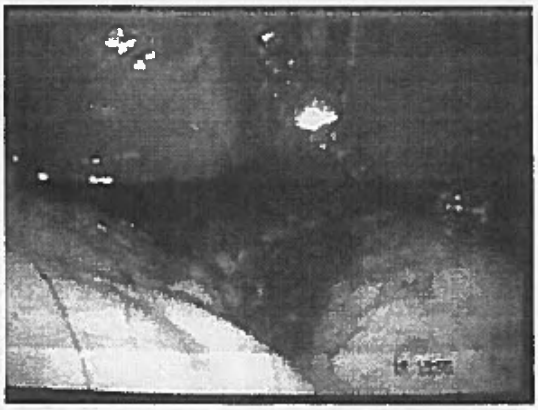
Author	Benefits
Bhargava et al [3]	Visual appearance super cede histology & culture for diagnosing tuberculosis
Rai & Thomas et al [4]	Early laparoscopy is beneficial for earlier diagnosis
Ibrahullah et al [5]	Laparoscopy is a safe and mortality free procedure
Razi hospital , Iran [6]	High sensitivity
Rajiv Jain et al, SAIMS	Early laparoscopy is the investigation of choice for abdominal Tuberculosis

Thus laparoscopy with tissue biopsy is the most sensitive and specific diagnostic procedure for abdominal tuberculosis and can be termed as the investigation of choice.



Laparoscopic technique showing port position

intra operative photograph in diagnostic laparoscopy showing thickened Omentum



intra operative photograph in diagnostic laparoscopy showing ascitic fluid.

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Original Research Article

A prospective study of epidemiology and clinical presentation of non-traumatic acute abdomen cases in a tertiary care hospital of central India

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ABSTRACT

Background: Acute Abdomen is a term used to encompass a spectrum of surgical, medical and gynecological conditions ranging from trivial to life threatening conditions, which require hospital admission, investigations and treatment. The purpose of this study was to identify the epidemiological pattern and to determine the spectrum of disease causing "non-traumatic acute abdomen in central India".
Methods: This is a prospective study of 98 patients of non-traumatic acute abdominal cases conducted in the Department of Surgery, Sri Aurobindo Medical College and PG Institute, Indore, Madhya Pradesh, India. In this study, preoperative detailed history and thorough physical examination was done for all acute abdominal emergencies, to arrive at pre-operative diagnosis.
Results: Amongst the study of 98 patients, males have higher incidence of acute abdomen with the young age group (21-30 years) most commonly affected. Perforation peritonitis constituted the most common cause of acute abdomen (39.7%), followed by acute appendicitis (37.7%), followed by intestinal obstruction (14.2%).
Conclusions: This study was conducted to evaluate the epidemiology, etiology and differential diagnosis of non-traumatic acute abdomen. At the end of the study, we had a better insight of the spectrum of the condition and we concluded that there is more scope for further work in the same field for better understanding of this topic.

Keywords: Acute Abdomen, Appendicitis, Perforation peritonitis

INTRODUCTION

Acute Abdomen is a term used to encompass a spectrum of surgical, medical and gynecological conditions ranging from trivial to life threatening conditions, which require hospital admission, investigations and treatment.[1] The term encompasses long list of differential diagnosis which may vary from self-limiting to life threatening conditions. Abdominal pain is one of the common reasons for visits to the emergency room. Although for the majority of patients, symptoms are benign and self-limited, a subset will be diagnosed with "acute abdomen", as a result of serious intra-abdominal pathology necessitating emergency intervention.[2] The most appropriate therapy should be initiated with the patient's clinical status optimized. The workup should first include a thorough but efficient acquisition of the patient's history and physical examination followed by judicious use of laboratory and radiologic studies.

The most common symptoms are abdominal pain and vomiting whereas tenderness and guarding were the most frequent clinical signs. Specifically, gastroenteritis, acute appendicitis and abdominal trauma are commonest causes of acute abdomen in children and young adults, whereas biliary disease, intestinal obstruction, diverticulitis and

such cases and will also help in establishment of prompt treatment guidelines of such patients.

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A PROSPECTIVE STUDY OF VARIOUS AVAILABLE DIAGNOSTIC AND TREATMENT MODALITIES AND INTRAOPERATIVE FINDINGS OF NON-TRAUMATIC ACUTE ABDOMINAL CASES IN A TERTIARY CARE HOSPITAL OF CENTRAL INDIA

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ABSTRACT

BACKGROUND
Acute abdominal pain is a common complaint of patients presenting at the Emergency Department. Patients presenting with acute abdominal condition which often requires an immediate surgical intervention and is one of the commonly encountered emergencies in the practice of General Surgery. Very often an accurate diagnosis cannot be made without surgery and many wonders are revealed on opening the abdomen. So it is often the last court of appeal in investigating abdominal cases.

MATERIALS AND METHODS
This is a prospective study of 98 patients of non-traumatic acute abdominal cases conducted in a Tertiary Care Hospital of Central India. In our study, all routine blood investigations were carried out and relevant radiological investigations like abdomen x-ray, ultrasound whole abdomen was done in majority of patients and CT scan was done wherever needed. In our study 97 patients were managed surgically, while conservative management is done in only 1 patient.

RESULTS
Amongst the study of 98 patients x-ray, USG and CT were used as diagnostic modalities. Maximum cases were operated, while conservative management was done in one patient.

CONCLUSION
Our study is a sincere attempt to know the sensitivity of diagnostic modalities and to evaluate the treatment protocol in non-traumatic acute abdomen cases.

KEYWORDS
Acute Abdomen, Laparotomy, Abdomen X-Ray, Ultrasound Abdomen.

HOW TO CITE THIS ARTICLE: Jain R, Gupta V. A prospective study of various available diagnostic and treatment modalities and intraoperative findings of non-traumatic acute abdominal cases in a tertiary care hospital of Central India. J. Evolution Med. Dent. Sci. 2016;5(92):6829-6834, DOI: 10.14260/Jemds/2016/1545

BACKGROUND

Acute abdominal pain is a common complaint of patients presenting at the Emergency Department.[1] Approximately, 10% of presentations at the Emergency Department are because of acute abdominal pain.[2] It can be caused by a variety of diseases ranging from mild and self-limiting to life-threatening diseases.[3] An early and accurate diagnosis results in more appropriate management and subsequently leads to better outcomes. The first step in the diagnostic pathway is clinical evaluation. In daily practice, a preliminary diagnosis should be made based on medical history, physical examination and in some cases laboratory parameters. After clinical assessment, the decision can be made to perform additional diagnostic investigations to increase certainty of the diagnosis. The use of additional imaging modalities such as plain radiography, ultrasound and Computed Tomography (CT) has increased over the years. Only a few decades ago, when imaging was not widely available and its diagnostic accuracy was low, patients would immediately proceed to the operating theatre. However, many causes can be treated conservatively and do not need diagnostic laparoscopy and laparotomy.[3]

The terms "acute abdomen" and "abdominal emergency," which are constantly applied to such cases signify the need for prompt diagnosis and early treatment. Patients presenting with acute abdominal condition, which often requires an immediate surgical intervention and is one of the commonly encountered emergencies in the practice of General Surgery.[4,5] Very often an accurate diagnosis cannot be made without surgery and many wonders are revealed on opening the abdomen. So it is often the last court of appeal in investigating abdominal cases.[6] The "aim of this study" was to study various diagnostic modalities, their effectiveness and treatment modalities in patients presenting with "Non-Traumatic Acute Abdomen in Central India."

MATERIALS AND METHODS

This is a prospective study of 98 patients of non-traumatic acute abdominal cases conducted in a Tertiary Care Hospital of Central India. In our study, all routine blood investigations were carried out and relevant radiological investigations like abdomen x-ray, ultrasound whole abdomen was done in majority of patients and CT scan was done wherever needed.

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The Sensitivity, Specificity, Positive Predictive Value and Negative Predictive Value of Computerised Tomography Scan is given below

Sensitivity:	81.81%
Specificity:	25%
Positive Predictive Value:	60.0%
Negative Predictive Value:	50.0%

(N = 98)

Type of Management	No.	%
Open surgery	88	92.6
Laparoscopic surgery	09	9.2
Conservative	01	1.0
Total	98	100.0

Table 5. Distribution of Patients according to Type of Management

As per above table out of 98 patients open surgical management was done in 88 (92.6%), while laparoscopic surgery was done in 9 (9.2%) and conservative management was done in only 1 (1.0%) of the total patients studied.

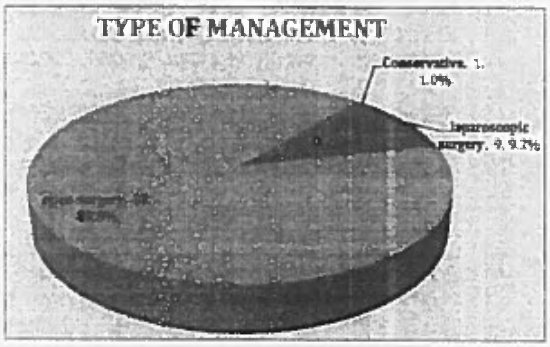

Figure 2. Pie Diagram showing Type of Management [Ref. Table No. 5]

(N = 39)

Site of Perforation	No.	%
Ileal	18	46.2
Gastric	14	35.9
Appendicular	2	5.1
Jejunal	2	5.1
Caecal	2	5.1
Sigmoid	1	2.6
Total	39	100.0

Table 6. Distribution of Cases of Perforation Peritonitis on the Basis of Site of Perforation

In our study, perforation peritonitis was seen in 39 patients. Of these 39 patients, perforation which formed the major cause of acute abdomen in the study was found to be ileal in 18 (46.2%) followed by gastric in 14 (35.9%).

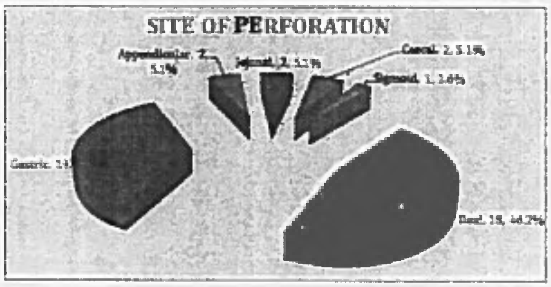

Figure 3. Pie Diagram showing Sites of Perforation [Ref. Table No. 6]

(N = 3)

Ruptured Liver Abscess	No.	%
Surgical	2	66.7
Laparoscopic drainage	1	33.3
Total	3	100.0

Table 7. Treatment of Ruptured Liver Abscess

There were 3 cases of ruptured liver abscess. Of these 2 (66.7%) were managed surgically, while laparoscopic drainage was done in 1 (33.3%) of the total patients studied.

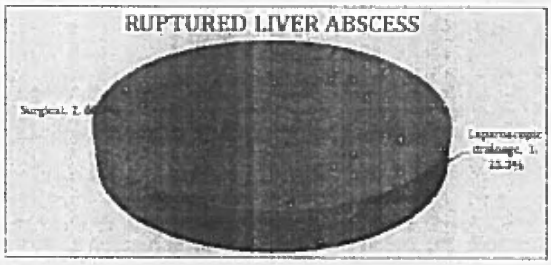

Figure 4. Pie Diagram showing Management of Ruptured Liver Abscess [Ref. Table No. 7]

(N = 13)

Aetiology	No.	%
Adhesions/bands	9	69.2
Volvulus	2	15.4
Foreign body	1	7.7
Internal hernias	1	7.7
Total	13	100.0

Table 8. Aetiology of Cases of Intestinal Obstruction

Intestinal obstruction was seen in 13 cases in our series. Of these, most common aetiology was found to be adhesions/bands in 9 (69.2%) followed by volvulus in 2 (one caecal and one sigmoid) (15.4%), foreign body and internal hernias in only 1 (7.7%) of the total patients studied.

role in making decision regarding surgery[7] and to know various treatment modalities in patients presenting with non-traumatic acute abdomen in a tertiary care hospital of Central India.

Investigations

In our study, abdomen x-ray is the investigation with highest sensitivity (95.2%) followed by ultrasound abdomen (93.65%). In a similar study done by K. Gupta et al[8] in 2005, where ultrasound is the investigation of choice with highest sensitivity (98.3%) followed by abdomen x-ray (70.9%). Hence, results in our study are different with the findings of the study done by K. Gupta et al.

Type of Management

In the present study, majority of patients were treated by open surgical method (92.6%) and some patients by laparoscopic surgery (9.2%). In a similar study done by Ferdinando Agresta et al[9] in 2004 where majority of patients were treated by laparoscopic surgery (94.1%), while less by open surgical method (5.8%). Hence, results in our study regarding type of management are different from the study done by the author.

Site of Perforation

In our study, the most commonest site of perforation peritonitis is ileal (46.2%) followed by gastric (35.9%). In a similar study done by Rajender Singh Jhobta et al[10] in 2006, where the most commonest site was duodenal (57%) followed by ileal (15%) and study done by Memon et al[11] in 2008, the commonest site was gastric (14.6%) followed by ileal (5.9%). Hence, findings in our study regarding site of perforation is different as compared with the findings of other authors.

Treatment of Ruptured Liver Abscess

In our study, majority of patients of ruptured liver abscess were treated by open surgical method (66.7%). In a similar study done by Jin Fu Tu et al[12] in 2011, majority of patients of ruptured liver abscess were treated by open surgical method (58.06%). Hence, findings in our study is similar to findings of Jin Fu Tu et al.

Aetiology and Management of Intestinal Obstruction

In our study, the common cause of intestinal obstruction is adhesions/bands (69.2%) followed by volvulus (15.4%). In a similar study done by Patrick G. Jackson et al[13] in 2011, the common cause is adhesions/bands (60%) followed by neoplasm (20%). Hence, our study on aetiology of intestinal obstruction matches with the study done by the author.

In our study, majority of cases of intestinal obstruction were managed by open surgical method (85.7%) and few cases by laparoscopic surgical management (7.1%) and remaining by conservative management (7.1%). In a similar study done by Adhikari Souvik et al[14] in 2010, majority of cases were managed by open surgical method (78.4%), while conservative management was done (14.17%) and in a similar study done by Mohamed AY et al[15] in 1997 majority of patients were managed by open surgical method (73%) and conservative management (27%). So our findings match with the findings of other studies and the standard treatment of acute intestinal obstruction is by surgery only.

Patients Treated by Laparoscopy

In present study out of nine patients in which laparoscopic surgery was done for management in majority of patients laparoscopic appendicectomy was done (33.3%) for acute appendicitis, diagnostic laparoscopy with appendicectomy (22.2%), laparoscopic cholecystectomy (22.2%) for gall bladder pathology, while laparoscopic adhesiolysis (11.1%) of intestinal obstruction. In a similar study done by Edvaldo Fahel et al[16] in 1999, where laparoscopic appendicectomy (44.15%) was done for acute appendicitis followed by laparoscopic cholecystectomy (21.4%) for gall bladder pathology. Thus, we conclude that in an era of laparoscopic surgery, it has been the "gold standard" for many elective procedures and has been used in abdominal emergencies for diagnosis as well as for treatment purposes. Different positions of appendix found during appendicectomy in the present study, the commonest position of appendix found during appendicectomy is retrocaecal (81.1%) followed by pelvic (10.1%). In a similar study done by Patel KG et al,[17] in 2013 the commonest position of appendix found during appendicectomy is retrocaecal (62%) followed by pelvic (13%). Hence, our study on different positions of appendix found during appendicectomy matches with the study done by author.

CONCLUSION

The increasing incidence of cases of non-traumatic acute abdomen is a diagnostic dilemma for the surgeons and warrants early recognition and prompt treatment to avoid major morbidity and mortality. Acute abdomen is often a surgical emergency and a challenge to any surgeon. Abdominal pain is a common presenting complaint in the emergency department and surgeons must consider multiple diagnoses, especially in those cases that require immediate intervention in order to limit morbidity and mortality. Rigorous approach to diagnosis is mandatory. It is extremely important for surgeons to develop the skill of identifying patients with an "acute abdomen" requiring immediate surgical intervention. Our study is a sincere attempt to know the sensitivity of diagnostic modalities, treatment protocol in non-traumatic acute abdomen cases presenting in tertiary care centre in Central India.

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ORIGINAL ARTICLE

CERVICAL TUBERCULAR LYMPHADENITIS:EVALUATION OF DIAGNOSTIC MODALITIES

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ABSTRACT: The diagnosis of cervical tuberculous lymphadenitis has been performed by histological examination using excisional biopsy specimens. However a non-invasive diagnostic procedure alternative to invasive excisional biopsy has been required and fine needle aspiration cytology as well the polymerase chain reaction (PCR) techniques have become useful modalities. The aim of this study was to evaluate and compare different diagnostic modalities and establish their effectiveness in current conditions. We performed a retrospective study of two hundred patients of tuberculous cervical lymphadenitis admitted in the department of surgery, SAIMS Medical college and PG institute in a two year period from January 2011 to December 2012. Excision biopsy specimens and needle aspiration specimens were collected from all patients who were suspected as having cervical tuberculous lymphadenitis on the basis of clinical features, Mantoux test and other diagnostic techniques. The histopathological positive rates, the time period necessary for diagnosis, the rupture rate of the local skin lesion and the detection ratio of mycobacterium were compared between the two percutaneous approaches. The diagnosis of tuberculous lymphadenitis was successful in all cases either by cytological examination or with the histological approach. The sensitivity and the diagnostic efficacy of FNAC in detecting tubercular lymphadenitis were 87% and 80% respectively. The rupture rate of the local skin after the excisional biopsy was higher than that of the needle aspiration procedure . The time required for diagnosis was significantly longer than that of the needle aspiration procedure . Fine needle aspiration cytology is highly recommended as a less invasive method of diagnosis of cervical tuberculous lymphadenitis, but excision biopsy and histological examination is the gold standard.

INTRODUCTION: Cervical lymphadenitis is the most common head and neck manifestation of tubercular infections. The incidence of tubercular cervical lymphadenitis has increased either as a manifestation of a systemic tuberculous disease or a unique clinical entity localized to neck. It remains a diagnostic and therapeutic challenge because it mimics other pathologic processes and yields inconsistent physical and laboratory findings.

A high index of suspicion is needed for the diagnosis of tubercular cervical lymphadenitis. A unilateral single or multiple painless lump, mostly located in posterior cervical or supraclavicular region can occur. A thorough history and physical examination, tuberculin test, staining for acid-fast bacilli, radiologic examination, fine-needle aspiration and PCR will be very helpful in arriving at an early diagnosis and institution of treatment before a final diagnosis can be made by biopsy and culture. Tubercular lymphadenitis is best treated as a systemic

Fine Needle Aspiration Cytology

Pathology	Number	Percentage
Tubercular	156	78
Reactive	24	12
Malignant	17	8.5
Others	3	1.5
Total	200	100

Excision biopsy

Pathology	Number	Percentage
Tubercular	138	69
Reactive	18	9
Malignant	38	19
Others	6	6
Total	200	100

COMPARITIVE ANALYSIS OF DIAGNOSTIC MODALITIES

		excision biopsy	
		tubercular	non tubercular
fine needle aspiration cytology	tubercular [156]	136 [tp]	20 [fp]
	non tubercular[44]	20 [fn]	24 [tn]
		excision biopsy	
		malignant	non malignant
fine needle aspiration cytology	malignant [17]	16 [tp]	1 [fp]
	non malignant [183]	22 [fn]	161 [tn]

A] TUBERCULOSIS

	FNAC	PERCENTAGE
SENSITIVITY	0.87	87.2
SPECIFICITY	0.54	54.5
POSITIVE PREDICTIVE VALUE	0.87	87.2
NEGATIVE PREDICTIVE VALUE	0.54	54.5
DIAGNOSTIC EFFICACY	0.80	80

B] MALIGNANCY

	FNAC	percentage
sensitivity	0.42	42.1
specificity	0.99	99.3
positive predictive value	0.94	94.1
negative predictive value	0.87	87.9
diagnostic efficacy	0.88	88.5

lymphadenopathy. We took the results confirmed by biopsy and histopathology as standard against which the results obtained by FNAC were compared. We found the sensitivity of FNAC in diagnosing Tubercular cervical lymphadenitis was 87% and specificity was 54%.
Manitchotpisit et al had shown sensitivity and specificity of 48% and 87.5% respectively in the diagnosis of cervical tuberculosis on FNAC.[9]

Many studies have found FNAC as an highly sensitive and specific tool for the diagnosis of metastatic malignancies.

In our study 17 cases were diagnosed as having metastatic carcinoma on FNAC. 22 cases of metastatic carcinoma were missed on FNAC which were picked by histopathology.

Thus sensitivity and specificity of FNAC in detecting malignant lymph node was 42% and 99% respectively.

This was in sharp contrast to a similar study done by Shahzad Et al who found sensitivity to be 95% with 100% positive predictive value.[10]

Squamous cell carcinoma is the commonest malignancy presenting in the cervical lymph nodes, metastasizing from upper aero digestive tract a fact validated in our study.

Thus in our study we found that the sensitivity and the diagnostic efficacy of FNAC is very high in diagnosing tubercular cervical lymphadenitis. Though in our study the sensitivity of FNAC in diagnosing metastatic lymphadenopathy was low but the specificity was very high [99%].so our study clearly highlights the diagnostic importance of FNAC in patients of cervical lymphadenopathy.

The relative sensitivities of different procedures and the potential therapeutic benefits should be considered in making the choice of diagnostic approach. Excisional biopsy is the most invasive approach to diagnosis; however, it has the highest sensitivity and may produce a more rapid and favorable symptomatic response [11] and has been recommended in cases involving multiple nodes [12]. Rare complications of biopsy include the rupture of the local skin lesion, postsurgical pain, wound infection, sinus formation, non healing ulcer and scar [13]. In a study from Hong Kong, 80% of specimens from excision biopsy yielded positive culture results, compared with 17% from fine-needle aspiration (FNA) specimens [14].

CONCLUSION: Histopathology is most rewarding for diagnosis of cervical lymphadenitis, its Feasibility is limited due to lack of facilities and non-acceptability, being an invasive procedure. Previously, biopsy was used for diagnosis of tubercular lymphadenitis; now FNAC is greatly replacing it because of it being a noninvasive, simple and cost effective procedure which can easily be done in office or outpatient sitting.

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A STUDY OF ABDOMINAL GOSSYPIBOMA

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ABSTRACT

BACKGROUND

Gossypiboma or textiloma is a term specifically coined to describe a retained surgical sponge in the body after a surgical procedure. Any foreign body accidentally left in the abdomen often requires reoperation for its removal which increases the morbidity of the patient, cost of treatment and medico legal problems. The aim of this research is to study the incidence, presenting features, management and outcome of Abdominal Gossypiboma. Design: Retrospective study. Setting & Duration: Department of Surgery, Sri Aurobindo Medical College & PG Institute, Indore, from 2005 to 2015. Patients: Patients presenting with a history of previous surgery, signs of an abdominal lump or acute abdomen, which turned out to be a Gossypiboma either in radiological investigations or during surgery were included in the study.

METHODOLOGY

The data of patients who underwent Laparotomy in last 10 years was collected from Medical Records Department and the cases of Abdominal Gossypiboma were selected. All the patients were clinically evaluated and radiological examinations of patients were done to confirm diagnosis. Every patient was optimized and subjected to Laparotomy.

RESULTS

A total of 6889 laparotomy operations were performed during this period, which translate incidence of Abdominal Gossypiboma to be one in 574 operations. A total number of 12 patients of Gossypibomas were studied, which presented with signs and symptoms of an abdominal mass with or without signs of acute abdomen. X-ray findings were foreign body with whorl appearance and gas bubbles. Ultrasound revealed hypo-echoic densities with encapsulation. Exploratory laparotomy was done in all the 12 cases.

CONCLUSION

Gossypiboma is rare but serious complication of any surgical procedure and hence every possible measure should be taken to prevent its occurrence. We recommend the adoption of a very systematic swab and instrument counting policy to prevent this complication.

KEYWORDS

Retained Sponge, Gossypiboma, Medico-legal.

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INTRODUCTION

Gossypiboma, is a term derived from the combination of Latin words "Gossypium" meaning cotton and Swahili word "Boma," which means place of concealment. It is a mass within the body consisting of a surgical sponge (Cotton matrix) surrounded by an inflammatory reaction. Surgical sponge left involuntarily inside a body cavity is a serious, but avoidable complication.

In the abdomen the surgical sponge or any foreign body can be surrounded by omentum and intestines, which attempt to encapsulate it in order to localize any foreign body reaction, but in the process various grievous complications can take place.

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The pressure and irritation on the intestines can hamper the blood supply and lead to gangrene of the bowel loops with the sponge eroding through its walls into the lumen. This can lead to intestinal obstruction, fistula formation or gangrenous bowel.

The reported incidence of gossypiboma is one in 100-5000 operations. Occurrence of this complication is very rare in western countries due to their strict adherence to operation theatre policies.

METHODOLOGY

We searched the medical records of all the patients who had undergone Laparotomy surgery during the study period of 10 years, i.e. from 2005 to 2015. We found a total of 12 confirmed cases of Abdominal Gossypiboma [Retained Surgical Sponge] after going through the medical records. All of these patients were treated in Department of Surgery, Sri Aurobindo Medical College and PG Institute during this period.

This medical college is a tertiary care centre of central India, catering to a large number of population from Madhya Pradesh state and the surrounding states. Relevant data about these 12 patients was retrieved from the Medical Records Department. The collected data was analysed and recorded in the parameters of age, sex, details of previous surgery, clinical

The investigations used for evaluation were erect abdominal radiograph, ultrasonography abdomen and CT scan of abdomen apart from routine haematological and biochemical tests.

Preoperative diagnosis of retained surgical sponge was made in 9 cases, while in 3 cases the confirmed diagnosis was possible during surgery only.

During surgery, in the cases which were diagnosed as intestinal obstruction [4 cases], the retained sponge was found between intestinal loops covered by fibrous tissues and causing dense adhesions between the bowel loops. Sharp dissection was done to separate the entangled bowel loops and the sponge was removed without damage to the adhered bowel loops.

Out of the 3 cases which were diagnosed as perforation peritonitis, in case no. 1 the retained sponge was found eroding the anterior wall of stomach. The sponge was removed and the rent in stomach was repaired in 2 layers. In case no. 2, the retained sponge folded in 2 layers was lying embedded in the transverse mesocolon and causing a large perforation on the mesenteric border of transverse colon. The sponge and involved part of mesocolon was removed and primary repair of colonic perforation was done in two layers. This patient developed a leak from the repair site in the postoperative period and subsequently burst abdomen. Relook laparotomy was done and the transverse loop colostomy was fashioned. While in Case No. 3, the sponge was forming an inseparable cocoon with loops of small bowel. Resection of involved segment of about one foot of Jejunum and end-to-end jejunojejunal anastomosis was done.

Out of the 5 patients who presented with asymptomatic lumps during surgery, the sponge was found at various places like adhered to anterior abdominal wall, uterus and adnexa, splenic fossa, etc. In Case No. 8, the sponge was found adhered to anterior abdominal wall and small bowel loops and left adnexa. While the other locations were right paracolic gutter [Case No. 9], pelvis [Case No. 10], splenic fossa [Case No. 11] and uterus and adnexa [Case No. 12]. In all cases, the sponge was removed by meticulous dissection without damage to adhered structures.

The patients who underwent planned laparotomies for asymptomatic lumps had uneventful recovery with no morbidity. Out of 4 patients of intestinal obstruction, 2 patients had prolonged ileus and 3 patients had wound related complications like seroma, pus discharge, etc. which were managed by conservative methods.

Out of the 3 patients of perforation peritonitis, all had wound related complications and 1 had burst abdomen [Case No. 2]. One patient [Case No. 2] developed a leak from repaired transverse colon perforation, which was detected on 5th POD. Relook laparotomy was done and loop transverse colostomy was fashioned. There was no mortality in our study.

Case No.	Case Diagnosis	Operation Done	Intra-Operative Findings	Post-Operative Complications
1.	Perforation Peritonitis	Exploratory Laparotomy	Sponge Causing Gastric Perforation	Wound Seroma
2.	Perforation Peritonitis	Exploratory Laparotomy	Sponge Eroding Transverse Colon	Burst Abdomen and Re-Exploration
3.	Perforation Peritonitis	Exploratory Laparotomy	Sponge Forming Inseparable Cocoon with Small Bowel Loops	Wound Pus Discharge
4.	Intestinal Obstruction	Exploratory Laparotomy	Sponge Adhered to Distal Ileum and Caecum	Prolonged Ileus
5.	Intestinal Obstruction	Exploratory Laparotomy	Sponge Adhered to Ileal Loops	Wound Seroma
6.	Intestinal Obstruction	Exploratory Laparotomy	Sponge Adhered to Jejunal Loops	Wound Pus Discharge
7.	Intestinal Obstruction	Exploratory Laparotomy	Sponge Adhered to Ileal Loops and Sigmoid Colon	Prolonged Ileus and Wound Seroma
8.	Abdominal Lump	Exploratory Laparotomy	Sponge Densely Adherent to Anterior Abdominal Wall, Small Bowel Loops & Left Adnexa	None
9.	Abdominal Lump	Exploratory Laparotomy	Sponge in Right Paracolic Gutter with Flimsy Adhesions to Small Bowel Loops	None
10.	Abdominal Lump	Exploratory Laparotomy	Sponge Lying in Pelvis and Adherent to Surrounding Structures	None
11	Abdominal Lump	Exploratory Laparotomy	Sponge in Splenic Fossa and Adherent to Parieties	None
12.	Abdominal Lump	Exploratory Laparotomy	Sponge Adhered to Uterus and Right Adnexa	None

Table 2: Table Showing Intraoperative Findings and Post-Operative Complications after Gossypiboma Surgery

DISCUSSION

Gossypiboma or retained sponge is an important topic of discussion, as it leads to significant embarrassment and can lead to humiliation and lawsuit as well. The reported incidence of gossypiboma varies in different studies and the actual number is difficult to ascertain, because of low reporting rate due to medico legal implications.[1] In world literature, various authors like Noyle,[2] Zbar,[3] and Risher,[4] have reported incidence of Gossypiboma to be one in 100 to 5000 operations. In our study, incidence was found to be 1 in 574 operations.

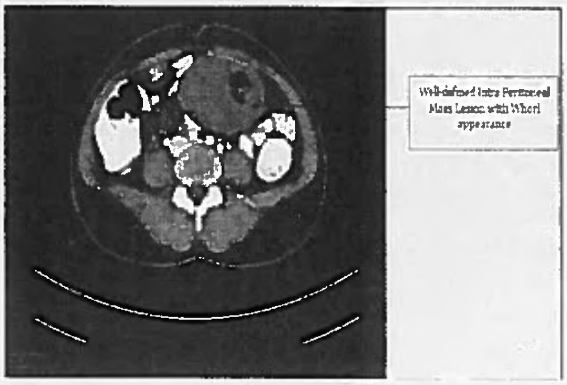

Fig. 2: CT Scan Coronal View of a Patient of Gossypiboma [Case 8]

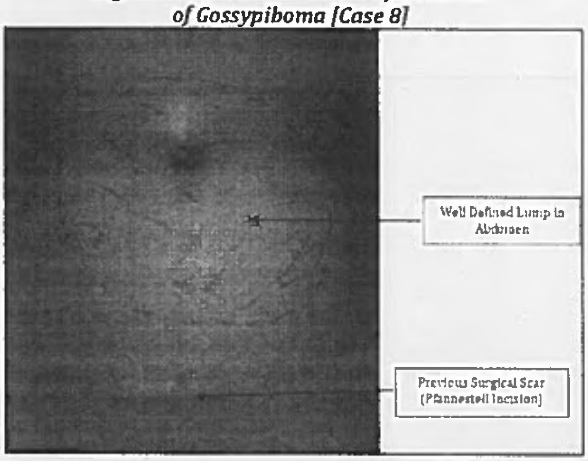

Fig. 3: Photograph of a Patient showing Abdominal Lump and Scar of Previous Surgery [Case 7]

Fig. 4: Intraoperative Photograph showing Gossypiboma Adhered to Adnexa [Case 12]

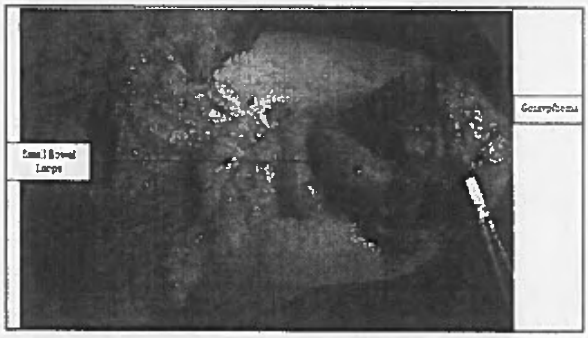

Fig. 5: Intraoperative Photograph showing Gossypiboma Adhered to Small Bowel Loops [Case 5]

Fig. 6: Intraoperative Photograph showing Gossypiboma Adhered to Transverse Mesocolon and Adjacent Structures [Case 2]

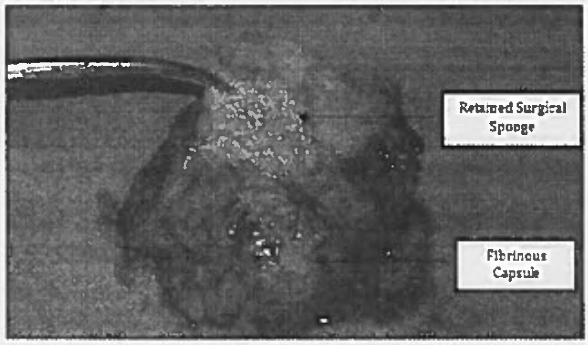

Fig. 7: Photograph of Specimen showing Retained Sponge Inside a Fibrinous Capsule [Case 10]

CONCLUSION

Gossypiboma is a rare, avoidable, but serious postoperative complication. It is usually asymptomatic and generally has nonspecific clinical findings. Hence, the diagnosis is often delayed. Abdominal Gossypiboma can cause wide variety of complications like perforation of viscera and adhesion to the adjacent structures. It can also be a cause for serious medico-legal problems. It is best to avoid gossypiboma. The surgeons should comply with the current recommendations on the prevention of retained foreign bodies including use of radiological markers and routine pre- and post-operative sponge count. Gossypiboma should be included in the differential diagnosis of soft-tissue masses or localized abdominal pains in patients with a history of prior operation.

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Management of various rare and atypical hernias: experience at a tertiary care centre in central India

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ABSTRACT

Background: Abdominal wall hernias are most frequently encountered in surgical practice accounting for 15% - 18% of all surgical procedures. The incidence of abdominal wall hernia in different countries varies from 100 -300/100000 per year. Of which most common being the inguinal hernias and femoral hernia being the least common. Midline ventral hernias are the next common variety of abdominal wall hernia after inguinal hernia. Ours is a tertiary care hospital, medical college and PG institute in central India. Apart from routine hernias, we have managed successfully some very rare varieties and developed management protocols. Here we are providing an analysis of these unusual presentations.

Methods: This is a retrospective study in which we analyzed the data's of hernia patients presented in our institute over the period of 7 years (2008-2014). Out of 765 patients, who were diagnosed having hernia, 680 were operated in our institute. Among these cases, we have selected 12 very rare and unusual cases which stood as diagnostic and management challenge and which were operated by a single surgeon and his team.

Results: Out of the 12 cases of atypical hernias, 11 patients underwent surgical intervention. There was no mortality. 6 patients had some postoperative complications which were managed during their Hospital stay only. After discharge, all the patients were followed at regular intervals. There was no recurrence or other complication noted in 1 year follow up. Most common post-op complication was seroma which was seen in 50% of the operated patients. Other complications were wound infection (16.66%) and wound dehiscence (8.33%).

Conclusions: The infrequent encounter with the unusual varieties of Hernias can lead to the mental bias and becomes a diagnostic challenge for the general surgeon. The purpose of publication of these rare varieties is to increase our spectrum of knowledge and to provide diagnostic and therapeutic armamentarium to deal with these difficult situations.

Keywords: Hernia, Supra pubic cystotomy, Enterocutaneous fistula, Femoral, Amayand's

INTRODUCTION

Hernia is derived from a Latin word meaning "a rupture". Abdominal wall hernias are most frequently encountered in surgical practice accounting for 15% - 18% of all surgical procedures.[1,2] Worldwide, more than 20 million hernias are operated per year.

The incidence of abdominal wall hernia in different countries varies from 100-300/100000 per year.[3] Of which most common being the inguinal hernias and femoral hernia being the least common. Midline ventral hernias are the next common variety of abdominal wall hernia after inguinal hernia, most common after interventions involving the lower abdomen (incisional hernia). According to their locations, these are further

The following cases and their management have been discussed in detail.

In both the cases of SPC site Hernia, previous SPC tract and hernia sac were isolated and excised, a new SPC tract was created 5 cm below and lateral to old site, hernia defect was closed, anterior rectus sheath was reconstructed and wide synthetic polypropylene mesh was placed.

Inonecase of Femoral hernia, the clinical and radiological diagnosis was inguinal hernia and the correct diagnosis of femoral hernia was established intraoperatively only. In the remaining 2 cases, femoral hernia was diagnosed through clinical and radiological methods. Lotheissen repair was done in all cases.

Two cases of inguinal hernia with fecal fistula were dealt in our hospital. Out of which one presented after Incision & Drainage of neglected obstructed inguinal hernia which was misdiagnosed as inguinal abscess and the other one presented with spontaneous fecal fistula. These two cases were managed in a similar manner with exploratory laparotomy and resection of obstructed fistulous ileal loopswith end to end Ileo-ileal anastamosis. Herniorrhaphy was done and inguinal area left opened for healing by secondary intention.

Two cases of incisional hernia with enterocutaneous fistulas were treated. One had the history of previous laparatomy and incisional hernia surgery, and the other had the history of previous 2 Caesarean sections and incisional hernia surgery. Exploratory laparotomy with resection of involved part of small intestine and end to end anastamosis of normal bowel was done. In first case, the previously placed mesh was found eroding into the bowel lumen and it was removed. Anatomical reconstruction of anterior abdominal wall was done in both the cases.

Three cases of Amayand's Hernia were managed. Intraoperatively, there was caecum with inflamed appendix as the content of hernia sac in both the cases. Appendicectomy with Hernioplasty was done.

One case of very rare Thoracic hernia was diagnosed. A60 year old male presented with a bulge over left chest wall since one year. The swelling was moving with respiration and coughing. He didn't have any history of thoracic surgery or chesttrauma. USG& HRCT chest showed a protrusion of lung through the intercostal space during valsalva and coughing. He was a known case of chronic obstructive pulmonary disease with severe pulmonary hypertension. Intervention was not done because patient was not fit for surgery.

Table 2: Showing post-op complications, postoperative stayand herniarecurrences.

Type of Hernia	Total no of cases	Post-op complications				Average post-operative stay(days)	Recurrences after 1 year
		Seroma	Infection	Wound dehiscence	Mesh infection		
SPC site hernia	2	1	0	0	0	8	No
Femoral hernia	3	2	0	0	-	5	No
Inguinal heruia presenting as fecal fistula	2	1	1	0	-	10	No
Incisional hernia with enterocutaneous fistula	2	1	1	1	-	15	No
Amayand's hernia	3	1	0	0	0	5	No
Total	12	6	2	1	0		-

Above table highlights the post operative complications and overall hospital stay after surgery. We found that the most common complication was Seroma formation that was seen in 6 out of 12 patients operated (50%). Wound infection was seen in 2 patients (16.66%), while wound dehiscence was seen in only 1 patient (8.33%).

The polypropylenemesh was placed in 5 of the 12 operated patients but mesh infection was not seen in any of them.

Out of two patients of inguinal hernia with fecal fistula, one patient developed Seroma while the other had wound infection. Out of the two patients of incisional hernia with enterocutaneous fistula, one patient developed only Seroma, and the other developed wound infection and later on, wound dehiscence also.

In cases of femoral and amayand's hernia , the only complication seen was Seroma formation that developed in 2 out of 3 femoral hernia cases and 1 out of 3 Amayand's hernia cases.

al[11] from Nigeria reported the case of a neglected Richter's inguinal hernia presenting with perforation and Fournier's gangrene. Three cases of spontaneous perforation of Richter's inguinal hernia with Fournier's gangrene were reported by Guzzo et al[12] in 2007 from the United States of America. One of our patient presented with spontaneous onset fecal fistula without any previous signs and symptoms of hernia and the other was a neglected undiagnosed obstructed inguinal hernia which was misdiagnosed as an inguinal abscess at the periphery and disastrous I & D was done. These finding were very unusual and final diagnosis was established by CECT abdomen and surgery was done. We do not recommend the use of mesh in the setting of abscess or fecal fistula. A good tightening of deep ring during laparotomy and free drainage from fistula site leads to healing and recurrence is prevented.

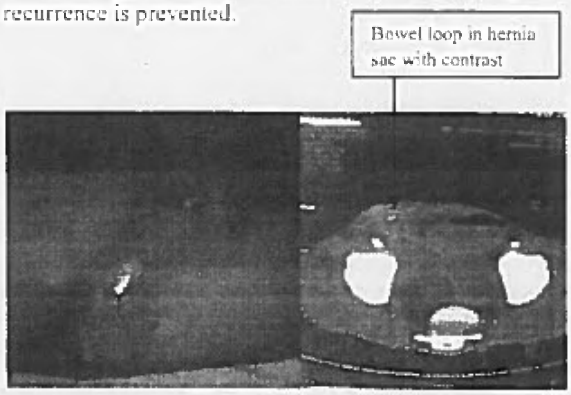

Figure 3 (a): Pre op. Figure 3 (b): CT scan.

Figure 3 (c): CT scan. Figure 3 (d): Post op.

Figure 3: Inguinal hernia as fecal fistula.

Incisional hernia with enterocutaneous fistula

Mesh hernia repair is a fairly common technique used to treat incisional hernias. Meshes have advantages and disadvantages. Whether meshes can cause enterocutaneous fistula, is a matter of debate. There are some studies which are against this possibility,[13,14] but there are also some studies in support of it.[15,16] In our case series, both the patients presented with recurrence of hernia along with enterocutaneous fistula few years after mesh repair for incisional hernia. In the first case, the incisional hernia had developed after Laparotomy, and in the other, the incisional hernia had developed after previous 2 Caesarean Sections. This suggests that a mesh can erode the bowel and that patients have a lifelong risk of this complication. We recommend the removal of whole involved mesh along with the resection of the involved part of intestine in such setting. The Anatomical repair of hernia can be done in such cases where the use of mesh is not indicated.

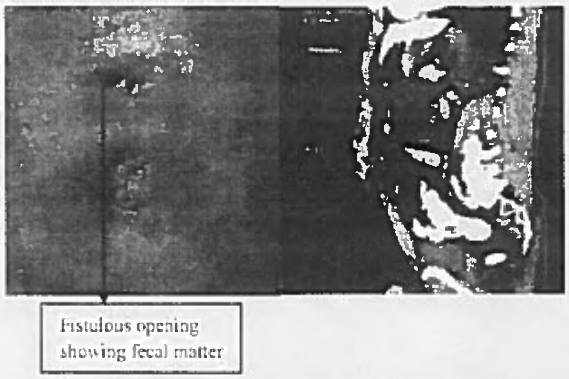

Figure 4 (a): Pre op. Figure 4 (b): CECT.

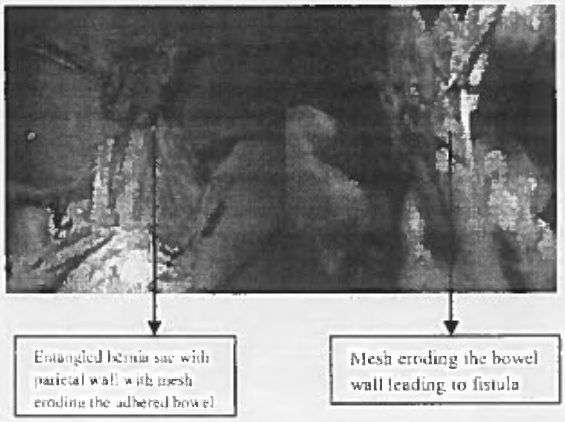

Figure 4 (c): Intra op-1. Figure 4 (d): Intra op-2.

Figure 4: Recurrent incisional hernia presenting as multiple enterocutaneous fistula.

Amayand's hernia

Amayand's hernia is named after Claudius Amayand (1680-1740), a French refugee and English surgeon who did the first recorded successful appendectomy in a case of hernia with appendicitis. When a hernial sac contains vermiform appendix, inflamed or un-inflamed, it is called as an Amayand's Hernia. True incidence of this condition is difficult to estimate as all the cases are not registered and reported. Ryan WJ et al[17] have reported only 11 cases of appendicitis out of 8692 (0.13%) cases of hernial sacs with appendix. D. Alia et al[18] observed presence of

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AN OBSERVATIONAL STUDY OF AETIOPATHOGENESIS, CLINICAL PROFILES AND MANAGEMENT OF NEONATAL NECROTISING ENTEROCOLITIS

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ABSTRACT

BACKGROUND
Necrotising enterocolitis is the commonest life threatening acquired gastrointestinal emergency of neonates in which lining of the intestinal wall gets necrosed. Although exact aetiology remains obscure, multiple factors like birth asphyxia, prematurity, low birth weight and use of certain drugs have been associated with necrotising enterocolitis.

MATERIALS AND METHODS
This observational study was carried out on 20 patients of neonatal necrotising enterocolitis in a tertiary care and referral hospital of Indore for a period of two and half years.

RESULTS
Eighty percent of patients were preterm births with low birth weight. Most of the cases (66%) presented in the first week of neonatal period. The Ileocaecal region was the most common part involved. Necrotising enterocolitis has significandly high mortality rate. In our study, 80% of cases died due to severe form of disease with associated morbidities.

CONCLUSION
With this study, we made an attempt to formulate a protocol to make an early diagnosis and to reduce the overall mortality.

KEYWORDS
Necrotising Enterocolitis (NEC), Low Birth Weight, Prematurity.

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BACKGROUND
Neonatal necrotising enterocolitis is the commonest life threatening acquired gastrointestinal emergency encountered in neonatal ICU in which the lining of intestine wall gets necrosed. In medical literature, clinical description of the condition matching with necrotising enterocolitis dates back to about two centuries. Siebold (1825),[1] Simpson (1838)[2] and Zilher (1883)[3] were the first few who reported cases suspected to have necrotising enterocolitis. There are few studies in the world literature, which have discussed some or the other parameter about this condition, but there was a need for a comprehensive study to analyse all the factors related to NEC.

The aim of our study was to make a comprehensive review of all the factors related to neonatal NEC and formulate a protocol to make early diagnosis by clinical picture and investigations so that management of these neonates can be improved and mortality can be reduced.

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MATERIALS AND METHODS
This prospective observational study was carried out between May 2004 to Oct. 2006 in the Department of Surgery, M.G.M. Medical College and M. Y. Group of Hospitals, Indore which is a tertiary care centre of central India.

Inclusion Criteria
All the patients who were admitted with suspected diagnosis of neonatal necrotising enterocolitis and later on confirmed by diagnostic modalities and/or surgery.

Exclusion Criteria
1. Patients which did not complete full treatment.
2. Patients who did not give consent to participate in the study.

All the patients included in the study were thoroughly examined and subjected to investigations as per need. The relevant data was recorded in a fixed proforma that included demographic profile, preoperative investigations, intraoperative findings and postoperative followup. At the end of study, the tabulated data on master chart was analysed by simple descriptive statistical method of percentages. Detailed review of literature was done and results of study were compared with other studies.

Findings	Abdominal Distension	Tenderness	Rigidity	Guarding	Visible Veins	Hypothermia	Ant. Abdomen Wall Erythema
Number	20	17	14	14	2	7	5
Percentage	100%	85%	70%	70%	10%	35%	25%

Table 9. Abdomen Examination Findings at Presentation

On studying the local examination findings of abdomen [Refer table No. 9], it was observed that the most frequent sign was distended abdomen (100%). Other clinical signs were tenderness (85%), rigidity (70%), guarding (70%), visible veins over the anterior abdominal wall (10%) and anterior abdominal wall erythema (25%). About 35% patients had temperature instability in form of hypothermia.

C-reactive protein	Positive	Negative
Number	17	03
Percentage	85%	15%

Table 10. C-reactive Protein Distribution N=20

Analysis of C- reactive protein was done in all the patients of NEC [Refer Table no 10] and it was observed that seventeen out of 20 Patients (85%) had raised C reactive protein value.

Radiological Findings	Persistent Dilated Bowel Loops	Pneumo- peritoneum	Pneumatosis Intestinalis
Number	8	7	5
Percentage	40%	35%	25%

Table 11. X-Ray of Abdomen

In our study, x-ray of abdomen was done in all the cases [Refer Table No. 11].

We observed that 40% of patients had findings of persistent dilated bowel loops in the consecutive x-rays, 35% showed findings of pneumoperitoneum in their x-rays and 25% of patients had pneumatosis intestinalis, which is the hallmark of NEC.

Treatment Modalities	Surgery	Conservative
No. of Patients	11	9
Percentage	55%	45%

Table 12. Treatment Modalities Used N=20

The management of the patients was decided on the basis of clinical and radiological parameters as per the protocol. We observed that 11 patients were managed surgically and 9 patients were managed conservatively. [Refer Table No. 12].

Gross Pathological Changes	Gangrenous Bowel	Perforation in the Bowel	Oedematous Bowel	Stricture in the Bowel
No. of Patients	5	4	1	1
Percentage	45.45%	36.36%	9.09%	9.09%

Table 13. Intraoperative Findings of Bowel Involvement N=11

Out of the 20 diagnosed cases of NEC, 11 cases were operated. 2 cases were planned for surgery, but they succumbed before commencement of surgery.

The most common intraoperative finding was gangrenous bowel (5 cases) and in 4 cases there were perforations in the bowel. [Refer Table no. 13]. Oedematous bowel and Stricture in the bowel as solitary findings were observed in one case each.

In 11 surgically managed cases, Exploratory Laparotomy was the operation done. Gangrenous bowel was found on exploration in 5 patients, so resection of gangrenous bowel with stoma formation was done.

Perforation in the bowel was found in 4 patients. Among them, 2 patients were managed with resection of perforated segment with anastomosis, 1 patient with primary repair of perforation and stoma formation was done in one patient.

Oedematous bowel was the only finding in 1 patient, so only peritoneal lavage was done. In 1 patient, one stricture was found in the bowel that was smoothly passable, so the bowel was left undisturbed.

Thus, the main surgical procedure was enterostomy in our study that was done in total 6 patients [54.54%].

Bowel Involved	Ileum	Caecum	Jejunum	Colon
No. of Patients	7	2	1	1
Percentage	63.63%	18.18%	9.09%	9.09%

Table 14. Segment of Bowel Involved N=11

In our study, the ileum was the most common part of bowel involved. [63.63%] [Refer Table No. 14]. In 2 cases, caecum was involved.

DISCUSSION

Siebold (1825),[1] Simpson (1838)[2] and Zilher (1883)[3] were the first few who reported cases suspected to have necrotising enterocolitis.

First survival of neonates following surgical repair of NEC is credited to Agerty[4] in 1943. Bell[5] published a severity based classification in 1978 which was modified by Walsh and Kliegem[6] in 1986.

The clinical presentations of patients of NEC were studied. We observed that all the patients of NEC presented with complaint of abdominal distension. [Refer Table no. 8]. Half (50%) of the total patients had melaena. Similar results were found by Grosfield,[12] Niyaz[8] and Echevarria et al[22] Eighteen (90%) patients had history of poor feeding. Other presenting complaints were vomiting, regurgitation and arrest of motion/flatus.

The clinical abdominal signs of patients were recorded in our study. The most frequent signs was distention of abdomen which was observed in all patients (100%). Other clinical signs were tenderness [85%], rigidity [70%], guarding [70%], visible veins over the anterior abdominal wall [10%] and anterior abdominal wall erythema [25%]. [Refer table No. 9]. Similar results were obtained in study done by Niyaz,[8] Grosfield,[12] Narang et al[17] Hamish Hwang[23] Christopher Cardot.[10] About 35% patients had temperature instability in form of hypothermia. Similar results were obtained by Niyaz[8] Hamish Hwang,[23] Christopher Cardot.[10]

Seventeen out of 20 Patients (85%) had raised C reactive Protein. [Refer Table no. 10] Similar results were obtained by Pourcyrous M.[24]

In our study, x-ray of abdomen was done in all the cases. [Refer Table No. 11]. We observed that 40% of patients had finding of persistent dilated bowel loops in the consecutive x-rays, 25% of patients had pneumatosis intestinalis [the most pathognomonic sign of NEC] and 35% showed findings of pneumoperitoneum in their x-rays. Similar results were obtained by Grosfield[12], Andreana Butter[15] Hamish Hwang.[23]

In our study, out of the 20 diagnosed cases of NEC, 11 cases were operated. 2 cases were planned for surgery, but they succumbed before commencement of surgery.

The most common pathological finding was gangrenous bowel with ischaemia (5 cases) and in 4 cases there were perforations in the bowel. [Refer Table No. 13]. Similar results were obtained by Grosfield,[12] Alda L.Tom.[25]

Exploratory Laparotomy was the operation done in 11 patients those who were managed surgically. Gangrenous bowel was found on exploration in 5 patients, so resection of gangrenous bowel with stoma formation was done.

Perforation in the bowel was found in 4 patients. Among them, 2 patients were managed with resection of perforated segment with anastomosis, 1 patient with primary repair of perforation and stoma formation was done in one patient.

Oedematous bowel was the only finding in 1 patient, so only peritoneal lavage was done. In 1 patient, one stricture was found in the bowel that was smoothly passable, so the bowel was left undisturbed.

Thus, the main surgical procedure was enterostomy in our study that was done in total 6 patients (54.54%). Similar results were obtained in the study done by Grosfield,[12] Joao Carlos,[13] Andreana Butter[14] and W B Kiesewetter.[26]

In our study, the ileum was the most common part of bowel involved. [63.63%] [Refer Table No. 14]. In 2 cases, caecum was involved. This area being more distal to the origin of the superior mesenteric artery has less blood supply and with hypoxic insult further increases the hypoxia and tissue damage. Similar results were obtained in the study done by Grosfield,[12] Niyaz[8] Kurschied T.[27]

CONCLUSION

NEC is the most common gastrointestinal emergency in the neonates. In western world, various research project has been carried out, but in our country not so many studies have been done for the NEC. So this study was carried out in Maharaja Yashwant Rao Hospital, Indore. The following conclusions were made from the study. NEC is a disease of preterm babies as their gastrointestinal tract being immature. Low birth weight is also a causative factor in the NEC. The full-term infants had early onset of NEC. This is due to earlier enteral feeding and rapid progression of feeding. Hypoxic or haemodynamic instability results in splanchnic vasoconstriction and reduced mesenteric flow inducing mucosal hypoxia and rendering the intestine susceptible to injury. High incidence in neonates who were delivered through vaginal delivery indicates that management of high risk conditions and prevention of hypoxic stress at delivery could be important in prevention of NEC. The ileocaecal region is the most common part involved as this area is being more distal to the origin of the superior mesenteric artery and has less blood supply. Since most of our cases had severe disease with multiple risk factors like prematurity, low birth weight, hypothermia, and complications like DIC, thrombocytopenia and renal failure etc, resulting in the high mortality rate. Similar results were obtained in the study done by Odita JC.[28] Our study is a modest attempt to identify and analyse various factors affecting neonatal NEC and the results of our study paves the way for further research on this topic.

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A COMPREHENSIVE STUDY OF SALIVARY GLAND TUMOURS IN A TERTIARY CARE CENTRE OF CENTRAL INDIA

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ABSTRACT

BACKGROUND

Salivary gland tumours are very common in India. The present study has analysed the incidence, clinical profile and differential diagnosis of various salivary gland tumours.

The aims of this study are to know the incidence of various salivary gland tumours in different age groups and in both sexes to know the distribution of different benign and malignant tumours in each variety of salivary glands.

MATERIALS AND METHODS

This study was conducted in a prospective and retrospective ways covering the patients admitted with salivary gland tumours in a period of 6 years from 2000 to 2006. Total 59 patients were enrolled and their data was recorded.

RESULTS

Salivary gland tumours are most common in 4th and 5th decade of life. The incidence of salivary gland tumours is almost equal in both sexes with slight female preponderance. The salivary gland most commonly found involved is the parotid. Benign neoplasms are the most common swellings of salivary glands. The most common benign tumour of salivary gland is pleomorphic adenoma. The most common location of pleomorphic adenoma is the parotid gland. The most common malignant tumour of salivary glands is mucoepidermoid carcinoma.

CONCLUSION

The present study gives some important data about salivary gland tumours and emphasises the need for a more bigger study involving a larger number of patients.

KEYWORDS

Salivary Gland Tumours, Parotid, Submandibular, Pleomorphic Adenoma.

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BACKGROUND

It is astonishing to consider how little is known of the pathological processes that affect any organ that is so near the surface, so accessible for clinical examination, so easy biopsies, so simple to obtain secretions for analysis and that organ is salivary gland.

Controversies surrounding the diagnosis and management of salivary gland masses often involve the limits of our technology. The primary controversy often lies not in how to treat a given disease, but by what means the diagnosis can be established without doubt. The present study is a modest attempt to find out the reasonable solutions of existing controversies.

The major salivary glands include parotid glands, submandibular glands and sublingual glands. There are also approximately 750 minor salivary glands scattered throughout the submucosa of the oral cavity, oropharynx, hypopharynx, larynx, parapharyngeal space and nasopharynx.

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Salivary gland neoplasms are relatively uncommon constituting 3 to 4% of all head and neck neoplasms. The incidence of salivary gland tumours is 1 to 2 cases per 100,000 people. Majority of them arise in parotid gland (70%), whereas tumours of submandibular glands (22%) and sublingual and minor salivary glands (8%) are less common. Salivary gland neoplasms most often present as slow growing, well-circumscribed masses. Symptoms such as pain, rapid growth, nerve weakness and paraesthesias and signs of cervical lymphadenopathy and fixation to skin or underlying muscles suggest malignancy.

Present study is to know the occurrence and incidence of various types of salivary gland tumours in patients presenting to M. Y. Hospital. The clinical presentation of these tumours is analysed. The differential diagnosis of these tumours is discussed. The histopathological examination reports of all cases are followed and the results analysed.

MATERIALS AND METHODS

M. Y. Hospital is a big tertiary care hospital covering a wide area with large number of admission of patients of various surgical disorders. The study was carried out in the Department of Surgery, M. G. M. Medical College and M. Y. Hospital, Indore.

Time Period

The total duration of the study was 6 years, 3 years retrospective and 3 years prospective.

DISCUSSION

The retrospective study was done from the year 2001 to 2003 and the prospective study was done from 2004 to 2006. In the retrospective group 30 cases were included and in the prospective group 29 cases were included. Thus, total 59 cases were studied.

In the retrospective group males predominated with 56.6% of the total cases, whereas females were 43.3%. In the prospective group females predominated with 58% of the total cases, whereas males were 42%. However, in the comprehensive study, the sex ratio was found to be almost equal with female comprising 51% and male 49%. Thus, the sex ratio was 0.96 with slight female preponderance. In a similar study done by Pablo Augustin et al, they have found a higher prevalence of salivary gland tumours in females (60%).[1] In contrast, Frade Gonzalez et al[2] observed a predominance of salivary gland tumours in the male group (58.75%).

The incidence of salivary gland neoplasms was most common in the 4th and 5th decade with 42.4% of cases belonging to age group 31 - 45 years, which is similar to the finding observed by Pablo Augustin et al,[1] while Frade Gonzalez et al[2] found highest incidence in the 7th decade of age.

Next high incidence was found in the age group 46 - 60 years with 16.3% of cases. The incidence was least common in the age group > 75 years with only 2 cases (3.4%). The incidence in paediatric age group (00 - 15 years) was also less with only 6 cases (10.2%).

In our study, the most common salivary gland involved was the parotid gland. It was involved in total 40 cases (67.8%). The next common salivary gland in the frequency of involvement was submandibular gland, which was involved in 27.1% of cases. The sublingual and minor salivary gland involvement was very rare. They were involved only in 1.7% and 3.4% of cases respectively. Similar observation was made in a study conducted by Eveson JW et al[3] and Pinkston JA et al.[4]

In this study, the benign neoplasms of salivary gland were found to have higher incidence as compared to malignant neoplasm and non-neoplastic swellings; 28 cases i.e. 47.5% were benign neoplasms of salivary glands, whereas malignant neoplasms comprised 18.6% of cases. We found the similar findings in the histopathological analysis done at the Armed Forces Institute of Pathology.[5]

The incidence of malignancy was found to increase in the extremes of the age groups, i.e. in the paediatric and the geriatric age groups. Out of the total 6 no. of cases in the paediatric age group, 2 were malignant (33%). Out of the total 9 no. of cases in the age group > 60 years, 6 were malignant (66%). Similar findings were observed in a study conducted by Narala Srivani et al.[6]

Also, the incidence of malignancy was more in the sublingual and minor salivary glands as compared to parotid and submandibular salivary glands. Out of the 2 cases of minor salivary gland tumours, 1 was malignant (Incidence 50%). Only 1 case of sublingual gland tumour was noticed in our study and it was malignant (Incidence 100%). Out of the 40 cases of parotid tumours, 6 were malignant (15%). Out of the 16 cases of submandibular tumours, 6 were malignant (37.5%). The preponderance of malignant tumours in sublingual and minor salivary glands was also observed in the study conducted by Narala Srivani et al.[6]

The most common benign major and minor salivary gland tumour was the pleomorphic adenoma, which constituted 66% of the total cases studied (39 cases out of 59 studied). In our study, we found that the most common location of pleomorphic adenoma was the parotid gland (71.7%) followed by the submandibular gland (25%). We found 1 case of pleomorphic adenoma in minor salivary gland, but we did not find any case of pleomorphic adenoma in sublingual glands.

In our study, the most common malignant salivary gland tumour was Mucoepidermoid Carcinoma, which was found in 6 cases (42.85%) out of total 14 cases of malignant tumours. Similar observation was made in the study conducted by Pinkston JA et al,[4] who observed that Mucoepidermoid carcinoma was the most frequent malignant tumour (51.3%). This observation is in contrast to the study conducted by Nagler et al,[7] in which they have found that the most commonly encountered malignant tumour was adenocarcinoma (including the acinic-cell and low-grade polymorphous subtypes) (27.7%). In the study conducted by Narala Srivani et al,[6] they have found that the most common malignant tumour was adenoid cystic carcinoma followed by carcinoma, ex-pleomorphic adenoma and polymorphous low-grade adenocarcinoma.

CONCLUSION

The main Results of our Study are -

1. Salivary gland neoplasms are relatively uncommon constituting 3 to 4% of all head and neck neoplasms. The incidence of salivary gland tumours is 1 to 2 cases per 100,000 people.
2. The incidence of salivary gland tumours is almost equal in both sexes with slight female preponderance.
3. Salivary gland tumours are most common in 4th and 5th decade of life. Incidence is rare in extremes of life, i.e. in the childhood and the old age.
4. The salivary gland most commonly found involved is the parotid followed by submandibular gland. Frequency in minor salivary gland is very less, while the sublingual gland tumours are rare.
5. Benign neoplasms are the most common swellings of salivary glands. Malignant neoplasms and non-neoplastic swellings are less frequently seen.
6. Incidence of malignant tumours is high in the paediatric and old age patients. Most of the neoplasms in the middle age group are benign.
7. Most of the parotid and submandibular gland tumours are benign, while the majority of sublingual and minor salivary gland tumours are malignant.
8. The most common benign tumour of salivary glands is pleomorphic adenoma. The most common location of pleomorphic adenoma is the parotid gland.
9. The most common malignant tumour of salivary glands is mucoepidermoid carcinoma.
10. In this study, we have done a modest attempt to solve some unresolved issues regarding salivary gland tumours. We believe that there is a need for further study on this subject.

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DEPARTMENT OF SURGERY

List of Publications

DR. PREM PRAKASH SHARMA				
1	ROLE OF WATER SOLUBLE CONTRAST RADIOLOGY IN SMALL INTESTINAL OBSTRUCTION	Dr. Sanjay K.Gupta, **Dr. P.P. Sharma**	Published by Association for Scientific and Medical Education (ASME) Page 166 Vol.1; Issue: 3;July-Sept 2014 http://www.ijmse.com International Journal of Medical Science and Education pISSN- 2348 4438 eISSN-2349- 3208	INDEX COPERNICUS
2	LAPAROSOPIC PEPTIC PERFORATION REPAIR : OUR EXPERIENCE AT RURAL TERTIARY CARE CENTRE	DR. ATUL JHANWAR, **DR.PREM PRAKASH SHARMA** & DR. FATEH SINGH	Sharma PP, Jhanwar A, Mehta FS. Laparoscopic peptic perforation repair: our experience at rural tertiary care center. Int Surg J 2016;3:1534-7	INDEX COPERNICUS
3	NERCOTIZING SOFT TISSUE INFECTIONS : OUR EXPERIENCE AT RURAL TERTIARY CARE CENTRE	DR. ATUL JHANWAR, **DR.PREM PRAKASH SHARMA** & DR. DIKSHA SHARMA	Sharma PP, Jhanwar A, Sharma D, Sharma S, Tripathi A. Necrotizing softtissue infections: our experience at rural tertiary care centre. Int Surg J 2016;3:1528-33.	INDEX COPERNICUS
4	BLUNT TRAUMA CHEST : OUR EXPERIENCE AT RURAL TERTIARY CARE CENTRE	DR. ATUL JHANWAR & **DR.PREM PRAKASH SHARMA,**	Sharma PP, Jhanwar A, Sharma D, Sharma S. Blunt trauma chest: our experience at rural tertiary care centre. Int Surg J 2016;3:261-5.	INDEX COPERNICUS
5	A PROSPECTIVE, RANDOMIZED, CONTROLLED STUDY FOR EFFICACY OF PHENYTOIN SODIUM POWDER, EUSOL SOLUTION, NANOCRYSTALLINE SILVER GEL IN DIABETIC FOOT ULCER	DR.AJAY CHAUHAN, DR.BHAVESH K. PATEL , **DR.P. P. SHARMA** ,DR. F. S. MEHTA	Ajay Chauhan, Bhavesh K. Patel, P. P. Sharma, F. S. Mehta , A Prospective, Randomized, Controlled Study For Efficacy of Phenytoin Sodium Powder, Eusol Solution, Nanocrystalline Silver Gel in Diabetic Foot Ulcer , International Journal of Contemporary Surgery: Vol. 7 No. 2 (2019): International Journal of Contemporary Surgery	INDEX COPERNICU
6	TREATMENT OF LIVER ABSCESS: A COMPARISON OF CATHETER DRAINAGE AND NEEDLE ASPIRATION	DR.AJAY CHAUHAN, YASHASVI PATEL, **DR.P. P. SHARMA** ,DR. F. S. MEHTA	Ajay Chauhan, Yashasvi Patel, P. P. Sharma, F. S. Mehta , Treatment of Liver Abscess: A Comparison of Catheter Drainage and Needle Aspiration , International Journal of Contemporary Surgery: Vol. 7 No. 2 (2019):	INDEX COPERNICU

Pre Operative Magnetic Resonance Cholangiopancreatography in Laparoscopic Cholecystectomy with Special Reference to Hepatobiliary Anatomic Variations and Undetected Choledocholithiasis

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Abstract

Background: Cholelithiasis is the most common disease state involving the gallbladder and biliary tree. Approximately 5-15 % patients with gallstones are associated with choledocholithiasis. Hepatobiliary anatomic variations are common and routinely encountered during laparoscopic cholecystectomy. Among all investigations, Magnetic Resonance Cholangiopancreatography (MRCP) showed high accuracy in detecting the choledocholithiasis and hepatobiliary anatomical variations. Role of routine MRCP in patients going for laparoscopic cholecystectomy is controversial.

Method: This study was carried out on 68 patients admitted in Geetanjali Medical College and Hospital, Udaipur, Rajasthan in Department of General Surgery from August 2017 to August 2019 with the confirm diagnosis of cholelithiasis and posted for laparoscopic cholecystectomy. All patients underwent MRCP and collected data was analysed.

Results: Among 68 patients, dilated CBD was diagnosed in 4 and 13 patients by USG and MRCP respectively. CBD stone was not detected by USG in any patient but MRCP detected CBD stone in 6 patients. All 6 patients with CBD stones had age of > 50 years. Normal course with right lateral insertion of cystic duct was the most common variant and was found in 57 patients in MRCP and 62 patients intraoperatively.

Conclusion: MRCP is non-invasive, non-ionizing imaging modality having higher specificity and sensitivity for asymptomatic choledocholithiasis as well as biliary tree anomalies prior to LC. But it is a costly investigation. So its routine use in preoperative evaluation for all patients undergoing for laparoscopic cholecystectomy is advisable in patients having age of > 50 years.

Keywords: *Choledocholithiasis, Hepatobiliary anatomic variations, Magnetic resonance cholangiopancreatography, Laparoscopic cholecystectomy.*

Introduction

The most common disease state involving the gallbladder and biliary tree is cholelithiasis. Because the gallbladder concentrates bile, the concentration of solutes in the gallbladder differs from that in the rest of biliary tree. This increase in solute concentration combined with stasis in the gallbladder between meals predispose to stone formation in the gallbladder.[1] First open cholecystectomy was done by Carl Langenbuch in 1882 and it was primary treatment of gallbladder disease through the early 1990s.[2] After more than 100 years, First laparoscopic cholecystectomy (LC) was done by Erich

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48.51±13.31 years. Incidence of cholelithiasis in male and female patients was common in the age group 18 to 50 years and 51 to 70 years respectively. (Table 1)

Wall thickness was found normal in both USG and MRCP in all patients preoperatively. During surgery, wall thickness was found normal in 47 patients (69.1%) while it was thickened and fibrotic in 19 (27.9%) and 2 (2.9%) patients respectively.

In present study, Dilated CBD was diagnosed in 4 patients (5.9%) by USG and in 13 patients (19.1%) by MRCP. Intraoperatively CBD caliber was found normal in all patients. (Table 2)

Table 1: Distribution of the patients according to Age & Sex

			Age groups		Total
			18 to 50 years	51 to 70 years	
Sex	Male	n	5	11	16
		%	31.25%	68.75%	100.0%
	Female	n	32	20	52
		%	61.5%	38.5%	100.0%
Total		n	37	31	68
		%	54.4%	45.6%	100.0%

Table 2: Distribution of the patients according to caliber of CBD

		Caliber of CBD		Total
		Normal	Dilated	
USG	n	64	4	68
	%	94.1%	5.9%	100.0%
MRCP	n	55	13	68
	%	80.9%	19.1%	100.0%
Intra-operative	n	68	0	68
	%	100.0%	0.0%	100.0%

In our study, CBD stone was not detected by USG in any patient. But MRCP detect CBD stone in 6 patients (8.8%). (Table 3) All 6 patients with CBD stones had age of > 50 years. 4 cases had CBD stone size of < 6 mm and 2 cases had size of > 6 mm. (Table 4)

Discussion

Gallstone diseases are one of the commonest surgical problems worldwide. Cholelithiasis is more common in females than in males. In our study, 52 patients were female (76%) and 16 patients were male (24%) (N=68). In this study, the participation of patients with different sex ratio was similar to the previous studies indicating female are more affected by cholelithiasis compared to males. In study by Al-Aubaidi T et al[11], 86 patients were female and 14 patients were male (N=100). Virzi V et al[12] found that 75 patients in their study were female out of 104 and rest 29 were male (N=104).

Current study included patients of age 18 to 70 years. The mean age of patients in our study was 48.51±13.31 years. Age of youngest male and female patient in our study was 22 years and 19 years respectively. Age of oldest male and female patients was 70 years. Rao GB et al[101] found that mean age of patients in their study was 54 years. Al-Aubaidi T et al[11] also noticed mean age of 46.8±8.1 and 45.9±9.5 in their both group. We found that highest incidences of cholelithiasis were present in age group 18 to 50 years which was 37 patients (54.4%) followed by in age group 51 to 70 years which was 31 patients (45.6%). Al-Aubaidi T et al[11] also found that highest number of patient were present in both study groups from age group of 45-55 years and second highest patients were found in age group of 55-65 years and 25-35 years in group 1 and group 2 respectively. We divided patients into two age groups, first 18 to 50 years and second 51 to 70 years. In current study we found that male patients were more common after the age of 50 years as maximum number of male patients were present in age group 51-70 years (11 patients, 68.75%) while female patients were more common in age group 18 to 50 years (32 patients, 61.5%). In study by Rao GB et al[13], male patients were common in age group 41-70 years (19 patients) while female patients were common in age group 21-40 years (27 patients).

It is also important to know the wall thickness pre operatively because thickened or fibrotic gallbladder wall cause difficulty in surgery. In our study we analysed gallbladder wall preoperatively by USG and MRCP. In all patients wall thickness was found normal by USG and MRCP. During surgery we found normal wall thickness in 47 patients (69.1%) while thickened gallbladder wall was present in 19 patients who were diagnosed as normal wall thickness preoperatively. Fibrotic gall bladder was found in 2 cases (2.9%). So the pre-operative investigations were not giving exact information about wall thickness in all cases. This concludes that MRCP as a tool to asses difficult laparoscopic cholecystectomy in view of wall thickness of gall bladder is not much helpful. In current study, difference found in wall thickness in USG, MRCP and intraoperative was significant (P value 0.000).

In current study, dilated CBD was detected in 4 cases (5.9%) without stone by USG. MRCP detected choledocholithiasis in 6 patients (8.8%). All these patients with choledocholithiasis were asymptomatic. MRCP showed dilated CBD in 13 patients (19.1%) but out of 13 only 6 patients had CBD stone. All CBD stones were removed by ECRP preoperatively. Rest cases with dilated CBD without stone on MRCP had normal LFT and no jaundice and they were diagnosed as type 1 choledochal cyst by Gastroenterologist, so they were directly posted for laparoscopic cholecystectomy (Table 3). These patients were followed up in postoperative period and none of them reported as retained bile duct stones or biliary leak, etc. This suggests that even if the LFT is normal, there are chances of CBD stones and MRCP is helpful in diagnosis of these cases. Result of our study was statistically significant (P value = 0.012).

Singh S et al[14] observed different sizes of CBD stones in MRCP. They found 7 cases of CBD stone with stone size ≤ 6 mm and 13 cases with stone size > 6 mm. The smallest stone detected by MRCP was 4 mm in diameter. In current study we observed that out of 6 cases of CBD stone detected by MRCP, 4 cases had CBD stone size of < 6 mm and 2 cases had > 6 mm. The smallest stone size was 4 mm. In study by Al-Aubaidi T et al[11] they found 2 cases of CBD stone detected by MRCP. Both these patients had age of > 45 years. In our study all 6 cases of CBD stone had age of > 50 years. Youngest patient with CBD stone was 51 years old and oldest patient with CBD stone was 70 years old. We conclude that there are higher chances of CBD stone in and after 5th decade of life. All patients having age of > 50 years must be investigated with MRCP before laparoscopic cholecystectomy because of higher chances of CBD stones in these patients. (Table 4)

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ORIGINAL RESEARCH PAPER

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COMPARISON BETWEEN TRENDELENBURG WITH STRIPPING AND RADIOFREQUENCY ABLATION OF THE GREAT SAPHENOUS VEIN FOR THE MANAGEMENT OF PRIMARY VARICOSE VEINS

Surgery

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ABSTRACT

Introduction : Varicose veins are most common in the superficial veins of the legs, which are subject to high pressure when standing. Besides cosmetic problems, varicose veins often itch and are painful, especially when standing or walking. Though varicose veins rarely present with an acute emergency or life threatening complication, symptoms like dragging sensation, heaviness, pain, bleeding, ulceration or lipodermatosclerosis require an active intervention to get relief from the disease. A new approach to management of saphenous vein reflux is endovascular obliteration of the vein with a radiofrequency generated heating probe placed through a percutaneous puncture or mini incision in the calf. The procedure is less invasive and may, therefore result in shorter convalescence and ability to resume work sooner, thus reducing the costs of the productivity. Any alternative technique to high ligation and stripping must ideally have the same or better outcome but without the associated morbidity.

Aims And Objectives: To assess and compare the efficacy of Trendelenburg and Stripping with RFA of GSV for the management of primary varicose veins in Indian setup.

Materials And Methods: Patients divided into two- Ligation-Stripping(LS) group (n=30) and; Radiofrequency Ablation(RFA) group (n=30). Patients were given a questionnaire (Likert's questionnaire) consisting of six questions to fill on postoperative day 3, 7, 28 and at 90 days.

Conclusion: Radiofrequency ablation of GSV for the treatment of varicose veins, is as effective as High ligation and stripping. The two procedures are comparable in terms of quality of life indicators, postoperatively, but the cost of RFA procedure is almost 3 times higher than the LS procedure of GSV.

KEYWORDS

Ligation-Stripping (LS); Radiofrequency Ablation (RFA); GSV; Trendelenburg; Saphenous Vein; Varicose Vein.

INTRODUCTION

Varicose veins are most common in the superficial veins of the legs, which are subject to high pressure when standing. Besides cosmetic problems, varicose veins often itch and are painful, especially when standing or walking. Though varicose veins rarely present with an acute emergency or life threatening complication, symptoms like dragging sensation, heaviness, pain, bleeding, ulceration or lipodermatosclerosis require an active intervention to get relief from the disease[1].

Non-surgical treatments include, compression elastic stockings, elevating the legs, and exercise. The traditional surgical treatment has been vein stripping to remove the affected veins. Because most of the blood in the legs is returned by the deep veins, the superficial veins, which return only about 10 per cent of the total blood of the legs, can usually be removed or ablated without serious harm[2]. Conventional surgery (stripping of the veins) has been the time tested modality of treatment for varicose veins.

The treatment of varicose veins has undergone vast research and modification in its course. The three mains categories of primary venous insufficiency are: telangiectasias, reticular varicosities, and varicose veins, all being physiologically similar, differing only in the caliber. The unifying end result is dilated, tortuous, elongated veins with dysfunctional or non-functional valves. Operations on varicose veins are amongst the most common surgical procedures. In the conventional management of the incompetent saphenous vein in patients with symptomatic varicose veins, it is generally believed that the best treatment is removal of the great saphenous vein (GSV) from the sapheno-femoral junction to the level of knee or below, along with individual ligation of the saphenous tributaries in the groin. The stripping operation is a relatively inexpensive day surgery procedure that needs no special instrumentation. Varicose vein surgery though regards as a safe and minor procedure[3] is nevertheless associated with significant surgical morbidity and dissatisfaction. Flush ligation and stripping of the GSV is standard treatment for varicose veins with highest rate of initial success and lower rates of recurrence. But recurrence rates as high as 10% at 5 years have been reported, and approximately 5% of varicose veins operations are done for recurrence, most common cause of recurrence being neovascularisation at the saphenofemoral junction.

But newer modalities have arisen which are less invasive. Newer, less invasive treatments, such as ultrasound-guided foam sclerotherapy, radiofrequency ablation and endovenous laser treatment, are slowly replacing traditional surgical treatments. Further experience with these procedures will help to determine which one will become method of choice for treating this complex disease process.

Increasingly well informed patients who pressure the treating surgeon for cosmetically acceptable results in conjunction with expansion of minimally invasive techniques have made the treatment of superficial venous reflux and varicose veins a rapidly evolving field. It is very likely that some of these procedures like RFA will replace the procedures that we currently use today[4]. In our study we will focus on the various aspects of conventional surgery and radiofrequency ablation and make a comparison between the two modalities.

A new approach to management of saphenous vein reflux is endovascular obliteration of the vein with a radiofrequency generated heating probe placed through a percutaneous puncture or mini incision in the calf. The procedure is less invasive and may, therefore result in shorter convalescence and ability to resume work sooner, thus reducing the costs of the productivity.

Any alternative technique to high ligation and stripping must ideally have the same or better outcome but without the associated morbidity.

AIMS AND OBJECTIVES

To assess and compare the efficacy of Trendelenburg and Stripping with Radiofrequency Ablation of Great Saphenous Veins for the management of primary varicose veins in Indian setup.

MATERIALS AND METHODS

This is a prospective randomized study conducted in the Department of General Surgery, and Department of Radio diagnosis at GMCH,

withdrawing the catheter 7 cm at a time. Percutaneous foam sclerotherapy of varicose vein is performed 50% STDS form without opacifying the deep system. The procedure was done by Consultant Interventional Radiologist. Efficacy outcome was assessed on the following parameters at baselines, 3 days, 7 days, 28 days, 3 months. Adverse events/complications were recorded along a checklist prepared for this study (intraoperative, postoperative day 3, 7, 28, 90). Patients were given a questionnaire (Likert's questionnaire) consisting of six questions to fill on postoperative day 3, 7, 28 and at 90 days. The patients marked their response as 100- definitely true; 50- can't say, 25 mostly false, 0 definitely false. The response was assessed with median and percentage.

Questionnaire

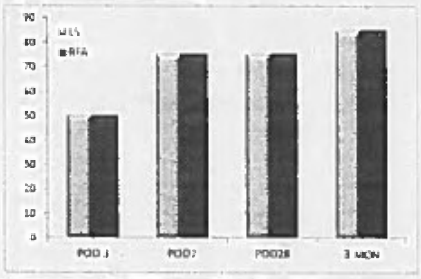
1. Was helped as much as I thought I will be post surgery.
2. My problem/ problems were reduced as much as I expected them to after surgery.
3. The benefit of my care outweigh the setback it caused me.
4. Overall I am happy with the care I am receiving for my legs.
5. All things considered, I would have the surgery again for the same reason.

RESULTS

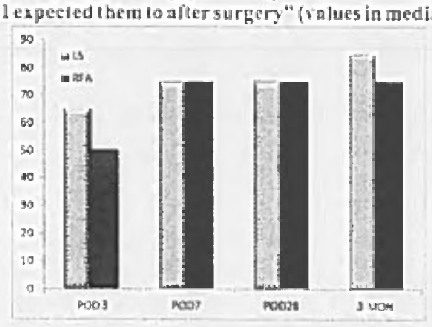
Table 1: Distribution of Patients According to Presenting Signs and Symptoms to Type of Skin Involvement to Limb Involvement

Factors	Stripping & flush ligation group (n=30)	Radio-frequency Ablation group (n=30)	P-value
Ulceration	None	None	-
Pain	13	9	NS
Itching	None	None	-
Skin involvement	12 (40%)	10 (33.33%)	NS
Left	25 (83.3%)	25 (83.3%)	NS
Right	5 (16.67%)	5 (16.67%)	
No. of incompetent perforators	15 (0-3)	15 (0-3)	NS

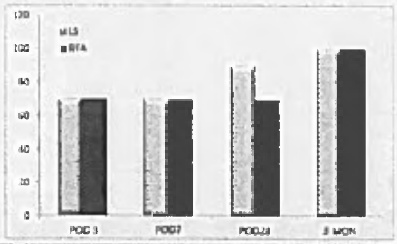
Graph 1: Response to "I was helped as much as I thought I will be post surgery" (values in median)



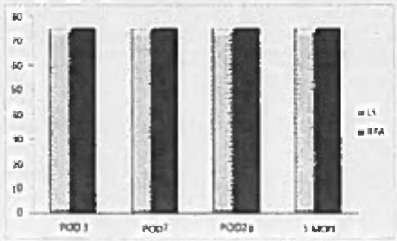
Graph 2: Response to "My problem/problems were reduced as much as I expected them to after surgery" (values in median)



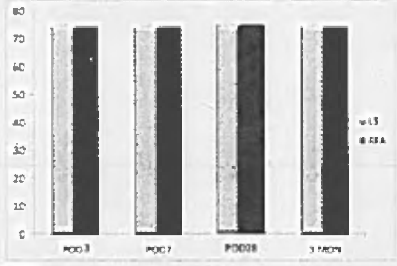
Graph 3: Response to "the benefit of my care outweigh the setback it caused me" (value in median)



Graph 4: Response to "Overall I am happy with the care I am receiving for my legs" (value in median)



Graph 5: Response to "All things considered, I would have the surgery again for the same reason" (value in median)



DISCUSSION

Treatment of varicose veins has been a topic of research and the search for adequate and ideal treatment of this common condition has seen various stages of evolution, ranging from conservative compression stocking to the most recent endovenous laser application. However, surgery in the form of high flush ligation of SFJ and striping of GSV has been traditionally described as the gold standard. Beale and colleagues in 2005, did a review of the various treatment options being used in the treatment of this disease'.

Operative treatment strategies can be minimally invasive ones, like RFA and EVLA, or conventional techniques like flush ligation with striping of GSV with its modifications. In RFA, the vein is cannulated at knee level using a 5-8Fr diode catheter and advanced to SFJ under USG control and then withdrawn slowly. Application of heat result in endothelial denudation, collagen denaturation and the actual vein contraction. The technique is suitable for veins upto 12mm diameter, thus not being applicable to all the patients.

Complications associated with this technique, apart from recanalisation, include thermal burns, saphenous neuritis, and DVT. Other minimally invasive endovenous technique is laser ablation. In this, the vein does not immediately shrink, but does so over a period of 6 weeks, then it eventually disappears. Main complications are bruising and thrombophlebitis, with less evidence of burns, paraesthesia and DVT. Complications associated with formal surgery include nerve injury, hematoma, wound infection, thromboembolism and recurrence.

Over the years, with the advancement of technology and the advent of radiofrequency and laser, and their application in surgical practice, has made these minimally invasive techniques lucrative treatment options. Proponents of these procedures claim to overcome the morbidity and complications associated with LS of GSV, but these techniques are not flawless and have their own complications.

In our study we compared the two procedures and assessed the outcomes in terms of occlusion rates, the complication rates and QOL measures. We found that we could achieve 100% occlusion rates in both the procedures, we did not find any statistically significant difference in the complication rates and the patients did not show any predilection towards any one specific mode of treatment. The cost of radio frequency ablation procedure is almost three times higher than the trendenburg and stripping procedure of GSV. We found that the two procedures were comparable to each other, in terms of the incidence of complications and recurrence of disease in our duration of study.

The clinical stage of disease, showed an improvement in all the treated patients regardless of the procedure they underwent. Deep vein thrombosis was not seen in any of the patient. We measured QOL indicators using direct questions and used a questionnaire which was based on Likert's scale. The responses did not show any significant

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Treatment of Liver Abscess: A Comparison of Catheter Drainage and Needle Aspiration

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Abstract

Background: The aim of the study was to evaluate the clinical presentation, and to investigate the effectiveness of continuous catheter drainage in comparison to needle aspiration in the treatment of liver abscesses.

Method: This is a comparative study of 50 patients, presented in outpatient and emergency department at the hospital,equally into two groups,

percutaneous needle aspiration and pigtail catheter drainage. The effectiveness of either treatment was measured in terms of duration of hospital stay, days to achieve clinical improvement, 50% reduction in abscess cavity size and total/near total resolution of abscess cavity.

Results: The success rate was significantly better in catheter drainage group. The patients in pigtail catheter drainage group showed earlier clinical improvement and decrease in abscess cavity volume as compared to those who underwent percutaneous needle aspiration.

Conclusions: Percutaneous catheter drainage is a better modality as compared to percutaneous needle aspiration especially in larger abscesses which are partially liquefied or with thick pus.

Keywords: *Liver abscess, Catheter drainage, Needle aspiration*

Introduction

Liver abscess has been recognized since hippocrates (400 B.C.)who speculated that the prognosis of patients were related to the type of fluid within the abscess cavity[1]. A liver abscess is a suppurative cavity in the liver resulting from the invasion and multiplication of microorganisms, entering through the blood vessels or by the way of the biliary ductal system. It is the commonest infection affecting liver. Liver comprises 48% of all the visceral abscesses[2]. Liver abscess is the constant source of mortality in developing country. India being a developing country, a large proportion of population living under poverty line, a good amount of people are predisposed to liver abscess. It is common in India with 2nd highest incidence due to poor sanitation, overcrowding and inadequate nutrition[3]. Prevalence of infection is higher than 5%-10% in endemic areas[4].

Liver abscess is a major tropical disease of the gastrointestinal system which is mainly classified into amoebic and pyogenic. Pyogenic liver abscess which used to be mainly tropical in location. Majority of liver abscess cases from developing country are of amoebic etiology.[5]

Liver abscess is found more commonly in men between 20 and 40 years of age but can occur at any age. Approximately 60% of the abscesses are solitary and mainly located in the right lobe of the liver, as a result of the streaming of the portal blood flow secondary to

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Results

In presenting study the age group of the patients ranged from the 20-72 years.

Highest incidence(66%) was found between 3rd - 4th decades. In this study

45 patients were male and 5 patients were female and ratio being, male : female was 9:1. 40 patients were from rural and 10 were from urban population and the incidence of alcohol consumption was 72%.

In present study, all patients gave history of right upper quadrant dull aching pain associated with anorexia and Fever. (Table 1)

Table 1: Symptoms & signs of liver abscesses (n=50)

Characteristic	Percutaneous needle aspiration(n=25)	Percutaneous catheter drainage (n=25)
Right upper quadrant pain	100%	100%
Right hypochondruim tenderness	100%	100%
Anorexia	100%	100%
Fever	96%	96%
Nausea & vomiting	60%	60%
Hepatomegaly	52%	88%
Respiratory symptoms	12%	32%
Jaundice	08%	12%
Diarrhoea	0%	0%

It was observed that 96% had leucocytosis (Table 2).

Table 2: Laboratory Data of all patients (N=50)

Investigation	Percutaneous needle aspiration (n=25)	Percutaneous catheter drainage (n=25)
Leucocytosis (>11000)	84%	100%
Elevated S. Bilirubin Total	12%	24%
Elevated SGOT	64%	84%
Elevated SGPT	64%	100%
Hypoalbuminemia	52%	96%
Elevated Alkaline phosphatase	64%	92%
Elevated INR	64%	88%

In the present study, 38(76%) patients had solitary abscess and 12(24%) patients showed multiple abscesses. 41(82%) had right lobe involvement, 6(12%) had left lobe involvement and 3(6%) had both lobes involved. Volume of abscess was measured, the smallest was 65 cc and the largest was 1200cc. It was observed that the volume of the abscess cavities was mostly between 150-350cc. Pus aspirated from all abscesses was sent for culture and sensitivity. Cultures were found to be positive in 16(32%) cases. The rest were sterile. Amoebic liver abscesses were encountered more frequently (68%) compared to pyogenic (30%). Only 1 (2%) case was encountered with mixed of liver abscess.

lobe abscesses were more common.

Amoebic abscesses were more common finding than pyogenic abscesses in our study. These findings were comparable with **Singh et al** study.

We performed image-guided percutaneous intervention in 50 patients. Their response to treatment was recorded and analyzed. Same results of PNA and PCD were reported by **Bansal et al**[18].

The time required for 50% reduction in the cavity size was significantly less in the PCD compared to PNA group. However, time required for total or near-total resolution of the abscess cavity did not show any significant difference in the two group. It can be concluded that the abscess cavities showed faster collapse during the initial period in the PCD group but it did not have an advantage as far as total or near-total resolution of cavity is concerned. Similar result were recorded by other researcher as **Rajak et al**[19].

Needle aspiration is simple, safe & acceptable treatment of choice in liver abscess less than 5cm in diameter under US guidance. The major advantages of PNA are easy to perform as a outdoor procedure, less invasive, less expensive with medical & nursing care, avoids problems related to catheter care, multiple abscess cavities can be aspirated easier in the same setting[20]. Inability to completely evacuate the Large (>5 cm) abscesses, thick viscous pus and rapid re-accumulation of pus are the important reasons for failure of needle aspiration[21]. Placement of an indwelling drainage catheter addresses all of these issues. This explains the higher success rates of PCD treatment group observed in our study and several previous studies[22].

Conclusion

Our study concludes that the percutaneous catheter drainage is a better and effective percutaneous treatment modality as compared to percutaneous needle aspiration in view of greater volume of pus drained in first sitting, in respect to clinical improvement, resolution of cavity, success rate but there was no significant morbidity - mortality occur during both the procedure.

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A Prospective, Randomized, Controlled Study For Efficacy of Phenytoin Sodium Powder, Eusol Solution, Nanocrystalline Silver Gel in Diabetic Foot Ulcer

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Abstract

Background: Diabetic foot is one of the most significant and devastating complications of diabetes. Not all foot complications can be prevented, but it is possible to dramatically reduce their incidence through appropriate management and prevention. Various dressings are available that fulfils a number of functions like cosmesis, haemostasis, protection, support and absorption.

Objectives: To study and compare the efficacy of different topical agents like phenytoin sodium powder, eusol solution, nanocrystalline silver gel in patient with diabetic foot ulcer by recording the mean ulcer size pre-treatment, during the course of treatment (1 week, 2 week, 3 week and 4 week follow up) and post- treatment and mean percentage of the wound size healing after treatment.

Material & Method: This prospective study was conducted in the Department of General Surgery, Geetanjali Medical College & Hospital, affiliated to Geetanjali University from January 2017 to June 2018. 90 patients with diabetic foot ulcers without any other co-morbid conditions and ulcers belonging to Grade I & II as per Wagner diabetic foot ulcers classification were compared with the efficacy of different topical agents.

Results: Out of 90 patients, there was a highly significant reduction in the mean ulcer size after 2 week, 3 week and 4 week follow up in nanocrystalline silver gel group ($p<0.05$) as compared to the phenytoin sodium powder and eusol solution group and the formation of granulation tissue was higher in nanocrystalline silver gel group (90%) as compared to phenytoin sodium powder (80%) and eusol solution (73.33%).

Conclusion: Dressings done with nanocrystalline silver gel was found to be more efficacious than the other topical agents in patients with diabetic foot ulcers in terms of increased rate of wound healing, greater reduction in the mean ulcer size after treatment, absence of pain, swelling and type of discharge after treatment, greater incidence of formation of granulation tissue and less duration of antibiotic therapy and hospital stay.

Keyword: *Diabetic foot ulcer, phenytoin sodium powder, nanocrystalline silver gel, eusol solution.*

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Introduction

Diabetic foot is one of the most significant and devastating complications of diabetes, and is defined as a foot affected by ulceration that is associated with neuropathy and ischaemia of the lower limb in a patient with diabetes [1]. In India, diabetic foot

Grade 3- deep ulcer with abscess

Grade 4- gangrene limited

Grade 5- gangrene extensive.

Patients were then subjected for detailed clinical examination with baseline investigations, were posted for surgical procedures (debridement) if required & follow up of patients during hospital stay and at 1st, 2nd, 3rd and 4th week was done. We did dressings of patients as required until wound healing achieved and changes in wound size (area of the wound was measured in square centimeters by taking an impression of the wound on a gauze piece and tracing it on graph paper on subsequent days) was recorded when the dressing was removed and changed. phenytoin sodium powder group, eusol solution group and nanocrystalline silver gel group to compare the effectiveness of these different topical agents on patients with diabetic foot ulcer in regards of presence of pus, swelling, pain before treatment and after treatment, mean ulcer size pre-treatment, during the course of treatment (1 week,2 week, 3 week and 4 week follow up) and post-treatment, mean percentage of the wound size healing after treatment, duration of antibiotic therapy, duration of hospital stay and formation of granulation tissue.

The quantitative data was represented as their mean ± SD. Categorical and nominal data was expressed in percentage. The t-test was used for analysing quantitative data, or else non parametric data was analyzed by Mann Whitney test and categorical data was analyzed by using chi-square test. Pearson's correlation coefficient was used to determine the correlation between parameters. The significance threshold of p-value was set at <0.05. All analysis was carried out by using SPSS software version 20.

Results

A total of 90 patients were included in the study under the age group of 40-70 years. Males (71) were more affected than females (19). Pain after treatment-lower pain scores in the nanocrystalline silver gel group (1.20 ± 1.24) as compared to the phenytoin sodium powder (2.03 ± 1.45) and eusol solution group (1.87 ± 1.57).

Table 1: Presence of Pain (VAS) after Treatment in all 3 groups

Pain (VAS)	Phenytoin Sodium Powder		Eusol Solution		Nanocrystalline Silver Gel	
	No.	%	No.	%	No.	%
0	7	23.33%	9	30.00%	12	40.00%
1	3	10.00%	4	13.33%	7	23.33%
2	8	26.67%	6	20.00%	5	16.67%
3	6	20.00%	4	13.33%	5	16.67%
4	6	20.00%	7	23.33%	1	3.33%
Mean±SD	2.03	1.45	1.87	1.57	1.20	1.24

The mean ulcer size was significantly smaller in the nanocrystalline silver gel group (3.41 ± 3.17) as compared to the phenytoin sodium powder (9.21 ± 7.41) and eusol solution (7.72 ± 6.65) group after 4 weeks follow up ($p<0.05$). Also, there was a highly significant reduction in the mean ulcer size after 2 week, 3 week and 4 week follow up in nanocrystalline silver gel group ($p<0.05$) as compared to the phenytoin sodium powder and eusol solution group.

Table 5: Duration of hospital stay in all 3 groups

	Phenytoin Sodium Powder		Eusol Solution		Nanocrystalline Silver Gel	
	Mean	SD	Mean	SD	Mean	SD
Duration (days)	14.97	5.73	13.30	4.48	10.27	5.27

Table 6: No. of Weeks and Dressings Required for Wound Healing in all 3 groups

	Phenytoin Sodium Powder		Eusol Solution		Nanocrystalline Silver Gel	
	No.	%	No.	%	No.	%
1 week	1	3.33%	0	0.00%	2	6.67%
2 weeks	6	20.00%	6	20.00%	8	26.67%
3 weeks	8	26.67%	8	26.67%	11	36.67%
4 weeks	9	30.00%	8	26.67%	6	20.00%
Total	24	80.00%	22	73.33%	27	90.00%

Discussion

Diabetic foot ulcer is one of the most devastating complications of diabetes mellitus and early effective management can reduce the severity of complications such as preventable amputations and possible mortality and can also improve the quality of life. Topical phenytoin is a known inexpensive therapeutic agent in wound healing as it induces growth of granulation tissue, angiogenesis and decreases the wound size. Eusol is a commonly used solution for wound healing as it is a desloughing agent and helps in effective healing. Nanocrystalline silver gel also promotes wound healing through the antiseptic, antimicrobial and anti-inflammatory properties of silver.

In our study, after treatment and follow-up of 4 weeks pain scores in all the three groups reduced, however, there was much lower pain scores in the nanocrystalline silver gel group (1.20 $\pm$ 1.24) as compared to the phenytoin sodium powder (2.03 $\pm$ 1.45) and eusol solution group (1.87 $\pm$ 1.57). Ramanaiah et al [8] also found a significant reduction in the pain scores in the nanocrystalline silver gel group post treatment in their study. Similarly, in a study done by Jayalal et al [9] on efficacy of topical phenytoin sodium powder in diabetic foot ulcer, pain scores were found to be significantly lower in the study group as compared to the control group.

Our study showed that the mean ulcer size after 1 week, 2 week and 3 week follow up in silver group reduced more as compared to the phenytoin sodium powder and eusol solution group. Similarly, Ramanaiah et al [8] found significant reduction in the wound size in their study after treatment with nanocrystalline silver gel dressings. Sharma et al [10] also found a significant reduction in the wound size with an effective wound healing with nanocrystalline silver gel dressings as compared to the conventional dressings.

In a study done by Jayalal et al [9] on the efficacy of topical application of phenytoin sodium powder in diabetic foot ulcer, there was a significant reduction in the slough and wound size area after treatment. Charne et al [11] demonstrated nanocrystalline silver gel had a much higher rate of healing ulcer size compared to other applications.

In our study, mean percentage of wound size healing of ulcer with nanocrystalline silver gel dressing is 83.07% as compared to the phenytoin sodium powder (57.98%) and eusol solution (63.69%).

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Research Article

Blunt trauma chest: our experience at rural tertiary care centre

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ABSTRACT

Background: Every hour, 40 people under the age of 25 die in road accidents around the globe. According to the WHO, this is the second most important cause of death for 15 to 29 year olds. According to the latest report of National Crime Records Bureau or NCRB, Over 1, 37,000 people were killed in road accidents in 2013. Thoracic trauma forms one of the major parts of multiple traumas and is responsible for significant mortality and morbidity especially at younger ages.
Methods: We carried out a retrospective study to assess the prevalence of chest injury patients at Geetanjali medical college and hospital, Udaipur (Tertiary care rural centre) in last two years. Clinical details of the patients were recorded from their case sheets and were analyzed with reference to their age, sex, mode of injury, severity of injury, treatment employed, complication and final outcome etc.
Results: Males were predominantly involved (88.2%). Majority (61.9%) were in the age group of 21-30 years.
Conclusions: Chest injury occurs in a significant number of trauma patients and commonly affected victims are males of 20-40 years age. The majority of these patients were managed by simple intervention i.e., intercostals chest tube drainage and non –invasive ventilation, only less than 3% require thoracotomy.

Keywords: Blunt trauma, Flial chest, Haemothorax, Inter costal chest tube drainage

INTRODUCTION

Accidents which are unexpected and unplanned events are becoming the major epidemic of non-communicable disease in the present century. The number of accidental deaths in India is even higher than in the Western World[1]. Thoracic trauma contributes heavily to these figures which may present as isolated injury or as a part of polytrauma. Blunt thoracic injuries are thought to result from a combination of crushing, compression, stretching and shearing forces. The magnitude of these forces directly related to the rate of their acceleration and deceleration and also their relative direction of impact. Although most of the fractures of bony thorax are benign entities and can be followed up without hospitalization, trauma limited to the thoracic cage itself may cause profound pathophysiological alterations, which may be fatal if not promptly treated. On the other hand, the accurate identification of a patient at high risk for major chest trauma is essential for regulation of over and under triage within a trauma system. The present study focuses on blunt chest injuries, especially rib fractures and associated injuries. In spite of the high mortality rates, about 90% of the patients with life-threatening thoracic injuries can be managed by a simple intervention like intercostals tube drainage and non invasive ventilation.[2]

Single rib fracture was evident on x-ray in 56 patients, two fractured ribs were seen in 186 patients and in 410 patients there were multiple ribs fractured. In 46 patients, multiple rib fractures were also associated with flail chest. In 30 cases there was no evidence of fractured ribs on x-ray but still they developed either pneumothorax or haemopneumothorax or occult pneumothorax.

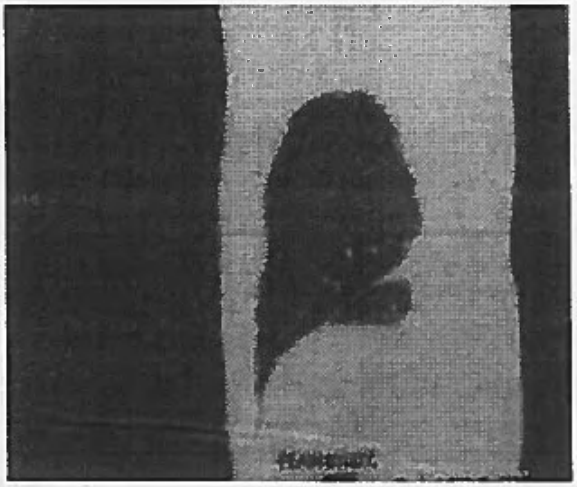

Figure 3: CT- THORAX showing occult pneumothorax.

Rib fractures were associated with subcutaneous emphysema in 186 patients (25.47%). Hemo/pneumothorax with subcutaneous emphysema was observed in 89 patients (12.19%). Subcutaneous emphysema without another complication was observed in 42 patients (5.75%), in most of patients it resolve spontaneously.

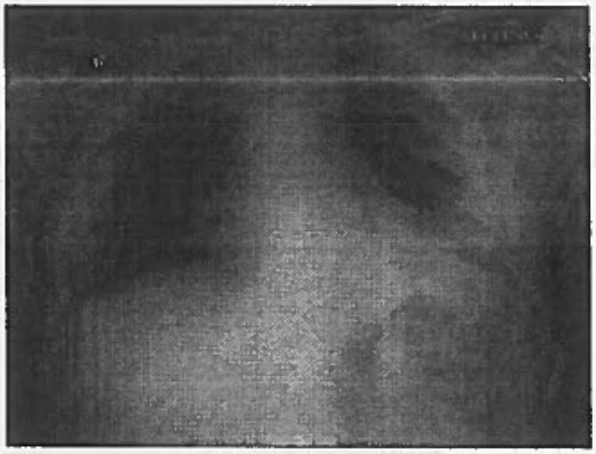

Figure 4: X-Ray chest showing surgical emphysema associated with flial chest.

Hemo-/pneumothorax were observed in 437 patients (59.86%) with rib fractures: In 13 (2.97%) patients with single rib fracture, in 109 patients (24.94%) with two rib fracture and 315 patients (72.08%) in more than two rib fractures out of 437 patients. The differences between the groups were statistically significant (P<0.001).

Table 4: Treatment modality.

Treatment	Number of patients	Percentage
No. active treatment	225	30.82
ICTD	331	45.34
Thoracotomy	12	1.64
Non invasive ventilation	134	18.35
Invasive ventilation	28	3.83

Chest tube drainage was performed in 331 patients with pneumothorax, hemothorax or hemopneumothorax. Patients with minimal (<20%) pneumothorax followed without chest tube drainage and patients with minimal hemothorax underwent thoracentesis alone. Chest tube was performed successfully in all. But five of these patients required thoracotomy (in 4 patients with massive bleeding, one patient with chylothorax).

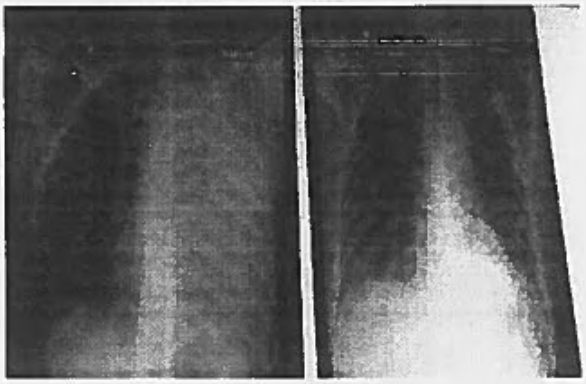

Figure 5: Inter costal tube drainage for left haemothorax.

46 patients presented with flail chest. All patients with flail chest were kept in the Intensive Care Unit. The management of these patients was based on the trend of serial measurements for arterial blood gases and serial x-ray chest PA view. In all patients with flail chest, tube thoracostomies was done and patient was put on non invasive ventilation whenever required. Analgesia was provided through administration of parenteral analgesics and epidural analgesics. In 10 of these patients, percutaneous tracheotomy was performed aiming suctioning of secretions and giving oxygen to the patients more effectively (reduction of dead space). These patients developed acute respiratory failure and invasive mechanical ventilation was indicated. In spite of aggressive critical care management seven patients died out of 46. Mean hospitalization time for these patients was 23 days.

patient. The incidence of empyema has been reported about 2 to 3 percent in patients with chest injury requiring tube thoracostomy in various studies.[6,12]

Overall, there were 17 deaths in this series, with most of patients having multiple fractures with flail chest and massive pulmonary contusions associated abdominal injuries and pelvic fracture. The mortality rate after severe chest injury was comparable with other studies reported in the literature.[12] The clinical state of the patient, severity of the trauma, age, presence of more than two rib fractures, presence of flail chest, and possible intrathoracic injury help in making the decision for proper treatment plan.

CONCLUSION

After comprehensive review of the present study, it is concluded that:

- Blunt trauma, mainly road-side accidents formed the most common cause of chest injury, followed by assault and falls from height etc. and commonly affected victims are males of productive age.
- The majority of these patients can be managed by simple intervention i.e., intercostal drainage. Patient with multiple rib fracture can be managed by non invasive ventilation and only few require thoracotomy.
- The risk of mortality in chest trauma has been associated with the presence of more than two rib fractures, age older than 60 years and with associated head and abdominal injury.
- The ability to identify those patients having significantly higher risk for morbidity and mortality ensures the establishment of treatment priorities and efficient management of existing injuries.

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Ethical approval: The study was approved by the institutional ethics committee

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Necrotizing soft-tissue infections: our experience at rural tertiary care centre

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ABSTRACT

Background: Necrotizing soft-tissue infections are infection of any of the layers within the soft tissue compartment that are associated with necrotizing changes. These infections are highly lethal if not diagnosed. The purpose of this article is to assess the different diagnostic tools.
Methods: We carried out a retrospective study to assess the prevalence of soft tissue infections at Geetanjali medical college and hospital, Udaipur (Tertiary care rural centre) in last four years. Clinical details of the 216 patients with soft tissue infection were recorded from their case sheets and were analyzed with reference to their age, sex, risk factor, symptoms, etiology, microbiology, treatment employed, complication and final outcome etc.
Results: Pain and swelling were commonest presenting symptoms found in every case. Diabetes and Trauma were major predisposing factor in our series. NSTI differ from NNSTI with respect to presence of blister (50% versus 5.8%), Dusky discoloration (58.3% versus 0%), Necrotic skin (51.04% versus 0%) and Crepitance (6.2% versus 0%). In present series' most common organism causing NSTI in our institute is gram negative bacilli .Prompt resuscitation followed by early and adequate debridement remains the cornerstone of management of NSTI.
Conclusions: Diagnosis of necrotizing infection is challenging but there are enough tools including clinical findings, biochemical parameters, imaging aids and invasive procedures that can help make the diagnosis. When in doubt, exploration of the compromised tissue should be performed. The mainstay of treatment is early and adequate surgical debridement.

Keywords: NSTI- Necrotizing soft-tissue infections, NNSTI - Non- Necrotizing soft-tissue infections, Debridement

INTRODUCTION

Necrotizing soft-tissue infections (NSTIs) are highly lethal infections. These infections were first described by Jones in 1871 and termed as "hospital gangrene".[1] Since then, multiple descriptions of NSTI have been published, and a wide number of terms, definitions, and classifications have been used.[2-5]

In 1951, Wilson coined the term "necrotizing fasciitis" to encompass some of these infections that is rapidly spreading and potentially devastating infection of the superficial and deep fascia with secondary necrosis of the overlying skin.[6]

The early diagnosis is main challenge in treating patients with NSTI, and knowledge of various clinical sign and laboratory markers can be helpful for distinguishing between cases of cellulitis, which should respond to

In present series' most common organism causing NSTI in our institute is gram negative bacilli followed by haemolytic streptococci. Most of the infection was polymicrobial in nature.

Table 5: Distribution of mode of treatment.

Management	No. of Pt.	% of Pt.
Multiple release incision and fasciotomy	26	27.08
Debridement	68	70.83
Amputation	2	2.08

In our series debridement was done in 70.8% of cases with in 8 hours of admission after initial resuscitation. Multiple release incision and fasciotomy was done in 22.9% of cases while amputation at mid-thigh level was done in 2 cases to save life of patient.

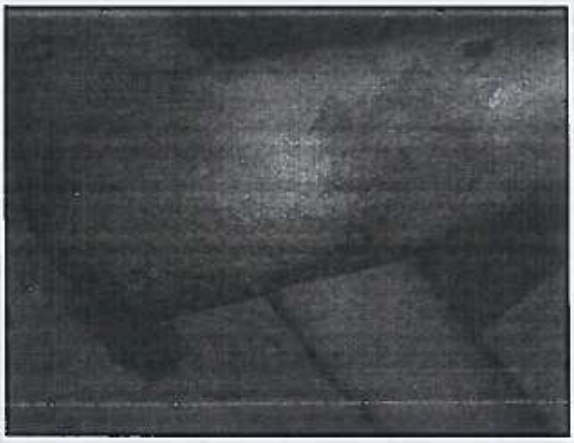

Figure 1: NSTI lower limb- showing blisters, dusky discoloration and skin necrosis.

Figure 2: NSTI lower limb showing blisters fiied with toxic fluid and pus, dusky discoloration and skin necrosis.

Figure 3: NSTI lower limb: debridement of necrotic tissue.

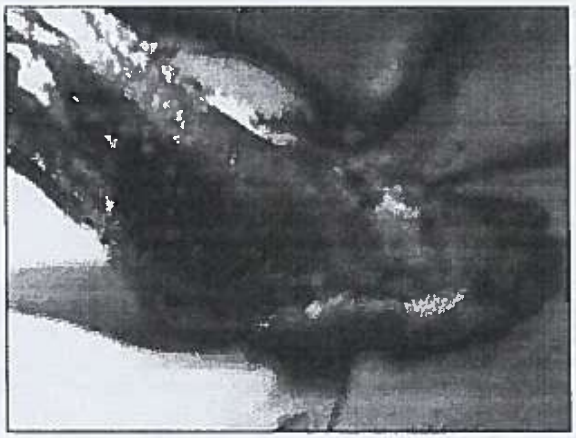

Figure 4: NSTI foot and lower leg; extensive necrosis of skin.

Figure 5: Figure NSTI foot and lower leg: extensive early and adequate debridement.

infected tissue that controls the source of infection and allows for future recovery. Broad-spectrum antimicrobial therapy should be started early to include coverage for gram-positive, gram-negative, and anaerobic organisms. Special consideration for group A *Streptococcus* and *Clostridium* species should be taken. Acceptable regimens include monotherapy agents, such as imipenem, meropenem, ertapenem, piperacillin/tazobactam, and tigecycline. Multidrug regimens have also been described, including triple-drug therapy regimens, such as high-dose penicillin, high-dose clindamycin, and a fluoroquinolone or an aminoglycoside for coverage of gram-negative organisms. Vancomycin, daptomycin, or linezolid should be included in the regimen until methicillin-resistant staphylococcal infection has been excluded. Antimicrobial administration should be continued until no further debridements are needed and the patient's physiology has improved.

Debridement of the necrotic tissue should be undertaken as soon as possible as it is probably the most important determinant of outcome in necrotizing soft tissue infections. This was well described in a study by Bilton, et al in which patients with necrotizing soft tissue infections who had adequate surgical debridement (early and complete) were compared to those with either delayed or incomplete debridements. The mortality in the latter group was 38% compared to 4.2% in the group receiving adequate surgical treatment.[14] During the operation, a generous incision is performed and if needed, the incision is extended to allow for complete debridement of the infected or necrotic tissue. Occasionally, amputation of a limb is necessary to achieve this goal to save life of patient. Healthy, viable, bleeding tissue should be present at the edges of the excision site, and aggressive resuscitation should accompany the perioperative period. Once the initial debridement has been done, management in an intensive care unit is recommended, and scheduled debridements at intervals of 6–48 h should be performed until no further necrosis or infected tissue is seen. Finally, physiologic support, combined with close monitoring in an intensive care unit is encouraged. It is not uncommon to see patients with NSTI develop organ failure, such as acute renal failure and acute respiratory distress syndrome, which require replacement therapies.

The most important discriminative information to be established in patients with soft-tissue infection is the presence of a necrotizing component. This will confirm NSTI, and by definition, will identify patients that require surgical debridement. The first and most important tool for early diagnosis of NSTI is to have a high index of suspicion. When in doubt, exploration of the compromised tissue should be performed. Intravenous drug user are found to be high-risk group for developing necrotizing soft tissue infections, and when evaluated for soft tissue infections they should undergo a thorough assessment that can confidently rule out a necrotizing infection. The mainstay of treatment is early and adequate surgical debridement with scheduled returns to the operating room. We have also observed that cases of NSTI without a recognized precipitating factor are more likely to be caused by group a streptococcal infection. More recently, NSTI without a recognized precipitating factor has also been identified with community-acquired methicillin-resistant staphylococcal infection.[14]

Since the first description by Jones, mortality in patients with NSTI remains high. He reported a mortality rate of 46%, and a recent pooled analysis determined it to be ~34%.[1,15] More recent series have reported mortality rates with a range of 16%, 24%, a rate that, although lower than the rate 100 years ago, still accounts for high mortality associated with NSTI. In our series mortality rate was 16.66 % .This low rate is related with early and adequate debridement within 8 hours of admission and aggressive critical care of these pt.

Bosshardt, et al published a series of patients with predominantly intravenous drug use-related necrotizing soft tissue infections over a 5-year period and showed that the incidence more than doubled when compared to the first years of the study.[20]

CONCLUSION

We also draw following conclusion. Pain and swelling were commonest presenting symptoms found in every case. Diabetes and Trauma were major predisposing factor in our series. NSTI differ from NNSTI with respect to presence of blister (50% versus 5.8%), Dusky discoloration (58.3 % versus 0%), Necrotic skin (51.04% versus 0%) and Crepitance (6.2% versus 0%). So Bullae, necrotic skin, dusky discoloration and crepitance are strongly predictive of NSTI. Four laboratory criteria that are strongly suggestive of NSTI ($P< 0.001$) i.e. statistically significant. Total Leucocytes Count more than 15 X 10 9/L. S. Creatinine more than 1.5 mg/dl.Serum Na+level less than 130 mmol/L. Presence of gas in x-ray of affected part. In present series' most common organism causing NSTI in our institute is gram negative bacilli followed by haemolytic streptococci. Most of the infection was polymicrobial in nature. Prompt resuscitation followed by early and adequate debridement remains the cornerstone of management of NSTI. Wound inspection after 24 hours to confirm the adequacy or to complete debridement. In conclusion of our study we would like to say that lack of awareness among clinician may play a major role in delay of diagnosis and institution of therapy that leads to subsequent high mortality and morbidity. The most important factor in survival in present series was related to rapidity of debridement within 8 hrs of admission after initial resuscitation. Utilizing these principal the morbidity and mortality of patients with NSTI should be substantially reduced.

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Research Article

Laparoscopic peptic perforation repair: our experience at rural tertiary care center

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ABSTRACT

Background: Peptic perforation is a life threatening complication of peptic ulcer disease requiring prompt surgical management. Omental patch repair with peritoneal lavage is the mainstay of treatment for perforated peptic ulcer at most of the centres. Laparoscopic repair has been described by various authors since 1990 in different part of world. In current study we have assessed the feasibility and safety of use of laparoscopy for this life threatening surgical emergency. The outcome were analyzed in terms of operating time, post-operative complications, medication, hospital stay, morbidity and mortality.
Methods: This study was carried out in period of two years from January 2012 to December 2013. Patients were initially assessed in emergency department and then after resuscitation taken up for surgery. Patients with provisional diagnosis of perforated peptic ulcer were included in the study, meeting inclusion criteria.
Results: Total 30 patients were studied out of total 38, who were operated in the study period. 26 males and 4 females, age ranged from 18-60 years, operative time was 55 to 110 minutes. In post-operative period the need for intravenous medication (analgesics and antibiotics) was less, early assumption of routine activity and early discharge. A very important factor noted that patient were psychologically so happy and convinced that they did not have big wound over abdomen and they can resume their routine activity as before.
Conclusions: Laparoscopic repair of perforated peptic ulcer is safe and effective in experienced hands in most of the patients. It offers all advantages of laparotomy without compromising the safety and outcome.

Keywords: Perforated peptic ulcer, Laparoscopy

INTRODUCTION

Peptic ulcer is a well-known disease widely prevalent in all socio economic strata all over world. The management of this common disease has evolved over a period of time. Current medical management with proton pump inhibitors and H.pylori eradications has drastically reduced the various complications and need of surgical interference. Still, peptic perforation is quite prevalent life threatening surgical emergency encountered in general surgical practice. Omental patch repair (modified Graham repair) with thorough peritoneal lavage is the mainstay of treatment at most of the centers.[1]

Laparoscopy has emerged as gold standard for surgical treatment of various diseases in last 2-3 decades due to it's certain advantages like less post-operative pain, less hospital stay, less wound complications, early return to normal activity etc.[2]

This study is aimed to assess the feasibility, safety and advantages of use of laparoscopy in the treatment of this

unchanged. Minimal access surgery has gained wide acceptance amongst surgeons and general public all over world due to its definitive advantages. Although there are still some constrains amongst conventional surgeons for the use of this technique in certain surgical emergencies.

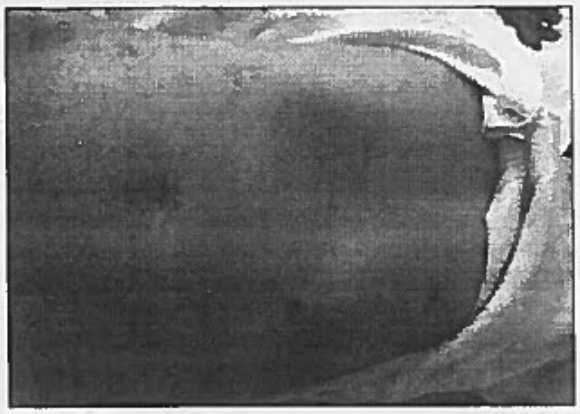

Figure 1: Post-operative photograph showing port position for laparoscopic peptic perforation repair.

In 1990 Mouret et al. reported the first laparoscopic sutureless fibrin glue omental patch for perforated duodenal ulcer repair.[5] The first successful laparoscopic suture repair for perforated peptic ulcer was described by Nathanson et al. in 1990.[6] Since then, many studies has been conducted by various authors in different part of world to define the use of laparoscopy in surgical management of perforated peptic ulcer. Costalat et al reported combined endoscopic and laparoscopic approach using ligamentum teres hepatis.[7] In 1993 Darzi et al, and Nassar et al in 1994 reported laparoscopic omental patch repair with use of automated stapler.[12,13] Siu WT et al described single stitch laparoscopic omental patch repair of perforated peptic ulcer in 1997.[3] Masao Matsuda et al from Japan also published an article suggesting that laparoscopic omental patch repair offers advantages of laparoscopic surgery and an attractive alternate to open surgery.[17]

After Mouret and Nathanson many authors worked in this field and described various techniques of perforated peptic ulcer closure i.e. simple suturing, by gelatin sponge and fibrin glue, stapled omental patch repair, gastroscopy assisted insertion of ligamentum teres hepatis to close the perforation, gastroscopic guided omental plugging to close the perforation.[22] single suture with omental patch repair.[3]

Studies were done to compare open versus laparoscopic repair.[16,19,20,23] Siu et al and found that laparoscopic repair was superior then open in terms of size of incision, requirement of post op analgesia, less hospital stay, early return of normal activity, less immediate and long term complications etc. although the operating time was more in laparoscopic group in some studies but can be reduced by adopting certain techniques and with more and more experience. Almost all study groups recommended proper selection of patients and demands surgeons having good laparoscopic suturing skills and experience.

In our study, after analyzing the results it was found that duration of surgery was between 55-110 minutes. Time taken was more in initial cases and in few more contaminated cases, after that the operating time was nearly same as we take in open surgery and even less in few cases. Post operatively patients needed round the clock Intravenous analgesics for 2-3 days, Ryles tube could be removed in 2-3 days except in two cases in which we had to keep ryles tube for 4 days which was badly contaminated large perforation of about 1cm. we have started oral feeding in 3-4 days in most of the cases except in 5 cases which were having large perforation with more peritoneal contamination. Hospital stay was 4-5 days in most of the cases; only 3 patients had 6 days stay. 2 patients had chest complications in immediate post op period which were managed comfortably in ICU and recovered in 2-3 days. There was no wound gap, no burst abdomen, no residual collection or pelvic abscess noted in any case. No incidence of any incisional hernia was noted in any case. Patients were allowed and encouraged to return to the normal activity after 7-10 days. No mortality was noted in our series.

CONCLUSION

The management of this common disease is evolved over a period of time. Current medical management has drastically reduced the various complications and need of surgical interference. Still peptic perforation is quite prevalent. Gold standard treatment is conventional laparotomy and omental patch repair (modified Graham repair). Laparoscopy has emerged as gold standard for surgical treatment of various diseases in last few decades. We conclude with the present study that laparoscopy is an effective tool in the surgical management of perforated peptic ulcer.

It requires experience and technical expertise in laparoscopic surgery. If proper selection of patients is done laparoscopic repair is safe and feasible. It does not increase the cost of treatment infact it helps in reducing the cost by less hospital stay, less medication required, less morbity, early return to normal activity and to workplace. We hereby recommend laparoscopic repair in selected patients as treatment of choice as it offers all the advantages of laparoscopy without increasing the risk. It is a safe, effective and cost effective method for the treatment of perforated peptic ulcer.

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Original research article

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ROLE OF WATER SOLUBLE CONTRAST RADIOLOGY IN SMALL INTESTINAL OBSTRUCTION

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ABSTRACT:

Objectives: To evaluate the water soluble contrast radiography as diagnostic modality in small intestinal obstruction, where plain X-ray abdomen is inconclusive. **Material and method:** Study was conducted upon 20 patients admitted in the surgical department of Geetanjali Medical college and Hospital, with features of intestinal obstruction but no concrete evidence of the same and hence underwent contrast study with water soluble contrast agent. After admission a brief history, clinical assessment and plain abdominal radiograph were taken in the standing and supine position and in case of suspicion, there the water soluble contrast study was carried out. **Results:** Total 20 patients were taken for contrast study on the basis of X-ray findings. Out of these, 6 patients showed clear cut off in the contrast level in the small intestine and were taken for surgery. Two patients in which findings were equivocal were also subjected to surgery and were found to have the intestinal obstruction. In 12 patients, dye passed freely into large bowel, so these patients were managed conservatively. Out of these, 3 Patients didn't respond to conservative management and were subjected to surgery. Thus in 17 patients' correct diagnosis could be made with the help of contrast studies. **Conclusion:** To Conclude water soluble contrast study is safe and easy to perform, and gives useful information regarding presence or absence of complete obstruction and aids in the decision making regarding the mode of management.

Keywords: water soluble contrast radiography, intestinal obstruction, plain X-ray abdomen

INTRODUCTION

Intestinal obstruction is a condition which is seen commonly in surgical practice and is responsible for 20% admission in surgical emergency. (1) (2) Mortality rates for intestinal obstruction are declining, but still remain as high as 5-11 %(3) (4). Despite of advancements made in the

around 40 ml in children. The dye was introduced through the Ryle's tube and the tube occluded. For the next four hours aspiration was not done.

Supine abdominal radiograph in the AP position were taken at 30 minutes and again at four hours after administration of dye.

The cases with a clear cut off in the contrast level in the small bowel, or if the contrast failed to reach large bowel by 4 hrs, were taken up for surgery. Cases in which second film showed persistently dilated gut loop around a fixed part or were not conclusive were taken for surgery.

The other cases in which the contrast passed off into the colon by end of 4 hour were managed conservatively.

Exclusion Criteria

1. Patients with clinically obvious intestinal obstruction such as obstructed inguinal hernia.

2. Patients suspected to have intestinal strangulation.

3. Patients who underwent barium contrast-study in immediate past.

RESULTS:

Study was conducted upon 20 patients with features of intestinal obstruction but no concrete evidence of the same and hence underwent contrast study with water soluble contrast agent.

Patients with obvious cause of intestinal obstruction or in whom there was the strong doubt of strangulation, were excluded from study.

When X-ray showed contrast in large bowel in 4 hours, these patients were considered to have no obstruction and were managed conservatively. Patients in which the contrast failed to does not reach large bowel in 4 hrs, were operated.

There were 11 males and 9 females in the study. Maximum incidence of intestinal obstruction was in the age group 20- 29 years and 40-49 years.

Pain was the commonest symptom and distension of abdomen was the commonest sign. Dilated gut loops were the commonest findings in supine X-ray abdomen.

In 6 patients dye showed clear cut off and on surgery all had the cause of intestinal obstruction. 2 patients in which the findings were equivocal were operated.

In 12 patients dye passed freely into colon. Out of 12 patients, 9 patients recovered on conservative management and 3 patients required surgery.

The commonest cause of intestinal obstruction was adhesive obstruction and intestinal tuberculosis. Water soluble contrast study was helpful in 85 % of the patients with intestinal obstruction and the outcome could be correctly predicted.

There was no side-effect noticed due to contrast agent. Mortality rate, observed in the study was 10 %.

correct and timely diagnosis for proper management to save his life.

In the present study, 50 % of the patients were seen in the less than 40 years of age group. Jean-Jacques Duron J.J. et al found that age of less than 40 years was a risk factor for the small intestine obstruction. The reason that less patient was seen in the age group of < 40 yrs may be due to the presence of Kalawati Saran children hospital in near vicinity. (8)

Sarr et al (1983) found a male: female ratio of 1.14: 1. (9)In the present study male: female ratio 1.2: 1. The degree of male predominance in our study is consistent with the previous studies.

Out of the cardinal features of intestinal obstruction i.e. pain, vomiting, distension and obstipation, all four were not present in all patients of intestinal obstruction, but were present in the varying combination each patient.

La Pass et al too found that patients commonest complaint were either crampy abdominal pain or vomiting and abdominal distension along with high pitched bowel sound were commonest physical findings. (10) Similar conclusion was derived in our study. The high incidence of abdominal pain could be due to the fact that it is the pain that makes the patients aware of their problem and brings them to the hospital.

Plain X-ray was done in the patients suspected of obstruction. Maglinte DD reported in their series that plain X-ray abdomen was diagnostic in 60% of cases. (11) Our present study diagnostic accuracy of plain X-ray abdomen was 60 %, which is same with literature.

In the present study, dye passed freely into colon in 12 patients. Out of these 12, 3 patients required surgery as their obstruction didn't relieved on conservative management. One of these patients refused surgery, one patient had the band as the cause of obstruction, one patient had appendicular perforation with flimsy adhesion. So the surgery could be avoided in 45% of the patients. Hok-Kwok Choi (2002) performed contrast study in nineteen patients. The use of Gastrografin significantly reduced the need for surgery by 74%. (12) Joyce et al managed 112 patients out of 127 patients without surgery on the basis of the water soluble contrast study. (13)

In the contrast study, when there was clear cut off, patients were considered to have complete obstruction, therefore subjected to surgery. Joyce et al operated on 15 patients out of 127 patients based on water soluble contrast radiography, as study showed clear cut off of the contrast level.(13) Dunn et al in their study of 327 patients, performed surgery in 42 patients, based on contrast study.(14)

They found causes as multiple adhesion, single obstructing band, intussusceptions, etc. In the present study 6 cases showed clear cut off in the contrast level and underwent surgery. All of them had intestinal obstruction proved on laparotomy.

When the contrast radiology does not fulfil the criteria of either obstruction or free passage, the surgeon is obliged to perform an operative procedure in order to make a diagnosis.

In the present study two patients, who had equivocal finding, were operated. One of them had pyloric stenosis with Para duodenal

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List of Publications

DR. VIKAS GUPTA				
1	QUALITY OF LIFE ASSESSMENT IN PATIENTS OF BLADDER CANCER WITH RADICAL CYSTECTOMY AND ILEAL CONDUIT	**DR. VIKAS GUPTA**, DR. VARDACHARY SRINIVAS	Gupta V. Srinivas V.Quality of life assessment in patients of bladder cancer with radical cystectomy and ileal conduit.Int. Surg J 2019;6:4012-6	Index Coppernicus
2	SKIN PREPARATION FOR THE PREVENTION OF SURGICAL SITE INFECTION: EFFICACY OF SODIUM FUSIDATE AND ETHANOL SPRAY OVER CONVENTIONAL METHODS	**DR. VIKAS GUPTA**, DR. SANJEEV KUMAR AND DR. K C VYAS	Dr. Vikas Gupta, Dr. Sanjeev Kumar, Dr. KC Vyas. Skin preparation for the prevention of surgical site infection: Efficacy of sodium fusidate and ethanol spray over conventional methods. Int J Surg Sci 2019;3(4):82-85. DOI: https://doi.org/10.33545/surgery.2019.v3.i4b.221	index copernicus

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Original Research Article

Quality of life assessment in patients of bladder cancer with radical cystectomy and ileal conduit

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ABSTRACT

Background: Bladder cancer, a lethal disease accounts for 3% of cancer deaths. With possibility of various urinary diversion options after bladder removal having comparable cancer control and complications, quality of life becomes an important factor in deciding the type of urinary diversion.

Methods: Retrospective observational study with statistically appropriate sample size of 50. Patients of radical cystectomy and ileal conduit given validated Functional Assessment Of Chronic Illness Therapy for Bladder Cancer (FACT-BI) Questionnaire to answer about post-operative quality of life in terms of five parameters i.e., physical, mental, social, emotional and cancer specific well-being after 1 year of surgery.

Results: Results analysed by FACIT-BI questionnaire analysis methods statistically, in terms of total scores and sub-scores. In our study the mean scores of physical well-being (PWB) subscale is 24.08±4.67 (range 0-28), social well-being (SWB) subscale is 23.52±4.35 (range 0-28) , emotional well-being (EWB) subscale is 20.06±5.09, functional well-being (FWB) subscale is 21.84±6.01 (range 0-28), bladder cancer subscale is 36.44±5.72 (range 0-48). While mean trial outcome index score is 82.16±3.5 (range 0-104), FACT- General (G) score is 89.50± 15.88 and mean FACT-BI total score is 125.94±19.04.These scores provides the quantitative assessment of the quality of life and higher scores indicates better quality of life.

Conclusions: Assessing quality of life for a particular type of urinary diversion, with questionnaires, gives surgeons and patients, guidance regarding diversion of choice.

Keywords: Bladder cancer, Radical cystectomy, Ileal conduit, Quality of life, Questionnaire

INTRODUCTION

Bladder cancer is a lethal disease which accounts for 3% of all cancer deaths. In 2010 there were estimated 70,530 new cases of bladder cancer in the United States, and over 500,000 current survivors.[1] The standard of care for muscle-invasive bladder cancer is radical cystoprostatectomy in men and anterior exenteration in women.

Options for urinary diversion after cystectomy include noncontinent conduits, continent cutaneous diversions, and orthotopic bladder substitutes have been shown to have similar perioperative complication rates, cancer control, and morbidity.[2,3]

For >30 years, the ileal conduit (IC) has been considered the "standard" urinary diversion for bladder cancer patients undergoing radical cystectomy.

which may be attributed to old age and other co-morbidities.

94% patient did not have any nausea while 6% patient had occasional nausea that is unrelated to the disease. Over 64% of the patients had 'no problems' in meeting the needs of their family and another 22% were also able to' fulfil family needs' without major problem. Only three patients because of their physical condition found it difficult to fulfil their family needs.

90% of the patients 'did not have any pain' while 10% patients felt 'some pain' at stoma and wound site.

The treatment is in the form of radical cystectomy so most (90%) of patients are 'not bothered with side effects of treatment' as seen in other modalities like chemotherapy and radiotherapy.

...e 'feeling of illness' was not there in 88% of patients ...ile one patient (2%) felt 'too ill'.

Only two patients in our study were forced to spend time in the bed because of their physical weakness, old age and disease while 76% cases were performing their normal physical activities.

The mean physical well-being (PWB) subscale score in our study is 24.08±4.67 (range 0-28).

Social/family well-being

In this study, data reveals that 76% patients felt closeness to their friends and 86% cases got a lot of emotional support from their families. None of them said that they were not supported by their families.

94% of patients said that their families have 'completely accepted' their illness and 88.3% felt closeness to their ...tner and they were 'fully satisfied with their family ...ommunication' about the disease. Regarding the question about satisfaction with sex life only 16 out of 50 patients answered their question. Only two patients seem to be 'satisfied' with their sex life while 9 patients were 'not at all' satisfied. The mean social/family well-being (SWB) subscale score of this study is 23.52±4.35 (range 0-28).

Emotional well-being

In our study majority of the patients were 'not sad' (84%) while only 2% were 'very sad' because of the disease. 76% patients were 'very much' satisfied with the way they were coping with their illness and 86% were fighting with the disease with 'high hopes'.

90% of the patients were 'not nervous' and were not worried about dying. 84% of the patients were not worried that 'their condition will get worse'.

The mean emotional well-being (EWB) subscale score in our study is 20.06±5.09.

Functional well being

82% of our patients were able to do work 'normally' while 10% patient were not able to work because of the disease, old age and effects of the surgery and while for majority of them (80%) work was 'fulfilling'.

74% of the patients were able to enjoy their life nicely and 'enjoy the things they usually do for fun'. 88% of the patients said, that they have 'accepted their illness fully'.

Majority of the patients (70%) were 'fully content with the quality of life right now' while 6% patients are not content with the quality of life because of their physical, mental and emotional factors.

The mean functional well-being (FWB) subscale score in our study is 21.84±6.01 (range 0-28).

Additional concerns for bladder cancer subscale

This subscale is specific for bladder cancer patients and assesses problems related specifically for bladder cancer. This includes 12 questions of which two are specific for patients with ostomy appliance and one question regarding erection is specific to men.

As our patients were with ileal conduit, so they had no issues regarding the control of their urine.

62% of the cases said that they have 'not lost the weight' while 26% said that they have lost it a 'little bit', 4% patients said that they have lost their weight 'very much', which may be because of the decrease in appetite or progression of the disease.

Control of the bowels and frequency of urination are the concerns mainly for the MAINZ type of diversion and for the neo bladder group so in our study 99.9% cases replied to have normal urine output. Although five patients said they had diarrhoea but the cause should not be attributed to the surgery.

In our study 74% of the patients had a 'very good' appetite and another 18% had adequate appetite.

Most of the patients were happy with the 'appearance of their body' which is related to the presence of urinary stoma on anterior abdominal wall.

53.1% patients have marked the response '4' i.e., very much and 40.8% patients have marked response '3' i.e., quite a bit. None of the patient was completely dissatisfied with their body appearance.

74% patients had no embarrassment with their stoma attributable to psychological counselling.

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Skin preparation for the prevention of surgical site infection: Efficacy of sodium fusidate and ethanol spray over conventional methods

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Abstract
Surgical site infection is an overwhelming menace for the surgeon and it increases the morbidity and mortality of the patient, increases the hospital stay and cost of the treatment. One of the important factors among these is the preoperative preparation of the skin with antiseptic agent. For centuries there has been a search for an ideal agent for this purpose. This study was undertaken to evaluate the newly introduced Sodium fusidate and Ethanol spray as a preoperative skin preparation agent and compared it with other conventional methods. This prospective study was conducted at Maharana Bhupal Government Hospital, Udaipur in the general surgical wards on 178 patients during the period of March 2009 to August 2010. It included all the clean and clean contaminated intra-abdominal surgical procedures conducted in planned surgery. In the present study, we observed wound sepsis in 24 cases out of a total of 178 cases. Postoperative wound sepsis rates were higher in clean contaminated wounds(16.52%) as compared to clean wounds(7.9%). Maximum infection rate was present in Savlon and Spirit group (14.28%), while it was least in Fusidic acid spray group (5.88%). The most common organism isolated from infected wound was *Staphylococcus aureus* (41.67%), followed by *E. coli* (20.83%) and *Streptococci* (16.67%). Sodium fusidate and Ethanol spray is an effective skin preparation agent as concluded by our study in clean and clean contaminated elective abdominal procedures.

Keywords: Surgical Site Infections (SSIs), sodium Fusidate and ethanol spray, conventional methods, abdominal procedures

Introduction
Surgical site infection (SSI) and post-operative wound sepsis is a serious problem and it continues to be a significant problem for surgeons in the modern era. Their spectrum of effect on individual's health ranges from slightest of inconvenience to major deleterious health effects and even death. The burden of high rates of surgical wound infection in terms of economics is also tremendous [1]. The financial drain that these infections place on the resource constrained hospitals in the form of prolonged hospitalization along with increased duration, dosage of medication, dressings and more intensive nursing care are like the proverb 'Last Straw Broke The Camel's Back'.

For almost a century, there has been a continuing search for an antiseptic agent capable of sterilizing skin prior to surgical operation. But it is not possible to sterilize the skin; skin antiseptic aims to reduce the number of viable resident flora on or in the skin and to destroy pathogenic organism that may be on the skin as transients. By definition preoperative skin preparation is a safe, fast acting, broad spectrum, antimicrobial containing preparation that significantly reduces the number of microorganisms on intact skin.

Several antiseptic agents are available for preoperative preparation of the skin at the incision site. These include Iodophores (e.g., Povidone iodine), alcohol containing products, mercurochrome, Cetrimide and chlorhexidine Gluconate [2]. It is beneficial to use the combination that contain two different antiseptics with two different mechanism of killing action to have an additive antiseptic effect and kill microorganism more effectively, that is critical [3-6].

Recently a newer Microbicidal agent Sodium Fusidate spray 2% with 60% ethanol has been introduced. This exerts antibacterial activity by inhibition of protein synthesis by inhibiting the translocation enzyme by interfering with the binding of amino acyl transfer ribonucleic acid to ribosomes. This is produced by the fungus *Fusidium coccineum*.

his study majority of the preoperative cultures were sterile, in positive cultures *Staphylococcus epidermis* was the most mon isolate followed by *Staphylococcus aureus*. The most common organism isolated from infected wound was *Staphylococcus aureus* followed by *Escherichia coli* and *Streptococci* as shown in Table 2.

Table 3: Wound sepsis rates with various agents in Clean and Clean contaminated surgeries

No.	Agent	Clean surgeries		Clean contaminated surgeries	
		No. of infected cases	Total no. of cases (%)	No. of infected cases	Total no. of cases (%)
1	Sodium Fusidate and Ethanol Spray	1	17 (5.88)	7	43 (16.28)
2	Povidone-Iodine	2	24 (8.33)	6	36 (16.66)
3	P-I & Metronidazole	1	15 (6.67)	3	23 (13.04)
4	Savlon & Spirit	1	7 (14.28)	3	13 (23.07)
5	Total	5	63 (7.9)	19	115 (16.52)

this study overall rate of infection in clean abdominal geries was 7.9%. Maximum infection rate was present in on and spirit group (14.28%), while it was least in Fusidic l spray group (5.88%). Overall wound sepsis rate in clean taminated abdominal surgeries was 16.52%. Maximum rate present in savlon & spirit group (23.07%), minimum in P-I metronidazole group (13.04%), while it was 16.28% in idic acid spray group as shown in Table 3.

uis[illegible]dy local reaction in the form of irritation, sneezing and g[illegible] were present with the use of Fusidic acid spray in 5% of cases while one patient developed mild erythema in P-metronidazole group. None of the patient developed any emic adverse effect.

cussion

his study male constituted 68.23% and females comprised remaining 38.76% of the study population. This distribution the patient population favouring males can probably be buted to two reasons; sex ratio of the population favors es and attendants were more readily agreeable for surgical rvention for male patients in this mainly tribal belt.

ing the period of this study, a wide range of abdominal gical procedures were performed on 178 patients who were uded in this study. The most commonly performed surgery inguinal hernioplasty (26.4%) and urologic procedures 4%).

operative follow up of the patients in this study showed that 8% developed postoperative surgical site infection. This [illegible]epsis rate of the present study is very high as compared [illegible] reported by Byrne [11] (4.1%), Cruse and Ford [10]), Mead [12] (2.8%) and Olson [13] (4.2%). The difference is stically highly significant ($P< 0.001$) and can be partially ained on the following reasons:

Poor nutritional status of the patient included in this study compared to the western studies.

Lack of facilities in the resource strapped government hospitals compared to western health care system.

Tendency of late discharge of patients from hospitals to provide adequate postoperative care and rest to patients who were mostly labourers and residents of rural interiors with minimal access to health care facilities.

Poor socio-economic status and the lack of health insurance coverage for the masses, limit the use of disposable and the latest technology, which carries a prohibitive price tag with it.

studying the rate of postoperative wound sepsis across the groups, our findings are essentially similar to the other rnational studies [12, 13]. On evaluating the distribution of operative wound sepsis across the wound class, clean-aminated wounds were associated with a higher rate of wound sepsis (16.52%) as compared to clean wounds (7.9%). The rates were significantly higher as compared to other international studies [12-14].

In the clean abdominal surgeries minimal wound sepsis rate was present in the in whom surgical site was prepared with Fusidic acid spray (5.88%). This may be explained due to the fact that Fusidic acid has high activity against *Staph. Aureus* [7] which is the most common isolate is clean surgical wounds. Spray form of application also helps in deeper and faster penetration of tissues and better efficacy. Maximum wound infection was seen when skin preparation was done only with Savlon and Spirit (14.28%). The infection rates in all groups when compared statistically was not significant (p=0.14).

In the clean contaminated abdominal surgical procedures least SSI rate (13.04%) was seen with Povidone-Iodine and metronidazole group. This can be explained by the fact that in clean contaminated surgeries the source of infection is mostly endogenous from the genito-urinary or alimentary tract as described by Hojer [15] and Cruse and Ford [16]. This combination covers the spectrum of activity against the causative pathogens. Maximum rate of infection was again seen with Savlon & Spirit group (23.07%) while the Fusidic acid spray group had the SSI rate of 16.28%. When analyzed statistically the difference was statistically non-significant among all groups (p=0.295).

In our study preoperative incision site culture swab showed sterile culture in 69.66% of cases, this may be explained due to soap and water scrub given to the patient and administration of preoperative antibiotics. In 17.97% of the cases *Staphylococcus epidermidis* was isolated while *Staphylococcus aureus* was isolated in 9.55% of cases.

Postoperative culture from infected wound showed *Staphylococcus aureus* to be the most common pathogen isolated from 41.67% of cases followed by E.coli in 20.83% cases and Streptococci in 16.67% cases. Hojer [15] studied that in clean operations exogenous *Staph. aureus* is the usual cause of infection. Curse and Ford [16] demonstrated that the most common isolate from class I wound was *Staph. aureus* followed by *Enterococci* and *Pseudomonas*. Class II wounds were most frequently infected by *Enterococci* then *Pseudomonas* and *Staph. aureus*. Haley *et al* [17] similarly showed that *Staphylococcus* was the most common pathogen, of these *CoNS* (*Coagulase negative Staphylocci*) accounted 18.9% of the isolates and *CoNS* were isolated in about 13.6%. Second most common offender was *Enterococcus* species at 13.6% of the isolates. Close on their heel were *E.coli* 8% and *Pseudomonas aeruginosa* 7.8%. Nichols [18], in his study showed that since 1984, *Staph. epidermidis* has been one of the three most frequently cultured wound infection pathogens, other two being *Staph. aureus* and *Pseudomonas*. Weiss *et al*. [19] described various pathogens isolated from postoperative SSI. *CoNS* were most common 25.6% followed by Enterococcus 11.5%, Staph

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List of Publications

DR. BHAVIN K BARIA				
1	ROLE OF DIAGNOSTIC LAPARAOSCOPY IN CHRONIC ABDOMINAL PAIN	**DR. BHAVIN BARIA,** DR. KAMLESH GOHIL, DR. SIDDHARTH KUMAR	Int J Res Med. 2017; 5(4); 42-45 e ISSN:2320-2742 p ISSN: 2320-2734	ISSN NO. 2277-8179
2	EFFECTS OF PRESSURE OFF-LOADING IN DIABETIC FOOT	DR. PRAFULL KUMAR, **DR. BHAVIN K BARIA,** DR. BHAUMIK BARAD DR. HIREN PARMAR	Dr.Praful Kumar Gamit, Dr. Bhavin K Baria, Dr. Bhaumik Barad, Dr. Hiren Parmar effects of pressure off-loading in diabetic foot, International Journal of Scientific Research, Volume 5, issue 9/September2016	EISSN:2320-2742, P ISSN : 2320-2734

ORIGINAL ARTICLE

Role of Diagnostic Laparoscopy in chronic Abdominal Pain

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ABSTRACT

BACKGROUND: Chronic Abdominal Pain is a common problem in hospital. Many patients presenting with chronic Abdominal Pain had no specific etiological diagnosis at end of their Diagnostic workup.with introduction of laproscopic surgery,a new tool has been added to our knowledge. Laparoscopy can identify abnormal finding and improve of patients with chronic pain. **MATERIAL AND METHODS:** A total number of 50 randomly selected patients withchronic Abdominal Pain were enrolled in the prospective cross sectional study.after laproscopic post operative outcome was analyzed. **RESULT:** We found in a selected patient group, laparoscopic evaluation of chronic Abdominal Pain is usually associated with a positive outcome in term of less or no pain after two months of Laparoscopy.

Key Words: Laparoscopy, Chronic Abdominal Pain, Postoperative evaluation

INTRODUCTION

Chronic abdominal pain is a common disorder both in general practice and in hospitals. Although patients with this type of pain may have undergone numerous diagnostic workups, including surgery, their pain remains a challenge to all known diagnostic and treatment methods. After all, more than 40% of patients presenting with chronic abdominal pain had no specific etiological diagnosis at the end of their diagnostic workup.[6-9] Chronic abdominal pain is associated with poor quality of life[10] and significant levels of depressive symptoms.[11] Much is about the prevalence and suffering associated with chronic abdominal pain.[6] Many common organic and functional diseases can cause it. The most common organic conditions include intestinal adhesions,[11,12] appendicular causes,[16] and biliary causes,[14,15] while functional conditions include irritable bowel disease,[17] functional dyspepsia,[18] and various motility disorders.[19] Abdominal wall pain is also common and frequently mistaken for visceral pail-.02°'21) After ruling out common diseases by careful investigations, many patients are still undiagnosed and represent a major diagnostic challenge to the surgeon.[22] With the introduction of laparoscopic surgery, a new tool has been added to our knowledge. The use of this new technology in the diagnosis and management of chronic abdominal pain has been tried in previous studies. Laparoscopy can identify abnormal findings and improve the outcome in majority of patients with chronic abdominal pain, as it allows surgeons to see and treat many abdominal conditions that cannot be diagnosed otherwise. It is a safe and effective tool and can establish the etiology and allows for appropriate interventions in such cases. Abdominal adhesions are the most likely findings, especially in patients with past history of abdominal operations. Other findings such as appendicular pathology, hepatobiliary causes, and endometriosis can be discovered and dealt with.[23] However the role of laparoscopy in chronic abdominal pain is still debated by some authors who do not recommend it as a treatment for adhesions in patients with chronic abdominal pain. In the present study we

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relief. All the patients were re-evaluated after two months. The pain in the late postoperative period was classified into: worse, unchanged, less pain, and disappearance of pain. Less pain and disappearance of pain were referred to as positive outcomes, while unchanged and worse pains were referred to as negative outcomes.

Statistical analysis: Gathered data were processed and analyzed.

RESULTS

The studied patients were in the age group ranging from 13 — 55 years. Most of the patients studied were females (84%). The mean duration of pain was seven months with the range of duration from three to eleven months. The most common site of pain was the right lower quadrant (50%) followed by the periumbilical region (40%). Twenty patients were using either non-steroidal drugs or pain killers to relieve the pain, and six patients were using proton pump inhibitors. Eleven patients (22%) had undergone at least one previous surgical abdominal procedure.

Table 1: Baseline Characteristics of the Studied Patients

Characters	Value
Age(years range)	13-55
Gender	
Male 8 (16%)	
Female 42 (84%)	
Duration of Pain (months) Mean (range)	7 (3-11)
Site of Pain	
Right Lower Quadrant	25 (50%)
Right Upper Quadrant	4 (8%)
Left Lower Quadrant	1 (2%)
Left Upper Quadrant	Nill
Periumbilical	20 (40%)
History of Previous Abdominal Surgery	11 (22%)

There were eight cases converted to open procedures. Out the 50 patients with chronic abdominal pain. a definitive diagnosis was established in 45 patients (90%), while no identifiable cause could be reached in five patients (10%). The most common laparoscopic findings were appendiceal pathology (40.7%). Other findings included ovarian cysts (16.7%), adhesions (14.8%), gall bladder pathology (7.4%), terminal ileitis (7.4%), mesenteric lymphadenopathy (5.6%), strictures (5.6%) and jejunal diverticulum (1.8%). Twenty-two patients showed appendiceal pathology: and their pathology revealed evidence of chronic appendicitis. All patients with adhesions had undergone previous abdominal surgery. Other pathological diagnoses such as chronic acalculus cholecystitis, and multiple enlarged mesenteric lymph nodes were found.

Table 2: Laparoscopic Findings, Intraoperative Data & Postoperative Characteristics

Findings	Value
Laproscopic Findings	
Abnormal Appendix	40.7%
Ovarian Cysts	16.7%
Adhesions	14.8%
Abnormal Gall Bladder	7.4%
Terminal Ileitis	7.4%
Enlarged Lymph Nodes	5.6%
Bowel Strictures	5.6%
Jejunal Diverticulum	1.8%
Postoperative Complications	
None	94%
Infection	6%
Postoperative Hospital Stay (Days Range)	2-14

Laproscopic management included appendectomy, adhesiolysis, cholecystectomy, ovarian cyst derrofing and cystectomy and lymph node biopsy. Five patients had no interventions performed. Postoperative hospital stay ranged from two to fourteen days. In most cases no postoperative complications had been reported except in three cases (showed infection). The wound infection responded well to oral antibiotic and daily dressing. During the time of follow up, all patients were re-evaluated for pain. After two months, positive outcome (less pain or disappearance of pain) was achieved in 47 patients (94%) while negative outcome (unchanged or worse pain) was noted in 3 patients (6%) in the first two months.

Table 3: Postoperative Pain Relief

Duration	Positive Outcome	Negative Outcome
After 2 months	94%	6%

DISCUSSION

Chronic idiopathic pain syndromes are among the most challenging and demanding conditions to treat across the whole age spectrum. Potentially it can be unrewarding for both the patients and the medical team.[24] Studies conducted with large community samples or hospital populations imply chronic abdominal pain is a pervasive problem. Abdominal pain was the third most common pain complaint of individuals enrolled in a large

Original Research Paper

Effects of Pressure off-Loading in Diabetic Foot

Medical Science

KEYWORDS :

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ABSTRACT

Background: Diabetic foot is a frequent complication involving the foot of diabetic patient. Diabetic foot poses a significant health problem. It is rather an endemic disease today. Complications involving the foot cause significant pain and suffering, loss of productive time, hospitalization, heavy expenses to the patient, community and nation as well. To add to above vascular insufficiency and neuropathy accompanying the diabetic foot most often necessitate amputation of the limb. Advances in treatment of diabetes have caused increase in life span of diabetic patient which has resulted in an increase in complications of Diabetes Mellitus like vasculopathy, neuropathy and nephropathy. This in return has increased the prevalence and incidence of diabetic foot. Material and methods: This is the prospective study of 100 patienrs of diabetic foot during duration of about 2 years. Study group of newly diagnosed cases of Diabetis mellitus with foot lesions requiring surgical care was made. Over a period of 2 ½ years we studied 100 patients of diabetes mellitus with following aims and objectives: To identify the importance of foot care and footwear modifications in the form of pressure offloading, To identify and study effects of pressure offloading in duration of healing and salvaging the limb in a patient of diabetic foot, To compare results in patients of diabetic foot treated with pressure offloading and without pressure offloading, To analyze the results of study and reach a consensus regarding a practical and ideal plan of management for cases of diabetic foot. Results: In our study age varied from 25 years to 85 years. The highest incidence was in age group of 46 to 65 years (57%). Majority of patients were of type 2 i.e. non insulin dependent diabetes. Majority of patients presented with gangrene (25%) or non healing wound (33%) on foot. 62% of patients with offloading got healed completely within 10 weeks. Conclusion: Offloading application in patients with diabetic foot ulcer decreases the time period for complete healing of ulcers and decreases rate of complications.

Introduction

Diabetic foot is a frequent complication involving the foot of diabetic patient.[1] It involves a spectrum from superficial ulceration to complete gangrene of foot. India presently has about 45 million patients of diabetes mellitus.[2] Diabetic foot poses a significant health problem. It is rather an endemic disease today. Complications involving the foot cause significant pain and suffering, loss of productive time, hospitalization, heavy expenses to the patient, community and nation as well. To add to above vascular insufficiency and neuropathy accompanying the diabetic foot most often necessitate amputation of the limb.[3] In INDIA habits like walking barefooted, lack of knowledge regarding diabetic foot, hot climate leading to increased perspiration, poor hygiene, poor sanitation, diet poor in proteins, general poverty, lack of basic medical infrastructure, etc have worsened the problem. Neglect from medical and surgical faculty due to lack of glamour associated with this field has added to the problem statement. Over the years the life expectancy of diabetic patients with gangrene of foot has not changed much. Advances in treatment of diabetes have caused increase in life span of diabetic patient which has resulted in an increase in complications of Diabetes Mellitus like vasculopathy, neuropathy and nephropathy. This in return has increased the prevalence and incidence of diabetic foot. With the above considerations we undertook the study of 100 patients of diabetic foot admitted in our institute over a period of 2yrs and 6 months. An emphasis was laid on determination of peripheral neurological status and to study in detail the risk factors responsible for late healing and amputation. Aims and objectives:

Over a period of 2 ½ years we studied 100 patients of diabetes mellitus with following aims and objectives.

1] To identify the importance of foot care and footwear modifications in the form of pressure offloading.
2] To identify and study effects of pressure offloading in duration of healing and salvaging the limb in a patient of diabetic foot.
3] To compare results in patients of diabetic foot treated with pressure offloading and without pressure offloading.
4] To analyze the results of study and reach a consensus regarding a practical and ideal plan of management for cases of diabetic foot.

Material and methods

This is the prospective study of 100 patienrs of diabetic foot during duration of about 2 years. Study group of newly diagnosed cases of Diabetis mellitus with foot lesions requiring surgical care was made. Informed and written consent were taken from all the patients before including them into study.Clinical history & findings were be noted. Necessary investigations were carried out. Comparison of healing time was done between patients who have been treated with and without offloads

Inclusion criteria:

1] New and known cases of diabetes mellitus.
2] Wound / ulcer / gangrene of feet due to diabetes.

Exclusion criteria:

1] Seriously ill patient who required intensive care unit monitoring.
2] Wound / ulcer / gangrene of feet due to diseases other than diabetes.

Half of the patients were given offloading as the form of total contact casting and rest half were not given offloading in the form of total contact casting. Patients were counselled for foot care and need for regular follow up on discharge.

decreases the time period for complete healing of ulcers and decreases rate of complications.[12]

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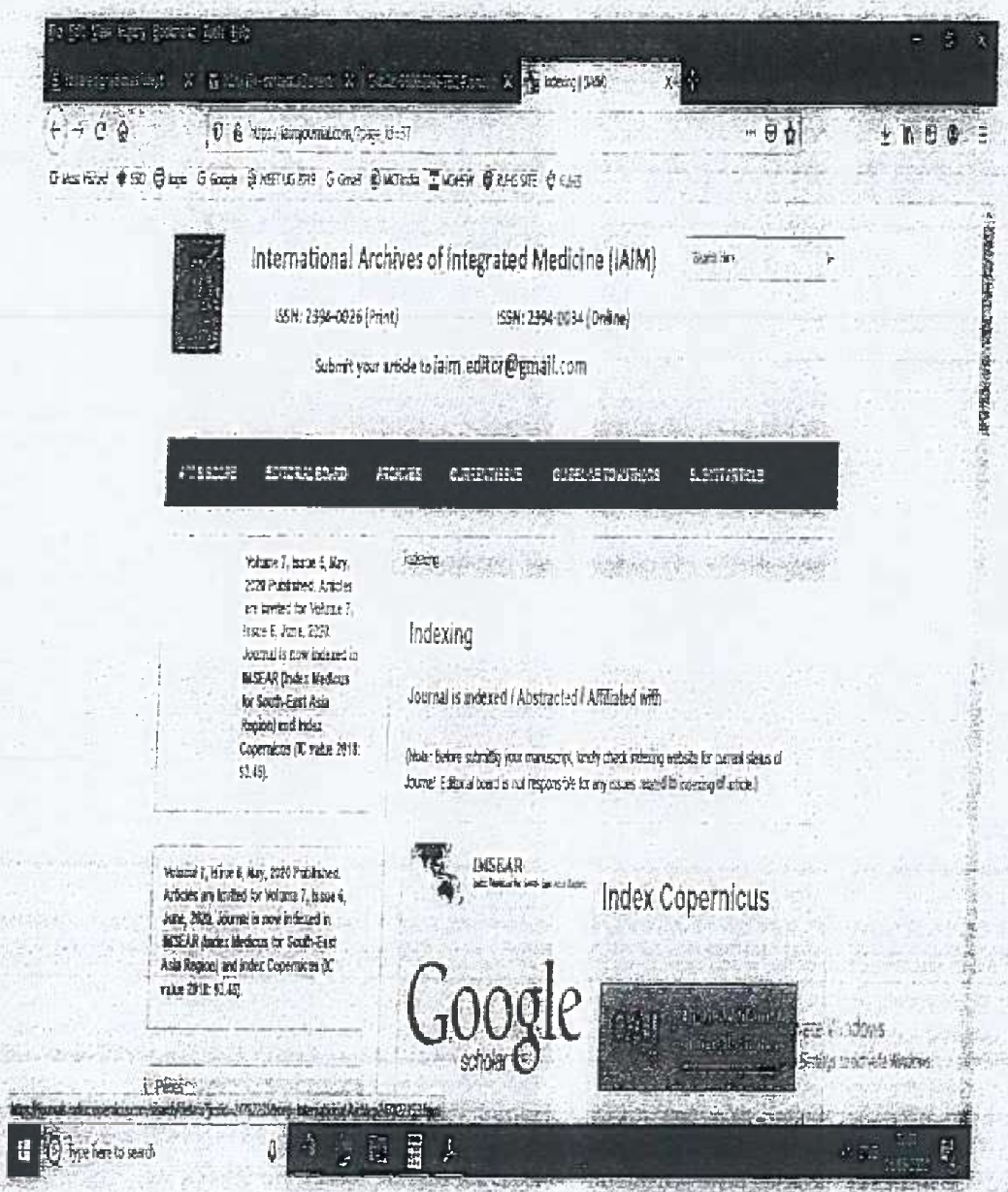

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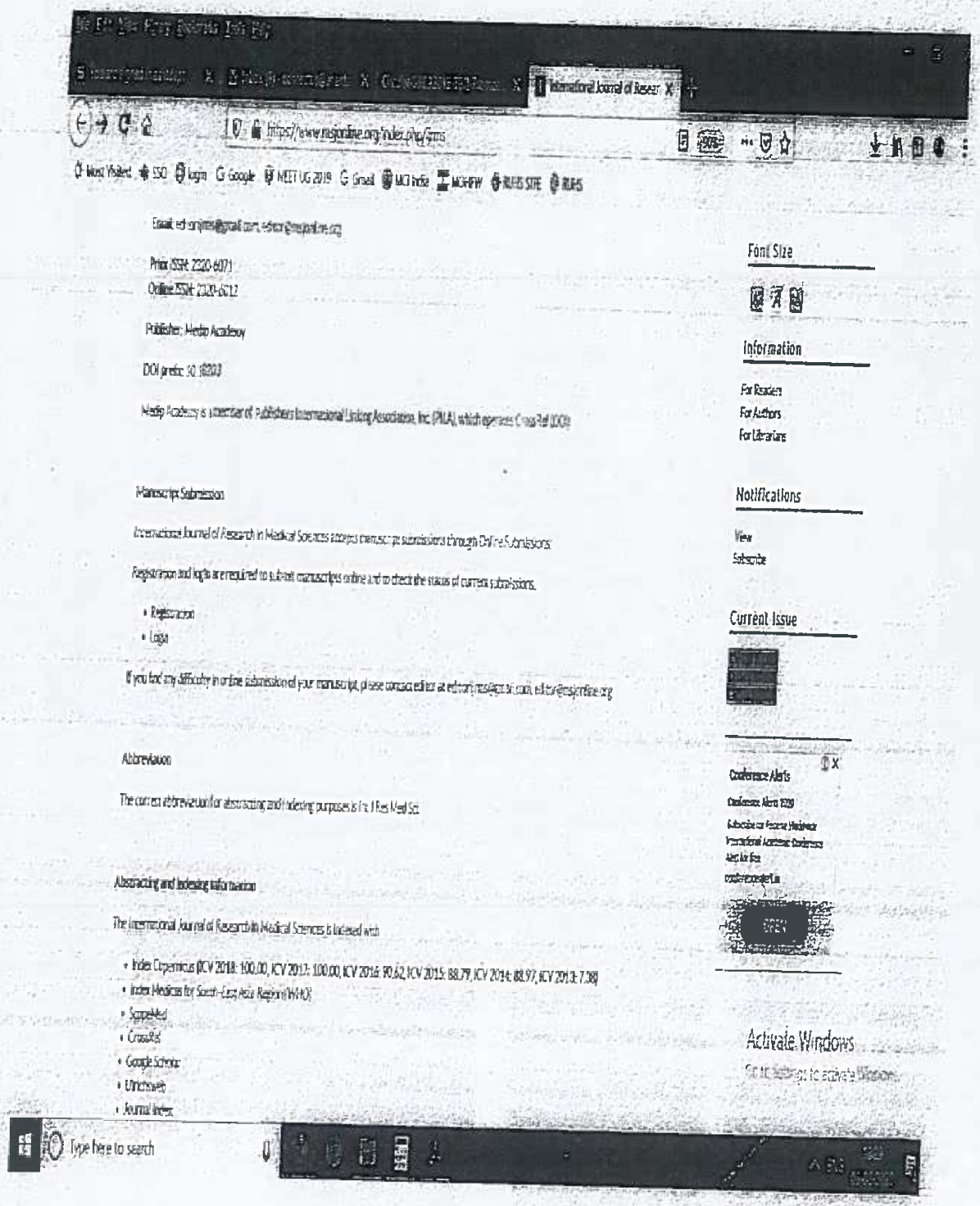

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List of Publications

DR. MOHAMMED ASHRAF KHAN				
1	A PROSPECTIVE STUDY ON PREVALENCE AND PERCENTAGE OF UNDIAGNOSED TYPE 2 DIABETICS PATIENTA UNDERGOING ELECTIVE SURGERY	DR. MOHAMMED ASHRAF KHAN	Mohammed Ashraf Khan. A Prospective Study on Prevalence and Percentage of Undiagnosed Type 2 Diabetics Patients Undergoing Elective Surgery. Int J Med Res Prof. 2019 Mar; 5(2):246-48. DOI:10.21276/ijmrp. 2019.5.2.054	INDEX COPER NICUS
2	A PROSPECTIVE STUDY ON ROLE OF PROPHYLACTIC ANTIBIOTIC AND INCIDENCE OF POSTOPERATIVE WOUND INFECTION IN SURGERY IPD	DR. MOHAMMED ASHRAF KHAN	Khan MA. A Prospective Study on Role of Prophylactic Antibiotics and Incidence of Postoperative Wound Infection in Surgery IPD. Int Arch BioMed Clin Res [Internet]. 2019Sep.30 [cited 2021Jan.28];5(3):86-8. Available from: https://iabcr.org/index.php/iabcr/article/view/509	INDEX COPER NICUS

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IJMRP

Original Research Article

A Prospective Study on Prevalence and Percentage of Undiagnosed Type 2 Diabetics Patients Undergoing Elective Surgery

Mohammed Ashraf Khan

**Assistant Professor, Department of General Surgery,
Ananta Institute of Medical Sciences and Research Centre, Rajsamand, Rajasthan, India.**

ABSTRACT

Introduction: The major form of diabetes mellitus is Type 2 diabetes. It accounts for 90 percent of the diabetic population. Patients with diabetes mellitus (DM) are prone to adverse outcomes. It is observed that one fifth of the patients undergoing surgery are diabetic.

Methodology: This study was conducted in the Department of Surgery in the Department of General Surgery, Ananta Institute of Medical Sciences and Research Centre, Rajsamand. 289 total numbers of cases were included in this study. Each case has Type 2 DM.

Results: In our study, 289 total numbers of cases were included. Among the 289 cases 53.9% were male & 46.1% were female. Incidence of Diabetic Mellitus in undiagnosed & diagnosed cases was found 41.5% & 58.5% respectively.

Conclusion: This study concludes that there is a strong need of awareness about diabetes and early diagnosis of diabetes to reduce its various complications.

Keywords: Diabetes Mellitus, Metabolic Disorder, Undiagnosed Cases, Diagnosed Cases.

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INTRODUCTION

Diabetes mellitus (DM) is a metabolic disorder. It results from a defect in insulin secretion or insulin action.[1-4] It was estimated that worldwide, more than 200 million people had DM in 2010, and 300 million will subsequently have the disease by 2025.[5-7] it has been reported that India had 32 million diabetic subjects in 2000 and by the year 2030, it will be 80 million.[8] The incidence of diabetes is rising all over the world at an alarming rate.[9] India is termed as the "Diabetes capital of the world", due to the highest number of diabetic patients in the world. The major form of diabetes mellitus is Type 2 diabetes. It accounts for 90 percent of the diabetic population. Patients with diabetes mellitus (DM) are prone to adverse outcomes.[10,11] it is observed that one fifth of the patients undergoing surgery are diabetic. However, several treatment strategies are employed to get rid of it globally. But in developing countries where resources are limited, needs to be reviewed. Over the past thirty years, the status of diabetes has changed from mild disorder to one of the major causes of morbidity and mortality.[8] It has been reported that there is a difference in percentage of urban-rural prevalence in type 2 DM in all parts of the globe including India. Hence, due to alarming rate of diabetes it was necessary to study the incidence of prevalence and percentage of undiagnosed type 2 diabetics admitted for elective surgery.

MATERIALS & METHODS

Study Area

This study was conducted in the Department of General Surgery, Ananta Institute of Medical Sciences and Research Centre, Rajsamand, Rajasthan, India.

Study Population

289 total numbers of cases were included in this study. Each case has Type 2 DM.

Study Duration

The duration of study was over a period of 2 year.

Data Collection

On enrolling the patients, routine investigation of fasting, random and post prandial blood glucose profile was done twice for confirmation by employing the glucose oxidation test for estimation of blood glucose.

The history and duration of diabetes in addition to epidemiological characteristic profile was noted. After being educated on diet, importance of insulin with special emphasis on need to adhere to treatment, the patients were allocated to different treatment groups for metabolic control.

Data Analysis

Data were analyzed by using Microsoft excel.

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Section General Surgery

Original Article

A Prospective Study on Role of Prophylactic Antibiotics and Incidence of Postoperative Wound Infection in Surgery IPD

Mohammed Ashraf Khan

Assistant Professor, Department of General Surgery, Ananta Institute of Medical Sciences and Research Centre, Rajsamand

ABSTRACT

Background: *In the advancement of surgery, post-operative wound infection has been the greatest obstacle from down the centuries. For safe surgery, Lister introduced antiseptic methods. The initiation of antibiotics did raise the hope of a permanent solution to post-operative infection but later it has become the nightmare of the surgeon.*

Methods: *Two groups were included in this study. Each group had 200 cases. This study conducted by department of Surgery in Ananta Institute of Medical Sciences and Research Centre, Rajsamand. The duration of the study over a period of one and half year.*

Results: *In our study, two groups were included, each group has 200 cases. In group A we had found 7% cases infected out of 200 cases, while in Group B had 34% infected cases out of total number of cases. Out of all cases we were found maximum infected cases from 41-50 ages in both groups.*

Conclusions: *This study concludes that, to prevent surgical-site infections, it is essential for the surgeons to take appropriate steps to avoid local microbial factors.*

Keywords: *SSIs, elective surgeries , emergency surgeries, wound infections*

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***Corresponding Author**

Dr. Mohammed Ashraf Khan
Assistant Professor, Department of General Surgery, Ananta Institute of Medical Sciences and Research Centre, Rajsamand.

INTRODUCTION

Postoperative wound infections are one of the major preventable problem. It plays an important role in morbidity, mortality. It also affects the health care costs.[1] on the basis of depth of infection, it can be classified into three types: superficial incisional, deep incisional and organ/space. The symptoms of infection should be presented within 30 days postoperative.[2] Prevention of surgical site infection is primary consideration throughout the whole phases of surgery.[3,4]

In the advancement of surgery, post-operative wound infection has been the greatest obstacle from down the centuries. For safe surgery, Lister introduced antiseptic methods. The initiation of antibiotics did raise the hope of a permanent solution to post-operative infection but later it has become the nightmare of the surgeon. Though, many considered antibiotic could cover their lapses in surgical technique and asepsis. Extensive and often indiscriminate use of antibiotics led to development of resistance by various organisms and resulting the problem of hospital infection.[5] it has been reported that the administration of antibacterial agents within three hours after contamination of wound, it has no influence on the infection rate of the operative wounds. Infection can be adequately prevented, if the body already has adequate antibiotic concentration at the time of contamination.[6]

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INTRODUCTION

Postoperative wound infections are one of the major preventable problem, it plays an important role in morbidity, mortality. It also affects the health care costs,[1] on the basis of depth of infection, it can be classified into three types: superficial incisional, deep incisional and organ/space. The symptoms of infection should be presented within 30 days postoperative.[2] Prevention of surgical site infection is primary consideration throughout the whole phases of surgery.[3,4]

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The concept of pre-operative antibiotic was introduced by Stranchan in 1977. He compared a single preoperative dose of Cefazolin with a regime of Cefazolin given for a period of 5 days post operatively. It has been observed that the infection rate seen in single dose was 3% and in multiple postoperative dose was 5%.[7] Prophylactic antibiotic therapy is clearly more effective where began preoperatively and continued through the intra operative period, with the aim of achieving therapeutic blood levels throughout the operative period.[8] In this study, the main emphasize on the risk factors that increase the SSI and role of prophylactic antibiotic administration to clean surgical cases in this institution.

METHODS

Study Population:- Two groups were included in this study. Each group had 200 cases.

Study Area:- This study conducted by department of Surgery in Department of General Surgery, Ananta Institute of Medical Sciences and Research Centre, Rajsamand

Study Duration:- The duration of the study over a period of one and half year.

Data Collection:- This study involved elective and emergency surgeries. Pregnant women and very elderly (>60 yr) were excluded. The group was split into group A and group B of 200 cases each. Group A comprised of patients who received a pre-operative single dose of Ceftriaxone. Group B received no such type of prophylactic antibiotic. The groups were split into two, taking consideration the type of surgeries, the age of the patient, the presence or absence of risk factors for development of SSI, and associated medical conditions, all of which were represented in both the groups almost equally and a comparative clinical study was made.

Data Analysis:-Data were analyzed by using Microsoft excel.

RESULTS

In our study, two groups were included, each group has 200 cases. In group A we had found 7% cases infected out of 200 cases, while in Group B had 34% infected cases out of total number of cases. In this study, we were included 10-50 age group of cases. Out of all cases we were found maximum infected cases from 41-50 ages in both groups. The incidence of risk factor also suggestive in this study in group A as well as in group B, which is showed in table no. 3.

Table 1: Distribution of groups according to infected cases

	Total no. of cases	infected cases	Percentage
Group A	200	14	7%
Group B	200	68	34%

Table 2: Distribution of groups according to age group

Age group	Group A	Number of infected cases	Group B	Number of infected cases
10-20	10	0	15	0
21-30	50	2	54	9
31-40	100	2	83	21
41-50	40	10	48	38

Table 3: Distribution of groups according to risk factor

Risk factor	Group A	Group B
Anemia	4	22
Prolonged duration of surgery	4	18
Diabetes mellitus	4	20
Obesity	2	8

DISCUSSION

For a prophylactic regimen to be effective, it should be directed against the most likely organisms. An Infection can be prevented only when the effective concentration of the drug is present in the blood and the tissues. Thus, antibiotic prophylaxis should begin just before the operation. Rao et al, observed in their study that SSI, incidence are doubled in the older age group 50- 70 yrs and severe complication following is increased in both extremes of ages i.e., < 10 yrs and > 60 yrs. Funary AP et al. found in their study that during the preoperative period blood glucose level were kept strictly below 200 mg/dl by continuous intravenous infusion of insulin reduced the incidence of SSI from 24% to 6.06% which was significant statistically. Some studies have revealed in their studies that diabetes mellitus is related with poor wound healing and high infection rates. Diabetes and the resultant hyperglycaemia lead to decreased function of leucocytes, especially phagocytosis. In the present study, 24 patients were diabetic.[9,10]

In the mid-1950s, the effectiveness of preoperative antibiotic prophylaxis is first shown in animals by Miles. If penicillin was given before guinea-pigs inoculation intradermal with Staphylococcus aureus, infection did not occur.[11]

Preoperative antibiotic prophylaxis was prescribed to prevent postoperative wound infection. On the other hand postoperative antibiotic for long duration has no effect in changing incidence of wound infection.[12]

CONCLUSION

To prevent surgical-site infections, it is essential for the surgeons to take appropriate steps to avoid local microbial factors. Simultaneously, it is also important to practice meticulous surgical techniques and unnecessary delay in the procedure. Prophylactic Antibiotics played a major role in reducing the post-operative wound infections.

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List of Publications

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2	NERCOTIZING SOFT TISSUE INFECTIONS : OUR EXPERIENCE AT RURAL TERTIARY CARE CENTRE	DR. ATUL JHANWAR, DR.PREM PRAKASH SHARMA & DR. DIKSHA SHARMA	Sharma PP, Jhanwar A, Sharma D, Sharma S, Tripathi A. Necrotizing softtissue infections: our experience at rural tertiary care centre. Int Surg J 2016;3:1528-33.	INDEX COPERNICUS
3	LAPAROSOPIC PEPTIC PERFORATION REPAIR : OUR EXPERIENCE AT RURAL TERTIARY CARE CENTRE	DR. ATUL JHANWAR, DR.PREM PRAKASH SHARMA & DR. FATEH SINGH	Sharma PP, Jhanwar A, Mehta FS. Laparoscopic peptic perforation repair: our experience at rural tertiary care center. Int Surg J 2016;3:1534-7	INDEX COPERNICUS
4	COMPARATIVE STUDY OF EVACUATION OF CHRONIC SUBDURAL HAEMATOMA TWO BURR HOLE TECHNIQUE VERSUS SINGLE BURR HOLE WITH PRACTICAL EXCISION OF MEMBRANE TECHNIQUE	DR. GUPTA SANJAY K, DR.JHANWAR ATUL	Published by Association for Scientific and Medical Education (ASME) Page 107 Vol.1; Issue: 2;April-June 2014 http://www.ijmse.com	INDEX COPERNICUS

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Research Article

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Blunt trauma chest: our experience at rural tertiary care centre

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ABSTRACT

Background: Every hour, 40 people under the age of 25 die in road accidents around the globe. According to the WHO, this is the second most important cause of death for 15 to 29 year olds. According to the latest report of National Crime Records Bureau or NCRB, Over 1, 37,000 people were killed in road accidents in 2013. Thoracic trauma forms one of the major parts of multiple traumas and is responsible for significant mortality and morbidity especially at younger ages.
Methods: We carried out a retrospective study to assess the prevalence of chest injury patients at Geetanjali medical college and hospital, Udaipur (Tertiary care rural centre) in last two years. Clinical details of the patients were recorded from their case sheets and were analyzed with reference to their age, sex, mode of injury, severity of injury, treatment employed, complication and final outcome etc.
Results: Males were predominantly involved (88.2%). Majority (61.9%) were in the age group of 21-30 years.
Conclusions: Chest injury occurs in a significant number of trauma patients and commonly affected victims are males of 20-40 years age. The majority of these patients were managed by simple intervention i.e., intercostals chest tube drainage and non –invasive ventilation, only less than 3% require thoracotomy.

Keywords: Blunt trauma, Flial chest, Haemothorax, Inter costal chest tube drainage

INTRODUCTION

Accidents which are unexpected and unplanned events are becoming the major epidemic of non-communicable disease in the present century. The number of accidental deaths in India is even higher than in the Western World[1]. Thoracic trauma contributes heavily to these figures which may present as isolated injury or as a part of polytrauma. Blunt thoracic injuries are thought to result from a combination of crushing, compression, stretching and shearing forces. The magnitude of these forces directly related to the rate of their acceleration and deceleration and also their relative direction of impact. Although most of the fractures of bony thorax are benign entities and can be followed up without hospitalization, trauma limited to the thoracic cage itself may cause profound pathophysiological alterations, which may be fatal if not promptly treated. On the other hand, the accurate identification of a patient at high risk for major chest trauma is essential for regulation of over and under triage within a trauma system. The present study focuses on blunt chest injuries, especially rib fractures and associated injuries. In spite of the high mortality rates, about 90% of the patients with life-threatening thoracic injuries can be managed by a simple intervention like intercostals tube drainage and non invasive ventilation.[12]

Table 5: Indication for thoracotomy.

Indication	No of patients
Massive bleeding	4
Oesophageal rupture	1
Chylothorax	1
Multiple displaced fracture	3
Diaphragmatic rupture	3

Thoracotomy was needed for twelve patients. Removal of intrathoracic hematoma and control of massive bleeding in four patients, for esophageal repair in one patient, for chylothorax in one patient, and thoracic wall stabilization and control of bleeding in three patients. Three patients underwent thoracotomy or laparatomy due to diaphragmatic rupture.

If we analyse the final outcome of all the chest injury patients (730), 615 patients were discharged in satisfactory condition within 7-9 days, while hospital stay was prolonged in 98 patients because of multiple rib fracture associated with other extra thoracic injury and various complication. Various complication were noted in 43 patients mainly residual hemothorax, recurrent pneumothorax, deep vein thrombosis, broncho pleural fistula, ARDS, aspiration pneumonitis ,pressure sore etc..17 patients could not be saved despite adequate and aggressive treatment. Out of 17 patients who expired, 10 were having multiple fractured ribs with associated abdominal injury and pelvic fracture. 7 patients were having flail chest with massive bilateral pulmonary contusion.

Table 6: Final outcome.

Final result	No. of patients
Discharge	615
Complication	43
Death	17

DISCUSSION

Trauma is the leading cause of mortality and morbidity during the first four decades of life, and one of the commonest causes of death all over world, more in India. The major reasons for blunt chest injuries are traffic accidents with an incidence of 70–80%.[2] Increased automobile traffic and ever increasing population together with intentional or unintentional ignorance of traffic rules account for the predominance of road-side accidents producing chest trauma. In 79.7% of our patients, traffic accidents were the cause of injuries which is consistent with the literature.[1] These findings were in accordance with the studies of Helling and Mattox, in which road accidents constituted the maximum number of cases.[3,4] The right side of the chest was involved commonly. The higher percentage of younger age group patients in the present study is comparable to studies of Muckart and Locurto et al Males outnumbered females by a huge margin because of their greater exposure to outdoor activities like drivers, industrial workers and labourers etc. These findings were comparable to findings of other studies.[5]

Subcutaneous emphysema is a clear indication of injury to the respiratory tract. All of the patients with subcutaneous emphysema had fractured ribs, which also led to lung injury. Kalyanaraman et al reported that lung injury seems to be associated with rib fractures in 74% of cases with subcutaneous emphysema.[9]

The presence of more than two rib fractures is a marker of severe injury. 59.86% of our patients had hemothorax and/or pneumothorax and most of them presented with associated extrathoracic injuries. Mortality rate was nil in patients with less than two rib fractures versus 4.14% in patients with more than two rib fractures. Lee reported that mortality doubles (1.8 versus 3.9%) for patients with three or more rib fractures and those with no rib fractures.[7] The presence of fractures of the first or second ribs has also been reported to be indicative of severe trauma. Poole reviewed all series of fractures of first and second ribs and found a 3% risk for aortic injury and a 4.5% risk for injury to a brachiocephalic vessel [8] However, no association between victims of trauma with or without rib fractures and aortic injury was reported.[7,8] In our series, we did not observe any major vascular injury.

In our study, the majority of patients (410) had fractures of more than two ribs and additionally 46 patients had flail chest; 242 patients had fracture of either one or two ribs and most of them could be managed by just observation with check x-ray of the chest after 24 hours of injury. With single or two rib fractures the incidence of pneumothorax/haemothorax is not as high but there is increasing likelihood of this complication as the number of fractured ribs increases.11 Flail chest was present in 46 patients in our series which was consistent with Pate who described flail chest occurring in about 8-10% percent of chest trauma patients.[9]

Regarding treatment profile, intercostal drainage was required in 331 patients and thoracotomy was needed in 12 patients only. Various indications of thoracotomy were as per Table 5. The commonest indication was massive bleeding, following ICD. Out of 730 patients, 331 patients were treated by simple Inter Costal tube drainage. Time taken for full expansion of the lung and removal of the chest tube was 2-8 days. In a study by Locurto, the chest tube was kept for an average 4.5 days with simple underwater seal drainage.[3]

Residual haemothorax was the commonest complication in our series, 24 of which were treated by simple aspiration while the remaining 2 required repeat ICD. Drummond observed residual haemothorax in about 15% of patients with haemopneumothorax where simple ICD was done. 6 there was no evidence of empyema in any

patient. The incidence of empyema has been reported about 2 to 3 percent in patients with chest injury requiring tube thoracostomy in various studies.[6,12]

Overall, there were 17 deaths in this series, with most of patients having multiple fractures with flail chest and massive pulmonary contusions associated abdominal injuries and pelvic fracture. The mortality rate after severe chest injury was comparable with other studies reported in the literature.[12] The clinical state of the patient, severity of the trauma, age, presence of more than two rib fractures, presence of flail chest, and possible intrathoracic injury help in making the decision for proper treatment plan.

CONCLUSION

After comprehensive review of the present study, it is concluded that:

- Blunt trauma, mainly road-side accidents formed the most common cause of chest injury, followed by assault and falls from height etc. and commonly affected victims are males of productive age.
- The majority of these patients can be managed by simple intervention i.e., intercostal drainage. Patient with multiple rib fracture can be managed by non invasive ventilation and only few require thoracotomy.
- The risk of mortality in chest trauma has been associated with the presence of more than two rib fractures, age older than 60 years and with associated head and abdominal injury.
- The ability to identify those patients having significantly higher risk for morbidity and mortality ensures the establishment of treatment priorities and efficient management of existing injuries.

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Research Article

Necrotizing soft-tissue infections: our experience at rural tertiary care centre

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ABSTRACT

Background: Necrotizing soft-tissue infections are infection of any of the layers within the soft tissue compartment that are associated with necrotizing changes. These infections are highly lethal if not diagnosed. The purpose of this article is to assess the different diagnostic tools.
Methods: We carried out a retrospective study to assess the prevalence of soft tissue infections at Geetanjali medical college and hospital, Udaipur (Tertiary care rural centre) in last four years. Clinical details of the 216 patients with soft tissue infection were recorded from their case sheets and were analyzed with reference to their age, sex, risk factor, symptoms, etiology, microbiology, treatment employed, complication and final outcome etc.
Results: Pain and swelling were commonest presenting symptoms found in every case. Diabetes and Trauma were major predisposing factor in our series. NSTI differ from NNSTI with respect to presence of blister (50% versus 5.8%), Dusky discoloration (58.3% versus 0%), Necrotic skin (51.04% versus 0%) and Crepitance (6.2% versus 0%). In present series' most common organism causing NSTI in our institute is gram negative bacilli .Prompt resuscitation followed by early and adequate debridement remains the cornerstone of management of NSTI.
Conclusions: Diagnosis of necrotizing infection is challenging but there are enough tools including clinical findings, biochemical parameters, imaging aids and invasive procedures that can help make the diagnosis. When in doubt, exploration of the compromised tissue should be performed. The mainstay of treatment is early and adequate surgical debridement.

Keywords: NSTI- Necrotizing soft-tissue infections, NNSTI - Non- Necrotizing soft-tissue infections, Debridement

INTRODUCTION

Necrotizing soft-tissue infections (NSTIs) are highly lethal infections. These infections were first described by Jones in 1871 and termed as "hospital gangrene".[1] Since then, multiple descriptions of NSTI have been published, and a wide number of terms, definitions, and classifications have been used.[2-5]

In 1951, Wilson coined the term "necrotizing fasciitis" to encompass some of these infections that is rapidly spreading and potentially devastating infection of the superficial and deep fascia with secondary necrosis of the overlying skin.[6]

The early diagnosis is main challenge in treating patients with NSTI, and knowledge of various clinical sign and laboratory markers can be helpful for distinguishing between cases of cellulitis, which should respond to

In present series' most common organism causing NSTI in our institute is gram negative bacilli followed by haemolytic streptococci. Most of the infection was polymicrobial in nature.

Table 5: Distribution of mode of treatment.

Management	No. of Pt.	% of Pt.
Multiple release incision and fasciotomy.	26	27.08
Debridement	68	70.83
Amputation	2	2.08

In our series debridement was done in 70.8% of cases with in 8 hours of admission after initial resuscitation. Multiple release incision and fasciotomy was done in 22.9% of cases while amputation at mid-thigh level was done in 2 cases to save life of patient.

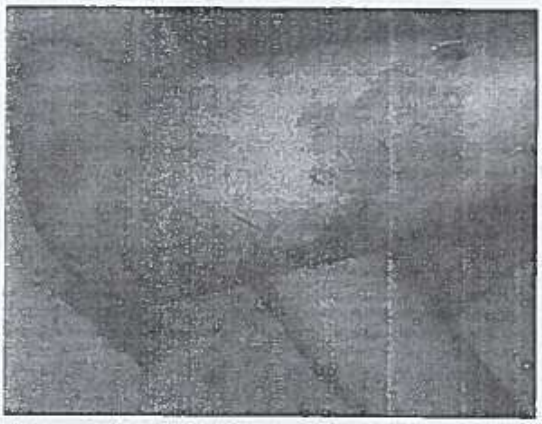

Figure 1: NSTI lower limb- showing blisters, dusky discoloration and skin necrosis.

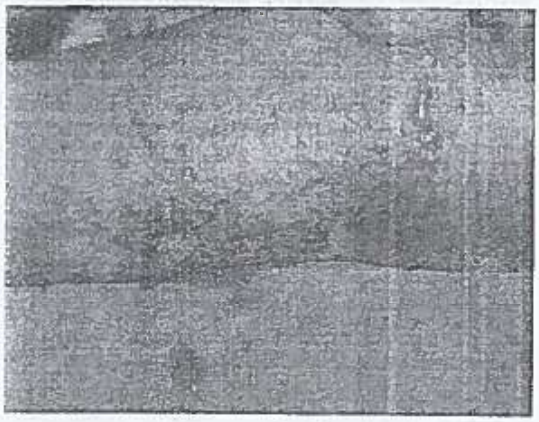

Figure 2: NSTI lower limb showing blisters filed with toxic fluid and pus, dusky discoloration and skin necrosis.

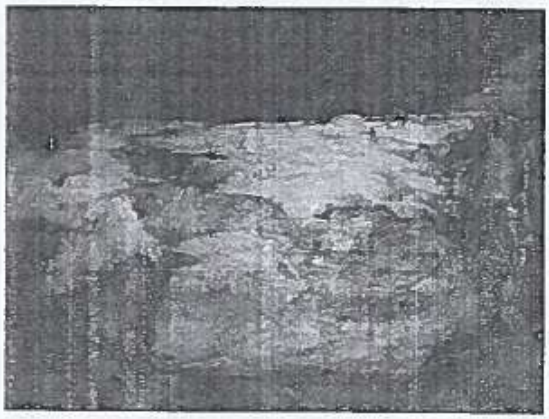

Figure 3: NSTI lower limb: debridement of necrotic tissue.

Figure 4: NSTI foot and lower leg; extensive necrosis of skin.

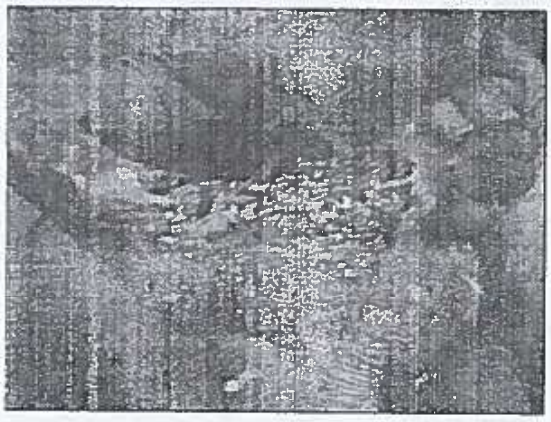

Figure 5: Figure NSTI foot and lower leg: extensive early and adequate debridement.

infected tissue that controls the source of infection and allows for future recovery. Broad-spectrum antimicrobial therapy should be started early to include coverage for gram-positive, gram-negative, and anaerobic organisms. Special consideration for group A *Streptococcus* and *Clostridium* species should be taken. Acceptable regimens include monotherapy agents, such as imipenem, meropenem, ertapenem, piperacillin/tazobactam, and tigecycline. Multidrug regimens have also been described, including triple-drug therapy regimens, such as high-dose penicillin, high-dose clindamycin, and a fluoroquinolone or an aminoglycoside for coverage of gram-negative organisms. Vancomycin, daptomycin, or linezolid should be included in the regimen until methicillin-resistant staphylococcal infection has been excluded. Antimicrobial administration should be continued until no further debridements are needed and the patient's physiology has improved.

Debridement of the necrotic tissue should be undertaken as soon as possible as it is probably the most important determinant of outcome in necrotizing soft tissue infections. This was well described in a study by Bilton, et al in which patients with necrotizing soft tissue infections who had adequate surgical debridement (early and complete) were compared to those with either delayed or incomplete debridements. The mortality in the latter group was 38% compared to 4.2% in the group receiving adequate surgical treatment.[14] During the operation, a generous incision is performed and if needed, the incision is extended to allow for complete debridement of the infected or necrotic tissue. Occasionally, amputation of a limb is necessary to achieve this goal to save life of patient. Healthy, viable, bleeding tissue should be present at the edges of the excision site, and aggressive resuscitation should accompany the perioperative period. Once the initial debridement has been done, management in an intensive care unit is recommended, and scheduled debridements at intervals of 6-48 h should be performed until no further necrosis or infected tissue is seen. Finally, physiologic support, combined with close monitoring in an intensive care unit is encouraged. It is not uncommon to see patients with NSTI develop organ failure, such as acute renal failure and acute respiratory distress syndrome, which require replacement therapies.

The most important discriminative information to be established in patients with soft-tissue infection is the presence of a necrotizing component. This will confirm NSTI, and by definition, will identify patients that require surgical debridement. The first and most important tool for early diagnosis of NSTI is to have a high index of suspicion. When in doubt, exploration of the compromised tissue should be performed. Intravenous drug user are found to be high-risk group for developing necrotizing soft tissue infections, and when evaluated for soft tissue infections they should undergo a thorough assessment that can confidently rule out a necrotizing infection. The mainstay of treatment is early and adequate surgical debridement with scheduled returns to the operating room. We have also observed that cases of NSTI without a recognized precipitating factor are more likely to be caused by group a streptococcal infection. More recently, NSTI without a recognized precipitating factor has also been identified with community-acquired methicillin-resistant staphylococcal infection.[14]

Since the first description by Jones, mortality in patients with NSTI remains high. He reported a mortality rate of 46%, and a recent pooled analysis determined it to be ~34%.[1,15] More recent series have reported mortality rates with a range of 16%, 24%, a rate that, although lower than the rate 100 years ago, still accounts for high mortality associated with NSTI. In our series mortality rate was 16.66 % .This low rate is related with early and adequate debridement within 8 hours of admission and aggressive critical care of these pt.

Bosshardt, et al published a series of patients with predominantly intravenous drug use-related necrotizing soft tissue infections over a 5-year period and showed that the incidence more than doubled when compared to the first years of the study.[20]

CONCLUSION

We also draw following conclusion. Pain and swelling were commonest presenting symptoms found in every case. Diabetes and Trauma were major predisposing factor in our series. NSTI differ from NNSTI with respect to presence of blister (50% versus 5.8%), Dusky discoloration (58.3 % versus 0%), Necrotic skin (51.04% versus 0%) and Crepitance (6.2% versus 0%). So Bullae, necrotic skin, dusky discoloration and crepitance are strongly predictive of NSTI. Four laboratory criteria that are strongly suggestive of NSTI ($P< 0.001$) i.e. statistically significant. Total Leucocytes Count more than 15 X 10 9/L. S. Creatinine more than 1.5 mg/dl.Serum Na+level less than 130 mmol/L. Presence of gas in x-ray of affected part. In present series' most common organism causing NSTI in our institute is gram negative bacilli followed by haemolytic streptococci. Most of the infection was polymicrobial in nature. Prompt resuscitation followed by early and adequate debridement remains the cornerstone of management of NSTI. Wound inspection after 24 hours to confirm the adequacy or to complete debridement. In conclusion of our study we would like to say that lack of awareness among clinician may play a major role in delay of diagnosis and institution of therapy that leads to subsequent high mortality and morbidity. The most important factor in survival in present series was related to rapidity of debridement within 8 hrs of admission after initial resuscitation. Utilizing these principal the morbidity and mortality of patients with NSTI should be substantially reduced.

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Research Article

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Laparoscopic peptic perforation repair: our experience at rural tertiary care center

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ABSTRACT

Background: Peptic perforation is a life threatening complication of peptic ulcer disease requiring prompt surgical management. Omental patch repair with peritoneal lavage is the mainstay of treatment for perforated peptic ulcer at most of the centres. Laparoscopic repair has been described by various authors since 1990 in different part of world. In current study we have assessed the feasibility and safety of use of laparoscopy for this life threatening surgical emergency. The outcome were analyzed in terms of operating time, post-operative complications, medication, hospital stay, morbidity and mortality.
Methods: This study was carried out in period of two years from January 2012 to December 2013. Patients were initially assessed in emergency department and then after resuscitation taken up for surgery. Patients with provisional diagnosis of perforated peptic ulcer were included in the study, meeting inclusion criteria.
Results: Total 30 patients were studied out of total 38, who were operated in the study period. 26 males and 4 females, age ranged from 18-60 years, operative time was 55 to 110 minutes. In post-operative period the need for intravenous medication (analgesics and antibiotics) was less, early assumption of routine activity and early discharge. A very important factor noted that patient were psychologically so happy and convinced that they did not have big wound over abdomen and they can resume their routine activity as before.
Conclusions: Laparoscopic repair of perforated peptic ulcer is safe and effective in experienced hands in most of the patients. It offers all advantages of laparotomy without compromising the safety and outcome.

Keywords: Perforated peptic ulcer, Laparoscopy

INTRODUCTION

Peptic ulcer is a well-known disease widely prevalent in all socio economic strata all over world. The management of this common disease has evolved over a period of time. Current medical management with proton pump inhibitors and H.pylori eradications has drastically reduced the various complications and need of surgical interference. Still, peptic perforation is quite prevalent life threatening surgical emergency encountered in general surgical practice. Omental patch repair (modified Graham repair) with thorough peritoneal lavage is the mainstay of treatment at most of the centers.[1]

Laparoscopy has emerged as gold standard for surgical treatment of various diseases in last 2-3 decades due to it's certain advantages like less post-operative pain, less hospital stay, less wound complications, early return to normal activity etc.[2]

This study is aimed to assess the feasibility, safety and advantages of use of laparoscopy in the treatment of this

unchanged. Minimal access surgery has gained wide acceptance amongst surgeons and general public all over world due to its definitive advantages. Although there are still some constrains amongst conventional surgeons for the use of this technique in certain surgical emergencies.

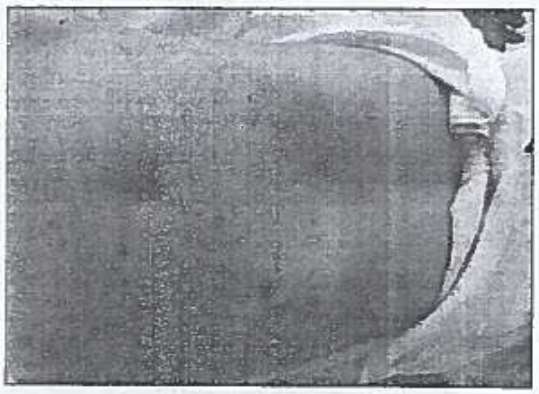

Figure 1: Post-operative photograph showing port position for laparoscopic peptic perforation repair.

In 1990 Mouret et al. reported the first laparoscopic sutureless fibrin glue omental patch for perforated duodenal ulcer repair.[1] The first successful laparoscopic suture repair for perforated peptic ulcer was described by Nathanson et al. in 1990.[5] Since then, many studies has been conducted by various authors in different part of world to define the use of laparoscopy in surgical management of perforated peptic ulcer. Costalat et al reported combined endoscopic and laparoscopic approach using ligamentum teres hepatis.[7] In 1993 Darzi et al, and Nassar et al in 1994 reported laparoscopic omental patch repair with use of automated stapler.[12,13] Siu WT et al described single stitch laparoscopic omental patch repair of perforated peptic ulcer in 1997.[3] Masao Matsuda et al from Japan also published an article suggesting that laparoscopic omental patch repair offers advantages of laparoscopic surgery and an attractive alternate to open surgery.[17]

After Mouret and Nathanson many authors worked in this field and described various techniques of perforated peptic ulcer closure i.e. simple suturing, by gelatin sponge and fibrin glue, stapled omental patch repair, gastroscopy assisted insertion of ligamentum teres hepatis to close the perforation, gastroscopic guided omental plugging to close the perforation.[22] single suture with omental patch repair.[3]

Studies were done to compare open versus laparoscopic repair.[16,19,20,23] Siu et al and found that laparoscopic repair was superior then open in terms of size of incision, requirement of post op analgesia, less hospital stay, early return of normal activity, less immediate and long term complications etc. although the operating time was more in laparoscopic group in some studies but can be reduced by adopting certain techniques and with more and more experience. Almost all study groups recommended proper selection of patients and demands surgeons having good laparoscopic suturing skills and experience.

In our study, after analyzing the results it was found that duration of surgery was between 55-110 minutes. Time taken was more in initial cases and in few more contaminated cases, after that the operating time was nearly same as we take in open surgery and even less in few cases. Post operatively patients needed round the clock Intravenous analgesics for 2-3 days, Ryles tube could be removed in 2-3 days except in two cases in which we had to keep ryles tube for 4 days which was badly contaminated large perforation of about 1cm, we have started oral feeding in 3-4 days in most of the cases except in 5 cases which were having large perforation with more peritoneal contamination. Hospital stay was 4-5 days in most of the cases; only 3 patients had 6 days stay. 2 patients had chest complications in immediate post op period which were managed comfortably in ICU and recovered in 2-3 days. There was no wound gap, no burst abdomen, no residual collection or pelvic abscess noted in any case. No incidence of any incisional hernia was noted in any case. Patients were allowed and encouraged to return to the normal activity after 7-10 days. No mortality was noted in our series.

CONCLUSION

The management of this common disease is evolved over a period of time. Current medical management has drastically reduced the various complications and need of surgical interference. Still peptic perforation is quite prevalent. Gold standard treatment is conventional laparotomy and omental patch repair (modified Graham repair). Laparoscopy has emerged as gold standard for surgical treatment of various diseases in last few decades. We conclude with the present study that laparoscopy is an effective tool in the surgical management of perforated peptic ulcer.

It requires experience and technical expertise in laparoscopic surgery. If proper selection of patients is done laparoscopic repair is safe and feasible. It does not increase the cost of treatment infact it helps in reducing the cost by less hospital stay, less medication required, less morbity, early return to normal activity and to workplace. We hereby recommend laparoscopic repair in selected patients as treatment of choice as it offers all the advantages of laparoscopy without increasing the risk. It is a safe, effective and cost effective method for the treatment of perforated peptic ulcer.

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Original Research Article

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COMPARATIVE STUDY OF EVACUATION OF CHRONIC SUBDURAL HAEMATOMA BY TWO BURR HOLE TECHNIQUE VERSUS SINGLE BURR HOLE WITH PARTIAL EXCISION OF MEMBRANE TECHNIQUE

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ABSTRACT:

OBJECTIVES: Present study was planned to compare the postoperative outcome of surgical evacuation of chronic subdural haematoma (SDH) through two burr hole technique versus single burr hole with partial excision of membrane technique. **METHODS:** All patients admitted in neurosurgery ward of Geetanjali Medical College and Hospital, Udaipur were evaluated by taking detailed history, clinical examination and investigations. After confirmation of chronic SDH by CT/MRI scan patients were operated. Initial 50 patient were operated by two burr hole technique and last 50 patient were operated by using single burr hole with parted excision of membrane technique. **RESULTS:** 50 patients were operated by Two Burr Hole technique and the duration of operation ranged from 15 to 40 min. Most of the symptoms relieved postoperatively within 6 hours to 6 days. Hospital stay found with average of 6.5 days. During follow-up 3 patients showed recurrence. The results after 3 months follow up were excellent in 86 %. 50 patients were treated with Single burr hole with partial excision of membrane technique techniques. The duration of operation ranged from 10-30 minutes. Most of the symptoms relieved within 6 hours to 6 days. Hospital stay of patients was with average of 5 days. Two patients, showed re-accumulation of chronic SDH during follow up. The results after 3 months follow up were excellent in 90 %. **CONCLUSIONS:** With this study, we have reached to the conclusion that single burr hole evacuation of chronic SDH with partial excision of membrane technique is simple, safe, less time consuming and effective treatment of chronic SDH.

Keywords: Chronic subdural haematoma, two burr hole technique , single burr hole technique.

INTRODUCTION

Chronic subdural haematoma (Ch. SDH) is a well-known entity and common surgical disorder managed by neurosurgeon and if not recognized and treated timely, may prove fatal. It can be non traumatic or post traumatic and all of them need urgent attention irrespective of etiology. (1) It manifest with progressive neurologic deficit that occur later than 2 weeks following head

Postoperative Management:-

Careful record of postoperative progress was kept in both of the groups as per standard format along with any postoperative complication. Early mobilization of patient was encouraged postoperatively. Patients were discharged at appropriate time and advised for regular follow up. Total duration of hospital stay and the mortality was noted. Follow up of the patients done for three months.

RESULTS:

The study was done on 100 patients of Ch. SDH admitted in neurosurgery ward during year 2000-2003. Out of these 100 patients most of the patients belonged to 6^{th} and 7^{th} decade of life. 17 % of Patients were in 8^{th} decade of life and ranged from 8 to 92 years,

20 % of the patients were female as compared to 80 % males. 60 % of patients were from urban population while 40 % patients were rural. The cause of urban preponderance is probably easy availability of CT scan and early approach to doctor in urban areas. Most of the patients presented with headache followed by weakness and paralysis, irrelevant talk, mental slowing fluctuating drowsiness etc. Eight of our patients presented with COMA. Previous head injury was found to be most common etiology in 68 patients.

Two Burr Hole technique :

50 patients were operated by this technique the duration of operation ranged from 15 to 40 min average of 30 min. 43 patients showed dramatic relief in symptoms postoperatively and most of the symptoms relieved within 6 hours to 6 days. Early mobilization of patients was encouraged in 3 patients showed partial improvement and 4 did not show any improvement. Hospital stay ranged from 2 to 24 days with average of 6.5 days. Four patients died postoperatively who presented with coma and did not show any improvement postoperatively.

During follow-up 3 patients showed recurrence. Needle aspiration was done but patients repeatedly returned back even after several re-aspiration of haematoma fluid. Finally, decision of membranectomy was taken and following membranectomy no any patient showed recurrence.

The results after 3 months follow up was excellent in 86 % in which, most of the symptoms relieved and patient showed no reccurence ,fair 6% in which patients showed recurrence and 8 % poor in which patients did not improved and died.

Single burr hole with partial excision of membrane technique

50 patients were treated with these techniques. The duration of operation ranged from 10-30 minutes, with average of 20 minutes. 45 patients showed dramatic improvement and most of the symptoms relieved within 6 hours to 6 days. Early mobilization was encouraged. 2 patients showed partial improvement and 3 patients did not show any improvement in symptoms.

Hospital stay of patients was ranged from 1 to 23 days with average of 5 days. Three patients died postoperatively; 2 of them were those who presented in deep coma with a prolonged history and found to have re-bleed following membranectomy. During follow up two patients

our study, mortality rate was 6% in single burr hole partial excision of membrane technique and 8% in two-burr hole technique. Mortality was because of haematoma.

A retrospective study mode by Benzel et at on 111 patient using single burr hole irrigation technique and postoperative outcome at 6 weeks was excellent in 90%. Fair 5.5 % and poor 4.5 %.(19) In our study, the post of outcome after 3 months was excellent 90%o fair 4 % and poor 6 % in single burr hole and partial excision of membrane technique and excellent 86%, fair 6%, and poor 8% in two burr hole technique.

CONCLUSION:

With this study, we have reached to the conclusion that single burr hole evacuation of Ch. SDH with partial excision of membrane technique is simple, safe, less time consuming and effective treatment of Ch SDH. Only one burr hole is required in this technique postoperative hospital stay is less and less re-accumulation of blood as well as number of aspiration with this technique, of course partial excision of membrane helps in it.

Other significant factors in the study were early mobilization of patient and no drain was used which most of authors recommend. Because of this reasons we have shifted from two-burr hole technique to single burr hole with partial excision of membrane technique.

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Conflict of interest: None declared

Ethical approval: The study was approved by the institutional ethics committee

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DEPARTMENT OF SURGERY

List of Publications

DR. VISHAL GAJBHIYE				
1	A PROSPECTIVE STUDY OF CLINICAL PRESENTATION & SURGICAL MANAGEMENT OF ABDOMINAL TUBERCULOSIS AT BMC, SAGAR	**DR.VISHAL GAJBHIYE,** DR.OMKAR THAKUR, DR. ABHISHEK VERMA & DR. R S VERMA	Dr. Vishal Gajbhiye, Dr. Omkar Thakur, Dr. Abhishek Verma, Dr. RS Verma. A prospective study of clinical presentation & surgical management of abdominal tuberculosis at BMC, Sagar. Int J Surg Sci 2020;4(3):211-213. DOI: https://doi.org/10.33545/surgery.2020.v4.i3d.493	INDEX COPERNICUS
2	ORCHIDOPEXY WITHOUT LIGATION OF HERNIA SAC: OUR EXPERIENCE	**DR.VISHAL GAJBHIYE,** DR. NAGENDRA SINGH, DR. SONA SINGH, DR. DUSHYANT ROHIT, DR. OMKAR THAKUR, DR. R.S. VERMA	Vishal Gajbhiye, Nagendra Singh, Sona Singh, Dushyant Rohit, Omkar Thakur, R. S. Verma. "Orchidopexy without Ligation of Hernia SAC: Our Experience". Journal of Evolution of Medical and Dental Sciences 2015; Vol. 4, Issue 30, April 13; Page: 5150-5153, DOI: 10.14260/jemds/2015/752	INDEX COPERNICUS
3	VAGINAL HYSTERECTOMY A SAFE OPTION IN NON-DESCENT UTERUS AS COMPARED TO ABDOMINAL HYSTERECTOMY	DR. SONA SINGH & **DR. VISHAL GAJBHIYE**	Singh S, Gajbhiye V. Vaginal hysterectomy a safe option in non-descent uterus as compared to abdominal hysterectomy. Int J Reprod Contracept Obstet Gynecol 2019;8:1162-6.	INDEX COPERNICUS

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A prospective study of clinical presentation & surgical management of abdominal tuberculosis at BMC, Sagar

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Abstract
Abdominal tuberculosis is an increasingly common disease that poses diagnostic challenge, as the nonspecific features of the disease which may lead to diagnostic delays and development of complications. This condition is regarded as a great mimicker of other abdominal pathology. A high index of suspicion is an important factor in early diagnosis. Abdominal involvement may occur in the gastrointestinal tract, peritoneum, lymphnodes or solid viscera. Various investigative methods have been used to aid in the diagnosis of abdominal tuberculosis. Early diagnosis and initiation of antituberculous therapy and surgical treatment are essential to prevent morbidity and mortality. Most of the patients respond very well to standard antitubercular therapy and surgery is required in some cases. Imaging plays an important role in diagnosis of abdominal tuberculosis because early recognition of this condition is important.
Abdominal tuberculosis constitutes a chief public health setback, presents a diagnostic challenge requiring a high index of clinical suspicion. Young age at presentation, delayed presentation, poverty & high morbidity & mortality are among the hallmarks of the disease in this region. These challenges need to be addressed in order to deliver optimal care for these patients. Early diagnosis, early antituberculous therapy & surgical treatment of the related complications are important for survival.

Keywords: Surgical, Abdominal & Tuberculosis.

Introduction
Tuberculosis (TB) is a life threatening disease which can virtually affect any organ system [1]. Abdominal TB comprises around 5 percent of all cases of TB [2]. The prevalence of TB has increased in both immunocompetent and immunocompromised and it can affect virtually any organ. The primary site of TB is usually lung, from which it can get disseminated into other parts of the body. The other routes of spread can be contiguous involvement from adjacent tuberculous lymphadenopathy or primary involvement of extrapulmonary organ. The diagnosis of extrapulmonary TB can be difficult as it presents with nonspecific clinical and radiological features and requires high degree of suspicion for diagnosis. The abdominal TB, which is not so commonly seen as pulmonary TB, can be a source of significant morbidity and mortality and is usually diagnosed late due to its nonspecific clinical presentation [3]. Approximately 15%-25% of cases with abdominal TB have concomitant pulmonary TB [4, 5]. Hence, it is quite important in identifying these lesions with high index of suspicion especially in endemic areas. ABDOMINAL TB is a type of TB that affects the Gut, Peritoneum, Abdominal lymph nodes and more rarely the solid organs in the abdomen (liver, pancreas, spleen). Abdominal TB leads to severe illness in adults and children and can cause complications such as bowel perforation can lead to death. Risk factors for development of abdominal TB include cirrhosis, HIV infection, diabetes mellitus, underlying malignancy, treatment with anti-tumor necrosis factor (TNF) agents, and use of peritoneal dialysis [6-10]

Material & Method
It is a prospective observational study including 100 patients were part of this study conducted from Dec 2019 to June 2020 with a diagnosis of abdominal tuberculosis confirmed histopathologically carried out in Bundelkhand Medical College, Sagar, Madhya Pradesh, India Detailed clinical examination of patients were evaluated. Investigations viz. blood CBC, RBS, serum urea, creatinine, BT, CT, Electrolytes, HbsAg, HIV, urinalysis, ECG, X-ray chest P.A.

In our study group four patients were treated conservatively and had recovered without any surgical intervention. There was mortality of two patients due poor general condition, fecal peritonitis and ongoing septicemia at the time of admission. Similar findings have been reported by Sadia J [13]

Conclusion

Abdominal tuberculosis constitutes a chief public health setback, presents a diagnostic challenge requiring a high index of clinical suspicion. Young age at presentation, delayed presentation, poverty & high morbidity & mortality are among the hallmarks of the disease in this region. These challenges need to be addressed in order to deliver optimal care for these patients. Early diagnosis, early antituberculous therapy & surgical treatment of the related complications are important for survival.

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Original Research Article

Vaginal hysterectomy a safe option in non-descent uterus as compared to abdominal hysterectomy

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ABSTRACT

Background: The objective of present study was to compare the advantage of vaginal hysterectomy over abdominal hysterectomy in non-descent uterus.

Methods: A non-randomized controlled trial was carried out in the Bundelkhand Medical College, Sagar and associated hospital from October 2015 to September 2017. A total of 150 cases were included in the study. Out on 150, 75 underwent vaginal hysterectomy for non-descent uterus and other 75 underwent abdominal hysterectomy for similar indications.

Results: Among total 150 cases, 75 were underwent non-descent vaginal hysterectomy and similar number of cases underwent abdominal hysterectomy. Common age group was 35-54 years. Commonest indication was DUB (48.7%). Postoperatively, complications were more common in those who underwent abdominal hysterectomy such as ambulation (18 hours), incidence of nausea, vomiting, abdominal discomfort, bladder injury and wound infection were less in vaginal hysterectomy compared to abdominal hysterectomy. It was also observed that blood transfusion requirement, operative timing and hospital stay (3 days) were less in vaginal hysterectomy group.

Conclusions: Vaginal hysterectomy for benign gynecological disorders is a safe, effective, least invasive and is associated with lesser complications as compare to abdominal hysterectomy. Today in the era where patient is more cosmetically concern, vaginal hysterectomy for non-descent uterine disorder needs to be considered as good and safe option.

Keywords: Nausea, Non-descent uterus and abdominal hysterectomy, Vaginal hysterectomy, Vomiting

INTRODUCTION

Hysterectomy is one of the most frequently performed elective major surgery in day to day Gynaecological practice. It can be done by open i.e. abdominal or vaginal route and laparoscopic route. Laparoscopy assisted vaginal hysterectomy (LAVH) and total laparoscopic hysterectomy (TLH) although gaining more popularity, is associated with higher cost, longer duration of surgery, and specially trained personnel.[1] Most of the literature supports the view that vaginal hysterectomy, when feasible, is the safest and most cost-effective procedure for removal of the uterus.[2] Nevertheless, the abdominal route is the most commonly chosen, 66% of hysterectomies are performed abdominally, 22% are performed vaginally, and 12% are performed laparoscopically.[3]

In today's world, vigorous attempts are being made to reduce the number of abdominal hysterectomy and replace them with vaginal hysterectomy or laparoscopic assisted vaginal hysterectomy as the next choice. It is

Table 2: Parity distribution.

Parity	VH n (%)	AH n (%)
0	4 (5.3)	7 (9.3)
1	6 (8)	5 (6.66)
2	30 (40)	35 (46.66)
3	21 (28)	26 (34.66)
4	12 (16)	10 (13.33)
5	2 (2.66)	2 (2.66)
Total	75	75

Chi= 1.38, p= 0.925

As shown in Table 2, hysterectomy (Vaginal or abdominal) is common in parity 02, and there was no significant difference.

Table 3: Diagnosis.

Diagnosis	VH n (%)	AH n (%)
DUB	35 (46.66)	39 (52)
Fibroid	28 (37.33)	27 (36)
Adenomyosis	8 (10.66)	6 (8)
PID	4 (5.33)	3 (4)
total	75	75

Chi= 0.66, p= 0.88. Not significant

Table 3 shows, commonest indication for both vaginal and abdominal hysterectomy is DUB followed by Uterine fibroid.

Table 4: Complications in VH and AH group in NDVH.

Complication	VH n (%)	AH n (%)	Chi square/ Fisher exact test, p value	Significance
Haemorrhage requiring blood transfusion	6 (8)	12 (16)	0.2082	Not significant
Bladder injury	2 (2.66)	5 (6.66)	0.4419	Not significant
UTI	1 (1.33)	6 (8)	0.1162	Not significant
Nausea / vomiting	4 (5.33)	16 (20.8)	0.0070	Significant
Abdominal distention	4 (5.33)	10 (13.33)	0.1587	Not significant
Wound infection	2 (2.66)	8 (10.66)	0.0976	Not significant

In the Table 4, there were 6 cases of haemorrhage requiring blood transfusion in vaginal group and 12 cases of haemorrhage requiring blood transfusion in abdominal. There were 2 case of bladder injury in vaginal group and 5 in abdominal. In the present study, post-operative complications like, UTI, abdominal discomfort and wound infection were more common in abdominal cases, but the difference was found to be statistically non-significant. Nausea, vomiting was significantly higher in abdominal hysterectomy (p=0.0070).

Table 5: Ambulation.

Duration of ambulation	VH n (%)	AH n (%)
Less than 12 hours after surgery	25 (33.33)	2 (2.66)
12 to 24 hours	40 (53.33)	15 (20)
More than 24 hours after surgery	10 (13.33)	58 (77.33)
Total	75	75

Chi= 64.83, p<0.0001, Highly significant

As shown in Table 5, majority of the patients in the vaginal group ambulated within 24 hours, while abdominal group ambulated after 24 hours. Mean time taken for ambulation in vaginal group is 18±4.81 and abdominal group is 32.06±5.37 which was statistically significant.

Table 6: Surgical results.

Parameter	VH	AH
Average operating time	50.43±7.256 min	86.6±8.363 min
Patient required blood transfusion due to hemorrhage	6	12
Average hospital stays in days	3	5

Table 6 shows, vaginal group was associated with less operative time, less intra-operative bleeding and early hospital discharge of patients.

DISCUSSION

As compare to abdominal approach, vaginal approach to hysterectomy has been gaining popularity among surgeons, now a day's patients are desperate to avoid an abdominal incision and demand scarless surgery. Vaginal route allows the surgeon to operate by the least invasive route of all, utilizing an anatomical orifice. Unfortunately, 70% to 80% of hysterectomies are performed by abdominal route and vaginal approach is usually reserved for uterovaginal prolapse.[7] With adequate vaginal access and good uterine mobility, vaginal hysterectomy can be easily performed.

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ORIGINAL ARTICLE

ORCHIDOPEXY WITHOUT LIGATION OF HERNIA SAC: OUR EXPERIENCE

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ABSTRACT: AIMS: To confirm that, the ligation of hernial sac during orchiopexy is not mandatory to prevent postoperative development of hernia. **METHODS:** This prospective study was conducted in 40 children with an age range of six months to 12 years with a diagnosis of undescended testis. Of the 40 cases, 30 were unilateral and 10 bilateral cases. Of the 30 unilateral undescended testis, 18 were right-sided and 12 left-sided. All children underwent standard orchiopexy without the ligation of the hernia sac. **RESULTS:** All the patients were followed up regularly up to a period ranging from 18 months to 24 months. No inguinal hernia was detected during the regular follow-up in any child. **CONCLUSION:** Ligation of herinal sac is not mandatory during orchipexy.
KEYWORDS: Undesended testes, inguinal hernia, orchidopexy.

INTRODUCTION: Herniotomy is performed along with orchidopexy for the closure of associated patent processus vaginalis. The conventional technique for undesended testis repair is high ligation of the hernial sac after proper dissection upto the deep ring, Mohta et al.[1] Observed that there is no untoward effect on the early complications and recurrence rate, if hernia sac is not ligated during herniotomy. During laparoscopic orchidopexy performed for contralateral testicle it was found that despite nonligation, the previous de peritonalized site got reperitonalized by itself and the sac which is dissected and left open deep to deep ring is not having hernia later in life. This is probably due to the closer of peritoneal defect within 24 hours by metamorphosis of the in situ mesodermal cells.[2]

We done a study on non-ligation of hernia sac during conventional orchiopexy in our institute to see the results and it's long term untowards effects and advantages over standard orchiopexy.

MATERIALS AND METHODS: This prospective study was conducted between May 2011 and Dec. 2014. Fourty children with an age range of six months to 12 years with a diagnosis of undescended testis were included. Of the 40 cases, 30 were unilateral and 10 bilateral cases. Of the 30 unilateral undescended testis, 18 were right-sided and 12 left-sided. In all the cases, testis was palpable. Only those cases were taken which were not associated with clinical hernia. Baseline investigations were done, informed consent of the parents was taken and the procedure explained to the parents. All children underwent standard orchiopexy without the ligation of the hernia sac.

The hernia sac was dealt with after complete mobilization of the testis through an inguinal incision. The sac was first opened up, divided and the proximal end of the divided sac was very gently peeled off with dissecting forceps as high as possible without damaging the cord structures. This was done to bring down the testis to its normal position as it results in achievement of adequate length of the cord as describe in standard orchidopexy technique. The dissected hernia sac was not ligated and left as such. Standard orchiopexy was then performed by making subdartos pouch. All the patients were followed up regularly up to a period ranging from 18 months to 24 months.

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processus vaginalis; myofibroblasts are found in association with smooth muscle. Smooth muscles dedifferentiation into myofibroblasts. This dedifferentiated state may represent attempted apoptosis, which results in disappearance of the smooth muscle and obliteration of the processus vaginalis after the descent of the testis into the scrotum.

Undescended testis may not share the same etiologic basis as hernia, because the sacs associated with undescended testis are without smooth muscles.

Handa et al.[6] Intentionally did not close the internal ring around the pulled-through spermatic cord. This approach was based on the observation that the majority of the testes lie near the internal ring. The mobilization of these testes by division of the gubernaculum and the dissection required to free a long loop vas deferens results in a large raw area at the internal ring. When the testis is pulled down into the scrotum, the mobilized surface of the spermatic cord is in apposition with the raw area at the internal ring.

As per many resent studies surgeons concluded that herniotomy in cases of hernia alone and hernia associated with UDT, hernial sac ligation is not required.[1],[2],[9],[10]

In our study, during inguinal orchiopexy, we did not ligate the hernia sac. After freeing the hernia sac from the cord, we simply dissected the hernia sac as high as possible and cut the proximal end near deep inguinal ring. We have performed 40 cases of inguinal orchiopexy with this procedure and followed up for 18 months to two years. We did not find any complication or untoward effect in any of our study cases.

Advantages asscociated with this advancement in standard procedure are:

1. Time saving: Several minutes of operating time are saved as we can avoid the holding of the proximal cut end of the hernial sac with multiple small haemostatic forceps and suture ligating it, especially when the sac is very thin and tends to tear very easily.
2. Length of testicular vessel: It is found that the most important criteria for bringing down the testes in the scrotum is the length of the testicular vessels; in this procedure extra length of the testicular vessel can be achieved by peeling off the peritoneum as high as possible.
3. Accidental ligation of the cord structures is avoided.
4. This technique decreases the anesthetic complications and reduces the undue stress of drugs and surgery.

CONCLUSION: In our study we also found that routine ligation of the hernial sac is not mandatory during orchidopexy. And it also reduces morbidity and operative time.

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List of Publications

DR.MOHAN LAL VISHNOI				
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2	A HOSPITAL BASED STUDY ON FIUNCTIONAL AND RADIOLOGICAL OUTCOME OF VOLAR BARTON'S FRACTURE TREATED WITH VOLAR T-PLATE	DR. MANISH & DR. MOHAN LAL VISHNOI	M, Vishnoi ML. A Hospital Based Study on Functional and Radiological Outcome of Volar Barton's Fracture treated with Volar T – Plate. Int Arch BioMed Clin Res [Internet]. 2020Jun.29 [cited 2021Jan.30];6(2):OP4-OP6. Available from: https://www.iabcr.org/index.php/iabcr/article/view/595	EISSN:2454-9894 PISSN:2454-9886
3	A HOSPITAL BASED PROSPECTIVE STUDY ON SCUTE SCROTUM: EVALUATION. DIAGNOSIS, INTERVENTION AND MANAGEMENT	DR. MANISH & DR. MOHAN LAL VISHNOI	Vishnoi ML, . M. A Hospital Based Prospective Study on Acute Scrotum: Evaluation, Diagnosis, Intervention and Management. Int Arch BioMed Clin Res [Internet]. 2020Jun.29 [cited 2021Jan.30];6(2):GS1-GS3. Available from: https://www.iabcr.org/index.php/iabcr/article/view/594	EISSN:2454-9894 PISSN:2454-9886
4	BACTERIOLOGICAL STUDY OF POST-OPERATIVE WOUND INFECTIONS IN IPD OF SURGERY IN A TERTIARY CARE TEACHING HOSPITAL	DR. MANISH & DR. MOHAN LAL VISHNOI	Vishnoi ML, . M. Bacteriological Study of Post-Operative Wound Infections in IPD of Surgery in a Tertiary Care Teaching Hospital. Int Arch BioMed Clin Res [Internet]. 2017Mar.18 [cited 2021Jan.30];3(1):95-8. Available from: https://www.iabcr.org/index.php/iabcr/article/view/579	INDEX COPERNICUS, IMSEAR

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Section Orthopaedics

Original Article

Clinical Analysis of Pathological Fracture: A Tertiary Care Teaching Hospital Based Study

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ABSTRACT

Background: *The aim of the present study was firstly, to know about the common causes of pathological fractures, secondly, to know the epidemiology of pathological fracture with respect to age, sex, and site and thirdly to know about the various modes of treatment options available in the management of pathological fractures.*

Methods: *108 total numbers of cases were included in this study. This study was conducted in Department of Orthopedics. The duration of study was over a period of one year.*

Results: *The most common cause was Osteoporosis of pathological fractures (44.4%) followed by other. Femur was the most common site and most fractures occurred in the trochanteric region. Operative treatment was carried out in most cases.*

Conclusions: *This study concluded that pathological fractures due to primary bone diseases should be dealt on individual basis depending upon the age, location, nature of lesion and stage of lesion.*

Key words: *Osteoporosis, Pathological fracture, clinical analysis*

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INTRODUCTION

A pathological fracture is considered as a fracture of an abnormal bone. Usually, the fracture happens during normal activity, as the abnormality of the bone reduces the strength of the bone and predisposes it to mechanical failure with minimal stress.[1] Tumors, osteonecrosis, metabolic diseases, apraxia, infections, and osteoporosis are some of the main reason behind pathological fractures. Bone tumors and lesions are the most common conditions.[2-8] Pathologic fractures due to neoplastic diseases are biologically different from fractures that are caused by non-neoplastic conditions such as trauma.[9] due to lack of adequate vigilance and insufficient knowledge of pathological fracture, misdiagnosis and mistreatment often occur with a high rate of 10% to 100%.[10,11] If pathological fractures resulted due to malignant bone tumors are mistreated, patients would lose opportunities of limb salvaging and their lives would be threatened. Previous studies mostly focused on the histopathology or surgical treatments of pathological fractures and have limited information about the diagnostic features of neoplastic pathological fractures.[2,3,7-18]

Therefore, the aim of the present study was firstly, to know

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to noneperative management. Similar results were found by Apostolos A. Tountas.

In this study, primary bone tumors were the second most common cause of pathological fracture accounting for 24 cases. 6 cases were due to benign bone tumors and rest cases were due to malignant bone tumors. In a retrospective study Sean P Scully (1996) revived 18 patients who sustained pathological fracture due to sarcoma. In the present study no case of sarcoma developed distant metastasis as against 33% undergoing amputation.

The third most common cause of pathological fracture in the present study was metastatic bone tumor. It was accounting for 21 cases. Similar results were found by Behr et al (20) . The most common metastasis was from breast (45%). Pain relief, restoration of function, decreased hospitalization and facilitation of nursing care was observed to be better with surgical management as compared to non-operative management. 6 case of pathological fractures due to infection was found in our study. Jenkins conducted a study on 74 patients of 70 years with fracture neck of femur evaluated by routine biochemical investigation and biopsy at the time of surgery. He found that subclinical osteomalacia is more prevalent than expected.

CONCLUSION

It can be concluded that pathological fractures due to primary bone diseases should be dealt on individual basis depending upon the age, location, nature of lesion and stage of lesion. Although the final outcome of the disease might not change yet adequate treatment of the fracture could provide the satisfactory pain relief and functional preservation for most cases. It requires regular follow-up and sometimes multiple surgical intervention in the proper management of pathological fractures. The treatment of the original condition is mandatory.

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Section General Surgery

Original Article

A Hospital Based Prospective Study on Acute Scrotum: Evaluation, Diagnosis, Intervention and Management

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ABSTRACT

Background: Generally, testis is partly covered by tunica vaginalis derived from procesus vaginalis in anterior part. If testis, epididymis and distal part of spermatic cord is covered by tunica–vaginalis, torsion of the testis may occur in this serosal space. The major differential diagnoses are acute epididymitis, strangulated hernia, hematocle, hydrocle, testis tumor and idiopathic scrotal edema

Methods: This prospective study was carried out among 100 male patients between the age group of 14 to 70 years. Around 100 cases were included in our study.

Results: We observed that swelling & pain seen in every cases while fever in 48 cases, burning micturition in 30 cases, abdominal pain in 16 cases & 12 cases of trauma. All the patients treated conservatively responded well with complete recovery.

Conclusions: Our study revealed that Conservative treatment in the form of rest, scrotal support, antibiotics and analgesics is effective in cases of epididymo orchitis and idiopathic scrotal edema.

Keywords: epididymo orchitis, Conservative treatment, tunica vaginalis

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INTRODUCTION

The term acute scrotum can be defined as signs and symptoms associated with local inflammation of the scrotum that appear suddenly and generally are not associated with trauma. These signs and symptoms are scrotal pain, swelling, redness and heat.[1] In other words, acute scrotum is an acute painful swelling of the scrotum or its contents accompanied by local signs and general symptoms. In children, the most common causes of acute scrotum are testicular torsion, appendix testis torsion, epididymitis, orchitis and pyocele.[2]

Spermatic cord or torsion of testis is certainly the most serious condition. It affects the scrotum[2] that requires urgent diagnosis and treatment to save the testis and avoid testicular loss, fertility problems and medicolegal issues.[1]

Testicular loss commences past twelve hours of initiation of symptoms. Testicular loss will definitely happen beyond twenty-four hours of symptoms. That is why in the absence of ancillary studies surgeons immediately explore the acute scrotum.[1]

Torsion of testis contains almost 15-40% of all acute testicular pain. This condition depends on abnormal relation of testis to scrotal tissue coverage.

Testicular scan and color doppler ultrasound are the two most commonly used preoperative studies. Testicular scans reliably reveal whether the testes have vascular flow or not but are difficult to be obtained during the night. Doppler ultrasounds are operator dependent and when done by

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right testis is injured more often than the left one. The reason could be its greater propensity to be trapped against the pubis or inner thigh.[5] Testicular rupture is a tears in the tunica albuginea resulting in extrusion of the testicular contents. Speedy surgical intervention is crucial. Ruptured testis can be salvaged, if surgical repair is performed within 72 hours of testicular injury.[5] In the present study, mean time between surgery and the initial trauma was 35 hours. Sports injuries were the most common causes of significant testicular injury. All testes were salvaged, though two boys developed testicular atrophy during follow up. In the diagnosis of testis torsion, standard and Doppler ultrasound accomplishes specificity of 80%-100%.[6] Acute phase proteins can be helpful in the differentiation of acute epididymitis from other non-inflammatory causes of acute scrotum.[6] Even with mentioned diagnostic procedures, sometimes it is not possible to distinguish between TT or some other conditions that mimics clinical presentation of TT. Hence, a surgical intervention is actually a diagnostic procedure. It is always justified in any dilemma for the accuracy of diagnosis. Previously, it has been shown that there is a positive correlation between low air temperature and TT.[7-9]

In this study, TT also most commonly occurred in January. A number of boys underwent surgery in winter and summer, and the lowest number in autumn. The reason could be the relative contraction of cremasteric muscle in winter and increased physical activity in summer, mainly water sports.

CONCLUSION

It can be concluded that Conservative treatment in the form of rest, scrotal support, antibiotics and analgesics is effective in cases of epididymo orchitis and idiopathic scrotal edema. Emergency surgical exploration is beneficial in cases of torsion testis and Fournier's gangrene. Follow up of the patients is essential to find out the complications in form of sterility, development of fistulae and involvement of contralateral side at a later period.

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Section Orthopaedics

Original Article

A Hospital Based Study on Functional and Radiological Outcome of Volar Barton's Fracture treated with Volar T – Plate

Manish[1], **Mohan Lal Vishnoi**[2*]

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ABSTRACT

Background: Fractures may occur due to low energy or high energy injuries. High energy injuries are more frequent cause of volar Barton's fracture.
Methods: 90 total number of cases were included in this study who attended the OPD. This study was conducted in Department of Orthopedics.
Results: In our study we were included total 90 cases of 0-60 age group. Mode of injury we were seen Fall on outstretched hand in 63 cases and Road traffic accident in rest cases. This study revealed that subject & functional result which were excellent in 18 & 27, good in 48 & 45 cases, fair in 15 & 6 cases, poor in 9& 12 cases respectively.
Conclusions: This study disclosed that maintaining anatomical reduction is key stone for satisfactory outcome. Best functional results were achieved till 6 months of treatment.

Keywords: Barton's fracture, Orthopedics, anatomical reduction

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INTRODUCTION

It well known that Barton's fractures is named after the American surgeon John Rhea Barton, who first described it in 1838. It is a fracture of the distal end of the radius which involves the articular surface.[1] This fracture can be either an anterior marginal or posterior marginal fracture. These fractures may occur due to low energy or high energy injuries. High energy injuries are more frequent cause of volar Barton's fracture.[2-5] Volar Barton's fractures are different from other distal radius fractures. There is an associated radio carpal dislocation in Barton's fracture. In these type of fractures, conservative treatment is usually unsuccessful. Whereas, in other distal radius fractures, the functional outcome with conservative treatment is good. Complications like loss of reduction, malunion, nonunion, deformity, subluxation and instability are also associated with these types of fractures.[6-8] Several surgical treatment methods are reported in literature. Open reduction and internal fixation with a volar plate system have displayed good results. The main advantages of this system are reduction of articular surface and achieves immediate stability of joint leading to early mobilization of wrist and potential reduction of wrist and finger stiffness and reduction of early onset of wrist osteoarthritis.[9-11]

Fractures of the distal radius found the most common skeletal injuries. It is treated by Orthopaedic surgeons. These

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Though, T-buttress plate is useful for achieving anatomical reduction, but care must be taken to avoid the complication of tendon rupture. The findings of this study showed that the scores of 27 patients were excellent, 45 patients good, and 12 patients fair.

CONCLUSION

This study analyzed 90 cases of volar Barton fracture operated by various surgeons. It can conclude that most common mode of injury was fall on outstretched hand. Anatomical and functional results were satisfactory in 80% cases fair in 13.3% cases and 6.6% cases had poor result. Complications were observed in 20% cases. Maintaining anatomical reduction is key stone for satisfactory outcome. Best functional results were achieved till 6 months of treatment.

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DEPARTMENT OF SURGERY

List of Publications

DR.MUKESH GARG				
1	PREVALENCE OF SURGICAL SITE INFECTION IN OPD :A HOSPITAL BASED STUDY	DR. MUKESH GARG	Garg M. Prevalence of Surgical Site Infections in IPD Department of Surgery: A Hospital Based Study. Int Arch BioMed Clin Res [Internet]. 2018Sep.30 [cited 2021Jan.28];4(3):73-5. Available from: https://iabcr.org/index.php/iabcr/article/view/408	INDEX COPER NICUS
2	ROLE OF PROPHYLACTIC ANTIBIOTICS AND PREVALENCE OF POST-OPERATIVE WOUND INFECTION IN SURGERY DEPARTMENT	DR. MUKESH GARG	arg M. Role of Prophylactic Antibiotics and Prevalence of Post-operative Wound Infection in Surgery Department. Int Arch BioMed Clin Res [Internet]. 2018Jun.29 [cited 2021Jan.28];4(2):187-9. Available from: https://iabcr.org/index.php/iabcr/article/view/390	E ISSN : 2454-9894 p-issn:2454-9886

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Section General Surgery

Original Article

Prevalence of Surgical Site Infections in IPD Department of Surgery: A Hospital Based Study

Mukesh Garg

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ABSTRACT

Background: *The most common causes of nosocomial infections are surgical site infections (SSIs). It is also reported that SSIs rate ranges from 2.5% to 41.9% worldwide and resulting in high morbidity and mortality.*

Methods: *This study conducted in Department of Surgery, Ananta Institute of Medical Sciences and Research Centre, Rajsamand.*

Results: *In this study, 410 cases were included, out of which 5.6% were infected post-surgery and 94.3% were non- infected. From the 5.6% cases 60.9% had mild infection and 30.4% had moderate infection and 8.7% had severe infection.*

Conclusions: *In the present study, the infection rate was higher. This high infection rate was due to the contaminated and dirty procedures where some of the patients were first seen about 2 to 3 days after development of pentonitis. It has been noted that the infection rate was higher in the emergency operative procedures in comparison to the elective procedures.*

Keywords: *Infection, wound, emergency, contaminated, moderate*

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INTRODUCTION

World Health Organization (WHO) reported that hospital acquired infections are one of the major infectious diseases which are having a critical economic impact worldwide.[1] These infections affect around two million people annually all over the world.[2,3]

The most common causes of nosocomial infections are surgical site infections (SSIs). It is also reported that SSIs rate ranges from 2.5% to 41.9% worldwide and resulting in high morbidity and mortality.[4-5] Every year approximately 2% to 5% of the 16 million people develop surgical site infections while undergoing surgical procedures.[6-7] It may causes death and an economic burden on the patients due to prolonged post-operative stay in the hospitals. In developing countries, the situation is worse due to the scarcity of resources and lack of trained staff. The essential component of total quality management is to control the post-operative complications. Therefore, it is important to determine the prevalence of surgical site infections, assess the magnitude of the problem and provide a rationale to set priorities in infection control in the hospitals. In India, very few researches have been done in this direction.

Therefore, the present study had been undertaken with the following aims and objectives-

- To isolate the different organisms from post- operative wound infections.
- To determine the antibiotic sensitivity pattern of these isolates, and
- To determine the rate of SSI.

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statistically significant and indicating a strong association between anemia and post-operative wound infection.

Pre-operative hospitalization has a significant effect on the post- operative wound infection. The normal bacterial flora of the patient is usually replaced by the resistant hospital flora as the duration of preoperative hospitalization increases.

In this study though the infection rate was higher when the pre- operative hospitalization was more than one week in comparison to less than one week. Though, the results are not statistically significant. Similar findings were found in the another study.[8,10]

In comparison to males (13.14%), females (15.28%) had higher infection rate but it was statistically insignificant. The small sample size of females can be held responsible for this insignificance. Infection rates were also found to be higher in cases with pre-operative hospitalization over 1 week and in cases over 60 years of age. These higher infections rates were again non - significant.

CONCLUSION

The present study suggested the effect of nature, duration and urgency of surgery along with diabetes, anemia and use of the drain as strong indicators of infection. The present study presented the changing outline of wound infection towards mixed infections.

If we get a chance, we would like to this study again with greater number of patients to get the better results and to validate our findings of the present study.

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Section Gen. Surgery

Original Article

Role of Prophylactic Antibiotics and Prevalence of Post-operative Wound Infection in Surgery Department

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ABSTRACT

Background: the Surgical Wound Infection Task Force changed the term 'surgical wound infection' with 'surgical site infection'. Surgical site infection is defined as superficial site infection and organ or space infection.
Methods: Total 100 cases were involved in this study , 50 for Group A and 50 as Group B. The case control study was carried out in the Departments of Surgery and Microbiology of Ananta Institute of Medical Sciences and Research Centre, Rajsamand. *Results:* Some associated factors were found such as Anemia Diabetes Mellitus Obesity & Prolonged duration of surgery in group A as well as group B. After post-operative surgery, we found that Staphylococcus aureus most popular organisms which causes infection followed by P. aeruginosa , K. pneumonia, Escherichia coli.
Conclusion: For surgical-site infections, surgeon should remember local and microbial factors should take appropriate measures to avoid them. One should use the most efficient and the best surgical techniques should try to avoid undue delays in the procedure to prevent postoperative wound infection.

Key words: Surgical Wound Infection, Post-operative, Staphylococcus aureus, Escherichia coli.

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INTRODUCTION

Surgical wound infection is one of the most common postoperative complications. It causes significant postoperative morbidity and mortality, prolonged stay in hospital and economic burden on patients as hospital costs. Though it is difficult to eliminate the wound infection completely yet a reduction in the infection rate to a minimal level could have significant benefits for the patient and medical resources.[1] Wound infection can be considered as any purulent discharge from a closed surgical incision, together with signs of inflammation of the surrounding tissue. There are chances of the occurrences of infection at an incision site within 30 days of an operation, but wounds which are closed and primarily healed are not considered infected. In 1992, the Surgical Wound Infection Task Force changed the term 'surgical wound infection' with 'surgical site infection'. Surgical site infection is defined as superficial site infection and organ or space infection.[2] The criteria laid for wound infection by Centers for Disease Control and Prevention (CDC) and the National Nosocomial Infection System is as follows:

1. A purulent discharge from a closed surgical incision.
2. A positive culture obtained from a surgical site which was closed initially

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glucose level below 200 mg/dl reduced the incidence of SSI significantly from 24% to 6.06%. In the present study, 12 cases were diabetic also.[10]

In our study, we found that 68% & 58% were male and 32% & 42% were female in group A and group B respectively. Among these cases group A had 26% of 41-50 age group & 28% of 21-30 Age in group B. Some associated factors were found such as Anemia Diabetes Mellitus Obesity & Prolonged duration of surgery in group A as well as group B. After post-operative surgery, we found that *Staphylococcus aureus* most popular organisms which causes infection followed by *P. aeruginosa, K. pneumonia, Escherichia coli.*

CONCLUSION

For effective prevention of surgical-site infections, surgeon should remember local and microbial factors should take appropriate measures to avoid them. One should use the most efficient and the best surgical techniques should try to avoid undue delays in the procedure to prevent postoperative wound infection. Prophylactic Antibiotics has been found to play a major role in preventing the post-operative wound infections.

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Section Microbiology

Original Article

Seroprevalence & Risk Factors of Hepatitis B Surface Antigen among Pregnant Women Attending a Tertiary Care Hospital of Southern Rajasthan, India

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ABSTRACT

Background: *Hepatitis B virus infection is a major global health problem and India accounts for 10-15%of the entire pool of HBV carriers of the world. Prevalence of Hepatitis B in pregnant women worldwide is 2.5 to 1.5%, whereas in India it is 2 to 7%. Hepatitis B virus is a double stranded DNA virus. The study was undertaken to determine the seroprevalence of Hepatitis B among the pregnant women in southern part of Rajasthan at a rural based tertiary care teaching hospital.* ***Methods:*** *This is a prospective study conducted at a tertiary care hospital, Udaipur, Rajasthan, from August 2015 to December 2017.Blood samples were collected from 1011 pregnant women with age ranging from 15-45 years. Screening of HBsAg was done by RPHA method and positive HBsAg tests were confirmed by ELISA. The data of those , who were found to be positive for HBsAg was statistically analyzed with the chi square tests, and results were considered significant if the p value was <0.05.*

Results: *The overall HBsAg seroprevalence rate was 1.28%, among the total 1011 pregnant women included in this study. HBsAg seroprevalence was highest, (1.64%) in 15-25 years of age group, and 1.71% in the second trimester of pregnancy. The correlations of seroprevalence rate of HBsAg among selected age groups and according to second trimester of pregnancy were not found statistically significant. (p value>0.05)*

Conclusion*: In this study the seroprevalence of Hepatitis B surface antigen was 1.28%. To prevent vertical transmission in the pregnant women, they should be screened for HBsAg at the first antenatal visit for appropriate management.*

Keywords: *Hepatitis B surface antigen, pregnant women, Vertical Transmission*

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INTRODUCTION

Hepatitis B Virus (HBV) infection is one of the most common public health problems. India has over 40 million hepatitis B virus carriers accounting for 10-15% of the entire pool of HBV carriers of the world.[1,2] However, the epidemiology and pattern and consequence of HBV infection varies greatly from one part of the world to another also changes with time. Hepatitis B is caused by double stranded DNA virus belonging to hepadnaviridae family. It leads to acute hepatitis and may also have serious complications like acute and chronic hepatitis, cirrhosis and hepatocellular carcinoma.[3-5] Hepatitis B Virus infection during pregnancy, is associated with a high risk of maternal complications. Prevalence of hepatitis B in pregnant women worldwide is 2.5 to 1.5%, whereas in India is 0.2 to 7.7%[6] Ten percent of infants born to women with acute HBV infection during the first trimester of pregnancy are HBsAg positive at birth, and 80 to 90% of neonates become HBsAg positive without prophylactic therapy, if acute maternal infection develops during the third trimester of pregnancy.[7,8] Screening and evaluation of hepatitis during the pregnancy is much more important to prevent mortality of mother and child. However there is a scarcity of systematic information on the prevalence of HBV infection among pregnant women in India including the study area. This will be useful to address the current prevalence status of hepatitis B during pregnancy, the present study aimed to determine the seroprevalence of hepatitis B surface antigen among pregnant women. The risk factors of Hepatitis B infection like IV drugs, previous Blood transfusion history, previous surgeries, tattooing, piercing etc were also

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evaluated, which would provide information to institutional and public measures to reduce the transmission of infection.

METHODS

The present study was undertaken over a period of one and half year from August 2015 to December 2017, approved by the institutional Ethics Committee. The present study was conducted at a rural based tertiary care teaching hospital at Udaipur district of Rajasthan. A population of 1011 pregnant women age ranging from 15-45 years attending Antenatal clinic was involved in the study. Individuals were interviewed by structured questionnaire including data regarding obstetric history, previous HBV vaccination, HBsAg status of self and spouse and the associated risk factors of infection were also asked.

Laboratory Assay: About 2 ml of venous blood was collected from each individual after obtaining a written consent under strict aseptic precautions. Rapid immunochromatography test (HEPA card) was employed to detect the presence of HBsAg. For confirmation, blood samples tested positive for HBsAg were subjected to commercially available fourth generation ELISA (Enzyme Linked Immunosorbent Assay) Kit Hepalisa by J. Mitra & Co. Pvt. Ltd with antigen sensitivity 0.1ng/ml was used. Manufacturer's instructions were followed during the entire test procedure.

RESULTS

A total of 1011 pregnant women attending antenatal clinic in a tertiary care hospital, were studied. All the women were asymptomatic and were unaware of Hepatitis B status. The subject age ranges from 15-45 years. The seroprevalence of HBsAg positivity in this current study was 1.28% among 1011 participants 13 women tested positive for HBsAg. Age distribution and HBsAg screening tests were given in Table1. In statistical analysis, the p-value obtained was >0.05 (statistically insignificant). The distribution of trimester of pregnancy and HBsAg screening results were given in Table 2. The p value obtained was >0.05 which is statistically insignificant. Analysis of age distribution of HBsAg positive women revealed a high prevalence (1.71%) among 15-25 years majority of them were primigravidae in second trimester of pregnancy. Associated risk factors distribution among HBsAg positive women was shown in Table 3.

Table 1:- Age wise distribution and HBsAg status (n=1011)

Age	Number tested	HBsAg positive	HBsAg negative
15-25	364	6(1.64%)	358 (98.35%)
26-30	384	4 (1.04%)	380 (98.95%)
31-35	208	3(1.44%)	205 (1.44%)
36-40	47	0	47(100%)
41-45	8	0	8(100%)
Total	1011	13	998

Table 2:- HBsAg seropositivity in different trimesters of pregnancy (n=1011)

Trimesters	No of Pregnant women	HBsAg positive (%)
First	243	3 (1.23%)
Second	467	8(1.71%)
Third	301	2 (0.66%)

Table-3 Risk Factors observed in HBsAg Positive women (n=13)

Risk Factors	No of ANC
History of Blood Transfusion	3(23.07%)
Previous Surgeries	2 (15.38%)
HIV status	0
Tattooing	4 (30.76%)
Piercing	13(100%)

DISCUSSION

The prevalence of HBsAg varies widely in different parts of the India. The variety of socioeconomic status of the population studied, genetic factors, and other risk factors contribute to the variance of seroprevalence rate. The prevalence of HBsAg positivity in pregnant women has been reported to range from 2.61-6.3% in various studies.[9-12] In our study, the overall seroprevalence of HBsAg positivity in pregnant women 1.28%, was in accordance with a seroprevalence of 1.1% reported by Pande et al[13] and also comparable to the seroprevalence 1.15% by Ambade et al.[14] Dwivedi et al[15] study shows the declining seroprevalence of HBsAg 0.91. Few other studies from India by Chatterjee et al[16] (0.82%) and Shazia Parveen S. et al[17](0.61%), the seroprevalence rate reported were lower than the present study. Other studies from India as carried out by Mittal et al,[18] Gill et al,[19] Nayak et al,[20] and Khakhkhar Vipul et al,[21] reported higher seroprevalence rate of 6.3%, 5%, 3.7% and 3.07% respectively in comparison of our study. Also, the seroprevalence of HBsAg among pregnant women in our study can also be comparable with 1.6%, 1.47% and 1.37% as reported in some countries respectively like Saudi Arabia,[22] Turkey[23] and Pakistan.[24] Regarding age, in the present study, high HBsAg seropositivity rate in pregnant women was found in age group of 15-25 years (1.64%) in agreement with Ambade et al, Dwivedi M et al and Khakhkhar Vipul et al, and smita Thakkarwad et al.[25] In our study highest seroprevalence of HBsAg positivity was found in second trimester 1.71%. This was with comparable studies of Padmavati Palange et al[23] and Mehta et al[26] and variance with the findings from similar works, Dwivedi M et al and Khakhkhar Vipul et al, and smita Thakkarwad et al.[25]

CONCLUSION

This study provides necessary information to detect the risk factors to formulate necessary preventive measures. The HBsAg seropositivity rate of 1.28% in pregnant women in this study recommends and supports an appropriate antenatal screening, so that the vertical transmission of Hepatitis B virus infection can be avoided. Public health policies should include routine universal screening of HBV infection and immunization of risk infants immediately after birth.

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Section Pulmonary Medicine

Original Article

Antimicrobial Resistance Pattern of Bacterial Isolates from Endotracheal Aspirate of Ventilated Patients at a Tertiary Care Hospital

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ABSTRACT

Background: *Respiratory infections among critically ill Patient are associated with high morbidity and mortality. Mechanically ventilated patients are at a high risk of acquiring respiratory infections due to complex interplay between the endotracheal tube, host immunity and virulence of invading bacteria. Irrational use of antibiotics increases the emergence of drug – resistant bacteria.* ***Objectives:*** *The aim of study was to investigate the bacterial isolates in the endotracheal aspirates of mechanically ventilated patients in ICU and see the antimicrobial resistance pattern of bacterial isolates.*

Methods: *Analysis of E.T aspirates of 459 patients over a period of 1 year (Aug 14 to Aug 15) was done. Aspirates were cultured on Blood and MacConkey agar isolation and identification was done using conventional techniques and biochemical reactions. Antibiotic sensitivity testing was done by Kirby-Bauer disc diffusion method as per CLSI guidelines.* ***Results:*** *Out of 459 Samples 365 was found to be positive. Acinetobacter sp (44.65%) was the most common isolate followed by Klebsiella sp (18.63%), Pseudomonas sp (11.23%), Candida (10.46%), Escherichia Coli (7.94%), COPS (3.28%), CONS (2.46%), Enterococci (0.82%), and Citrobacter (0.54%). The gram-negative bacilli were mostly sensitive to Tigecycline, Colistin, Imipenem, Meropenem, Amikacin and Piperacillin/Tazobactam. Gram positive Cocci were mostly sensitive to Vancomycin, Linezolid and Gentamicin.*

Conclusion*: The isolation and antimicrobial resistance pattern of the microorganisms is necessary for their effective management. Endotracheal intubation is one of the major risk factors in causing iatrogenic infections to patients. A local antibiogram for each hospital, based on bacteriological patterns and susceptibility is essential to initiate empirical therapy.*

Keywords: *Endotracheal aspirates, ventilated patients, antibiogram of bacterial isolate*

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INTRODUCTION

Mechanical ventilation is a life-saving procedure for many patients in intensive care unit. Patients who are intubated and mechanically ventilated are further at a high risk of acquiring respiratory infections due to complex interplay between the endotracheal tube, host immunity and virulence of invading bacteria which may lead to ventilator associated pneumonia (VAP).Tracheal colonization of different bacteria may be responsible for added or super infections and at the same time, increases the risk of mortality[1]. The etiological agents may vary according to the population of patients in ICU, duration of hospital stay, pre-existing and prior antimicrobial therapy.

To add to the trouble, the statistical data and evidences from research prove that multi drug resistance bacteria are rapidly emerging across the world and pose a big challenge to health care system. Extensive and non-specific use of broad-spectrum antibiotics in hospitalized patients has led to both increased carriage and the development of multi drug resistant strains.[2] Multi drug resistance bacteria cause serious nosocomial and community acquired infections that are hard to eradicate. One must use existing antibiotics skillfully and more judiciously. It is difficult to manage these infections effectively unless we are armed with adequate and good quality data about the antibiotics susceptibility pattern of organisms causing respiratory infections among mechanically ventilated patients in intensive care unit. To be more effective this data has to be region specific and also

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has to be updated regularly as bacterial susceptibility varies with time and space. Unfortunately, such data is scanty, and this has led to a wide spread of mortality and morbidity due to respiratory infections. Therefore, updated knowledge of local epidemiology and susceptibility profile is recommended for guiding the clinicians regarding empirical choice of antibiotics and should become mandatory along with adequate clinical diagnosis and bacterial confirmation.[3]
Hence, the study was planned to identify pattern of bacterial isolates responsible for respiratory tract infections among mechanically ventilated patients at intensive care unit and to make their antimicrobial resistance pattern.

Aims & Objectives:

1. To study the microorganism's profile in the ICU during the study period in endotracheal tube culture.
2. To study the antibiotics to which these microorganisms are susceptible.
3. To propose a proper empirical antibiotic therapy in intubated patients according to prevalence of microbiological organisms in ICUs.

METHODS

The prospective study was carried out with the samples of endotracheal aspirates and endotracheal tube tip received from ICUs in the microbiology laboratory over a period of one year (Aug-2014 – Aug-2015). Samples were collected under sterile conditions from patients admitted in both medical and surgical intensive care unit who were ventilated for at least 48 hrs.

Collection of Specimen:

Endotracheal Aspirate: Sampling was done by introducing a catheter aseptically through the endotracheal tube and secretions aspirated into a sterile syringe.
Endo-tracheal tube tip: The endo-tracheal tube tip was cut aseptically into a sterile container and sent to the Microbiology laboratory.

Processing of Specimen:

Endotracheal Aspirate*:*
Both 10µl of the specimen and 1 µl of the specimen was inoculated in blood agar and MacConkey agar.
Endotracheal tube tip: The lumen of endotracheal tube tip was rinsed with 0.5 ml of sterile normal saline. 10µl of the fluid was inoculated on blood agar and MacConkey agar. A gram's stain of the endotracheal secretions / endotracheal tube tip fluid was done to assess the number of pus cells and the presence of bacteria. A semi quantitative method was followed, and plates were incubated overnight at 37°C.13. The organisms isolated were identified based on colony characteristics on Blood agar and MacConkey agar, Gram's stain, Biochemical reactions by using standard microbiological techniques. Isolates identified as commensals or contaminants were excluded from further process. A Kirby-Bauer method was used to test the susceptibility of organisms to various antibiotics. As per Clinical and Laboratory Standards guideline (2014).[4]

Antibiotics used:

Ampicillin/Sulbactam (AS-10/10µg), Cefuroxime (CXM-30µg), Cefoxitin (CX-30 µg), Ceftriaxone(CTR-30µg),Vancomycin (VA-30µg), Linezolid (LZ-30µg), Piperacillin/Tazobactam (PIT-100/10µg), Ceftazidime/Clavulanic acid (CAC-30µg/10µg), Cefotaxime/Sulbactam (CFS-5/30µg), Cefepime (CPM-5µg), Ceftriaxone (CTR-30µg),Gentamicin (GEN-10µg), Amikacin (AK-30µg), Aztreonam (AT-30µg),Azithromycin- AZM-15 µg), Ciprofloxacin (CIP-5µg), Levofloxacin-(LE5µg), Amoxicillin/Sulbactam (A/S-30µg), Imipenem (IMP-10µg), Colistin (CL-10µg), Meropenem (MRP- 10µg), Polymyxin B (PB-300U), Tigecycline (E- strip).Zone diameter was measured and interpreted as per the Clinical and Laboratory Standards Institute(CLSI) guidelines (2014)[4].

RESULTS

A total of 459 samples were collected from 459 patients during the study period of one year. Out of 459, 94 samples were either sterile or were polymicrobial growth which were not processed further for the study. Among 365, 184 samples (50.4%) were of male and rest were of female181 (49.58%). The organism isolated were *Acinetobacter sp*. 163 (44.65%), *Klebsiella sp* 68 (18.63%), *Pseudomonas sp* 41 (11.23%), *Escherichia Coli* 29 (7.94%), *Candida* 38 (10.41%), *Coagulase Positive staphylococcus aureus* (COPS)12 (3.28%), *Coagulase Negative Staphylococcus aureus* (COPS) 9 (2.46%), *Enterococci* (0.82%), and *Citrobacter* 02 (0.54%)
Acinetobacter was the most resistant of all other isolates. It was sensitive to Tigecycline (98.15%), Colistin (96.9%0, Meropenem (94.4%), Imipenem (92.02%), followed by Amikacin 36.80%, Levofloxacin 30.6%, Piperacillin/Tazobactam (25.7%), Ciprofloxacin 25.15%. (table-2).

Table 1: Micro-organisms isolated and percentage (n=459)

Micro-organisms	%
Acinetobacter sp	163(44.65%)
Klebsiella sp	68(18.63%)
Pseudomonas sp	41(11.23%)
Candida	38(10.46%)
Escherichia Coli	29(7.94%)
Citrobacter	2(0.54%)
Coagulase Negative Staphylococci (CONS)	9(2.46%)
Coagulase Positive Staphylococci (COPS)	12(3.28%)
Enterococci	3(0.82%)
No growth	94
Total	459

All isolates of Pseudomonas sp were sensitive to Imipenem 100%, Meropenem 100%, Tigecycline 100%, Colistin 100%, Polymyxin-B 100%, followed by Amikacin 68.2%, Piperacillin/ Tazobactam 68.2, Levofloxacin 56.09%. (table-2).
All Klebsiella sp were 100% sensitive to Tigecycline and Colistin followed by Imipenem 86.76%, Meropenem 88.2%, Levofloxacin 23.5%, Amikacin 35.29%, Piperacillin/Tazobactam 19.11, Ciprofloxacin 11 (16.17%). Other drugs were 7.3% sensitive were highly resistant with sensitivity of 7.3% (Ceftazidime/ C.A, Cefotaxime/ Sulbactam, Cefepime, Ceftriaxone) (table-2).
Similarly, all strains of Escherichia Coli were 100% sensitive to Tigecycline and Colistin only. Followed by Imipenem

89.6%, and Meropenem 89.6%, followed by Amikacin 79.3%, Piperacillin/ Tazobactam 68.9%, Levofloxacin 41.3%, Ciprofloxacin 34.4% (table-2.)

Only two isolates of *Citrobacter* were found which were 100% sensitive towards Amikacin, Piperacillin/Tazobactam, Imipenem, Tigecycline, Colistin, Meropenem.

In case of Gram positive bacteria all 12 (3.28%) COPS were 100% sensitive towards Vancomycin and Linezolid, followed by Gentamicin 78%, Fluoroquinolones as 41.6%, followed by Amoxicillin/Clavulanic acid and Ampicillin / Sulbactam and Cotrimoxazole 33.3%,each , other cephalosporins , (Cefuroxime, ceftizoxime, ceftriaxone, cefixime and cefoxitin) as 25% sensitive only.(Table-3)

CONS isolates were 100% sensitive towards Vancomycin and Linezolid, followed by Gentamicin 77.7%, Levofloxacin 55.5% Cotrimoxazole 33.3%) followed by other cephalosporins and Ciprofloxacin as 22.2% sensitive. (Table-3)

Enterococci show 100% sensitivity towards Vancomycin, Amoxicillin/ C.A, Ampicillin/ Sulbactam and linezolid and Gentamicin.

Table- 2 Antibiotic Sensitivity pattern of Gram-negative Clinical isolates

Organism/Antibiotics	Klebsiella sp n = 68	Acinetobacter sp n = 163	Pseudomonas sp n = 41	Escherichia Coli n = 29	Citrobacter n = 2
Amikacin	24(35.29%)	60(36.80%)	28(68.2%)	23(79.3%)	2(100%)
Piperacillin/Tazobactam	13(19.11%)	42(25.7%)	28(68.2%)	20(68.(%)	2(100%)
Ciprofloxacin	11(16.17%)	41(25.15%)	20(48.7%)	10(34.4%)	0
Levofloxacin	16(23.5%)	50(30.6%)	23(56.09%)	12(41.3%)	0
Imipenem	59(86.76%)	150(92.02%)	41(100%)	26(89.6%)	2(100%)
Tigecycline	68(100%)	160(98.15%)	41(100%)	29(100%)	2(100%)
Colistin	68(100%)	158(96.9%)	41(100%)	29(100%)	2(100%)
Meropenem	60(88.2%)	154(94.4%)	41(100%)	26(89.6%)	2(100%)
Ceftazidime/Clavulanic acid	5(7.3%)	0	18(43.9%)	9(31.03%)	0
Cefotaxime/Sulbactam	5(7.3%)	0	18(43.9%)	9(31.03%)	0
Cefepime	5(7.3%)	0	18(43.9%)	9(31.03%)	0
Ceftriaxone	5(7.3%)	0	18(43.9%)	7(24.13%)	0
Polymixin-B	ND	ND	41(100%)	ND	ND
Ampicillin/ Sulbactam	ND	ND	ND	11(37.9%)	ND

DISCUSSION

To prevent or combat respiratory failure, life- saving procedures are done on emerging or elective basis such as endotracheal intubation and mechanical ventilation. Many clinical conditions warrant need for ventilated support like life threatening infections, sepsis in acute respiratory distress syndrome, neurological dysfunction due to poisoning drug toxicity, cerebrovascular accidents, traumas and others. Mechanical Ventilation helps to prevent deaths due to respiratory failure but on the other hand it possess great threat, by host immune response and infectious organisms that lead to life threatening lung infection.[5] Mechanically ventilated and tracheotraumatized patients are colonized with bacteria of either endogenous or exogenous origin which might end up in Vat or VAP.[6] Healthcare associated infections continue to be a major cause of patient morbidity and mortality in ICUs.

The various organisms were isolated and cultured from these samples and their susceptibility testing was done according to clinical and Laboratory standard Institute guidelines (CLSI)[4] with the intention of assessing the discriminative prevalence of various common bacteria and to identify the local prevalent antibiotic response against the detected pathogens.

Table-3 Antibiotic susceptibility pattern of Gram-positive clinical isolates

Antibiotics	COPS	CONS	Enterococci
Total Strains	n = 12	n = 9	n = 3
Gentamicin	9(78%)	7 (77.77%)	3(100%)
Cefuroxime	3(25%)	2(22.2%)	0
Ceftozoxime	3(25%)	2(22.2%)	0
Ceftriaxone	3(25%)	2(22.2%)	0
Cefixime	3(25%)	2(22.2%)	0
Vancomycin	12(100%)	9(100%)	3(100%)
Azithromycin	3(25%)	2(22.2%)	0
Amoxcillin +Calvulanic Acid	4(33.3%)	2(22.2%)	3 (100%)
Ampicillin/Sulbactam	4(33.3%)	2(22.2%)	3 (100%)
Ciprofloxacin	5(41.6%)	2(22.2%)	0
Levofloxacin	5(41.6%)	5(55.5%)	0
Cotrimoxazole	4(33.3%)	3(33.3%)	0
Linezolid	12(100%)	9(100%)	3(100%)
Cefoxitin	3(25%)	2(22.2%)	0
Penicillin	2(22.2%)	5(55.5%)	0

Our study showed 80% growth from endotracheal aspirates which are concurrent with the study of Bhaskar Thakuria et al[7]. who has reported 85% growth and V.R. Rathod et al[8] who also has also reported 85% of endotracheal aspirate growth. Another study of Santosh Khanal et al[9] Ada Siler Junior et al.[10] and Koirala et al[11]have variable growth rate of (78-92%). Another Study by Kartik S.L. et. al.[12] gave a lower growth rate of 70.07%.

As far as the bacterial profile is concerned out of 365 isolates, 303 (83.47%) were gram negative bacterial isolates (GNB) and only 22 (6.06%) were GPC, similar findings has been quoted by V.S. Rathod et al[8] in which 80% were GNB, 20% were GPC. Our study correlates with many studies and particularly as shown in one systemic review article by Yaseena Arabi et al[13] were GNB range from 41 to 92%, GPC between 6-58%. In our study 38 (10.41%) isolates were fungus whose DST was not followed as our aim of study was to chart out antibiotic susceptibility profile of the bacterial isolates only.

In our study bacterial isolates identified are *Acinetobacter sp.* 44.65%, *Klebsiella sp* 18.63%, *Pseudomonas sp.* 11.23%, *Escherichia Coli* 7.94%, *Citrobacter* 0.54%,. Similar findings were reported by Priya Santharam et. al.[14] Acinetobacter followed *Pseudomonas, klebsiella pneumonia*. Non fermenter gram negative bacilli, Escherichia Coli and then *Citrbacter*. Our study also coincides with study conducted by N. Shanmuga vadivoo et. al.[15] that *Acinetobacter* has over taken the pathogenic role in ventilated patients.

V.S. rathod et al[8] quoted *Klebsiella pneumonia* as the most common isolate followed by *pseudomonas aeriginosa* and *Acinetocabter baumannii*, in his study which coincides with vadivoo et al[15] which reported *Klebsiella* followed by *Acinetobacter* and *Pseudomonas*. Also, Shilpi Dhakar et. al.[16] detected *Klebsiella* as most common pathogen followed by *Pseudomonas, staphylococcus*, *Acinetobacter* and *Escherichia Coli* with small number of *enterobacter*, and *streptococcus.* Such contrast can be due to discriminative prevalence due to the change in the demographic region of all studies conducted.

Among GPC, in our study 3.28% were COPS, 2.46% CONS and 0.821% were Enterococci isolates which is in similarity to the findings of V.S. Rathod et al [8] were GPC contributed to 6% among micro-organisms isolates. Priya Santharam et al[14] figured out 8% *Staphylococcus aureus* and were as Dipti Chandra et. al.[17] also reported 8.82% of *Staphylococcus aureus.*

In our study *Acinetobacter* was found to be the most predominant bacteria which shows high resistance towards penicillin, cephalosporins (ceftazidime and cefepime), intermediate sensitivity for aminoglycoside (Amikacin as 36.80%) followed by fluoroquinolones (Ciprofloxacin and Levofloxacin). *Acinetobacter sp* were highly sensitive towards carbapenems (Imipenem 92.02%, Meropenem 94.4%) followed by Colistin 96.9% and Tigecycline 98.15%. 40 (24.53%) strains of *Acinetobacter sp* was multidrug resistant.

Sensitivity pattern of *Klebsiella sp.* shows high resistance towards cephalosporins. Intermediate sensitivity towards Amikacin 35.29%, 23.5% for levofloxacin and 16.17% for Ciprofloxacin. Carbapenems shows 88.2% sensitivity. Most sensitive drugs against *Klebsiella sp* were Tigecycline and Colistin as 100% each. 44(64.70%) strains of *Klebsiella sp* were multi drug resistant[18]

In our study *Pseudomonas sp* shows high sensitivity pattern towards Tigecycline 100%, Colistin 100%, Meropenem 100%, Imipenem 100%, Polymixin B 100%, followed by Amikacin 68.2%, and combination Piperacillin/ Tazobactam 68.2%. Cephalosporins gave 43.9% sensitivity for pseudomonas. Flouroquinolones were also intermediate sensitive for Pseudomonas (Levofloxacin 56.09% and Ciprofloxacin 48.70 %.)

Tigecycline and Colistin were 100% sensitive for *Eschericha Coli* followed by Carbapenems (Imipenem and Meropenem 89.6% each). Amikacin has also significant sensitivity pattern for *Escherichia Coli* 79.3% followed by combination of Piperacillin/Tazobactam. Levofloxacin has lesser senstivity 41.3% and Ciprofloxacin 34.4%. All specimens show a great resistance towards cephalosporins with a sensitivity pattern of 24.13%.

Few species of *Citrobacter* were isolated which were highly sensitive towards Amikacin, Piperacillin /Tazobactam, Imipenem, Meropenem, Colistin, Tigecycline as 100% sensitive. But all were resistant towards flouroquinolones and cephalosporins.

In case of *COPS, CONS* and *Enterococci* all isolates were found 100% sensitive towards Vancomycin and Linizolid followed by Gentamicin,(78%) Flouroquinolones 41.6%, combination of Amoxicillin/C.A 33.3% /22.2% respectively and Ampicillin /Sulbactam 33.2%/ 22.2% respectively. 9 (75%) strains were identified as Methicillin resistant *Staphylococcus aureus*. Gram positive organisms of E.T. aspirates in our ICU set up were mostly resistant to penicillin derivatives and cephalosporins.

CONCLUSION

The study reveals that the antibiotic susceptibility pattern varies across region and timeline and hence studies examining the local susceptibility pattern should be carried out at every centre. Endotracheal Intubation is a major risk factor in causing iatrogenic infections to patient which leads to an increase in the morbidity and mortality. Our study reported a high percentage resistance among gram negative bacilli to cephalosporins. Aminoglycosides (Amikacin), and a combination of Piperacillin/Tazobactam were found to be moderately effective. Carbapenems, Colistin and Tigecycline were found to be most effective drug of choice.

For gram positive bacterial isolates shows significantly high resistance for penicillin and cephalosporin. 75% MRSA strains were also indentified. Vancomycin and linezolid were found to be most sensitive followed by Aminoglycoside (Gentamicin).

From present study we have concluded that analyzing the E.T aspirate was important as the sensitivity to the antibiotic obtained, is an alarming factor for efficacious and judicious use for antibiotics. This study will help us in implementing different antibiotics prophylactically with regard to the commonly obtained sensitivity pattern.

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Seroprevalence of Hepatitis B Virus Infection among OPD Patients Attending Tertiary Care Hospital

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ABSTRACT

Background: *Hepatitis B infection is a major global health problem. The hepatitis B surface antigen (HBsAg) in serum is the first seromarker to indicate active HBV infection either acute or chronic. The seroprevalence of Hepatitis B surface antigen among general population attending OPD at a tertiary care hospital is useful in assessing true nature of problem, which can help to estimate the magnitude of HBV infection and aid in devising preventive measures. The aim of the study was to determine the seroprevalence of Hepatitis B infection among OPD patients attending a tertiary care hospital.* ***Methods:*** *Data from Dec 2015- April-2017 for OPD patients underwent HBsAg screening were collected and analysed.* ***Results:*** *A total number of 3891 patients were screened for HBsAg among them 1731 (44.48%) were males and 2160 (55.51%) were females. The seroprevalence of HBsAg in total OPD patients was 90(2.31%), was higher in males 46(2.65%) as compared to females 44(2.03%). The highest seroprevalence was found in 60-71 (4%) age group.* ***Conclusions:*** *The seroprevalence of Hepatitis B positive cases was 2.31% among OPD patients. Also, the rising seroprevalence rates of hepatitis B in males need urgent attention.*

Key words: *HBsAg, seroprevalence, OPD patients, tertiary care hospital*

INTRODUCTION

About 30% of the world population has serological evidence of current or past infection with hepatitis B virus. It is known to be the 10th leading cause of death and HBV related hepatocellular carcinoma is the 5th most frequent cancer worldwide.[1] About 2 billion people (or 30% of world population) worldwide have serological evidence of current or past HBV infection, and an estimated 350 million people harbor chronic infection[2]. India has been placed into the intermediate zone of prevalence of hepatitis B (2-7% prevalence rate by WHO).[2] Indian population forms the second largest global pool of chronic HBV infections and the number of HBV carriers in India is estimated to be 50 million.[3] The virus is transmitted by either per-cutaneous or mucous membrane contact with infected blood or other body fluid and is found in highest concentrations in blood and serous exudates. The primary routes of transmission are peri-natal, early childhood exposure, sexual contact, and per cutaneous exposure to blood or body fluids (i.e. injections, needle stick, blood transfusion). The hepatitis B surface antigen (HBsAg) in serum is the first seromarker to indicate active HBV infection, either acute or chronic.[4]

A large population of patients suffering from hepatitis B may be asymptomatic and can transit the disease to healthy population. The patients presenting to the OPDs of a hospital are generally those seeking treatment for mostly community acquired ailments hence the estimation of seroprevalence of hepatitis B surface antigen in such patients can be considered as a surrogate marker to represent the dynamics of virus transmission in the community. Studies have been conducted to estimate the prevalence of hepatitis B virus in selected group of people with higher risk factors such as blood donors, pregnant women, drug addicts and patients with liver disorders.

However, there is paucity of information in India on prevalence of HBV infection among general population. That is why a prevalence based study of patients at a

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tertiary care teaching hospital is helpful in assessing true nature of problem in the community, which can help in assessing the magnitude of HBV infection and aid in devising preventive measures.

Community based seroprevalence studies are difficult to conduct in a developing country like India, because of socioeconomic hurdles and logistics difficulties. More than one half ambulatory and two- thirds outpatients care are catered by private health care in India.[5]

A private tertiary teaching hospital catering to the needs of a large population thus represents an important center for serological surveys. Also, the available data at Rajasthan state level on the seroprevalence and distribution of this blood borne pathogen is limited.

It was against the above backdrop that the present study was undertaken to estimate the seroprevalence of Hepatitis B viral infection among OPD patients attending tertiary care hospital.

METHODS

The present study is a prospective hospital based study conducted in the department of Microbiology, at Ananta Institute of Medical Sciences & Research Center, Rajsamand from December 2015 to April 2017. A total of 3891 blood samples were collected from patients attending different OPDs, for whom HBsAg detection was sought after a written consent. For the evaluation of HBsAg, a one-step rapid immunochromatographic Assay (ICA) was used. The qualitative detection of HBsAg was determined using a rapid Card (Hepacard-Biomed industries). The ICA are rapid and sensitive methods for detecting HBsAg. They are economical and do not require special instrumentation for analysis and have been recommended for use in clinical microbiology laboratories.[6] Immnunochromatoghraphic Assay has high sensitivity and specificity.[7] The reactive samples were retested in duplicates with fresh blood samples, if found reactive were considered as reactive.

RESULTS

We report here a study to assess the epidemiology of HBV prevalence among the OPD patients attending a tertiary care hospital of Rajsamand (Rajasthan).

A total of 3891 serum samples were processed for HBsAg detection over a period of 12 months, among them 1731 (44.48%) were male and 2160 (55.51%) were female. Table 2 shows age and sex distribution of hospital based population. The seroprevalence of HBsAg was 90 (2.31%). It was higher in males 46 (2.65%) as compared to females 44 (2.03%). The highest seroprevalence was found to be among 61-70 age groups which were (4%). The highest seroprevalence among HBsAg positive male was found in 61-70 age group which was 5.47% and among females were in age group 41-50 which was 3.71.

DISCUSSION

The seroprevalence of HBsAg in the present study was found to be 2.31%. India has been placed into the intermediate zone of prevalence of hepatitis B (2-7%) so present study findings correspond to it. HBV prevalence among the hospital based population at Karad, Maharashtra in a tertiary care hospital by Patil et al 2016,[8] the seroprevalence of HBsAg was found to be 2.25%. A study conducted by Tripathi P.c. et al 2015[9] seroprevalence of hepatitis B surface antigen at a tertiary care center in Telangna was 1.69%. Samtha P et al 2014[10] in their hospital based population at Guntur Andhra Pradesh reported prevalence of hepatitis B surface antigen was 2.4%, which approximately coincides with our study. Quadri S.A. at al 2013[11] reported the prevalence of HBsAg to be 1.63%, in a hospital based study at Bijapur, Karnataka. A recent study conducted in Rajasthan by Payal Mathur et al 2016[12] at a tertiary care teaching hospital situated at district Ajmer, the seroprevalence of HBsAg was found to be 0.94% only. Another hospital based population study conducted by Smita Sood 2013[13] at Jaipur district of Rajasthan at a superspeciality private hospital among OPD attendees, the prevalence of hepatitis B surface antigen was observed to be 1.73%. There are several studies conducted on seroprevalence of HBsAg in India. The point of hepatitis B in non-tribal population is 3.07% and among the tribal population is 11.85%. Batham A et al in their review of 54 studies on seroprevalence of HBsAg was observed 2.4% in non-tribal population and 15.9% among tribal population. Another review of hepatitis B prevalence in India by Lodha et al has conducted that it is in between 1-2%[14]. High prevalence of HBsAg (between 2-7%) has been reported in the past, and a community based study carried out in Tamil Nadu reported the prevalence of HBsAg was 5.7%.[15] Another study conducted in Sarkhet Valley, HBsAg prevalence rate was found to be 8.8% in the hospital patients.[16] The prevalence of HBsAg in patients attending surgical OPD at Fauji Foundation hospital, Rawalpindi, Pakistan has been reported as 2.28%.[17] Seroprevalence of Hepatitis B was 2.11% to3.53%[18, 19] in Rawalpindi, and 4% from Jamshoro (Sindh).[20] Very Low prevalence rate of HBsAg also has been observed in few studies Smita Sood and Shirish Malvankar 2010[21] in a study of HBsAg prevalence in hospital based population was noted to be 0.87%. The relative low prevalence in their study could be due to the fact that it was conducted in a private hospital catering usually to economically privileged class patients. Another low prevalence of 0.62% has been reported among blood donors from coastal Karnataka.[22]

Table-1 Gender Distribution of HBsAg Positive Patients

Gender	No. of sera tested	HBsAg positive sera	Percentage
Male	1731	46	2.65
Female	2160	44	2.03

Prevalence of Hepatitis B varies from country to country and depends upon a complex mixture of behavioural, environmental and host factors. In general, it is lowest in countries or areas with high standards of living (eg. Australia, North America, North Europe) and Highest in countries or area where socioeconomic level is lower (eg. China, South-East Asia, South America)[23] Most of the studies have reported high prevalence of HBsAg in males as compared to females, which is also true in our study.

Table -2 Age and Sex distribution of OPD patients with hepatitis B seropositivity

Age Group	Male	Female	HBsAg (+) Male %	HBsAg (+) Female%	Total Patients Tested	Total Patients HBsAg (+)%
0-10	36	18	0(0%)	0(0%)	54	0(0%)
11-20	80	74	2(2.5%)	0(0%)	154	2(1.29%)
21-30	338	739	8(2.36%)	8(1.08%)	1077	16(1.48%)
31-40	392	588	8(2.04%)	14(2.38%)	980	22(2.24%)
41-50	315	296	10(3.17%)	11(3.71%)	611	21(3.43%)
51-60	352	234	9(2.55%)	8(3.41%)	586	17(2.90%)
61-70	146	129	8(5.47%)	3(2.32%)	275	11(4%)
Above 71	72	82	1(1.38%)	0(0%)	154	1(0.64%)
Total	**1731 44.48%**	**2160 55.51%**	**46 2.65%**	**44 (2.03%)**	**3891**	**90 (2.31%)**

Smita sood and Shirish Malvankar have reported the prevalence to be 1.04% and 0.58%in males and females respectively.[21] Tripathi et al reported HBsAg prevalence in males 1.97% and in 1.28% females, Payal Mathur et al reported 1.12% in males and 0.7% in female, Samtha et al reported males 2.5% and 1.13% in females. There has been no plausible explanation for the higher rates in males in the general population but probably due to the higher exposure to occupational HBV, and also probably because females clear the HBV more efficiently as compared to males. In the present study, highest prevalence was found to be among 61-70 yrs age group i.e 4% followed by 41-50 i.e. 3.43% and 51-60 age group with 2.90%. Quadari et al reported relatively higher percentage of subjects in 6^{th}, 3^{rd}, and 2^{nd} decade of life respectively were found with HBsAg in their sera. Smita Sood and Shirish Malvankar reported highest prevalence among 2^{nd}, 5^{th} and elderly patients. Patil et al reported highest HBsAg prevalence among 51-60 yrs age group (5.24%) in both males (5.51%) and females (4.78%). A community based study carried out in Tamil Nadu reported that age specific prevalence for the overall exposure to HBV, HBsAg, HBeAg was not significantly different in different age group.[24] In another population studies, conducted on blood donors the HBsAg carrier rate is observed to increased directly with age up to a peak and then to decline among the older age group.[25]

CONCLUSION

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Original Article

Seroprevalence of Hepatitis B Virus Infection among OPD Patients Attending Tertiary Care Hospital

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ABSTRACT

Background: *Hepatitis B infection is a major global health problem. The hepatitis B surface antigen (HBsAg) in serum is the first seromarker to indicate active HBV infection either acute or chronic. The seroprevalence of Hepatitis B surface antigen among general population attending OPD at a tertiary care hospital is useful in assessing true nature of problem, which can help to estimate the magnitude of HBV infection and aid in devising preventive measures. The aim of the study was to determine the seroprevalence of Hepatitis B infection among OPD patients attending a tertiary care hospital.* ***Methods:*** *Data from Dec 2015- April-2017 for OPD patients underwent HBsAg screening were collected and analysed.* ***Results:*** *A total number of 3891 patients were screened for HBsAg among them 1731 (44.48%) were males and 2160 (55.51%) were females. The seroprevalence of HBsAg in total OPD patients was 90(2.31%), was higher in males 46(2.65%) as compared to females 44(2.03%). The highest seroprevalence was found in 60-71 (4%) age group.* ***Conclusions:*** *The seroprevalence of Hepatitis B positive cases was 2.31% among OPD patients. Also, the rising seroprevalence rates of hepatitis B in males need urgent attention.*

Key words: *HBsAg, seroprevalence, OPD patients, tertiary care hospital*

INTRODUCTION

About 30% of the world population has serological evidence of current or past infection with hepatitis B virus. It is known to be the 10th leading cause of death and HBV related hepatocellular carcinoma is the 5th most frequent cancer worldwide.[1] About 2 billion people (or 30% of world population) worldwide have serological evidence of current or past HBV infection, and an estimated 350 million people harbor chronic infection[2]. India has been placed into the intermediate zone of prevalence of hepatitis B (2-7% prevalence rate by WHO).[2] Indian population forms the second largest global pool of chronic HBV infections and the number of HBV carriers in India is estimated to be 50 million.[3] The virus is transmitted by either per-cutaneous or mucous membrane contact with infected blood or other body fluid and is found in highest concentrations in blood and serous exudates. The primary routes of transmission are peri-natal, early childhood exposure, sexual contact, and per cutaneous exposure to blood or body fluids (i.e. injections, needle stick, blood transfusion). The hepatitis B surface antigen (HBsAg) in serum is the first seromarker to indicate active HBV infection, either acute or chronic.[4]

A large population of patients suffering from hepatitis B may be asymptomatic and can transit the disease to healthy population. The patients presenting to the OPDs of a hospital are generally those seeking treatment for mostly community acquired ailments hence the estimation of seroprevalence of hepatitis B surface antigen in such patients can be considered as a surrogate marker to represent the dynamics of virus transmission in the community. Studies have been conducted to estimate the prevalence of hepatitis B virus in selected group of people with higher risk factors such as blood donors, pregnant women, drug addicts and patients with liver disorders.

However, there is paucity of information in India on prevalence of HBV infection among general population. That is why a prevalence based study of patients at a

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tertiary care teaching hospital is helpful in assessing true nature of problem in the community, which can help in assessing the magnitude of HBV infection and aid in devising preventive measures.

Community based seroprevalence studies are difficult to conduct in a developing country like India, because of socioeconomic hurdles and logistics difficulties. More than one half ambulatory and two- thirds outpatients care are catered by private health care in India.[5]

A private tertiary teaching hospital catering to the needs of a large population thus represents an important center for serological surveys. Also, the available data at Rajasthan state level on the seroprevalence and distribution of this blood borne pathogen is limited.

It was against the above backdrop that the present study was undertaken to estimate the seroprevalence of Hepatitis B viral infection among OPD patients attending tertiary care hospital.

METHODS

The present study is a prospective hospital based study conducted in the department of Microbiology, at Ananta Institute of Medical Sciences & Research Center, Rajsamand from December 2015 to April 2017. A total of 3891 blood samples were collected from patients attending different OPDs, for whom HBsAg detection was sought after a written consent. For the evaluation of HBsAg, a one-step rapid immunochromatographic Assay (ICA) was used. The qualitative detection of HBsAg was determined using a rapid Card (Hepacard-Biomed industries). The ICA are rapid and sensitive methods for detecting HBsAg. They are economical and do not require special instrumentation for analysis and have been recommended for use in clinical microbiology laboratories.[6] Immnunochromatoghraphic Assay has high sensitivity and specificity.[7] The reactive samples were retested in duplicates with fresh blood samples, if found reactive were considered as reactive.

RESULTS

We report here a study to assess the epidemiology of HBV prevalence among the OPD patients attending a tertiary care hospital of Rajsamand (Rajasthan).

A total of 3891 serum samples were processed for HBsAg detection over a period of 12 months, among them 1731 (44.48%) were male and 2160 (55.51%) were female. Table 2 shows age and sex distribution of hospital based population. The seroprevalence of HBsAg was 90 (2.31%). It was higher in males 46 (2.65%) as compared to females 44 (2.03%). The highest seroprevalence was found to be among 61-70 age groups which were (4%). The highest seroprevalence among HBsAg positive male was found in 61-70 age group which was 5.47% and among females were in age group 41-50 which was 3.71.

DISCUSSION

The seroprevalence of HBsAg in the present study was found to be 2.31%. India has been placed into the intermediate zone of prevalence of hepatitis B (2-7%) so present study findings correspond to it. HBV prevalence among the hospital based population at Karad, Maharashtra in a tertiary care hospital by Patil et al 2016,[8] the seroprevalence of HBsAg was found to be 2.25%. A study conducted by Tripathi P.c. et al 2015[9] seroprevalence of hepatitis B surface antigen at a tertiary care center in Telangna was 1.69%. Samtha P et al 2014[10] in their hospital based population at Guntur Andhra Pradesh reported prevalence of hepatitis B surface antigen was 2.4%, which approximately coincides with our study. Quadri S.A. at al 2013[11] reported the prevalence of HBsAg to be 1.63%, in a hospital based study at Bijapur, Karnataka. A recent study conducted in Rajasthan by Payal Mathur et al 2016[12] at a tertiary care teaching hospital situated at district Ajmer, the seroprevalence of HBsAg was found to be 0.94% only. Another hospital based population study conducted by Smita Sood 2013[13] at Jaipur district of Rajasthan at a superspeciality private hospital among OPD attendees, the prevalence of hepatitis B surface antigen was observed to be 1.73%. There are several studies conducted on seroprevalence of HBsAg in India. The point of hepatitis B in non-tribal population is 3.07% and among the tribal population is 11.85%. Batham A et al in their review of 54 studies on seroprevalence of HBsAg was observed 2.4% in non-tribal population and 15.9% among tribal population. Another review of hepatitis B prevalence in India by Lodha et al has conducted that it is in between 1-2%[14]. High prevalence of HBsAg (between 2-7%) has been reported in the past, and a community based study carried out in Tamil Nadu reported the prevalence of HBsAg was 5.7%.[15] Another study conducted in Sarkhet Valley, HBsAg prevalence rate was found to be 8.8% in the hospital patients.[16] The prevalence of HBsAg in patients attending surgical OPD at Fauji Foundation hospital, Rawalpindi, Pakistan has been reported as 2.28%.[17] Seroprevalence of Hepatitis B was 2.11% to3.53%[18, 19] in Rawalpindi, and 4% from Jamshoro (Sindh).[20] Very Low prevalence rate of HBsAg also has been observed in few studies Smita Sood and Shirish Malvankar 2010[21] in a study of HBsAg prevalence in hospital based population was noted to be 0.87%. The relative low prevalence in their study could be due to the fact that it was conducted in a private hospital catering usually to economically privileged class patients. Another low prevalence of 0.62% has been reported among blood donors from coastal Karnataka.[22]

Table-1 Gender Distribution of HBsAg Positive Patients

Gender	No. of sera tested	HBsAg positive sera	Percentage
Male	1731	46	2.65
Female	2160	44	2.03

Prevalence of Hepatitis B varies from country to country and depends upon a complex mixture of behavioural, environmental and host factors. In general, it is lowest in countries or areas with high standards of living (eg. Australia, North America, North Europe) and Highest in countries or area where socioeconomic level is lower (eg. China, South-East Asia, South America)[23] Most of the studies have reported high prevalence of HBsAg in males as compared to females, which is also true in our study.

Table -2 Age and Sex distribution of OPD patients with hepatitis B seropositivity

Age Group	Male	Female	HBsAg (+) Male %	HBsAg (+) Female%	Total Patients Tested	Total Patients HBsAg (+)%
0-10	36	18	0(0%)	0(0%)	54	0(0%)
11-20	80	74	2(2.5%)	0(0%)	154	2(1.29%)
21-30	338	739	8(2.36%)	8(1.08%)	1077	16(1.48%)
31-40	392	588	8(2.04%)	14(2.38%)	980	22(2.24%)
41-50	315	296	10(3.17%)	11(3.71%)	611	21(3.43%)
51-60	352	234	9(2.55%)	8(3.41%)	586	17(2.90%)
61-70	146	129	8(5.47%)	3(2.32%)	275	11(4%)
Above 71	72	82	1(1.38%)	0(0%)	154	1(0.64%)
Total	**1731 44.48%**	**2160 55.51%**	**46 2.65%**	**44 (2.03%)**	**3891**	**90 (2.31%)**

Smita sood and Shirish Malvankar have reported the prevalence to be 1.04% and 0.58%in males and females respectively.[21] Tripathi et al reported HBsAg prevalence in males 1.97% and in 1.28% females, Payal Mathur et al reported 1.12% in males and 0.7% in female, Samtha et al reported males 2.5% and 1.13% in females. There has been no plausible explanation for the higher rates in males in the general population but probably due to the higher exposure to occupational HBV, and also probably because females clear the HBV more efficiently as compared to males. In the present study, highest prevalence was found to be among 61-70 yrs age group i.e 4% followed by 41-50 i.e. 3.43% and 51-60 age group with 2.90%. Quadari et al reported relatively higher percentage of subjects in 6^{th}, 3^{rd}, and 2^{nd} decade of life respectively were found with HBsAg in their sera. Smita Sood and Shirish Malvankar reported highest prevalence among 2^{nd}, 5^{th} and elderly patients. Patil et al reported highest HBsAg prevalence among 51-60 yrs age group (5.24%) in both males (5.51%) and females (4.78%). A community based study carried out in Tamil Nadu reported that age specific prevalence for the overall exposure to HBV, HBsAg, HBeAg was not significantly different in different age group.[24] In another population studies, conducted on blood donors the HBsAg carrier rate is observed to increased directly with age up to a peak and then to decline among the older age group.[25]

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ABSTRACT

Background: *Hepatitis B infection is a major global health problem. The hepatitis B surface antigen (HBsAg) in serum is the first seromarker to indicate active HBV infection either acute or chronic. The seroprevalence of Hepatitis B surface antigen among general population attending OPD at a tertiary care hospital is useful in assessing true nature of problem, which can help to estimate the magnitude of HBV infection and aid in devising preventive measures. The aim of the study was to determine the seroprevalence of Hepatitis B infection among OPD patients attending a tertiary care hospital.* ***Methods:*** *Data from Dec 2015- April-2017 for OPD patients underwent HBsAg screening were collected and analysed.* ***Results:*** *A total number of 3891 patients were screened for HBsAg among them 1731 (44.48%) were males and 2160 (55.51%) were females. The seroprevalence of HBsAg in total OPD patients was 90(2.31%), was higher in males 46(2.65%) as compared to females 44(2.03%). The highest seroprevalence was found in 60-71 (4%) age group.* ***Conclusions:*** *The seroprevalence of Hepatitis B positive cases was 2.31% among OPD patients. Also, the rising seroprevalence rates of hepatitis B in males need urgent attention.*

Key words: *HBsAg, seroprevalence, OPD patients, tertiary care hospital*

INTRODUCTION

About 30% of the world population has serological evidence of current or past infection with hepatitis B virus. It is known to be the 10th leading cause of death and HBV related hepatocellular carcinoma is the 5th most frequent cancer worldwide.[1] About 2 billion people (or 30% of world population) worldwide have serological evidence of current or past HBV infection, and an estimated 350 million people harbor chronic infection[2]. India has been placed into the intermediate zone of prevalence of hepatitis B (2-7% prevalence rate by WHO).[2] Indian population forms the second largest global pool of chronic HBV infections and the number of HBV carriers in India is estimated to be 50 million.[3] The virus is transmitted by either per-cutaneous or mucous membrane contact with infected blood or other body fluid and is found in highest concentrations in blood and serous exudates. The primary routes of transmission are peri-natal, early childhood exposure, sexual contact, and per cutaneous exposure to blood or body fluids (i.e. injections, needle stick, blood transfusion). The hepatitis B surface antigen (HBsAg) in serum is the first seromarker to indicate active HBV infection, either acute or chronic.[4]

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tertiary care teaching hospital is helpful in assessing true nature of problem in the community, which can help in assessing the magnitude of HBV infection and aid in devising preventive measures.

Community based seroprevalence studies are difficult to conduct in a developing country like India, because of socioeconomic hurdles and logistics difficulties. More than one half ambulatory and two- thirds outpatients care are catered by private health care in India.[5]

A private tertiary teaching hospital catering to the needs of a large population thus represents an important center for serological surveys. Also, the available data at Rajasthan state level on the seroprevalence and distribution of this blood borne pathogen is limited.

It was against the above backdrop that the present study was undertaken to estimate the seroprevalence of Hepatitis B viral infection among OPD patients attending tertiary care hospital.

METHODS

The present study is a prospective hospital based study conducted in the department of Microbiology, at Ananta Institute of Medical Sciences & Research Center, Rajsamand from December 2015 to April 2017. A total of 3891 blood samples were collected from patients attending different OPDs, for whom HBsAg detection was sought after a written consent. For the evaluation of HBsAg, a one-step rapid immunochromatographic Assay (ICA) was used. The qualitative detection of HBsAg was determined using a rapid Card (Hepacard-Biomed industries). The ICA are rapid and sensitive methods for detecting HBsAg. They are economical and do not require special instrumentation for analysis and have been recommended for use in clinical microbiology laboratories.[6] Immnunochromatoghraphic Assay has high sensitivity and specificity.[7] The reactive samples were retested in duplicates with fresh blood samples, if found reactive were considered as reactive.

RESULTS

We report here a study to assess the epidemiology of HBV prevalence among the OPD patients attending a tertiary care hospital of Rajsamand (Rajasthan).

A total of 3891 serum samples were processed for HBsAg detection over a period of 12 months, among them 1731 (44.48%) were male and 2160 (55.51%) were female. Table 2 shows age and sex distribution of hospital based population. The seroprevalence of HBsAg was 90 (2.31%). It was higher in males 46 (2.65%) as compared to females 44 (2.03%). The highest seroprevalence was found to be among 61-70 age groups which were (4%). The highest seroprevalence among HBsAg positive male was found in 61-70 age group which was 5.47% and among females were in age group 41-50 which was 3.71.

DISCUSSION

The seroprevalence of HBsAg in the present study was found to be 2.31%. India has been placed into the intermediate zone of prevalence of hepatitis B (2-7%) so present study findings correspond to it. HBV prevalence among the hospital based population at Karad, Maharashtra in a tertiary care hospital by Patil et al 2016,[8] the seroprevalence of HBsAg was found to be 2.25%. A study conducted by Tripathi P.c. et al 2015[9] seroprevalence of hepatitis B surface antigen at a tertiary care center in Telangna was 1.69%. Samtha P et al 2014[10] in their hospital based population at Guntur Andhra Pradesh reported prevalence of hepatitis B surface antigen was 2.4%, which approximately coincides with our study. Quadri S.A. at al 2013[11] reported the prevalence of HBsAg to be 1.63%, in a hospital based study at Bijapur, Karnataka. A recent study conducted in Rajasthan by Payal Mathur et al 2016[12] at a tertiary care teaching hospital situated at district Ajmer, the seroprevalence of HBsAg was found to be 0.94% only. Another hospital based population study conducted by Smita Sood 2013[13] at Jaipur district of Rajasthan at a superspeciality private hospital among OPD attendees, the prevalence of hepatitis B surface antigen was observed to be 1.73%. There are several studies conducted on seroprevalence of HBsAg in India. The point of hepatitis B in non-tribal population is 3.07% and among the tribal population is 11.85%. Batham A et al in their review of 54 studies on seroprevalence of HBsAg was observed 2.4% in non-tribal population and 15.9% among tribal population. Another review of hepatitis B prevalence in India by Lodha et al has conducted that it is in between 1-2%[14]. High prevalence of HBsAg (between 2-7%) has been reported in the past, and a community based study carried out in Tamil Nadu reported the prevalence of HBsAg was 5.7%.[15] Another study conducted in Sarkhet Valley, HBsAg prevalence rate was found to be 8.8% in the hospital patients.[16] The prevalence of HBsAg in patients attending surgical OPD at Fauji Foundation hospital, Rawalpindi, Pakistan has been reported as 2.28%.[17] Seroprevalence of Hepatitis B was 2.11% to3.53%[18, 19] in Rawalpindi, and 4% from Jamshoro (Sindh).[20] Very Low prevalence rate of HBsAg also has been observed in few studies Smita Sood and Shirish Malvankar 2010[21] in a study of HBsAg prevalence in hospital based population was noted to be 0.87%. The relative low prevalence in their study could be due to the fact that it was conducted in a private hospital catering usually to economically privileged class patients. Another low prevalence of 0.62% has been reported among blood donors from coastal Karnataka.[22]

Table-1 Gender Distribution of HBsAg Positive Patients

Gender	No. of sera tested	HBsAg positive sera	Percentage
Male	1731	46	2.65
Female	2160	44	2.03

Prevalence of Hepatitis B varies from country to country and depends upon a complex mixture of behavioural, environmental and host factors. In general, it is lowest in countries or areas with high standards of living (eg. Australia, North America, North Europe) and Highest in countries or area where socioeconomic level is lower (eg. China, South-East Asia, South America)[23] Most of the studies have reported high prevalence of HBsAg in males as compared to females, which is also true in our study.

Table -2 Age and Sex distribution of OPD patients with hepatitis B seropositivity

Age Group	Male	Female	HBsAg (+) Male %	HBsAg (+) Female%	Total Patients Tested	Total Patients HBsAg (+)%
0-10	36	18	0(0%)	0(0%)	54	0(0%)
11-20	80	74	2(2.5%)	0(0%)	154	2(1.29%)
21-30	338	739	8(2.36%)	8(1.08%)	1077	16(1.48%)
31-40	392	588	8(2.04%)	14(2.38%)	980	22(2.24%)
41-50	315	296	10(3.17%)	11(3.71%)	611	21(3.43%)
51-60	352	234	9(2.55%)	8(3.41%)	586	17(2.90%)
61-70	146	129	8(5.47%)	3(2.32%)	275	11(4%)
Above 71	72	82	1(1.38%)	0(0%)	154	1(0.64%)
Total	**1731 44.48%**	**2160 55.51%**	**46 2.65%**	**44 (2.03%)**	**3891**	**90 (2.31%)**

Smita sood and Shirish Malvankar have reported the prevalence to be 1.04% and 0.58%in males and females respectively.[21] Tripathi et al reported HBsAg prevalence in males 1.97% and in 1.28% females, Payal Mathur et al reported 1.12% in males and 0.7% in female, Samtha et al reported males 2.5% and 1.13% in females. There has been no plausible explanation for the higher rates in males in the general population but probably due to the higher exposure to occupational HBV, and also probably because females clear the HBV more efficiently as compared to males. In the present study, highest prevalence was found to be among 61-70 yrs age group i.e 4% followed by 41-50 i.e. 3.43% and 51-60 age group with 2.90%. Quadari et al reported relatively higher percentage of subjects in 6^{th}, 3^{rd}, and 2^{nd} decade of life respectively were found with HBsAg in their sera. Smita Sood and Shirish Malvankar reported highest prevalence among 2^{nd}, 5^{th} and elderly patients. Patil et al reported highest HBsAg prevalence among 51-60 yrs age group (5.24%) in both males (5.51%) and females (4.78%). A community based study carried out in Tamil Nadu reported that age specific prevalence for the overall exposure to HBV, HBsAg, HBeAg was not significantly different in different age group.[24] In another population studies, conducted on blood donors the HBsAg carrier rate is observed to increased directly with age up to a peak and then to decline among the older age group.[25]

CONCLUSION

Present study reported Seroprevalence of HBsAg as well as its age and sex wise distribution, our study highlights HBV infection rate in this part of the country and shall provide reference to future studies on the epidemiology of HBV infection, to understand and assess the magnitude of disease in a community and for its control and prevention. This study also shows that the ever rising Seroprevalence rates of hepatitis B among the males, is a cause of alarm in the country which also should be taken into consideration.

Permission obtained from Institution Ethics Committee.

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Research Article

A COMPARATIVE EVALUATION OF SCREENING HEPATITIS B SURFACE ANTIGEN BY ENZYME-LINKED IMMUNOSORBENT ASSAY AND RAPID CARD TEST

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A B S T R A C T

Background: Hepatitis B virus (HBV) is one of the major causes of death in developing countries. The most important marker for diagnosis is detection of Hepatitis B surface antigen in blood. Objective: The aim of present study was to compare two different brand rapid card test kits (Brand A and Brand B) for screening of hepatitis B virus infection with gold standard enzyme linked immunosorbent assay method. Method: This study was conducted in Department of Microbiology at government Medical College and associated hospital for a period of 6 months. Result: Out of 4200 blood samples tested for hepatitis B surface B antigen (HBsAg), 89 (2.09%) were positive by enzyme linked immunosorbent assay (ELISA), 87 (2.04%) positive by Brand A rapid card and 86 (2.02%) were positive by Brand B rapid card. The sensitivity of rapid card test Brand A was 97.75%, specificity was 100%, positive predictive value was 97.75%, negative predictive value was 99.95%, and diagnostic accuracy was 99.95%. The sensitivity of rapid card test Brand B was 96.62%, specificity was 100%, positive predictive value was 96.63%, negative predictive value was 99.93%, and diagnostic accuracy was 99.93%.Conclusion: The sensitivity and specificity of both brands rapid card test (Brand A and Brand B) is comparable with ELISA. These rapid kits are easy to perform and less cheap in compare with cost of ELISA. There use should be encourages at rural area where cannotafford the cost of ELISA test so that the patient should be channelized faster towards specific and accurate diagnosis.

INTRODUCTION

Hepatitis B virus which causes hepatocellular carcinoma is one of the important target for global elimination by 2030 [1]. The world health organization estimated that 257 million people were living with HBV infection in 2015 and responsible for 887000 deaths every year [2-3].Based on the prevalence of HBV in different areas of the world are classified as high (≥8%), Intermediate (2-7%), or low (≤2%) HBV endemicity. India has an intermediate prevalence of hepatitis B virus with a 4% to 5.4% infected population [4-5]. HBV has a double-stranded DNA genome of around 3200 base pairs encoding for P, X Core and surface proteins. The envelop proteins are surface glycoprotein and assigned as hepatitis B surface antigen [6-7]. HBsAg appears in serum within 2-10weeks after exposure to HBV and before the onset of symptoms or elevation of serum aminotransferase level. Chronic HBV infection progresses nonlinearly through 3-4 phases, from the immune-tolerance phase to immune clearance or immume-active phase to non-replicative inactive phase and possible HBsAgusually becomes undetectable after 4-6 months [8-9].

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HBsAg has been found to be an important viral marker for population screening as well as diagnosis because it is the primary way to identify persons with chronic HBV infection and several characteristics of this serological marker increase the precision of HBsAg estimates, including high specificity, long serum persistence, low possibility of chronic cases losing HBsAg [10,11,12]. Early and accurate detection of HBV infection using sensitive and specific methods allow investigators to evaluate the status of HBV infection and develop strategies to prevent transmission. There are many methods for diagnosis of hepatitis B surface antigen but rapid card test is a rapid screening test for qualitative detection of HBsAg in whole blood, serum or plasma specimen. The test utilized a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum, or plasma [8, 13]. On the other hand ELISA is enzymatic immunoassay technique of the sandwich type for the detection of HBV in human serum or plasma, in which antigens or antibodies are covalently bound with suitable enzymes that can catalyze the change of substrates into dyed products. It is an approved technique to investigate diverse serological markers [14]. The rapid immunochromatography tests are known to have less sensitivity and specificity than enzyme immunoassay [15, 16]. A major concern in utilizing rapid screening test is that these tests should have a high degree of sensitivity and a reasonable

level of specificity to minimize false positive and false negative results. The present study was designed to check the sensitivity and specificity of two different rapid cards of HBsAg which are frequently used in many labs and hospitals of Kannauj district, Uttar Pradesh, India and to compare with already confirmed cases on ELISA. The ultimate goal of this study was to recommend most reliable, specific and sensitive rapid cards for the diagnosis of HBV in areas where advance diagnostic facilities are not available.

MATERIAL AND METHOD

This prospective study was conducted in the government medical college and associated hospital at Tirwa, Kannauj, India, from November 2018- April 2019.Two most common used brands of rapid cards for HBsAg in many laboratories and hospitals were selected for the study. ELISA was used as gold standard for comparative evaluation. Prior to selection of rapid cards, a verbal survey was done in the major laboratories and hospitals to find out which brands rapid cards are being used by these outlets. For study Reckon diagnostic and SD bioline were selected.

A total of 4250HBsAg samples included 89 positive by ELISA and 4161 negative by ELISA. All samples were selected and tested on two different immunochromatography cards. As this is prospective study all samples during study period were included.

Sample collection-2-3 ml whole blood Samples were collected from patients in plain vial with clot activator and left them for 10-15 minutes at room temperature. Blood samples were then centrifuged at 1500 round per minutes for 5-10 minutes to collect serum. We used serum for performing ELISA and rapid card tests for all patients.

Sample processing- Each blood sample was tested for HBsAg using two different brands rapid card (Brand A= Reckon diagnostics pvt. LTD, Brand B= SDbioline, standard diagnostic, INC.) and ELISA by Hepalisa- J.Mitra& Co. Pvt. Ltd

Before performing the test all the samples and reagents were brought to room temperature as per kit manual.

Determination of Hepatitis B surface antigen

By Enzyme linked Immuno-sorbent assay

HEPALISA assay test kit by J. MITRA Diagnostic manufacture in India is used for ELISA technique. HEPALISA is a solid phase enzyme linked immunosorbent assay based on the 'Direct Sandwich' principle. The microwells are coated with monoclonal antibodies with high reactivity for hepatitis B surface antigen. The samples are added in the wells followed by addition of enzyme conjugate (polyclonal antibodies linked to horseradish peroxidase). A sandwiched complex is formed in the well wherein hepatitis B surface antigen (from serum samples) is trapped or "sandwiched" between the antibody and antibody horseradish peroxidase conjugate. Unbound conjugate is then washed off with wash buffer. The amount of unbound peroxidase is proportional to the concentration of HBsAg present in the sample. Upon addition of the substrate buffer &chromogen, a blue colour develops. The intensity of developed blue colour is proportional to concentration of HBsAgin sample. To limit the enzyme-substrate reaction, stop solution is added & a yellow colour develops which is finally read at 450nm spectrophotometrically.

Test Procedure: All the samples were run along with negative control (NC) and positive control (PC) according to test procedure given by manufacturer (J. Mitra Diagnostic).

Calculation of Result: Compute mean of NC and PC absorbance.

Test validity:

Positive control acceptance criteria

PC or PC$\bar{x}$ must be >0.5, if it is so, then run is invalid

Negative control acceptance criteria

NC or NC$\bar{x}$ must be <0.150

Cut off value

Cut off value is determined by using the given formula below

Cut off value = NC$\bar{x}$+0.1

Where NC$\bar{x}$ is the mean absorbance of negative control
All samples with absorbance value more than cut off value were taken as positive for hepatitis B surface antigen. The minimum detectable concentration of HBsAgby this assay is estimated to be 0.1ng/ml as per the kit used.

Determination of Hepatitis B surface antigen by Rapid card test

Rapid card (A= Reckon diagnostics pvt. LTD, B= SD diagnostic pvt. LTD)is a one -step immunoassay based on the antigen capture or sandwich principle. The method uses monoclonal antibodies conjugated to colloidal gold and polyclonal antibodies immobilized on a nitrocellulose strip in a thin line. The test sample is introduced to and to flow laterally through an absorbent pad where it mixed with the signal reagents. If the sample contains hepatitis B surface antigen, the colloidal gold-antibody conjugate binds to the antigen, forming an antigen-antibody-colloidal gold complex. The complex then migrates through the nitrocellulose strip by capillary action. When the complex meets the line of immobilized antibody (test line) 'T', complex is trapped forming an antigen-antibody colloidal gold complex. This forms a pink band indicating the sample is reactive forHBsAg.

Test procedure for both Brand's rapid card (Brand A& Brand B) as per kits

- Using the dropper provided put 2-3 drops (25µl) of serum into the sample well.
- Let the reaction to proceed until the appearance of positive line and control line or upto 20 minutes.
- Read result after 20 minutes. Strong positive reaction may visible within 5 minutes.

Interpretation of Result:		
Interpretation	Control Line	Test Line
Negative Test	Pink Line	No pink Line
Positive Test	Pink Line	Pink Line
Invalid Test	No pink Line	No pink Line/ Pink Line

Test card was stored at 4^{O}C as advised by manufacturer. The test kit was kept away from direct sunlight, moisture and heat.

RESULT

The results of different rapid cards on the basis of sensitivity, specificity, negative predictive value, positive predictive value, disease prevalence and diagnostic accuracy of Immunochromatography technique with that of ELISA which is considered as gold standard technique for the detection of HBsAg.

Out of 4250 samples, 89 (2.09%) were HBsAg positive by ELISA.
The age range of the HBsAg positive patients (n=89) was between 5-80 years with mean of 36.34±17.44 years. (Table No. 1)
Out of 89 ELISA positive samples tested on rapid card test Brand A, 87 samples were positive and 02 samples were negative for HBsAg.

On further testing on rapid card test Brand B, 86 samples were positive and 03 samples were negative for HBsAg.

The reason for false negative is unclear; this may be due to low viremia or less than 0.5ng/ml. The rapid card test (Both brands) used in this study can detect hepatitis B surface antigen in serum or plasma as low as 0.5ng/ml while HEPALISA kit has a sensitivity of 0.1ng/ml as per kit manual. For further satisfactory statement titre of hepatitis surface antigen, viral load, and other quantitative immunological markers should be perform.

On comparison with ELISA, two false negative were detected for brand A, and three false negative were detcted for brand B.

Table No. 1 Age distribution of subject (n=89) of HBsAg positive

Age Group	Subject Tested
<10	02 (2.25%)
11-20	04 4.5%)
21-30	47 (52.80%)
31-40	07 (7.87%)
41-50	11 (12.36%)
>50	18 (20.22%)
Total (n)	89 (100%)

Table No 2 Comparison of ELISA, Rapid card Brand A and Brand B

Total No of subjects	4250
Positive by ELISA	89 (2.09%)
Positive by Brand A	87 (2.04%)
Positive by Brand B	86 (2.02%)
False negative by Brand A	02 (2.24%)
False negative by Brand A	03(3.37%)

Using ELISA as a gold standard confirmatory method, comparison between ELISA and Brand A

The sensitivity of rapid card test Brand A was 97.75%, specificity was 100%, positive predictive value was 97.75%, negative predictive value was 99.95%, diagnostic accuracy was 99.95%, and disease prevalence was 2.09%. (Table No 3)

Using ELISA as a gold standard confirmatory method, comparison between ELISA and Brand B

The sensitivity of rapid card test Brand B was 96.62%, specificity was 100%, positive predictive value was 96.63%, negative predictive value was 99.93%, diagnostic accuracy was 99.99%, and disease prevalence was 2.02%. (Table No. 3)

DISCUSSION

Serological assays detect the host immune response (antibodies to HCV) or a viral antigen (HBsAg, HCVcAg). They are based on the immunoassay principle, and are available in the form of rapid diagnostic tests (RDTs) or laboratory-based enzyme immunoassays (EIAs), chemoluminescence immunoassays (CLIAs) and electrochemoluminescence immunoassays (ECLs).

In contrast, NAT technologies are typically used to detect the presence of the virus, determine if the infection is active and if the individual would benefit from antiviral treatment. NAT technologies are also used to determine when antiviral treatment should be discontinued (due to non-response or resistance) or to confirm virological cure (HCV) or effective suppression (HBV).

Most laboratory-based serological immunoassays (EIAs, CLIAs and ECLs) detect antibodies, antigens or a combination of both and differ only in the mode of detection of immune complexes formed. A cut-off value, usually determined by the manufacturer of the assay, specifies the point at which the results are considered to be reactive, and therefore, EIA results are generally reported as optical density divided by the assay cut-off (OD/CO) values.

Rapid diagnostic tests (RDTs) are single-use disposable assays that are provided in simple-to-use formats that generally require no additional reagents except those supplied in the test kit. They are read visually and can give a simple qualitative result in under 30 minutes. Quality-assured RDTs are therefore particularly useful in settings where conventional laboratory-based testing services are not available or accessible.

Table No 3 Evaluation of Rapid Card Test Brand A and Brand B with ELISA

Rapid card Brands For HBsAg		ELISA (Gold Standard)			Results for screening test									
		Reactive (n=89)	Non-reactive (n=4161)	Total	True Positive	True Negative	False Positive	False Negative	Sensitivity	Specificity	Positive Predictive Valve	Negative Predictive Value	Diagnostic accuracy	Kappa Value
Brand A (SD Bioline)	Reactive	87	-	87	87	4163	-	02	97.75%	100%	100%	99.95%	0.975	0.975
	Non-Reactive	02	4161	4163										
Brand B (Reckone)	Reactive	86	-	86	86	4164	-	03	96.62%	100%	100%	99.93%	0.975	0.975
	Non-reactive	03	4161	4164										

The choice of assay format will depend on a variety of factors, most importantly, performance characteristics (sensitivity and specificity), cost, ease of use and the characteristics of the testing site, such as storage facilities, infrastructure, and level of staff skills. WHO recommends the use of standardized testing strategies to both maximize the accuracy of HBsAg or HCV antibody testing while simplifying the process through streamlining procurement and training [17].

The choice between a one-assay versus two-assay serological testing strategy will depend on the seroprevalence in the population to be tested and diagnostic accuracy (sensitivity and specificity) of the assays used.

In many developing countries, rapid card test is widely used to detect hepatitis B surface antigen for diagnosis as well as screening for hepatitis B virus infections [18] as these are cheap and does not need expertise.

In present study, the infection rate of hepatitis B virus found to be 2.09% by ELISA test, 2.04% and 2.02% by Brand A and Brand B. A prospective study conducted in Kannauj, Uttar Pradesh, India supports our findings with infection rate of 2.28%. [19]

From the systemic review & meta-analysis on the HBsAg diagnostic accuracy of rapid cards Vs enzyme immunoassay and nucleic-acid test (NAT), three studies [20,21, 22] evaluated 7 rapid cards in samples from 510 patients against a NAT reference standard. One study [21] used plasma from Nigerian repeat blood donors. Sensitivities ranged from 38% to 99% and specificities ranged from 94% to 99%. Over all pooled sensitivity and specificity were 93.3% and 98.1% respectively.

Five studies [22,23,24,25, 26] evaluated enzyme immunoassays based on a NAT reference, using samples from 1194 patients. Pooled sensitivity and specificity were 75.7% and 86.1% respectively.

In present study we tested the serum of patientswith two differentbrands (Rapid card Brand A& Brand B) of immunochromatographic methods and subjected to compare same sere to Elisa methods.

The sensitivity of rapid card Brand A and Brand B was 100% for both with reference to ELISA and specificity was 99.95% and 99.93% respectively. Sharma M *et al* [10] reported sensitivity of rapid card was 100% and specificity was 99.56%. Another study by Akhtar *et al* [27] showed 100% sensitivity of rapid card test kit with specificity of 91.7% for hepatitis B surface antigen. A study conducted by Lin *et al* [28] by using ICTs the sensitivity and specificity was 100% respectively. A study conducted by Maity *et al* [29] a comparative study, 3 different HBsAg ICT kits Hepacard, Crystal NS SD bioline, were evaluated, all of them showing 100% sensitivity and 100% specificity. Another study shows the sensitivity of ICT can vary from 50-94% [30].Immunochromatography based assay used for HBsAg detection may not have the same accuracy indices in every region due to differences in a given population. The prevalent subtype of HBV infecting population can be different. ICT for HBsAg detection must be validated before being used in resource limited settings.

The ELISA kit that was used in this study showed to have analytical sensitivity of 0.1ng/ml and detects all the known 11 subtypes of HBV.A similar study shows that ELISA is known to detect the antigen concentration of less than 0.4 ng/ml of HBsAg while as rapid card tests based on lateral-flow technology, which appears to be most sensitive format do not achieve sensitivity of 1 IU/ml for HBsAg [15, 31]. Another study by Mubashirnazir *et al* [32] the ELISA kit that was used shows sensitivity of 0.1ng/ml.

Some studies suggest that the diagnostic performance of RDT is comparable to ELISA [33]. A study by Mizuochi. *et al* [34] shows that newly developed HBsAg rapid test had an analytical detection limit between 0.2 and 0.8 IU/ml values are similar to those of HBsAg EIAs detection.

A positive result can be followed by more accurate and advance method to confirm the infection presence unlike a negative result. In present study negative predictive value for rapid card Brand A and Brand B was 100% for both. Sensitivity and Negative predictive value are two most important parameters for choosing a test rather than specificity and positive predictive value for routine use [35].

Further work is needed as data on the circulating serotype and mutants of hepatitis B virus are widely available in India. Failure to detection hepatitis surface antigen by rapid card may be due to not proper and inadequate antigen coating, genetic heterogeneity of the virus prevalent in that area.

CONCLUSION

Results from this study indicate thatimmunochromatography based rapid card test is a simple, rapid and highly sensitive for screening for hepatitis B surface antigen. Overall performance of these rapid tests was not only compatible with currently established and advanced diagnostic methods but also cheaper. The rapid card test can be used bed site and do not need any expertise to perform and are easy to use. The ultimate goal of this study was to recommend ELISA comparable rapid device for initially screening of hepatitis B, in remote areas or where cost is an issue.

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Study on Bacterial Spectrum of Organism Causing Diabetic Foot Ulcers with its Antibiogram in Dr. B.R. Ambedkar Medical College, Bangalore, India

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A B S T R A C T

Diabetic foot is one of the serious complications associated with diabetes and affects quality of life in respective patients in all ages and races. Diabetes mellitus is a disorder that shares the phenotype of hyperglycaemia. The prevalence of diabetes depends on many etiological factors such as age, sex, heredity, diet, socio-economic conditions and physical activity, environmental factors, life style choices etc. Diabetes is multi factorial disease in which various factors act in complex manner. A prospective study was carried out in department of microbiology at DR.B R Ambedkar Medical College & Hospital, Bangalore. Total of 120 samples with the clinical diagnosis of Diabetic Foot ulcer were collected and processed. Of the total 120 diabetic foot patients samples studied 80 were males and 40 were females, the male: female ratio being 2:1. The maximum number of patients having diabetic foot infections belonged to the age group of 56-65 years. Among the total pathogens isolated, 52.38% gram negative isolates and gram positive isolates i.e *Staphylococcus aureus* accounted for 47.62% and was the most common organism isolated, followed by *Pseudomonas aeruginosa & Klebsiella spp, Escherichia coli*.

Introduction

Diabetic foot is one of the serious complications associated with diabetes and affects quality of life in respective patients in all ages and races. Diabetes mellitus is a disorder that shares the phenotype of hyperglycaemia. The prevalence of diabetes depends on many aetiological factors such as age, sex, heredity, diet, socio-economic conditions and physical activity, environmental factors, life style choices etc. Diabetes is multi factorial disease in which various factors act in complex manner (Kasper Dennis *et al*., 2005).

Neuropathy, peripheral arterial disease, and pressure overload make the sufferers prone to ulcer. Among persons with diabetes mellitus, the risk of developing a foot ulcer is estimated to be 15%. Based on recent studies, the annual population based incidence ranges from 1.0% to 4.1% and the prevalence range from 4% to 10%, suggesting the life time incidence as high as 25% (Singh *et al*., 2005).

Patients with diabetes lose the protective sensations for temperature and pain, impairing awareness of trauma such as abrasions, blistering, or penetrating foreign body (Lipsky *et al*., 2004). Motor neuropathy can result in foot deformities that contribute to local pressure from footwear, making skin ulceration even more likely. Once the skin is

broken (typically on the plantar surface), the underlying tissues are exposed to colonization by pathogenic organisms. The resulting wound infection may begin superficially, but with delay in treatment and impaired body defense mechanisms caused by neutrophil dysfunction and vascular insufficiency, it can spread to the contiguous subcutaneous tissues and to even deeper structures (Abdulrazak *et al*., 2005). So the present study is designed to isolate and identify bacterial causes in diabetic patients and assess their susceptibility to antibiotics.

Materials and Methods

A prospective study was carried out in department of microbiology at DR.B R Ambedkar Medical College & Hospital, Bangalore, India.

Swabs obtained from diabetic foot ulcers cases during one year period from Dec 2015-Jan2017 were collected & processed. Patients details including age, sex, registration no, unit, occupation, history of trauma, habits of bare foot walking, alcohol, smoking, socio-economic status, past history of the disease and duration of the disease, treatment taken and any complications, existing co-morbidities.

E.g. Hypertension, Tuberculosis, Malnutrition, Anemia, Peripheral vascular disease were obtained

Collection of specimen*:* Discharge from margins and edges of ulcer were collected with help of two sterile swabs, one of which was used for gram stain and other for culture before antiseptic dressing was applied. Then swabs were immediately transported to the laboratory for culture.

Laboratory Procedures*:* All samples were subjected to conventional culture methods. All the samples were subjected to Gram's staining for microscopic examination and culture as per standard guidelines. The exudates were cultured on Blood agar and MacConkey agar. The specific identification of bacterial pathogens was based on microscopic morphology, staining characteristics, culture and biochemical properties using standard laboratory criteria. Antimicrobial sensitivity of the bacterial isolates was done on Mueller Hinton agar using Kirby Bauer disc diffusion method as recommended by Clinical and Laboratory Standards Institute (CLSI).

Results and Discussion

Total of 120 samples with the clinical diagnosis of Diabetic Foot ulcer were collected and processed. Out of 120 specimens, 105 (87.5%) specimens showed bacterial growth, while 15 (12.5%) specimens did not show any growth.

Of the total 120 diabetic foot patients samples studied 80 were males and 40 were females, the male: female ratio being 2:1.Age group ranged from 28 years to 70 years with an average of 55 years. The maximum number of patients having diabetic foot infections belonged to the age group of 56-65 years.

Table 2 Illustrates the bacterial isolates which shows52.38% gram negative isolates and gram positive isolates i.e *Staphylococcus aureus* accounted for 47.62% and was the most common organism isolated, followed by *Pseudomonas aeruginosa* & *Klebsiella spp, Escherichia coli.*

The Result of the test for susceptibility to the commonly used antibiotics are shown in Table no. 3, 4and 5. Antibiotic sensitivity pattern of *staphylococcus aureus* showed that Cefoxitin resistance i.e., Methicillin resistant *S.aureus (MRSA)* was 54%, combination of

Amoxycillin/Clavulanic acid showed 70% sensitivity while Gentamicin and Cefuroxime showed 65% and 50% sensitivity respectively. Erythromycin and Azithromycin showed 75% resistant pattern while Cefadroxil showed 55% resistance. Almost all isolates of *Pseudomonas aeruginosa* were sensitive to Piperacillin + Tazobactam, Cefipime and Imepenem, 80%, 76%, 100% respectively.

Foot ulceration is the most severe complication affecting diabetic patients which is not confined to certain superficial underlying subcutaneous tissue. Diabetic foot ulceration (DFU) arises from uncontrolled diabetes and incomplete health self-care (Mendes *et al*., 2012; American Diabetes Association, 2011).

This study investigates clinical and microbiological findings of DFU in patients. The majority of the patients with DFU were male and older than 50 years, consistent with other reported studies such as llanes *et al.*, (2001) which shows maximum age group above 57 years. This may be due to factors such as the differences in life styles and professional activities and jobs, causing the feet to tolerate more pressure.

In the present study, 105 organisms were isolated from 120 patients and *S.aureus* accounts for the major organism isolated. The observations are similar with Chincholikar (2002) while differ significantly from Ekta *et al.*, (2008) in which the major organism are GNB which again indicated the role of geographical variations in microbial etiology. *Staphylococcus aureus* was predominantly isolated organism (47.62%) followed by Pseudomonas *aeruginosa* (23.81%), *Klebsiella* (14.29%) and *E coli* (4.76%).

Other organisms like *Proteus mirabilis*, *P.vulgaris*, *Citrobacter spp* and *Acinetobacter spp* were also isolated. Almost similar results were obtained by Vvimalin Hena *et al.*, (2010) & Murtada Jeber *et al.*, (2013). In our study, Methicillin resistance was seen in 54% of the *S. aureus* which is also in concordance with findings by Gadepalli *et al.*, Ekta *et al.*, (2008) and Chincholikar (2002) in which MRSA was seen in 56%, 55.50% and 55.56% respectively. *Staphylococcus* spp., being the predominant organism isolated showed linezolid and teicoplanin to be the most effective antibiotics with 100% sensitivity and low resistance was seen to amoxy-clav (40%,n=50)& gentamicin (44%,n=50) but a high resistance was exhibited to other antibiotics. Other studies have shown different susceptibility antibiotic patterns and approximately in most vancomycin and linezolid have shown good activity against the strains. The antibiotic sensitivity pattern of Pseudomonas was approximately similar to study by Ekta *et al*., (2008). Most of the isolates were sensitive to almost all drugs used with Piperacilin/Tazobactam (80%:n=25),being most sensitive (80%,n=25),followed by Ceftazidime (72%,n=25), Cefepime (76%, n=25), Amikacin (64%, n=25) & low level of resistance seen to Flouroquinolones.

Table.1 Pattern of isolation of microbial growth from Diabetic Foot Ulcer

Total Patients examined	120
Patients with microbial growth n (%)	105(87.5%)
No growth n (%)	15(12.5%)
Gram Positive Isolates	47.62%
Gram Negative Isolates	52.38%

Table.2 Bacterial Pathogens isolated from 105 Culture Positive Diabetic Foot Ulcers

Organism	**Isolates**	**(n=105) (%)**
Staphylococcus aureus	50	47.62%
Pseudomonas aeruginosa	25	23.81%
Klebsiella spp	15	14.29%
Escherischia coli	5	4.76%
Proteus mirabilis	3	2.86%
Proteus vulgaris	3	2.86%
Citrobacter spp.	2	1.90%
Acinetobactor spp	2	1.90%

Table.3 Antibiogram of Staphylococcal isolates from diabetic foot ulcers (n= 50)

	(n=50)			
Anti microbial agent	S	%	R	%
Amoxycillin/Clav.acid	30	60.00%	20	40.00%
Azithromycin	15	30.00%	35	70.00%
Erythromycin	12	24.00%	38	76.00%
Cefuroxime	25	50.00%	25	50.00%
Cefoxitin sensitive	27	54.00%	23	46.00%
Cefadroxil	28	56.00%	22	44.00%
Gentamicin	28	56.00%	22	44.00%
Linezolid	45	90.00%	5	10.00%
Teicoplanin	50	100.00%	-	-

Table.4 Antimicrobial sensitivity of isolates of Pseudomonas aeruginosa (n = 25)

	n=25			
Anti microbial agent	S	%	R	%
Piperacilin/Tazobactam	20	80.00%	5	20.00%
Ceftazidime	18	72.00%	7	28.00%
Cefepime	19	76.00%	6	24.00%
Amikacin	16	64.00%	9	36.00%
Gentamicin	17	68.00%	8	32.00%
Ciprofloxacin	10	40.00%	15	60.00%
Levofloxacin	12	48.00%	13	52.00%
Doripenem	24	96.00%	1	4.00%
Imepenem	25	100.00%	0	0.00%

Table.5 Antimicrobial susceptibility pattern of gram negative bacteria except *Pseudomonas* (n = 105)

	n=105					
Anti microbial agent	*Klebsiella* spp	*Escherischia coli*	*Proteus mirabilis*	*Proteus vulgaris*	*Citrobacter* spp.	*Acinetobacter* spp
Imipenem	86.67%	80.00%	100.00%	100.00%	100.00%	100.00%
Amikacin	66.67%	60.00%	66.67%	33.33%	50.00%	50.00%
Gentamicin	73.33%	60.00%	66.67%	33.33%	100.00%	50.00%
Ciprofloxacin	46.67%	40.00%	33.33%	66.67%	50.00%	0.00%
Levofloxacin	40.00%	40.00%	33.33%	66.67%	100.00%	0.00%
Ofloxacin	40.00%	60.00%	33.33%	66.67%	100.00%	50.00%
Cefotaxime	33.33%	40.00%	66.67%	33.33%	50.00%	50.00%
Ceftriaxone	46.67%	60.00%	66.67%	33.33%	50.00%	100.00%
Cefipime	66.67%	80.00%	66.67%	66.67%	100.00%	100.00%
Co–trimoxazole	40.00%	40.00%	100.00%	66.67%	100.00%	50.00%
Ampicillin/ Sulbactam	80.00%	100.00%	66.67%	100.00%	100.00%	100.00%

All isolates were found 100% sensitivity to Imipenam. In present study, *Klebsiella* and *E. coli* were mostsensitive to combination like Ampicillin + Sulbactam, Gentamicin, Cefipime, Imepenem and these organisms were resistant to other Cephalosporins, Cotrimoxazole and Flouroquinolone. Similar results were found by Ekta *et al.,* (2008). The antibiotic resistance shown in the present study may be due to such factors including hospitalization, recent use of broad-spectrum antibiotics, history of surgery and chronic wounds, irrational use of antibiotics, and the transfer of resistance genes by transport means. To alleviate this situation and also reduce the rate of amputation, clinicians should prescribe antibiotics rationally, timely, and sufficiently and there should be periodic supervisions on the drug consumption by the respective organizations (Farshad *et al*., 2011).

It can be concluded that culture specimens for correct management of the DFI and knowledge of the susceptibility of antimicrobial drugs are essential for the choice of appropriate antibiotics with maximum efficacy. Diabetic foot infections are polymicrobial in nature

Organisms in mixed infections showed multidrug resistance as compared to single isolated strain.

These multidrug resistant organisms are frequently resistant to many classes of antibiotics so it is necessary for the clinician to be completely aware of the prevalence rate of multidrug resistant organisms and their management strategies. So this study will help the clicians to choose appropriate antibiotic or combination of antibiotics forthe treatment of Diabetic Foot Ulcer.

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A Study on Bacteriological Spectrum of Post-Operative Orthopaedic Implant Infections and their Antibiotic Sensitivity Pattern in a Tertiary Care Hospital

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Abstract
Background: *Post operative infections in orthopedic implants is a major problem in orthopedic patients nowadays which can lead to implant failure and in severe cases can even lead to amputation and mortality.These are mainly associated with Open reduction and internal fixation (ORIF) of fractures with implants and prosthesis which has become the first line in the management of fractures in most traumacentres in recent times. This is also associated with high morbidity and cost for patient during his hospital stay.*
Objectives: *The objective of this paper is to isolate and identify the bacteriological isolates responsible and their antimicrobial sensitivity from post-operative orthopedic implant infections.*
Materials and Methods: *This was a prospective study carried out at a tertiary care hospital in India over a period of six months. The study was conducted on 50 cases of infected implants from orthopaedic wards, admitted in DR.B.R Ambedkar Medical College, Bangalore from 1st July to 1st December 2016.Pus samples were collected using two sterile swabs .One is used for Grams stain and other for inoculation on Mac conkey and blood agar. Susceptibility testing was performed by Kirby-Bauer disk diffusion technique.*
Results: *Out of the 50 samples processed, 40 (80%) of specimens showed culture positivity. Staphylococcus aureus 14(35%) was the predominant isolate followed by Escherichia coli 10(25%),Klebsiellaspp 8(20%), Pseudomonasspp 5(12.5%),Acinetobacterspp2(5%) and Proteus spp1 (2.5%). All Gram-positive cocci were susceptible to vancomycin and linezolid.*
Gram negative bacilli were resistant to ceftriaxone (84.6%), ciprofloxacin(69.2%), cotrimoxazole (69.2%)and sensitive to carbapenems and piperaciillintazobactam. ESBL production is seen in 11(61%) cases of Gram negative bacteria.
Pseudomonas isolates were susceptible to piperacillin-tazobactam, and meropenem.
Conclusion: *Orthopedic implant post-operative infections are a major concern in the present scenario. There is an increase incidence of multidrug resistance among the pathogens isolated from these isolates. Adequate preventive measures should be taken to prevent these antibiotic resistance amongst organisms. In this study Gram Positive Organisms has emerged as major threat for orthopedic implants.*
Key Words: *Bacterial isolates; Antibiogram; Orthop edic infection; Wounds; ESBL.*

Introduction

Infection is a major concern in orthopedic implants leading to implant failure. It is very difficult to treat orthopedic implant infections which may lead to implant failure. Sources of infection include environment of operating room, surgical equipments, clothing worn by medical and paramedical staff. Implant related infections can be due to biofilm formation also which is very common nowadays. In most of the cases removal of the infected prostheses is the ideal solution to cure these infections.

Orthopedic infections are one of the most common which can occur in approximately 1% of all orthopedic operations.[1] The most common orthopedic infections are surgical site infections (SSI) and implant infections in open or closed wounds. [2,3] Wound is a breach in the skin leading to exposure of subcutaneous tissue caused by trauma, surgeries, burns, diabetic ulcers, etc. It provides a moist, warm and nutrient environment that is conductive to microbial colonization and proliferation that leads to serious bacterial infections and death. Wound infections are one of the most common hospital-acquired infections morbidity and account for70-80% mortality.[4]

Surgical site infection (SSI) as defined by US Centers for Diseases Control (CDC) in 1992 is an infection occurring within 30 or 90 days after a surgical operation (or within 1year if an implant is left in place after procedure) and affecting either incision or deep tissues at the operation site. These infections may be superficial or deep incisional infection or infections involving organ or body space. [5]

Open or compound fractures are fractures that communicate with the outside environment through skin wounds. [6] The main causes of open fracture include road traffic accidents, fall from height, assaults, machine injury and others. Anglen JO et al reported 3-4% of all fractures are open fractures and the development of infection is favored by devitalization of bone and soft-tissue. Use of implants and prosthesis during the orthopedic surgeries can pose greater risk of microbial contamination and infection. [7]

Numerous studies have documented that gram-positive organisms are the most common bacteria causing infections associated with joint arthroplasty, with Staphylococcus aureusand Staphylococcus epidermidis causing the majority of the infections. [8,9-11] Enterococcus, Streptococcus, and gram-negative organisms such as Escherichia coli, Pseudomonas species, and Klebsiella species are less common but have been frequently reported [12]. These microorganisms can all be part of normalskin flora; hence, direct inoculation at the time of the operation as well as airborne contamination are the most likely causes of these infections. Although Staphylococcus epidermidis is generally not considered pathogenic, infections surrounding a joint replacement prosthesis may be more difficult to treat because of the bacterial biofilms typically produced by Staphylococcus aureus and Staphylococcus epidermidis around orthopaedicimplants [13,14]. This glycocalyx layer, which is formed on the surface of the orthopaedic devices, creates a complex environment for the bacteria. Numerous factors, including restricted penetration of antimicrobials into the biofilm, decreased bacterial growth rates, and expression of biofilm-specific resistance genes, all contribute to bacterial and biofilm resistance [15].

In addition to the irrational use of broad spectrum antibiotics, the changing pattern of microbial etiology and increasing challenge for both the patient and clinician.

In recent years the organisms from these infected cases are showing increased resistance to commonly used first line drugs and multi drug resistance. Methicillin resistance has become most common and also ESBL producers.

So the present study was conducted to delineate the occurrence and sensitivity pattern of such infections for a better management, thereby reducing both mortality and cost issues.

Materials and Methods

Study center

This was a prospective study carried out at a tertiary care hospital in India over a period of six months. (from 1st July to 1st December 2016).

Patient's selection

All the patients who had close fractures of long bones treated by ORIF with purulent discharge from incision or drain within a week after surgery or after few weeks after discharge from hospital of all age groups and both sexes were included into the study.

Patients with use of antibiotics after diagnosis of infection were excluded. Intra-operatively, cefuroxime (Zinacef) or Ceftriaxone (Rocephin) were used for perioperative antibiotic prophylaxis.

Processing of specimens

Swabs from open fractures, bed sores and wounds clinically suspected to be infected were collected with all aseptic precautions to avoid contamination and were immediately transported to the Microbiology laboratory. The pathogens were identified by standard laboratory procedures including gram's staining, motility, colony characters and biochemical reactions. for culture the specimens were inoculated into mac conkey and blood agar. Antibiotic susceptibility testing was done by Kirby-Bauer disc diffusion method as per CLSI guidelines[16]. Following antimicrobials were used

Table 1-The concentration of the antibiotics employed were as per CLSI guidelines .[16]

The drugs used for Gram positive organisms Were:	The drugs used for Gram negative organismswere:-
Azithromycin (AZM) 15 µg Clindamycin (CD) 2 µg Cefoxitin (CN) 30 µg Penicillin (P) 10 units Co-trimoxazole (COT) 25 µg(1.25/23.75 µg) Linezolid (LZ) 30 µg Vancomycin (VA) 30 µg Tetracycline (TE) 30 µg Levofloxacin (LE) 5 µg Gentamicin (GEN) 10 µg Gentamicin (HLG) 120 µg Erythromycin(E) 15µg Teicoplanin(TEI)30 µg Amoxyclav(AMC) 50/10 µg	Ampicillin (AMP) 10 µg Gentamicin (GEN) 10 µg Tobramycin (TOB) 10 µg Amoxycillin - Clavulanic acid (AMC) 20 µg + 10 µg Ampicillin – Sulbactam (AS) 10 µg + 10 µg Cefoxitin (CN) 30 µg Cefotaxime (CTX) 30 µg Cefepime (CPM) 30 µg Ceftazidime (CAZ) 30 µg Levofloxacin (LE) 5 µg Co-trimoxazole (COT) 25 µg Piperacillin (PC) 100 µg Piperacillin – Tazobactam (PIT) 100/10 µg Imipenem (IPM) 10 µg Meropenem (MRP) 10 µg Aztreonam (AT) 30 µg. Norfloxacin(NX)-10 µg Nitrofurantoin(NIT)-300 µg

For Pseudomonas species

Ceftazidime (30mg), gentamicin (10mg), amikacin (30mg), piperacillin/tazobactam (100mg/10mg), cefepime (30mg), cefoperazone/ sulbactam (75mg/30mg), aztreonam (30mg), ofloxacin (5mg), imipenem (10mg),ceftriaxone (30mg), netilmicin (30mg), ceftizoxime (30mg). All the antibiotic discs used were obtained from Hi-Media Laboratories Pvt. Ltd.

Detection of MRSA[17]

Inoculum was prepared by emulsifying 2-3 identical colonies in the broth. Inoculum turbidity was adjusted to 0.5 McFarland turbidity tube. A lawn culture was made on the surface of the MHA agar plate using sterile cotton swab and 30 µg Cefoxitin antibiotic disc was applied. The antimicrobial discs were obtained from Hi Media Laboratories Private Limited, Mumbai. The plates were incubated for 18-24 hours at 37 0 C. After 24

hours reading was taken and zone of inhibition was read and reported. The diameter of each zone (including the diameter of the disc) of inhibition was measured and recorded in millimeters and the result was then compared with the zone size interpretative chart.

If Zone if inhibition of cefoxitin is > 22 mm it is sensitive. If < 21 mm then reported as Methicillin Resistant. The concentration of the antibiotics employed were as per CLSI guidelines

Detection of ESBL[18]

Phenotypic Confirmatory test was followed using Cefotaxime 30 µg Cefotaxime-clavulanate 30/10 µg and Ceftazidime 30 µg Ceftazidime-clavulanate 30/10 µg. Standard Disk diffusion procedure followed and the disks were placed on MHA on which a lawn culture of the test organism was done. The plates were incubated for 18-24 hours at 37 0 C. After 24 hours reading was taken and zone of inhibition was read .A≥ 5-mm increase in a zone diameter for either antimicrobial agent tested in combination with clavulanate vs the zone diameter of the agent when tested alone=ESBL .

Results

Out of the 50 samples, 40(80%) culture were positive and 10(20%) culture were negative.

Out of 40 culture positive cases, 31 (77.5%) were males and 9(22.5%) cases were females. Out of 40 culture positives, 14 (35%)were Gram positive cocci and 26(65%) were Gram negative bacilli.

Staphylococcus aureus (35%) was the most common isolate followed by E coli(25%), Klebsiellaspp(20%) , Pseudomonasspp (12.5%), Acinetobacterspp(5%) and Proteusspp (2.5%).

Antibiogram of gram positive cocci showed highest resistance to Penicillin[100%], Amox-clav [71%], Cotrimoxazole [71%], Levofloxacin [57%] and Gentamicin[57%].Vancomycin, teicoplanin and linezolid did not show any resistance. MRSA was seen in (71.42%)% cases of Staphylococcus aureus.

About 100% of E.coli was sensitive to imipenem and 70 % sensitive to nitrofurantoin. However it was found resistant to ceftriaxone (90%), Ciprofloxacin (80%) and cotrimoxazole (80%). Among aminoglycoside, amikacin and gentamicin showed good sensitivity (70 %). Klebsiellaspp was equally sensitive (75%) to nitrofurantoin and amikacin and gentamicin (87%). Proteusspp was sensitive to most of the antibiotics. However, number of isolates was very small to draw a definitive conclusion. Proteus mirabilis was also sensitive to most of antibiotics with 100% sensitive to amikacin, cotrimoxazole and piperacillin-tazobactam.

Among E coli, 6(60%) cases were ESBL and Klebsiellaspp 5(62.5%) were ESBL.

Acinetobacter baumanii isolates were found to be highly sensitive (100%) imipenem. It was highly resistant to, ciprofloxacin (50%) and cotrimoxazole (50%). Pseudomonas aeruginosa isolates were sensitive to most of the antibiotics.

Table 2: Distribution of culture positive and culture negative samples

	cases	percentage
Growth	40	80%
No growth	10	20%
Total	50	100%

Table 3: Sex distribution

	Male	Female
Total cases(40)	31(77.5%)	09(22.5%)

Table 4: Distribution of single bacterial isolates

Bacteria	Isolate No. (%)
Staphylococcus aureus	14(35%)
Escherichia coli	10(25%)
Klebsiella species	08(20%)
Pseudomonas species	05(12.5%)
Acinetobacter spp	02(5%)
Proteus spp	01(2.5%)
Total	40(80%)

Table 5: Antibiotic resistance pattern of bacterial isolates

Isolate	CTX	LEV	GEN	NIT	NX	AK	CPM	CAZ	IMP	COT	CIP	PTZ
E. Coli	09	05	03	03	05	03	02	02	0	08	08	0
Klebsiellaspp	06	04	02	02	04	01	01	01	0	05	06	0
Pseudomonas spp	04	03	02	01	01	01	03	02	0	03	03	0
Acinetobacter	02	02	02	01	02	01	02	02	0	01	01	0
Proteus spp	01	01	0	0	0	0	01	01	0	01	0	01

Table 6: Antibiotic resistance pattern of gram positive isolates

Organism	P	AMC	COT	CX	E	VA	TEI	LZ	LE	GEN	NIT	NX
S.aureus(14)	14	10	10	8	10	0	0	0	08	08	09	10

Table 7: Distribution of ESBL isolates:

Isolates	ESBL	NON-ESBL
E.coli (10)	6(60%)	4(40%)
Klebsiella (8)	5(62.5%)	3(37.5%)
	11(61.1%)	7(38.9%)

Fig 1 Disk diffusion test for MRSA detection

Discussion

In our study, out of 50 samples, 40 (80%) were culture positive.

This is similar to study conducted by Devi et al [19], in which out of 100 samples, 68% samples yielded growth. Among them, predominant organisms were Gram-negative bacilli with Pseudomonas (18 isolates) being most common organism with the highest sensitivity to piperacillin + tazobactam, imipenem and amikacin. Among the Gram-positive organisms isolated, S. aureus (17 isolates)

was the most common organism with maximum sensitivity to vancomycin and linezolid. Abraham Y et al [20] study which showed 41% positivity, whereas Gomez et al [21] and Zimmeli et al [22] reported positive cultures in 60% and 89% respectively.

Staphylococcus aureus was the most commonly isolated micro-organism in this study accounting for 35%. This was similar to a study conducted by Sonawane et al [23] where staphylococcus was the dominant organism (29.26%). This was similar to study conducted by Goel et al [24] 2013(32.8%).

But there are few studies where gram negative organisms were isolated the most. In a study conducted by Suneet Tandon et al [25%], Klebsiella (39.53%) was most isolated species. In our study maximum resistance is shown to penicillin among gram positive cocci which is similar to study conducted by Sonawane et al in 2010 and Jain et al 2014

In our study (71.42%) were MRSA, which does not correlate with other studies. Bergqvist et al [26] and Dan et al [27] found that 29.8% of hospitalized patients and 26.6% of hospital staff respectively are carriers. 12.5% (11/88) of our isolates are Methicillin Resistant Staphylococcus aureus. ESBL production is (61.1%) which corelates with Sonawane [23] et al 2010(71.72%).

The gram-negative aerobic rods like E.Coli, Pseudomonas, Proteus and Klebsiella were found to be sensitive to amikacin while essentially resistant to the cephalosporin tested. this was similar to study conducted by Satya Chandrika et al. [28] From our results, we observed that amoxicillin/clavulanic acid, ceftriaxone and ceftazidime cannot be recommended for use as an empirical therapy in SSI and open fracture infections because these drugs were inactive against most strains. Based on the antimicrobial susceptibility data, we suggest that piperacillin/ tazobactum and imipenem are the most effective agents against most of gram negative bacteria and vancomycin, teicoplanin and linezolid are the

most effective agents against gram positive organisms.

Conclusion

As there is high antibiotic resistance observed in our study, it is necessary for routine microbial analysis of samples and their antibiogram. Multidisciplinary collaboration with orthopedic surgeons, infectious disease specialist and clinical microbiologist is needed to reduce the incidence of orthopedic infections. There is a need for formulation of antibiotic policy and formulary restriction.

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HAS HAART WON HEART OF HIV/AIDS PATIENTS?

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ABSTRACT

Background: The Human Immunodeficiency Virus (HIV) has changed from life threatening to chronic condition due to the almost universal use and accessibility of antiretroviral treatment (ART) among HIV patients. Antiretroviral (ARV) treatment works by suppressing the viral load and restoring the immune system. Once patients start Highly Active Antiretroviral Therapy (HAART), it is to be continued lifelong in spite of its many adverse side effects. **Objective:** To identify the adverse drug reactions (ADRs) to antiretroviral therapy (ART) and to assess their impact on treatment compliance in patients with HIV/AIDS in western India. **Methods:** A retrospective study was conducted in Gujarat to study the adverse effects after HAART initiation in 1244 patients on HAART who were evaluated retrospectively for their adverse drug reactions (ADRs). **Results:** The most common first line regimen was stavudine+lamivudine+efavirenz (d4T +3TC + EFV)(68.6 %) followed by stavudine + lamivudine + nevirapine (d4T + 3TC + NVP)(17.9%); zidovudine+ lamivudine + nevirapine(AZT+3TC+NVP) (10.9 %); and zidovudine+lamivudine+efavirenz

(AZT + 3TC +EFV) 2.5%. The first line of regimen was modified in 136(10.9%) patients, the most common cause for modifying therapy being development of an adverse effect 721(57.9%) and completion of antituberculous therapy in 510 cases(41.%). The most common cause for modifying therapy was skin rashes due to NVP in 279(22.4%) followed by loss of appetite 195(17.2%). **Conclusion:** A significant proportion of patients had adverse effects of HAART. A significant proportion of those started on NVP-based regimens are more likely to substitute therapy when compared with those on non-NVP-based regimens.

KEYWORDS: HIV, AIDS, ART, HAART, Adverse Drug Reaction (ADR), CD4 Count.

ABBREVIATIONS

HIV – Human Immunodeficiency Virus

AIDS - Acquired immune deficiency syndrome

ART - Antiretroviral Treatment

ARV – Antiretroviral

HAART - Highly Active Antiretroviral Therapy

ADR - Adverse Drug Reaction

INTRODUCTION

The Human Immunodeficiency Virus (HIV) has changed from life threatening to chronic condition due to the almost universal use and accessibility of antiretroviral treatment (ART) among HIV patients [1]. Antiretroviral (ARV) treatment works by providing suppression of viral load and restoring the immune system. It is estimated that out of the 35.3 million people living with HIV worldwide, 10.6 million were receiving ART in 2012 [2]. Nearly, 6.6 million HIV/AIDS related deaths worldwide have been prevented as a result of ART [2]. Despite these gains, adverse reactions to these medicines remain a significant public health concern and may compromise the effectiveness of the ART programmes [3,4].

In India, approximately 2.4 million people were living with human immunodeficiency virus (HIV) in 2009, which is estimated to be the third largest population of HIV affected people in the world.[5] With the availability of new antiretroviral drugs, there has been a decline in morbidity and mortality due to acquired immunodeficiency syndrome (AIDS).

The advent of highly active antiretroviral therapy (HAART) has resulted in significant decreases in HIV-related morbidity and mortality in both the developed and developing

world[6-8] and HAART has been touted as one of the greatest breakthroughs in the response to the HIV pandemic. HAART may be modified or interrupted as a result of many reasons, key among which are adverse effects and virological failure [8-11]. The adverse effects may in themselves result in virological failure or disease progression as a result of sub optimal dosing or treatment interruption.

In a study done in India, 90.6% of all the patients on HAART developed an adverse drug reaction and there were 618 episodes in various systems, the abdominal and central nervous systems were the most affected [12]. Luma and colleagues, studying patients in Cameroun found an adverse drug reaction (ADR) prevalence of 19.5% of which 21.2% were due to peripheral neuropathy. Overall 56.1% of ADR were attributed to the use of stavudine (d4T)[13]. Anaemia was observed as an ADR in many patients on ART, especially whenever the patients took zidovudine (ZDV) [14].

In an effort to scale up HAART to those who needed it most, the WHO in 2003 launched the "3 by 5" initiative with an objective of placing 3 million persons living with HIV on HAART by 2005[15]. In line with this initiative the World Health Organisation (WHO) developed guidelines on antiretroviral therapy for resource poor countries. The guidelines recommended a combination of two nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitor (NNRTI) as first-line regimens in resource-constrained settings[16].

Access to antiretroviral therapy (ART) has improved tremendously over the last few years due to implementation and enforcement of various strategies by National AIDS Control Organization (NACO). NACO has established ART centres in selected government hospitals which offer free treatment for HIV/AIDS and related opportunistic infections. [17] In India, as of May 2009, there were 174 ART centres and 1,55,000 patients were on therapy. [18] By 2012, National AIDS Control Program III (2007-2012) aims to increase number of ART centres up to 250 where 3,00,000 adults will be given free ART. [17] In addition, 10 centres of excellence responsible for training, research work and mentoring of ART centres linked to them have been established across the country.[19]

HAART is the corner stone of management of patients with HIV/AIDS infection. [20] Consistent use is vital for drugs to be effective and to prevent emergence of resistance. However, ARV drugs are highly toxic and are associated with various adverse

drug reactions (ADRs) due to which many patients require withdrawal of the drug or even discontinue the treatment resulting in treatment failure. [21] Hence, monitoring and reporting of ADRs in HIV/AIDS patients receiving ART assumes great importance. There is paucity of data on ADRs to ART in Indian population. Keeping this in view, the present study was designed to identify the ADRs in patients receiving ART and to assess their impact on the compliance to the prescribed treatment.

MATERIAL AND METHODS

It was a retrospective study conducted at various ART centres of western India. The study was approved by GSACS, Ahmedabad.

A cross sectional retrospective study was conducted reviewing data of 1244 patients initiated on HAART. Univariate analysis was done for the dependent and independent variables. Stepwise logistic regression procedures were used to model the effect of gender on the development of ADRs controlling other variables like age, marital status, weight at baseline and CD4 at baseline.

From the patients records, findings of complete general, physical, systemic examination and all laboratory investigations were recorded. ADR monitoring was done in a systemic manner adopting both spontaneous and intensive monitoring approaches. The WHO definition of an ADR was adopted [22]. A pre-designed and pre-tested proforma had been confidentially used for ADR record keeping.

If the patient developed any ADR, the drug which was most commonly implicated in the causation was challenged by the treating physician and was replaced by another drug from the same class. The patient was then monitored for recovery from the symptoms.

The World Health Organisation (WHO) ADR probability scale was used for causality assessment.

With respect to ADR, following parameters were recorded.

1. Number of adverse drug reactions with different treatment regimens,
2. Nature of adverse drug reactions,
3. Severity of adverse drug reactions,

4. Incidence of each adverse drug reaction-calculated by dividing the number of patients suffereing from a particular adverse drug reaction by the total number of patients taking the same suspected drug,
5. Requirement of de-challenge,
6. Compliance to the prescribed treatment- monitored by pill count at each visit and as reported by the patient, and
7. Number of deaths.

RESULTS AND DISCUSSION

One thousand two hundred forty four (1244) patients who had been on ART were included in the present study, Out of which 1132(90.99%) patients complained of ADRs and few of them even recorded to have multiple ADRs.

Patients received four first line regimens as per the NACO guidelines [Table 1]. Stavudine +Lamivudine + Efavirenz was the most widely used combination [Table 2]. Drugs were given in the following dosages: Stavudine 40 mg B.D., Lamivudine 150 mg B.D., Nevirapine 150 mg B.D., Zidovudine 300 mg B.D. and Efavirenz 600mg H.S.

Out of the 1244 patients enrolled, 1132(90.99%) patients were recorded to report ADRs. About 74.91 % were recorded to develop more than one adverse reaction. A total of 1511 adverse drug reactions affecting various systems were observed in 1132 patients [Table 3]. Majority of adverse reactions were observed related to the gastrointestinal system and central nervous system including loss of appetite and insomnia each accounting for 28 percent. Maximum adverse reactions (872 out of 1511) were observed in patients who were prescribed treatment Ia (Stavudine + Lamivudine + Nevirapine). This was followed by 338 ADRs in patients receiving treatment regimen IIa, 223 ADRs in the patients taking treatment regimen I, and 78 ADRs in the patients taking treatment regimen II.

Irregular menstrual cycle was reported by 10 patients, 3 each in treatment I, II, and IIa. Loss of smell sensation and hearing impairment was observed in 2 patients receiving treatment regimen I and in 3 patients in regimen Ia.

Incidence of ADRs to a particular drug was calculated based on only the dechallenge test. Incidence of peripheral neuropathy and fat redistribution due to stavudine was 6.98% and

2.67%, respectively, and incidence of skin rash due to nevirapine was 7.23%, incidence of hepatitis due to nevirapine and efavirenz was 2.96% and 2.17 % respectively.

Even though HAART showed plenty of adverse drug reactions, at the same time it decreased morbidity and mortality in HIV/AIDS patients, it improved health status, body weight and even CD4 counts in almost about 90 % of the patients who adhere to this treatment strictly [Table 4].

The basic configuration of antiretroviral regimens is unchanged. The most common initial regimens are a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI) with two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs). Common toxicities of ART can make adherence to therapy difficult. However, adherence is important to prevent the development of drug resistance. Unlike therapy for other diseases, a strategy of decreasing the dose or switching to a different drug to minimize toxicity and maximize adherence may not be possible with ART; the benefit of suppressing HIV may override other considerations. Identification and awareness of ART toxicity are necessary to facilitate patient adherence and determine when a change in therapy may be needed.

Routine monitoring in patients receiving ART includes a complete blood count and a comprehensive metabolic panel every three to six months. A lipid profile and urinalysis for proteinuria should be performed annually. When ART is changed, a complete blood count, metabolic panel, and lipid profile should be performed two to eight weeks afterward. Abnormal results should prompt more frequent testing based on clinical assessment.

According to Joint United Nations Programme on HIV and AIDS (UNAIDS) and WHO estimates, approximately 1,58,000 people all over the world were receiving ART in 2007[23]. It is well known that anti-retroviral drugs are highly toxic and therefore, early detection of ADRs by continuous monitoring is indispensable for successful treatment. In the present study, 1511 ADRs were observed in 1132 (90.99%) patients. Main risk factors associated with development of ADRs in HIV patients as determined by the researchers in previous studies included illiteracy, female gender, CD4 < 200 cells/µL, and opportunistic infections such as tuberculosis.[24] Earlier studies have also documented that a majority of ADRs were predictable and preventable.[24,25]

We observed that the maximum numbers of ADRs were related to the gastrointestinal system which is in agreement with findings of Modayil *et al*.[24] In our study, apparently maximum ADRs occurred in patients receiving stavudine+lamivudine+efavirenz which may be attributable to larger number of patients receiving this combination; however, it was observed that the incidence of ADRs was highest with the stavudine+lamivudine+nevirapine regimen.

Most cases (18/21) of peripheral neuropathy and all cases of lipodystrophy were observed in patients receiving stavudine therapy. Similar findings have been reported earlier. [24] We observed an incidence of 1.39% of peripheral neuropathy but no case of fat redistribution with stavudine. However, earlier studies have reported an incidence of peripheral neuropathy as 10%, 12% and a prevalence of lipodystrophy as 25%.[26,27.28] Low incidence seen in our study may be contributed to under diagnosis and that the drug is well tolerated in this part of the world. Recently updated WHO guidelines on ART for HIV/AIDS patients do not recommend use of stavudine as a first choice in first-line regimens due to these adverse effects.[20]

Incidence of skin rash (18.46%) and hepatotoxicity (3.19%) due to nevirapine seen in our study was almost the same when compared to that observed by Rotunda *et al*. (skin rash-15%),[29] Martinez *et al*. (hepatotoxicity-12.5%),[30] and Sulkowski *et al*. (hepatotoxicity-15.6%).[31] Latter also reported that the incidence of hepatitis due to efavirenz was 8%, whereas we found an incidence of only 0.43%. Further, in our study dechallenge with nevirapine and efavirenz in these patients resulted in resolution of hepatitis gradually over a period of 3 weeks and 1 month, respectively.

Few ADRs never documented earlier in the literature with use of ART such as irregular menstrual cycle, hearing impairment and loss of smell were also observed in the present study.

Issue of non-compliance is of major concern in management of HIV patients keeping in view that it requires lifelong treatment. Non-compliance causes significant economic implications by complicating disease management and its subsequent healthcare and social costs. Earlier studies have documented that most important factor resulting in non adherence to ART is toxicity.[32] We observed that it was mainly the severe ADRs which affected the patients' compliance. We observed that 22.1% of patients were non-compliant to ART because of

ADRs. These findings are in concordance with that of Monforte *et al.* who reported non compliance in 21.1% of Italian patients due to ADRs to ART.[32]

The risk of adverse drug reactions (ADRs) arises because of the effect of the disease on the immune systems and the safety profiles of the complex ART drugs [3]. There are a number of ADRs related to ART that have been documented, and may be mild to severe; and short to long term depending on the environment[1,5,33]. ADRs in developing countries may differ from those in developed countries because of high prevalence of conditions such as malnutrition, tuberculosis and patients presenting with advanced HIV disease [34]. For instance, it has been found that in Africa, neuropathy, neutropenia and lipodystrophy are the predominant ADRs[35]. Short term ADRs are a potential threat to successful initiation and adherence to ART[36]. The timing of ADRs may also depend on the type of drugs. Studies have shown that patients on Efavirenz, Lamivudine and Zidivudine or Indinavir, Zidovudine and Lamivudine may present with ADRs within the first 12 and 24 weeks, respectively[37]. ADRs may be common or specific to class of drugs [1,36]. Drugs classified as non-nucleoside reverse transcriptase inhibitors (NNRTIs) which include Efavirenz (EFZ) and Nevirapine (NVP) are known to cause rashes and hepatotoxicity. On the other hand, drugs classified as nucleoside reverse transcriptase inhibitors (NRTIs) including Zidovudine (AZT) and Stavudine (d4T) are known to cause anaemia, nausea, rashes, lipoatrophy and lactic acidosis.[1]

Apart from ADR depending on the environment and the type of ART regimen, a number of other risk factors have been identified, that include patient age, gender, duration of treatment, disease biomarkers such as CD4 count and viral load and body mass index (BMI) [38]. These risk factors have been found to interact with type of ADR. For instance, females are more likely to develop rashes and hepatotoxicity[38]; and patients aged 40 years and above are at a higher risk of developing peripheral neuropathy when taking d4T[39]. The longer a patient is on ART the less likely they would experience ADRs; possibly as a result of stability in ARV regimen, coming after many changes and eventually settling on an acceptable regimen [30].

Monitoring safety and toxicity related to ART remains a challenge facing the public health sector. Monitoring is usually done using spontaneous surveillance of HIV patients on treatment. Spontaneous reporting of ADRs is a very inefficient system in detecting drug-related conditions, leading to underestimation of the burden due to ADRs [3,40]. Thus, more systematic and robust surveillance methods including structured surveillance

pharmacovigilance systems, which assess and monitor safety profile and impact of antiretroviral medicines have been advocated. Structured surveillance tracks HIV positive patients who are on ART to assess drug related morbidity and mortality over time. South Africa, a country heavily hit by the HIV epidemic, uses spontaneous surveillance of HIV patients on ART to assess ART-related adverse effects. Though these data are routinely available, the coverage may not be adequate. Thus, for the purposes of this study, data from a structured surveillance system in Western India are used.

The adverse drug reaction events in patients often are of recurrent nature, such that the repetitions tend to cluster more in some patients than in others. Analyses of these data are complicated due to the fact that independence between the recurrent event times cannot be predicted in a subject. In medical studies, time-to-event models have been developed to account for possible dependence between recurrent events data [42]. The aim of this study was to provide a unified analysis of recurrent ADR events data from a structured antiretroviral pharmacovigilance surveillance system.

Table 1: Treatment Regimens as per NACO guidelines.

Treatment Regimens	Drugs in combination	No Patients
I	Zidovudine + Lamivudine + Nevirapine	136
Ia	Stavudine + Lamivudine + Nevirapine	223
II	Zidovudine + Lamivudine + Efavirenz	31
IIa	Stavudine + Lamivudine + Efavirenz	854

Table 2: Patient's characteristic in different treatment groups.

	Treatment regimen I	Treatment regimen Ia	Treatment regimen II	Treatment regimen IIa
No of patients	136	223	31	854
Mean Age(years)	36 + 8.34	40 + 2.87	33 + 7.20	38 + 4.31
Sex(M/F)	92/44	155/68	20/11	532/322
Weight (kg)	50 + 6.65	53 + 9.22	51 + 5.13	58 + 5.22
Current CD4 count				
< 200	43	78	21	247
> 200	93	145	10	607

Table 3: ADRs related to different systems.

System Involved	No. of patients with ADRs (%)
Gastrointestinal system	**678(36.45%)**
Loss of appetite	195(28.76%)
Dyspepsia	154(22.71%)
Abdominal Discomfort	81(11.94%)

Diarrhoea	74(10.91%)
Constipation	54(07.96%)
Nausea	51(07.52%)
Vomiting	43(06.34%)
Abdominal Pain	21(03.10%)
Hepatitis	05(00.59%)
Central Nervous System	**415(22.31%)**
Insomnia	111(28.75%)
Headache	89(21.45%)
Dizziness	78(18.80%)
Anxiety	57(13.73%)
Nightmare	27(06.51%)
Peripheral neuropathy	21(05.06%)
Excessive sleep at night	19(04.58%)
Delusion	14(03.37%)
Dermatological	**287(15.43%)**
Skin rashes & itching	279(97.21%)
Facial discolouration	08(02.79%)
Metabolic	**178(09.57%)**
Fatigue	109(61.24%)
Dyspnea	69(38.76%)
Musculoskeleton	**106(05.70%)**
Body ache	51(48.11%)
Vague chest pain	28(26.41%)
Pain in legs	27(25.47%)
Miscellaneous	**15(00.81%)**
Irregular menstruation	10(66.67%)
Loss of smell sensation	3(20.00%)
Hearing impairment	2(13.33%)

Table 4: Descriptive analysis of socio-demographic and health status of the patients at ART clinic.

	Variables	**n(%), N = 1244**
1	**Socio-demographic**	
(i)	Education (primary and above)	871(70.1)
(ii)	Work status (unemployed)	247 (19.9)
(iii)	Age (≤40 years)	705(56.7)
(iv)	Gender (female)	445(35.8)
(v)	Marital status (married)	1068 (85.9)
(vi)	Residency (urban)	466 (37.5)
2	**Clinical variables**	
(i)	Duration of ART (≤4 years)	495(39.8)
(ii)	Current CD4 level (cells/mm^3)	
a.	< 200	389(31.3)
b.	>200	855(68.7)
(iii)	Non adherence	47(3.8)
3	**General profile**	
	General health at the start of treatment	

(i)	Healthy	257(20.67)
(ii)	Mild to severely ill	987 (79.5)
4	**CD $_4$ count after treatment**	
(i)	Increased	1135 (91.2)
(ii)	Decreased	27(2.1)
(iii)`	No change	82(6.6)
5	**Health status after ART start**	
(i)	Improved	1114(89.5)
(ii)	Not improved	130(10.4)
6	**Body weight**	
(i)	Increased	1009(84.1)
(ii)	Decreased	91(7.3)
(iii)	No change	144(11.6)

CONCLUSION

HAART has decreased morbidity and mortality up to the expectation along with increasing considerable longevity of life of the HIV/AIDS patients. But all these antiretroviral drugs are highly toxic and associated with myriad adverse drug reactions and that too with a very high frequency. These ADRs are adding to the problem of non-compliance which in itself is a very big issue with ART. Hence, it is prudent to recognize these ADRs as early as possible in the course of treatment. This goal can be achieved by regular monitoring and reporting of ADRs which is indispensable for improving the treatment outcome.

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BACTERIOLOGICAL PROFILE AND ANTIBIOTIC SUSCEPTIBILITY PATTERN (ANTIBIOGRAM) OF URINARY TRACT INFECTIONS IN TERTIARY CARE HOSPITAL AT RAJSAMAND

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ABSTRACT

Background: To detect the prevalence rate of bacterial infection among urinary isolates and to determine the antimicrobial susceptibility pattern in the rural area of Rajsamand. **Aim:** of the study was to find prevalence of uropathogen in this part of world along with to study the antibiogram of UTI cases. **Material and Method:** A retrospective analysis of bacterial pathogens and their antimicrobial susceptibility was done on urine sample s at tertiary care hospital. Antimicrobial susceptibility tests were done using disc diffusion technique as per the standard of Kirby-Bauer method. **Results:** Out of total 600 samples, 193 samples were found positive. Out of which males 74(38%) and females119(62%) were positive. Females showed higher prevalence rate of UTI than males. Gram negative bacteria were found in high prevalence rate than gram positive bacteria. E. coli 101(52 %) was the most common organism, followed by Klebsiella 25(13%), CoNs22(11%), Pseudomonas13(7%), CoPs11(6%), Enterococcus12(6%) Candida Sp. 6(3%) and Proteus Sp. 3(2%). **Conclusion:** There is a need for constant monitoring of susceptibility of specific pathogens in different populations to commonly used anti-microbial agents.

KEYWORDS: Urinary tract infection, Antibiotic Susceptibility Pattern, Uropathogenes.

INTRODUCTION

Urinary tract infection (UTI) is an important health-care problem affecting millions every year in the community and tertiary care settings. It is a term applied to a variety of clinical conditions ranging from asymptomatic presence of bacteria in the urine to severe of the kidney with sepsis.[1]

A count of $>10^5$ colony forming units (CFU)/mL of urine is considered as significant bacteriuria.[2] Etiological agents of UTI are variable and usually depend on time, geographical location and age of patients.[3] Most UTIs are caused by Gram-negative bacteria like Escherichia coli (E. coli), Klebsiella spp., Proteus mirabilis, Pseudomonas aeruginosa, Acinetobacter spp., and Serratia spp. and Gram-positive bacteria such as Enterococcus spp. and Staphylococcus spp[3]. E. coli is the single most common pathogen accounting for 70-75% of all cases of UTI.[2]

The antimicrobial agents used in treatment of UTI include cell wall inhibitors like Penicillin, Cephalosporins, DNA gyrase inhibitors like Floroquinolones and Aminoglycosides that are protein synthesis inhibitors. Inappropriate and extensive use of antibiotics has lead to the development of multidrug resistance among the pathogens. To ensure appropriate treatment, knowledge of the organisms that cause UTI and their antibiotic susceptibility pattern is mandatory.

MATERIAL AND METHOD

The study was conducted in a tertiary care hospital, Rajsamand, Rajasthan. All positive urine culture and sensitivity reports of males and females over a period of one year were included in the study. Urine culture and sensitivity reports with more than one causative organism were excluded from the study Sample size. The organism isolated and the antimicrobial susceptibility profiles were collected from the registration records using a standard data collection form.

Culture and Identification

As per the standard operating procedures, clean-catch midstream morning urine specimen were collected under

sterile conditions in a sterile wide mouth container. All samples were completely processed within 1–2 h after arrival, to avoid overgrowth of any contaminating bacteria. Urine samples were plated on Nutrient agar, Blood agar and MacConkey agar using calibrated wire loops and then incubated aerobically at 37 °C for 24 h. From positive cultures, uropathogens were identified based on biochemical reaction.[4]

Antimicrobial susceptibility tests

According to the standard operational procedures, antimicrobial susceptibility tests were done on Mueller-Hinton agar (Oxoid, Hampshire, England) using Kirby-Bauer disk diffusion method[8] antimicrobial agents of variable strength. Resistance data were interpreted according to Clinical laboratory Standards Institute. Reference strains of E. coli ATCC 25922 and Staphylococcus aureus ATCC 25923 (S. aureus) were used for quality control for antimicrobial susceptibility tests.[9] Statistical Analysis: Data entry was done using Microsoft Excel and the data was analysed using SPSS 16.

RESULTS

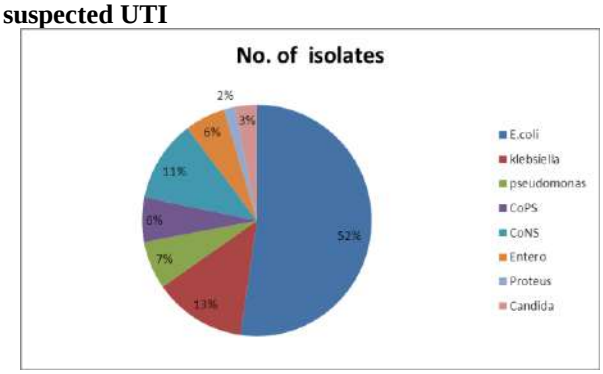
A total of 600 samples were taken during a period of 2015 -2016, out of which 193 were culture positive cases. The identification of bacteria and culture and sensitivity was carried out for the same. Out of 193 cases, males were 74 (38%) and females were 119(62%) and more common in 21-40 age group. The number of organisms isolated from females subjects were more than males (Table 1). E. coli 101(52 %) was the most common organism, followed by Klebsiella 25(13%), CoNs 22(11%), Pseudomonas 13(7%), CoPS 11(6%), Enterococcus 12(6%) Candida Sp. 6(3%) and Proteus Sp.3(2%). Sex-wise distribution of UTI by organism, Out of 74 males E. coli was isolated from 34 and Klebsiella 14 and out of 119 females E. coli was isolated from 65 and Klebsiella 11.E.coli (52%) , followed by Klebsiella (13%) were the commonest in both sexes (Table 4).The antibiotic susceptibility profile of gram negative organisms showed that E.coli and klebsiella were highly susceptible (100%) to imipenem followed by Nitrofurantoin, Amikacin, Piperacillin tazobactum, Ceftazidime/clavulanic acid while its resistance profile showed that they were more resistant to sulphamethoxazoles followed by amoxclav, ampicillin sulbactum, cephalosporins, and ceftriaxone. Staphylococcus aureus and Enterococcus were highly sensitive to Nitrofurantoin followed by Vancomycin, Linezolid, Gentamicin, Ciprofloxacin, Levofloxacin, Cotrimoxazole and Cephalosporins.

Table 1: Age and Sex distribution of patients with suspected UTI.

Age Group	Male	Female	Total
0-20	10	15	25
21-40	20	55	75
41-60	16	33	49
61-80	26	14	40
81-100	02	02	04
Total	74(38%)	119(62%)	193

Out of total 600 urine culture, 193 cases were culture Positive and sensitivity was also carried out for the same. Out of 193 cases, males were 74 (38%) and females were 119(62%) and more common in 21-40 age group. (Table.1).

Bacterial isolates from urine sample of patients with suspected UTI



E. coli 101(52 %) was the most common organism, followed by Klebsiella 25(13%), CoNs22(11%), Pseudomonas 13(7%), CoPs11(6%), Enterococcus 12(6%) Candida Sp. 6(3%) and Proteus Sp. 3(2%).

Table 2: Age- Sex distribution of patients with suspected UTI according to type of uropathogen.

Organisms	0-20		21-40		41-60		61-80		81-100		Total (n=193)
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	
E.coli	4	9	8	26	9	20	15	9	-	1	101
Klebsiella	3	2	3	4	4	4	4	1	-	-	25
Pseudomonas	1	-	2	4	-	3	1	1	1	-	13
Proteus sp.	-	-	-	-	-	-	1	2	-	-	3
Cons	-	4	2	9	2	2	2	1	-	-	22
Cops	-	-	-	9	-	1	2	-	-	-	12
Enterococcus	2	-	4	3	-	1	-	-	1	-	11
Candida	-	-	1	-	1	2	1	-	-	1	6

According to Age-Sex distribution of Patients, Out of 74 males E. coli was isolated from 34 and Klebsiella 14 and out of 119 females E. coli was isolated from 65 and Klebsiella 11.(Table 2).

Table 3: Resistant pattern of Antibiotic in bacterial isolates from patients with suspected UTI.

Organisms	E.coli (n=101)	Klebsiella (n=(25)	Pseudo monas (n=13)	Proteus sp. (n=3)	Cons (n=22)	Cops (n=12)	Entero Coccus (n=11)
Amikacin/ Gentamycin	12 (12%)	06(24%)	03(23%)	01(33%)	NA	01(8%)	0
Cefuroxime	80(79%)	22(88%)	11(85%)	03(100%)	12(54%)	05(42%)	11(100%)
Ceftizoxime	71(70%)	20(80%)	10(77%)	02(67%)	15(68%)	05(42%)	11(100%)
Ceftriaxone	70(69%)	19(76%)	10(77%)	02(67%)	10(45%)	05(42%)	11(100%)
Ceftazidime + clavulanic acid	33(33%)	11(44%)	05(38%)	01(33%)	NA	NA	NA
Cefoperazone + sulbactam	22(22%)	11(44%)	04(30%)	01(33%)	NA	NA	NA
Cefixime	75(74%)	22(88%)	13(100%)	02(67%)	17(77%)	05(42%)	11(100%)
Vancomycin	NA	NA	NA	NA	0	0	0
Azithromycin	NA	NA	NA	NA	13(33%)	04(33%)	09(81%)
Amoxycillin + clavulanic acid	84(83%)	22(88%)	13(100%)	03(100%)	10(45%)	05(42%)	07(63%)
Ampicillin + Sulbactam	73(72%)	18(72%)	13(100%)	03(100%)	08(36%)	05(42%)	07(63%)
Piperacillin + tazobactam	18(18%)	07(28%)	05(38%)	01(33%)	NA	NA	NA
Ciprofloxacin	63(62%)	14(56%)	07(54%)	01(33%)	08(36%)	01(8%)	08(73%)
Levofloxacin	51(50 %)	13(52%)	07(54%)	01(33%)	07(32%)	0	08(73%)
Co trimoxazole	78(77%)	17(68%)	13(100%)	03(100%)	13(33%)	04(33%)	08(73%)
Linezolid	NA	NA	NA	NA	0	0	0
Aztreonam	61(60%)	19(76%)	10(77%)	02(67%)	NA	NA	NA
Imipenam	02(2%)	0	0	0	NA	NA	NA
Meropenam	02(2%)	0	0	0	NA	NA	NA
Nitrofurantoin	04(4%)	06(24%)	13(100%)	03(100%)	03(14%)	0	01(9%)
Clindamycin	NA	NA	NA	NA	11(50%)	0	NA

The overall susceptibility profiles of bacterial isolates are shown in Table 3. Amongst gram negative bacilli, amox-clav and cefuroxime had the highest overall resistance followed by Ampicillin -Sulbactam, Cefixime, Ceftizoxime, Co trimoxazole whereas other drugs showed sensitive pattern. Cephalosporins were most resistant drugs in gram positive bacilli followed by amox-clav, Azithromycin, Ampicillin- Sulbactam, Co trimoxazole, Ciprofloxacin, Levofloxacin, Clindamycin, Nitrofurantoin.

DISCUSSION

Urinary tract infection is huge burden on health care due to high prevalence of infection in both community and nosocomial settings. It is caused by variety of pathogens including *E. coli*, *K. pneumoniae* and *P. aeruginosa*. Continuous surveillance of antibiotic susceptibility patterns of uropathogens at local level is crucial in dealing with emerging problems of antibiotic resistance and provides assistance in managing effective initial therapy.[4] In present study, the prevalence of UTI in females is higher than the males which is attributed to factors like close proximity of the uretheral meatus to the anus, shorter urethra. This finding is consistent with other studies done by Jubina Bency et al Prakasam A., K.C et al and Azra S. Akram T et al. There was significant growth of E.Coli, Klebsiella, Enterococci, Staphylococcus and Pseudomonas. Ecoli & Klebsiella infections were most common organisms similar to Jubina Bency et al. *Enterococcus* was sensitive to Vancomycin & Linezolid. *Staphylococcus* was sensitive to Vancomycin.[6] The pattern of antimicrobial resistance of the micro-organisms causing UTIs vary in their susceptibility to antimicrobials from place to place and from time to time. World wide data shows that there is an increasing resistance among UTI pathogens to convential drugs. Resistance has emerged even to newer more potent antimicrobial agents.

E.coli(52 %) was the most common organism, followed by Klebsiella(13%), CoNs(11%), Pseudomonas(7%), CoPs(6%), Enterococcus(6%) Candida Sp. (3%) and Proteus Sp.(2%). This finding patterns were similar with the study of Savitha like E.coli(48.04%), Klebsiella species(8.82%) and Proteus spp.(4.90%).

It has been observed that there is slow but persistent decrease in the sensitivity of gram negative and gram positive bacteria to some quinolones derivative, Ampicillin and Sulphonamides which is alarming because these antibiotics have been one of the best options for treatment of UTI in both outdoor patients and hospitalized patients. Other factors which may influence

the sensitivity of urinary pathogens includes, routes of administration, dosage schedule, choice of antibiotic, misuse of antibiotic and condition of patients and self-medication.[7]

CONCLUSION

In this study, higher prevalence rates of urinary bacterial isolates are observed in females the most commonly found organisms were *E. coli* and *Klebsiella*. There is an emerging resistance of commonly isolated bacteria to routinely used antibiotics, which can be ascribed to inappropriate antibiotic administration. Important infecting organisms are found to be the commensals of perianal and vaginal regions, emphasizing a need to have proper hygienic practices.

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Original Research Article

Spectrum of aerobic bacteria and their antimicrobial pattern in blood stream infections of hospitalised patients: a retrospective study

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ABSTRACT

Background: Bacteria associated with blood stream infections are an important public health problem which results in morbidity and mortality globally. Emergence of multidrug resistant isolates in hospitalized patients is a major problem. Automation techniques play a major role in early identification of the isolate and its drug susceptibility testing which is important for better outcome of the treatment. This study was aimed to detect the blood stream isolates and their drug susceptibility pattern in hospitalized patients.
Methods: This was a retrospective study conducted from 377 records of automated blood culture (bact/alert) and drug susceptibility testing (vitek) results. Positive blood culture bottles were sub cultured to different culture media and the isolates were identified and screened for drug susceptibility testing on Vitek II.
Results: Around 20.68% of samples were positive for blood stream infections caused by different pathogens. A total of 78 microorganisms were isolated from 377 samples. Among which gram negative bacilli was observed in 52.56%, gram positive cocci in 44.87% and yeast in 2.56% samples. Coagulase negative *staphylococci* and *Klebsiella pneumoniae* were the predominant isolates of the study.
Conclusions: Early diagnosis of blood stream infections in hospitalized patients is life saving. Hence a continuous monitoring of isolates and their drug susceptibility is the need of the day.

Keywords: Blood stream infections, Coagulase negative *staphylococcus, Klebsiella pneumoniae*

INTRODUCTION

Blood stream infection (BSI) remains one of the foremost important causes of morbidity and mortality globally. The infection may range from self limiting to life threatening sepsis.[1,2] As case fatality rate is high it requires appropriate and immediate antimicrobial therapy. Different bacteria were associated with (BSI) from time to time at different geographical areas. These bacteria play an important role in causing mortality, increasing the length of hospital stay and also the health care cost.[3]

Drug resistance of these bacteria is an important issue of public health concern. Since many studies have reported that gram negative and gram positive bacteria are associates with these infections which are often drug resistant. Empirical antibiotic therapy is initiated in almost all cases before the blood culture reports are available. Choice of right empirical therapy is important. An early blood culture report may help in selection of appropriate antibiotics.[2,4]

Minimal time is required to get a blood culture report using automated systems. The etiology and antimicrobial pattern of (BSI) may vary at different times in the same region hence a continuous update is essential for epidemiological purpose and also for rational and accurate use of antibiotics by clinicians. The present

study aimed to determine the etiology and antibiotic resistance pattern in blood stream infections.

METHODS

Study design

A retrospective study was conducted from the records of automated blood culture (bact alert) and drug susceptibility testing (vitek) results in the clinical microbiology laboratory from June, 2016 to July, 2018 at Ananta institute of medical sciences and research centre, Rajsamand. This data includes 377 records of hospitalised patients who were admitted to different units of hospital during the study period.

Sampling technique and data collection

Blood cultures were performed for different age groups up to 90 years. Samples were collected by phlebotomist from the patients after disinfection of vein puncture site with 70% alcohol. 3-4ml of blood was inoculated in 30ml BacT/Alert blood culture bottles for paediatrics and 4-5ml blood was inoculated in 30ml BacT/Alert blood culture bottles for adults. These bottles were incubated in BacT/Alert automated system. The bottles which showed positive signal for growth were removed from the automated system and subculture was done on Nutrient agar, blood agar and MacConkey's agar. Smears from the colony of different agar plates were prepared and stained with Gram stain to identify the growth (i.e. gram positive or gram negative bacteria). Then the growth of the bacteria was run on VITEK II automated system for identification of the organism and Antibiotic Sensitivity. If there is no growth of bacteria within five days of inoculation of blood sample into BacT/Alert blood culture bottle then the sample is considered to be negative.

Data regarding the age, sex, isolate and its antimicrobial pattern was collected and statistical analysis of the data was done by Chi square test to study the P value using social science statistics online software.

RESULTS

A total of 377 samples were screened for blood culture from hospitalized patients of different units. 20.68% of samples were positive for blood stream infections caused by different pathogens (Table 1).

A total of 78 microorganisms were isolated from 377 samples. Among which gram negative bacilli was observed in 52.56%, gram positive cocci in 44.87% and yeast in 2.56% samples. The leading isolate among the gram positive cocci were CONS (coagulase negative *staphylococci*) and among the gram negative bacilli, *Klebsiella pneumoniae*. Details of each isolate were mentioned in Table 1. Only two samples were found to be positive for yeast i.e. *Candida tropicalis*.

Table 1: Bacteria and yeast isolated from blood culture samples.

	Isolate	Positive %
Gram negative bacilli (A)	*Acinetobacter baumannii*	4 (9.75%)
	Acinetobacter iwoffii	1 (2.44%)
	Burkholderia cepaciae	1 (2.44%)
	Escherichia coli	10 (24.39%)
	Enterobacter cloacae Complex	2 (4.87%)
	Klebsiella pneumoniae	17 (41.46%)
	Pseudomonas aeruginosa	3 (7.31%)
	Spingomonas paucimobilis	1 (2.44%)
	Stenotrophomonas maltophilia	1 (2.44%)
	Serratia marcescenes	1 (2.44%)
Total		41 (100%)
Gram positive cocci (B)	*Staphylococcus aureus*	3 (8.57%)
	Staphylococcus cohnii#	2 (5.71%)
	Staphylococcus epidermidis#	6 (17.14%)
	Staphylococcus haemolyticus#	4 (11.48%)
	Staphylococcus hominis#	3 (8.57%)
	Staphylococcus lentus#	2 (5.71%)
	Staphylococcus pseudintermedius#	2 (5.71%)
	Enterococcus faecalis	3 (8.57%)
	CONS	10 (28.57%)
Total		35 (100%)
Yeast (C)	*Candida tropicalis*	2(100%)
Total (A+B+C)		78/377* (20.68%)

*Total number of samples tested, CONS-coagulase negative *staphylococcus*, # CONS

Isolates were predominant in males (62.82%) as compared to females (37.18%) (Table 2). Paediatric patients were more (31.57%) exposed to BSI than adult and elderly patients (23.52%). Statistical analysis showed a P value of 0.03. CONS were the leading pathogens in paediatric patients. *Klebsiella pneumoniae* was the leading pathogen among the adult and elderly patients. 83.3% (65) of samples were culture positive in <24hours, 15.4% (12) in between 24 <48hours, 1.3% (1) between 48-72hours.

Table 2: Sex wise and age wise distribution of positive and negative blood culture samples.

Variable	Blood culture result			P value
	Positive	Negative	Total	
Male	49	191	240	X^2=0.03 P=0.86
Female	29	108	137	
Age				
<5 years	25	58	83	X^2=6.88 P=0.03
5 <15 year	5	37	42	
>15 years	48	204	252	

Among the gram-negative isolates, *Escherichia coli* showed 100% sensitivity to colistin and tigecycline, 80% to ertapenem. *Acinetobacter* species showed 80% sensitivity to colistin and 70% to amikacin. *Enterobacter cloacae* showed 100% sensitivity to tigecycline,

Klebsiella pneumoniae showed 100% sensitivity to colistin and 88.3% to tigecycline. *Pseudomonas aeruginosa* showed 66.7% sensitivity to colistin (Table 3). Among gram positive isolates, CONS showed 93.1% sensitivity to linezolid, 89.7% to tigecycline and 86.2% to vancomycin. *Staphylococcus aureus* showed 100% sensitivity to oxacillin, gentamicin, linezolid, vancomycin, tetracycline and tigecycline. E*nterococcus faecalis* showed 100% sensitivity to gentamicin, linezolid and vancomycin (Table 4).

Very low positivity 1 (2.44%) was observed for *Spingomonas paucimobilis, Stenotrophomonas maltophilia, Burkholderia cepaciae* and *Serratia marcescenes.*

Table 3: Antibiotic resistance of gram negative bacilli isolated from blood culture.

Antimicrobial agent	Resistance percentage of gram negative bacilli				
	***Eschericia coli* (n=10)**	***Acinetobacter species* (n=05)**	***Enterobacter cloacae* (n=02)**	***Klebsiella pneumoniae* (n=17)**	***Pseudomonas aeruginosa* (n=03)**
Ampicillin	100	100	NT	100	NT
Amoxicillin/clavulanate	80	100	100	94.1	NT
Piperacillin/tazobactam	80	80	100	94.1	66.6
Cefuroxime	100	100	100	100	NT
Cefuroxime axetil	100	100	100	100	NT
Ceftriaxone	100	80	100	100	NT
Cefaperazone/sulbactum	70	80	100	94.1	100
Ertapenem	20	NT	NT	NT	NT
Cefepime	70	80	100	100	100
Imipenem	50	70	100	35.3	66.6
Meropenem	60	70	100	58.8	66.6
Amikacin	30	30	100	88.2	66.6
Gentamicin	30	80	100	100	66.6
Nalidixic acid	80	80	100	82.3	NT
Ciprofloxacin	80	80	100	82.3	66.6
Tigecycline	0	60	0	11.7	100
Trimethoprim/ sulphamethoxazole	60	80	100	52.9	NT
Colistin	0	20	NT	0	33.3

NT - Not Tested

Table 4: Antibiotic resistance of gram-positive cocci isolated from blood culture.

Antimicrobial agent	Resistance percentage of gram-positive cocci		
	Cons* (n=29)	***Staphylococcus aureus* (n=03)**	***Enterococcus faecalis* (n=03)**
Benzylpenicillin	96.5	100	100
Oxacillin	82.7	0	100
Gentamicin	31.3	0	0
Ciprofloxacin	65.5	33.3	50
Levofloxacin	65.5	33.3	50
Erythromycon	89.6	66.6	100
Linezolid	6.9	0	0
Clindamycin	86.2	66.6	100
Tecoplanin	27.5	80	50
Vancomycin	13.8	0	0
Tetracycline	27.6	0	50
Tigecycline	10.3	0	100
Trimethoprim	51.7	66.6	50

DISCUSSION

The overall frequency of blood culture isolates in present study was (20.68%). This is comparable with studies conducted in India by Pal et al, 2016 (22.3%) and Gill et al, 2016 (24.8%).[5,4] However, some studies have reported high frequency of bacterial pathogens from blood cultures (24.2%-37.1%).[6,7] This may be due to use of different blood culture systems, different sample size, variations in study design and protocols, different geographical locations, variations in causative agents and the policies adopted for infection control between countries. Incidence of gram negative bacilli (GNB) was 52.56% and gram positive cocci (GPC) were 44.87%. Similar findings with high frequency of GNB as compared to GPC were previously reported by an Indian study.[8]

In our study, coagulase negative *staphylococcus* was the leading blood culture isolates (37.1%). Similar results were reported from India (61%) and globally (42%).[9,10] They often occur as skin contaminants during the collection of blood. Cross infections in ICU'S with multidrug resistant CONS can be prevented by use of appropriate antimicrobial agents. There is a need for differentiation between true pathogen and contaminant which can be achieved by correlating clinically the blood culture isolate and time taken for positivity of CONS.[11] Among the GPC group CONS showed high frequency of antimicrobial resistance as compared to others (Table 4). *Staphylococcus* aureus was 100% sensitivite to oxacillin, gentamicin, linezolid, vancomycin, tetracycline and tigecycline. Similarly, an earlier study reported 100% sensitivity to linezolid and vancomycin.[8]

Enterococcus faecalis was observed in (8.5%) of gram positive cocci. Similar findings (8.4%) were reported by an earlier Indian study.[11] It is a normal flora of female genitourinary tract and gastrointestinal tract. Though vancomycin resistance was reported since a decade, in the present study no resistance to vancomycin was observed for *Enterococcus faecalis*. This may be due to differences in the circulating strains. However, an earlier study from north India reported 23% of vancomycin rersistant enterococci.[11]

Gram negative bacteria accounted for more than fifty percent among the total isolates of the blood culture. This is consistent with an earlier study, though there is difference in the range of isolates.[1] Among the non fermenters, *Acinetobacter* species and *psuedomonas aeruginosa* showed high level resistance to cephalosporins and carbapenems. There is increase in the trend of carbapenem resistance to *Acinetobacter* species.[11] This may be because of extensive use of these antimicrobials. The overall antimicrobial resistance of gram negative bacteria and gram positive bacteria varied from 0% to 100% in our study. This is different when compared to a previous study which reported a higher resistance in gram negative bacteria (20-100%) as compared to gram positive bacteria (23.5%-58.8%).[12] Among the *Klebsiella pneumoniae* isolates high level sensitivity was shown by colistin 100% followed by tigecycline 88.3%, imipenem 64.7% and meropenem 41.2%. Singh et al, 2014 reported 100% and 71.4% sensitivity for imipenem and meropenem respectively each.[8] *Eschericia coli* showed high level sensitivity to colistin and tigecycline 100%, followed by ertapenem 80%, amikacin and gentamicin 70%. The sensitivity of gentamicin in our study was much higher as compared to an earlier Indian study 35%.[13]

Differences in antimicrobial resistant pattern in different studies may be due to circulation of different strains in different regions at different times.

Among the yeast isolates *Candida tropicalis* was isolated in two blood culture samples. Both the isolates were 100% sensitive to fluconozole, voriconazole, caspofungi, micafungin, amphotericin-B, and flucytosin. However, studies from different parts of India reported the emergence of *nonalbicans Candida* and resistant to widely used antifungal agents.[14,15]

CONCLUSION

Coagulase negative *staphylococcus* and *Klebsiella pneumoniae* were the predominant isolates of the study. High level multidrug resistance was observed in both GPC and GNB. Tigecycline and colistin remains the choice of antibiotics for gram-negative bacilli. Gentamicin, linezolid, vancomycin and tigecycline are the choice of antibiotics for gram positive cocci. Good antibiotic policy and strict hospital infection control measures may help to curb the emergence of multidrug resistant pathogens. There is a need for continuous monitoring and updating the BSI isolates and their antimicrobial patterns for an early effective approach to treatment.

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Phenotypic Screening for Asymptomatic Rectal Colonization by Resistant *Enterobacteriaceae* and Nasal MRSA Colonization in Critical Care Patients

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A B S T R A C T

Critical care populations are at high risk for Multi drug resistant organisms (MDRO) colonization because of rampant use of broad-spectrum antibiotics leading to colonization with resistant strains, Screening for MDR organisms is one of the many approaches needed to deal with the very major clinical problem concerning drug resistance. This study was planned to look for antibiotic resistance by simple phenotypic methods to detect Resistant *Enterobacteriaceae* include broad spectrum β-lactamase producing *Enterobacteriaceae* (ESBL and AmpC β-lactamases) and carbapenem-resistant *Enterobacteriaceae* (CRE)and or combinations of any in one go and nasal screening for Methicillin Resistant Staphylococcus Aureus (MRSA). Total of 110 patients admitted intensive care unit were screened by taking rectal and nasal swab over period of year. In our study 234-gram negative bacilli were isolated from 110 rectal swabs among those were 54(23.7%) ESBL, 22(9.4%) Amp C, and 30 (12.8%) isolates were carbapenem resistant which includes 21(8.9%) isolates were cabapenemase producer by MHT and MBL screen and 9(2.64%) isolates were carbapenemase +Amp C+ESBL combined producers. Nasal MRSA carriage rate was 8%. Present study emphasis the need for strong infection control programs to detect colonization of gut and other anatomical site by multidrug resistant organisms. Need to reduce overuse of antibiotics and establish good antibiotic stewardship programs and implementation of screening in intensive care unit.

Introduction

Human body commensal flora is a diverse ecosystem which is inhabited by aplethora of bacteria (Qin *et al.*, 2010). The healthy microbiota provides protective functions including ability to prevent colonization and or expansion of pathogens. Changes in the composition of the gut flora, may reduce colonization resistance and select for antibiotic resistance and which can happen silently, leading to the selection of highly resistant bacteria. An increase in gut permeability allows Bacterial translocation that is the invasion of indigenous intestinal bacteria through the gut mucosa to normally sterile tissues and the internal organs. (Vaishnavi, 2013) Endotoxins and other toxins can also cross the gut barrier. Bacteremia and endo-toxinaemia are among the mechanisms involved in severe sepsis and multiple organ failure (Arrieta *et al.*, 2006).

MDROs are defined as microorganisms, predominantly bacteria, that are resistant to one or more classes of antimicrobial agents. Critical care populations considered at high risk for Multi drug resistant organisms (MDRO) colonization based on factors such as antibiotic exposure history, presence of underlying diseases, prolonged duration of stay, exposure to other MDRO colonized patients, patients transferred from other facilities known to have a high prevalence of MDRO carriage, or having a history of recent hospital or nursing home stays so thereby induce healthcare-associated infections, undergo cross-transmission to other individuals, and cause limited outbreaks (MDROGuidelines2012 & MRGN guidelines 2016)

Staphylococcus aureus is a member of commensal micro flora and readily colonizes the anterior nares. Nasal carriage of S.aureus act as endogenous reservoir for clinical infections in colonized individuals or as a source of cross colonization for community spread (Kashmir *et al.*, 2014)

Screening for Multi-resistant Gram-negative bacilli (MRGN) organisms by a sensitive, specific and cost effective screening test may help the clinicians in the choice of appropriate antimicrobial therapy, provide baseline data about the epidemiology of MDR pathogen, to guide policy recommendations and help in infection control by early identification of patients, thereby facilitating an informed decision about infection control interventions These interventions may include notification to the concerned clinical and nursing team, infection control precautions such as isolation or cohort nursing of such patients, use of decolonization regimens, use of antibacterial prophylaxis during surgery or other invasive interventions of use of an appropriate agent for empirical antibiotic therapy in case of unconfirmed infection in a colonized patient (Bhattacharya 2011 & Deepa *et al.*, 2014). This study was planned to look for antibiotic resistance by simple phenotypic methods to detect Resistant.Multi-resistant Gram-negative bacilli include broad spectrum β-lactamase producing *Enterobacteriaceae* (ESBL and AmpC β-lactamases) and carbapenem-resistant Enterobacteriaceae (CRE)and or combinations of any in one go and nasal screening for Methicillin Resistant Staphylococcus Aureus(MRSA).

Materials and Methods

The present observational study was carried out in the Department of Microbiologyin tertiary care hospital.

Inclusion criteria

Patients admitted to intensive care unit with factors such as antibiotic exposure history, presence of underlying diseases, prolonged duration of stay, exposure to other MDRO colonized patients, or having a history of recent hospital or nursing home stays.

Exclusion criteria

Patients should not be a health worker, should not have any history of immuno-compromised status and patients who are not receiving antimicrobials.

Sample collection

2 Nasal swabs and 1 Rectal swab were collected from each patient admitted to intensive care unit.

Nasal swabs were taken by swirled while applying even pressure inside anterior nares with a sterile cotton swab (16). Rectal samples were collected in the sterile swab by inserting the swab 1cm into the rectum while rotating the swab. Rectal swabs are an appropriate

alternative to stool specimens (Lerner *et al.,* 2013). Total transit time to the laboratory was within 30 minutes. Samples were processed as per the standard protocols (Deepa *et al.,* 2014 & Lerner *et al.,* 2013)

All isolates of staphylococcus aureus from nasal swabs were processed routinely and tested with 30 mg cefoxitin discs (Hi-Media) on Mueller–Hinton agar plates by disk diffusion methodfor MRSA detection ((M100 27th edition 2017),16,17).

Resistant *Enterobacteriaceae* isolates to one or more classes of antimicrobial agents, resistant to third generation cephalosporins, resistant toeither of the carbapenems namely Imipenem, Ertapenem or Meropenem were selected for study. All the selected gram negative Enterobacteriaceae were tested by disc placement method (Deepa *et al.,* 2014, Neena *et al.,* 2012 & Shamsadh Begum *et al.,* 2015).

The lawn culture of test organismwas made on Muller–Hinton agar (MHA) as done for discdiffusion antimicrobial susceptibility test. In the center ofthe plate, imipenem (10 µg) (Inducer) disc was applied. At Antimicrobial susceptibility: the distance of 20 mm, the disc of cefotaxime (30 µg) was placed. From this disc, in a circular manner, clockwise, the discs of cefoxitin (30 µg) (Inducer), ceftriaxone (30 µg), ceftazidime (30 µg), ceftazidime + clavulinic acid (30/10µg), and aztreonam (30 µg) were placed such that any two adjacent discs were 20 mm apart from center to center (Figure 1). On overnight aerobic incubation at 37°C, the diameters of zones of inhibition were measured and interpreted as follows:

Extended-spectrum b-lactamase (Figure 2)

Zone diameter for aztreonam ≤27 mm, cefotaxime≤27 mm, ceftazidime ≤22 mm, and ceftriaxone ≤25 mm.

Susceptible to cefoxitin.

Increase in zone size with addition of inhibitor (ceftazidime+ clavulanic acid) by 5 mm or more.

AmpC b-lactamase (Figure 3)

Inducible

The blunting of zone of inhibition of Ceftazidime discs toward inducers

No increase of zone size with addition of inhibitor

Depressed mutants (DM)

Resistant to cefoxitin (≤ 14 mm) and cefotaxime

No increase of zone size with addition of inhibitor

Metalloβ-lactamases

Strains showing resistance to imipenem.

Multiple mechanisms

Resistant to cefoxitin

Blunting of zone toward inducer

Increase of zone size with addition of inhibitor by 5 mmor more.

The isolates showing resistance either of Carbapenemswere further analyzed as Carbapenem resistance in Gram-negative rods is mainly due to two mechanisms: first the production of carbapenem-hydrolyzing enzymes (i.e. serine carbapenemases and metallo-β-lactamases, and second the combination of membrane impermeability with production of ESBLs, pAmpC or ampC

overexpression (MDROGuidelines 2012). Double disc potentiation test (Figure 6) and Modified Hodge test (Figure 5) (Neena *et al.,* 2012; Shamsadh Begum *et al.,* 2015) was done on those carbapenem resistant isolates.

Modified Hodge test (Lee *et al.,* 2001 and Yong, *et al.,* 2002)

An overnight culture suspension of E. coli ATCC 25922 adjusted to 0.5 McFarland standard was inoculated using a sterile cotton swab on the surface of a MHA. After drying 10 µg imipenem disc was placed at the center of the plate and the test strain was streaked heavily from the edge of the disc to the periphery of the plate. The plate was incubated overnight at 37°C. Indentation produced in the zone of inhibition produced by the imipenem indicates a positive test. Maximum four strains can be tested at a time (all four directions) which gives a presence of a "cloverleaf shaped" zone of inhibition if all four test strains are positive for MBL production

Double disc potentiation test (Lee *et al.,* 2001 & Yong, *et al.,* 2002)

A 0.5 M EDTA solution was prepared by dissolving 186.1 g of disodium EDTA. (REACHEM, Chennai, India) in1000 ml of distilled water. The pH was adjusted to 8.0 by using NaOH (HI-MEDIA) and was sterilized by autoclaving.

An overnight liquid culture of the test isolate was adjusted to a turbidity of 0.5 McFarland standard and spread on the surface of a MHA plate. Two 10 µg imipenem discs were placed on the agar 15 mm apart (center to center). 10 µl of0.5 M EDTA is added to one of the imipenem disc to get a desired concentration of 750 µg. After incubating overnight at 37°C, the presence of an expanded growth inhibition zone between the two discs or increase of zone size of more than 7 mm in the disc potentiated with the EDTA (chelating agents) was interpreted as positive for MBL production

All the tests and their interpretations were according to the CLSIGuidelines (M100 27th edition 2017) and well-accepted methods by various authorities. (Lerner A *et al.,* 2013, Rodrigues C *et al.,* 2004, Neena V *et al.,* 2012 & Shamsadh Begum *et al.,* 2015)] the identity of the isolates and resistance pattern was further confirmed by using Vitek 2 GN ID (BioMerieux, France) with appropriate quality control.

Results and Discussion

Total of 110 patients admitted intensive care unit were screened over period of year.110 nasal swabs yielded 117 isolates most common being methicillin sensitive coagulase negative staphylococcus(MSCONS)42.7%, methicillin resistant coagulase negative staphylococcus (MRCONS) 34.18%, methicillin resistant coagulase positive staphylococcus(MRSA)8%, methicillin sensitive coagulase positive staphylococcus (MSSA) 10.25%. Nasal swab also yielded Serratia, Pseudomonas aeruginosa, Escherichia coli in five critically ill patients (Table 1).

110 rectal swabs yielded 234 isolates Resistant isolates toone or more classes of antimicrobial agents to third generation cephalosporins, either of the Carbapenems namely Imipenem, Ertapenem or Meropenem or Cefoxitin by disk diffusion method were selected for the study. Of the 234 isolates from rectal swab 112 isolates were multi drug resistant (Table 2). Among 125 (53.41%) isolates of Escherichia coli showed 68% were multi drug resistant.50 (1.47%) *Klebsiella spp.* showed 86% multi drug resistant. Only 7 of Enterobacter species were isolated but resistance rate was high as71%. There were few isolates of Citrobacter species, Proteus species.

Table.1 Isolates from nasal samples

Organisms	No of isolates.
MRCONS	40(34.18%)
MSCONS	50(42.7%)
MRSA	10(8%)
MSSA	12(10.25%)
Serratia maracescence	1(0.008%)
Pseudomonas aeruginosa.	2(0.017%)
Escherichia coli.	2(0.017%)
Total	117

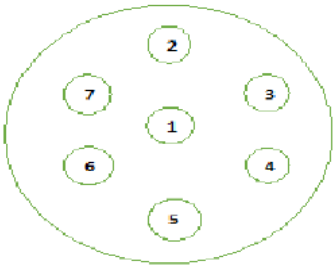
Table.2 Isolates from rectal swabs

Organisms	No of isolates.	MDRO
Escherichia coli	125 (53.41%)	85(68%)
Klebsiella spp.	50 (1.47%)	43(86%)
Citrobacter	09 (0.03%)	6(66%)
Proteus species.	12 (0.05%)	5(41%)
Enterobacter	07 (0.02%)	5(71%)
Enterococcus species	20 (0.085%)	2(10%)
Candida species	11 (0.32%)	--
Total	234	146(62%)

Table.3 Distribution of various types of -β lactamases in Family Enterobacteriaceae

Organisms	ESBL positive	MHT positive	MBL positive	Both MHT& MBL positive	Amp C positive	Carbapenemase+ Amp C+ESBL β Lactamases.	Total
Escherichia coli(n=125)	**25(20%)**	**8(6.4%)**	**5(4%)**	**5(4%)**	**15(12%)**	**5(4%)**	**63(50.4%)**
Klebsiella pneumoniae(n=50)	**20(40%)**	**6(12%)**	**3(6%)**	**2(4%)**	**7(14%)**	**3(6%)**	**41(82%)**
Enterobacter species (n=07)	**3(42%)**	**1(14%)**	**-**	**-**		**1(14%)**	**5(71%)**
Citrobacter freundii (n=09)	**4(44%)**	**1(11%)**	**-**	**-**	**-**	**-**	**5(55.5%)**
Proteus species. (n=12)	**2(16.6%)**	**-**	**-**	**-**	**-**	**-**	**2(16.6%)**
Total -203	**54(23.7%)**	**16(6.8%)**	**8(3.4%)**	**7(2.9%)**	**22(9.4%)**	**9(2.64%)**	**112(47.8%)**

Fig.1 Novel disk placement method



1. Imipenem, 2. Cefotaxime, 3. Cefoxitin, 4. Ceftriaxone
5. Ceftazidime –clavulanic acid, 6. Ceftazidime, 7. Azetrionam

Fig.2 ESBL producer

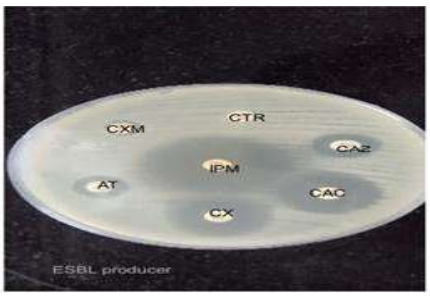


Fig.3 AMP c*b-lactamase* producer

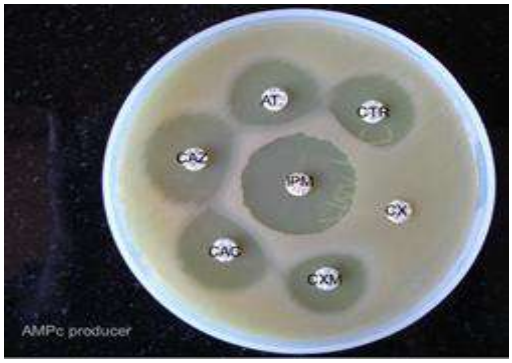


Fig.4 ESBL and AMPc producer

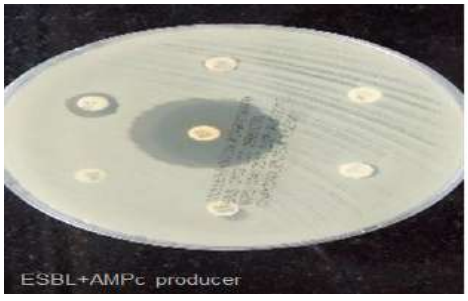


Fig.5 ESBL+ AMPc + carbapenemase producer

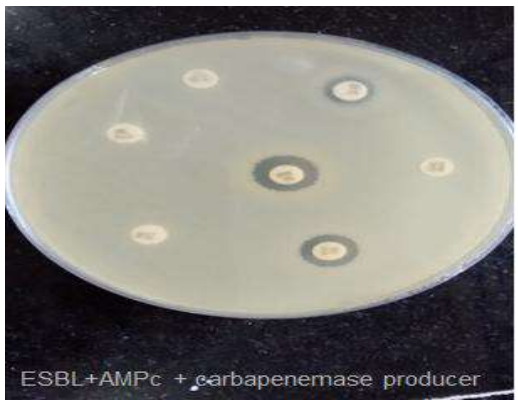
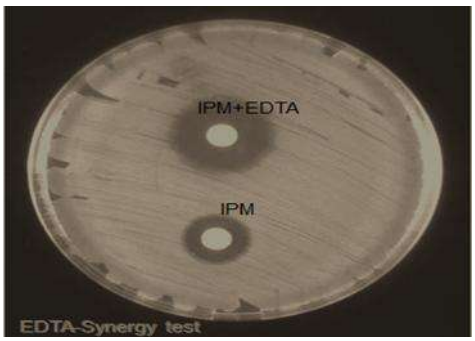


Fig.6 Modified HODGE test

Fig.7 Double disc potentiation test



Enterococcus species and Candida species *as a* rectal colonizer. 54(28.7%) isolates ESBL producing *Enterobacteriaceae,* 31(13.1%) isolates were cabapenemase producer 9(2.64%) isolates were cabapenemase +Amp C+ESBL combined producers (Table 3). Beta-lactamases also known as penicillinase are enzymes produced bacteria that provide multi resistance to β-lactam antibiotics such as penicilins cephalosporins, cephamycins, and carbapenems**.** Bacterial translocation of such multi resistant organism may be a normal phenomenon occurring on frequent basis in healthy individuals without any deleterious consequences. But when the immune system is challenged extensively, it

breaks down and results in septic complications at different sites away from the main focus. Cross transmission of the resistant strains can occur relatively easily if strong hygiene measures are not taken.

In our study 234-gram negative bacilli were isolated from 110 rectal swabs among them 146 were multi drug resistant gram-negative bacilli, among those 112(47.8%) were-β lactamases producers 54(23.7%) ESBL, 22(9.4%) Amp C, and 31(13.1%) isolates were cabapenemase producer by MHT and MBL screen and 9(2.64%) isolates were cabapenemase + Amp C + ESBL combined producers. Shamshad begum Esak *et al.,* 2015; Deshmukh *et al.,* 2011; Shanmugan *et al.,* 2013 Priya Data *et al.,* 2012; Gupta *et al.,* 2006have reported varying resistance rates of carbapenem in Enterobacteriaceae ranging from 5,75% to 51 %. Similar study by Deepa *et al.,* 2014 showed 42.8% isolates were cabapenemase producer from gut asymptomatic colonization.

In present study nasal MRSA carriage rate was8%as compared to study by Eddie Chi Man Leung *et al.,* (2013) it was 1.38%, 14% in study by A Kohlenberg *et al.,* (2011). Screening for asymptomatic MDRO colonization will reduced the prevalence of MDRO among hospitalized patients by using a variety of combined interventions like improvements in hand hygiene, use of Contact Precautions until patients are culture-negative for a target MDRO, active surveillance cultures (ASC), education, enhanced environmental cleaning, and improvements in communication about patients with MDROs within and between healthcare facilities. However, screening patients who were not receiving antimicrobials had a minimal beneficial impact. There are few limitations in the study that we screened only nasal and gut Enterobacteriaceae colonization, need to include other anatomical sites from other wards like long term care facilities and conduct larger epidemiological study.

Present study emphasis the need for strong infection control programs to detect colonization of gut and other anatomical site by multidrug resistant organisms. Need to reduce overuse of Antibiotics and establish good antibiotic stewardship programs. Implementation of screening in intensive care unit could reduce the MDRO transmission.

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Secular Trend of Antibiotic Resistance in Blood Stream Infections-A retrospective Analysis

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A B S T R A C T

Bloodstream infections (BSIs) are among the most serious infections acquired by hospitalized patients requiring intensive care. The existence of a pathogen population with an ever-increasing resistance to antibiotics has complicated the clinical problems. This retrospective study was undertaken with a view to compile and analyse the common isolates of BSIs along with resistance pattern in a tertiary care teaching hospital. Retrospective study was conducted to identify the microbial profile in the blood culture isolates and their antibiotic susceptibility patterns in a tertiary care teaching hospital. The reports of specimens submitted for blood culture during the period of 2012-2015 to the microbiology laboratory were obtained, the positive cultures were identified, and data on the microbial species and their antibiotic patterns were collected and statically analysed. There were 4964 blood culture samples, of which 543were identified to be culture positive. Of the total culture positives177 (32.59%) were Gram positive bacteria; 309 (56.91%) were gram negative bacteria and 57 (10.50%) were *Candida species*. Among the gram positive bacteria150 (27.62%) were Coagulase negative Staphylococci (CoNS); 16 (2.94%) were *Staphylococococcus aureus* and 11 (2.02%) were Enterococcus species. In the Gram negative bacteria *E.coli* was 140 (25.78%); *Klebsiella pneumonia* was 92 (16.94%); *Acinetobacter* species was 25 (4.60%); *Pseudomonas species*was32 (5.89%). Statically significant resistance was observed in CoNS for Oxacillin; in *E.coli* for Ciproflaxacin, Amoxicillin-clavulanic acid, Piperacillin + tazobactam, Cefuroxime; and in *Klebsiella pneumoniae* for Amoxicillin-clavulanic acid, Piperacillin+tazobactam, Imipenem. CoNS is the common gram positive isolates followed by *E.coli* and *Klebsiella pneumoniae* in gram negative organisms of BSI in our setup. Significant resistance was observed for third generation cephalosporins, fluoroquinoles and piperacillin +tazobactam combination. Ongoing surveillance for antimicrobial susceptibility remains essential in case of BSI and will enhance efforts to identify resistance and attempt to prevent its spread.

Introduction

One of the major global problems is the rising trend in antibiotic-resistance mainly in hospitals, and also in the community which is a difficult condition to control without considerable measures and resources. The consequences of increased drug resistance are by far-reaching beyond any doubt when

it is concerned with Blood stream Infection (BSI) making antibiotic resistance an important health issue. In many countries antimicrobial resistance among bloodstream pathogens have severe consequences including increased health care cost, morbidity and mortality. This is especially true in countries like India, where, antibiotics are used extensively and considerable resistance is reported from all over the country.

BSI is potentially life-threatening condition and requires rapid identification with the antibiotic susceptibility pattern of the causative agent in order to facilitate specific antimicrobial therapy. Despite the availability of newer antibiotics, emerging antimicrobial resistance has become an increasing problem in many pathogens throughout the world. The organisms responsible for bacteraemia vary across geographical boundaries; but few of the pathogens like *E. coli, Klebsiella spp., Staphylococcus aureus, Coagulase negative Staphylococci (CoNS), Pseudomonas spp., Salmonella spp. and Acinetobacter spp.* are constantly associated with bacteraemia because of their frequent isolation and multi-drug resistance which has reached worrying levels. Also some phenotypes such as MRSA, VRE, MR-CoNS, and Carabapenamase producing gram negative organisms such as *P.aeruginosa* & *Acinetobacter baumanii* are of particular concern. Even central venous catheter, invasive devices, surgery and long term stay in ICUs puts the patients at higher risk of BSI.

For practicing physicians, clinical microbiologists and public health officials, knowledge of local antimicrobial resistance patterns is essential to guide empirical and pathogen specific therapy. This information is also critical for optimal decisions regarding formulation of hospital infection control policies, rational public healthcare policies, and national and international research agendas in that area. Antimicrobial resistance surveillance is essential to track changes in microbial populations, estimate the magnitude of the problem and to design and evaluate interventions. However, there is no national level information on resistance among bacteria causing bloodstream infections in India.

Therefore, the present study was a modest attempt with an objective to evaluate the bacteriological profile and tracing resistance among patients with BSI at our hospital. This study also summarizes the strategic resistance patterns of the isolated organisms from the patients admitted in our tertiary care hospital.

Materials and Methods

This retrospective analysis on blood culture-positive isolates and their antimicrobial susceptibility pattern was carried out during the period starting from 2012-2015 in a tertiary care teaching hospital in southern Rajasthan. Approval for the study was obtained from hospital ethics committee and consent was waived since this is a retrospective evaluation. Only one blood isolate per patient was included in the study. The blood sample were collected in BacT/ALERT FA (adult) and BacT/ALERT PFplus (paediatric) bottles; and received in the department. Inoculated bottles were incubated in BacT/ALERT 3D (Biomerieux) and growth indicated bottles were processed as per company instructions. Identification of microorganisms to species level and antimicrobial susceptibility testing was performed with the automated system vitek 2 compact (Biomerieux).

Statistical analysis was conducted using Microsoft excel 2010. Chi-square test was applied for the comparison of categorical

variables. *p* values less than 0.05 were considered as statically significant.

Results and Discussion

A total of 543 isolates from 4964 blood specimens cultured were analysed during study duration of 2.5 years (2012-2015). The overall culture positivity rate thus obtained was 10.93%. Out of the total isolates analysed, 84.71% were from intensive care units and rest 15.28% were from different wards (Table no.I).

The relative distribution frequency of blood isolates is depicted in table no. II. The aerobic or facultative bacterial isolates was found to be 89.50% and candida species were 10.50%. Among the pathogens; the most common isolates were 27.62% Coagulase negative staphylococci (CoNS), 25.78% *Escherichia coli*, 16.94% *Klebsiella pneumoniae*, 5.89% *Pseudomonas aeruginosa* and 5.70% *Non-albicans Candida species.*

The resistance pattern to antibiotics for gram negative isolates and gram positive isolates is shown in table no. III and IV respectively.

According to global surveillance reports, bloodstream isolates are the best candidates for the study of antimicrobial susceptibility of human bacterial pathogens. Patients with bacteraemia have remained a treatment challenge. The present study illustrates the BSI bacterial spectrum and antimicrobial resistance pattern in a tertiary care teaching hospital of southern Rajasthan.

During the study period a total 4964 blood samples for aerobic bacterial culture were received in the department for processing, of which 543 were culture positive; with an over all culture positivity rate of 10.93%.Similar rate of blood culture positivity of 12.7% was also reported by Chand wattal *et al.*,., from north India. Several studies across India have reported a varied range of positivity ranging from 3.72% to 44%.The varying rates of blood culture depends upon numerous factors such as the number and amount of blood cultures taken, the system and type of blood culture medium used for bacterial detection. In addition to this most of the patients already received some kind of antibiotics before they come to the tertiary care hospital and self-medication is very common because of the counter availability of medicines (Asmita Ashok, 2016).

In the present study, Gram negative bacteria was found to be responsible for56.90% and Gram positive bacteria caused 32.59% of the BSI. This observation is similar to the various studies done in the patients of developing countries (Vanitha 21-24). In the study conducted by Vanitha *et al.*, had reported 59.1% of gram negative organisms and 37.7% gram positive organisms. Similarly Mehta *et al.*,., also have reported gram negative organisms as the primary cause of BSI but with a higher rate of 80.96%; whereas only 18% were gram positives organisms in their study.

In the present study, CoNS were the most commonly isolated Gram positive cocci with an isolation rate of 27.62%, followed by the isolates of *S. aureus* and *Enterococci* contributing only 2.94% and 2.02% of respective isolation rates. In contrast, Asmita Patil *et al.*, and Rakhee baby *et al.*, have reported a higher isolation rate of 27.66% and 21.46% for S. aureus. Similar to our CoNS isolation rates; Chand Wattal also have reported 20.3%in blood. Anu Gupta *et al.*, and Mukherjee *et al.*, also had reported CoNS as most common Gram positive isolate; but with different isolation rates of 9.1% and 61% individually. Similar studies

from other countries carried out by Karlowsky *et al.,* and Japoni *et al.,* had reported 42% and 67.7% CoNS respectively. Previously, CoNS isolated from blood culture were considered as contaminants. But in recent years because of the increased use of intra-vascular devices, increase in immunocompromised patients and propensity to form biofilm by the organism; they are now considered as important agent for nosocomial bacteraemia. Meticulous skin disinfection at the time of venepuncture, determination of time to positivity, clinical correlation and appropriate antimicrobial therapy to prevent cross transmission from patient-to- patient can help to differentiate CoNS as potential contaminants or as true pathogens (Cockerill *et al.,* 1997, Kumar Y *et al.,* 2001). Also interpretation of blood cultures that are positive for CoNS require careful reasoning (Anu Gupta, 2010).

Among the Gram negative isolates, *E.coli,* (25.78%) was the primary isolate followed by *Klebsiella pneumoniae (16.94%),P. aeruginosa (5.89%),* and *Acinetobacter ssp. (4.60%)*. Similarly *E.coli* were reported to be most common gram negative bacilli from BSI in many studies. (Vinitha). Kalpesh Gohel *et al.,*; Wagner *et al.,* also reported E coli as commonest gram negative isolate in BSI. Although Kumar *et al.,* reported predominance of *Klebsiella* bacteraemia; in the current analysis it was the second most common gram negative organism. This diversity in the frequency can be justified due to the difference in the study plan, geographical location, seasonal variation, hospital infection control policies and disparity of the etiological agents (Asmita Ashok Patil, 2016).

In the present study, *Candida* spp. accounted for 10.50% of the BSI pathogens (5.70% Non-albicans candida and 4.78% *Candida albicans*). This data is comparable to the studies conducted by Anu Gupta *et al.,* (13%) and Chand Wattal *et al.,* (17.5%). According to surveillance data from the US centre for disease control and prevention, candida accounts for 12% of all hospital acquired BSIs (Hidron *et al.,* 2008). The fungal BSI are on rise due to extensive use of antibiotics, aggressive treatment of various diseases, increasing use of invasive devices, an increasing surviving AIDS patients etc. (Anu Gupta, 2010). These all factors in addition to solid organ malignancy, previous surgery, and increase in use of antifungal agents also contributed for the same (Chand Wattal, 2014).

The antimicrobial resistance pattern in the present study for Gram positive isolates was statically significant only for Oxacillin in CoNS isolates during the study period .Anu Gupta *et al.,* also had stated increased methicillin resistant during the two year study periods. This indicates that infections by CoNS may constitute a significant threat to septicemia in our locale and the spectrum of organisms is subject to geographical alterations. We report 100% sensitivity to vancomycin and linezolid in *Staphylococcus aureus*; whereas vancomycin resistance of 36.36% (4/11) in Enterococci was noted with 100% linezolid sensitivity. Anu Gupta *et al.,* also had reported 16.8% vancomycin resistance in Enterococci. The possible explanation for this may be due to lower number of isolates of S. aureus in comparison to CoNS; and may be the judicious use of vancomycin and linezolid in our setup.

Among the Enterobactericiae; *E. Coli* and *Klebsiella pneumonia* were the commonest to be isolated. Stastical comparison was done between the resistance pattern of isolated strains in the year 2012-2013 and 2014-2015. Statistically significant

resistance was observed for Ciprofloxacin, Amoxicillin-clavulanic acid, Piperacillin-tazobactam, and Cefuroxime in E.coli. Imipenem did not show any significant resistance in *E.coli* during study period. In *Klebsiella pneumoniae* Amoxicillin-clavulanic acid, Piperacillin- tazobactam, and Imipenem were significantly resistant. Anu Gupta *et al.,* also had reported alarming increase of resistance for most of the antibiotics during the study period. Also there was increase in the imipenem resistance in *E.coli*.

Among the Non-Enterobactericiae; no significant resistance was observed for any antibiotics during the study period. The possible explanation may be the fewer isolates of Pseudomonas species and *Acinetobacter* species.

Table.1 Distribution of positive blood cultures based on location of the patient (ICU & Wards)

Location	**2012**	**2013**	**2014**	**2015**	**Total**
ICUs	73	101	133	153	460 (84.71%)
Wards	17	21	28	17	83(15.28%)

Table.2 Year wise distribution of number of blood isolates

Micro-organism	**2012 (n=90)**	**2013 (n=122)**	**2014 (n=161)**	**2015 (n=170)**	**Total (n=543)**
Gram positive bacteria					
CONS	26	32	41	51	150 (27.62%)
Staphylococcus aureus	00	04	07	5	16 (2.94%)
Enterococcus species	03	02	02	4	11 (2.02%)
Total gram positive	**29**	**38**	**50**	**60**	**177 (32.59%)**
Gram negative bacteria					
Escherichia coli	30	34	40	36	140 (25.78%)
Klebsiella pneumoniae	10	21	28	33	92 (16.94%)
Acinetobacterbaumanii	02	05	09	09	25 (4.60%)
Pseudomonas aeruginosa	04	07	09	12	32 (5.89%)
Others	03	04	07	06	20 (3.68%)
Total gram negative	**49**	**71**	**93**	**96**	**309 (56.91%)**
Candida albicans	06	06	08	06	26 (4.78%)
Candida ssp. (Non albicans)	06	07	10	08	31 (5.70%)
Total fungi	**12**	**13**	**18**	**14**	**57 (10.50%)**

Table.3 Trend of antimicrobial resistance in Gram positive bacteria

Organism/ Antibiotic	2012	2013	2014	2015	2012-2013	2014-2015	P value	
CONS								
Oxacillin	12/26	31/32	45/41	47/51	**43/58**	**92/92**	**<0.0001**	**Statistically significant**
Gentamicin	4/26	6/32	08/41	08/51	**10/58**	**16/92**	1	Not significant
Vancomycin	0/26	0/32	1/41	0/65	**00/58**	**01/92**	0.444	Not significant
Linezolid	0/26	0/32	1/41	1/65	**00/58**	**02/92**	0.278	Not significant
Staphylococcus aureus								
Oxacillin	00/00	2/4	4/7	3/5	**02/04**	**07/12**	0.780	Not significant
Gentamicin	00/00	1/4	1/7	0/5	**01/04**	**01/12**	0.369	Not significant
Vancomycin	00/00	00/04	00/07	00/05	**00/04**	**00/12**	NA	
Linezolid	00/00	00/04	00/07	00/05	**00/04**	**00/12**	NA	
Enterococcus								
Vancomycin	00/03	01/02	01/02	02/04	**01/05**	**03/06**	0.303	Not significant
Linezolid	00/03	00/02	00/02	00/04	**00/05**	**00/06**	NA	

Table.4 Trend of antimicrobial resistance of blood isolates in gram negative bacteria

Organism/antibiotic	**2012**	**2013**	**2014**	**2015**	**2012-2013**	**2014-2015**	**p-value**	
E. coli								
Amikacin	06/30	5/34	4/40	7/36	**11/64**	**11/76**	0.623	Not significant
Ciproflaxacin	20/30	28/34	36/40	33/36	**48/64**	**69/76**	**0.018**	**Statistically significant**
Amoxi-clav	04/30	6/34	14/40	17/36	**10/64**	**31/76**	**0.001**	**Statistically significant**
Piperacillin+Tazobactam	02/30	05/34	08/40	12/36	**07/64**	**20/76**	**0.015**	**Statistically significant**
Cefuroxime	02/30	4/34	08/40	09/36	**06/64**	**17/76**	**0.036**	**Statistically significant**
Imipenem	0/30	0/34	1/40	1/36	**00/64**	**02/76**	0.255	Not significant
Klebsiella								
Amikacin	4/10	08/21	11/28	11/33	**12/31**	**22/61**	0.850	Not significant
Ciproflaxacin	08/10	17/21	21/28	26/33	**25/31**	**47/61**	0.742	Not significant
Amoxi-clav	2/10	4/21	11/28	16/33	**06/31**	**27/61**	**0.017**	**Statistically significant**
Piperacillin+Tazobactam	2/10	4/21	14/28	19/33	**06/31**	**33/61**	**0.001**	**Statistically significant**
Cefuroxime	1/10	2/21	4/28	6/33	**03/31**	**10/61**	0.355	Not significant
Imipenem	0/10	1/21	8/28	11/33	**01/31**	**19/61**	**0.002**	**Statistically significant**
Acinetobacter								
Amikacin	1/2	3/5	4/9	5/9	**04/07**	**9/18**	0.753	Not significant
Gentamicin	1/2	1/5	1/9	1/9	**02/07**	**02/18**	0.294	Not significant
Ciproflaxacin	1/2	3/5	6/9	6/9	**04/07**	**12/18**	0.674	Not significant
Imipenem	1/2	1/5	3/9	4/9	**02/07**	**07/18**	0.638	Not significant
Piperacillin+Tazobactam	1/2	2/5	4/9	5/9	**03/07**	**09/18**	0.719	Not significant
Pseudomonas								
Amikacin	2/4	2/7	1/9	2/12	**04/11**	**03/21**	0.150	Not significant
Ceftazidime	2/4	3/7	2/9	2/12	**05/11**	**04/21**	0.119	Not significant
Ciproflaxacin	2/4	1/7	3/9	3/12	**03/11**	**06/21**	0.952	Not significant
Piperacillin+Tazobactam	0/5	1/7	1/9	2/12	**01/11**	**03/21**	0.682	Not significant
Imipenem	1/5	2/7	2/9	3/12	**03/11**	**05/21**	0.802	Not significant

One of the important outcomes of the present study was the relief for intensivist that resistant level of life saving drugs like Meropenem and Imipenem has not yet

increased to alarming stage. Thus these antimicrobials can be used as an early commencement treatment and later deescalate which can plays a vital role in reducing morbidity and mortality in BSI. The basis for this early treatment is the information about the likely pathogen and its antibiotic resistance pattern. Present study provides much needed information on the prevalence and antibiotic sensitivity pattern of prevalent blood pathogens. The analysis of resistance will help in formulating antibiotic policy and to decide the vacation period for any antibiotic in particular if required. The data will also help in limiting the indiscriminate use of antibiotics (Asmita *et al*., 2016). The main forces driving the increase in antimicrobial resistant bacteria are poor infection control practices and inappropriate use of antibiotics. Specific antibiotic utilization strategies like antibiotic restriction, combination therapy, and antibiotic recycling may help to decrease or prevent the emergence of resistance. Specific usage based on susceptibility testing may also reduce the incidence of BSIs (Vanitha).

In the current study, we also acknowledge several limitations to our study. First this is a single centre study and may not reflect the true status of the antimicrobial pattern. Second, the duration of the study is short and needed to be extended to get a prolific result. Though the fungaemia was seen due to Candida isolates (non-albicans), data from antifungal susceptilibility could be added benefit.

In conclusion, the present study revealed that Gram negative bacilli i.e. *E. coli* and *Klebsiella pneumoniae* predominantly an leading cause of BSI in our tertiary care setup; followed by CoNS. The significance of CoNS bacteraemia should be evaluated better in light of clinical profile of patient. In present study, increased resistance was observed in CoNS for oxacillin; an alarming increase of antibiotic resistance for various antibiotics was noted for *Klebsiella pneumoniae* during study period. E.coli showed significant resistant to Ciprofloxacin, Amoxicillin-clavulanic acid, Piperacillin- tazobactam, and Cefuroxime in *E.coli* with no increase in carbapenems resistance. This calls for implementation of strict antibiotic prescribing policies and hospital infection control guidelines. Ongoing surveillance for antimicrobial susceptibility remains essential in case of BSI and will enhance efforts to identify resistance and attempt to prevent its spread.

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Original Research Article

Prevalence of otomycosis in patients of chronic suppurative otitis media at ENT clinic in Udaipur (Rajasthan)

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ABSTRACT

Background: Otomycosis is one of the most common forms of otitis externa. It is often seen in cases of Chronic Suppurative Otitis Media. It is important to treat otomycosis effectively in cases of CSOM as both conditions worsen each other.
Objectives: To study the aetiology of otomycosis and fungal profile in patients of diagnosed CSOM at ENT Clinic, Udaipur.
Materials & Methods: A total of 100 clinically diagnosed patients of CSOM were enrolled in the study and the samples were obtained from each patient using sterile cotton swab and were studied for fungal profile.
Results: The most common fungi found in CSOM are Candida and Aspergillus species. In the present study out of 95 culture positive cases of CSOM, fungi were found in 13 cases (13.68%). Candida species was most common found in 10.52% of all cases and Aspergillus was observed in 3.15% of all cases. Out of all candida species 60% were albicans.

1. Introduction

Fungal infections are also closely associated with cases of CSOM as fungi thrive well in moist pus but many authors have focused their attention on the bacterial flora, and very little is known about the mycological aspects of these, the importance of which has been increasing in the recent years because of the excessive use of broad spectrum antibiotics, corticosteroids and cytotoxic chemotherapy and an increase in the number of immune deficiency conditions.[1] Most common fungi being Aspergillus spp. and Candida spp.[2]

Chronicity of ear discharge is important factor in the cause of fungal infection of otitis media. It causes humid condition in the ear and alters the pH to alkaline. Epithelial debris which eventually helps the growth of fungus. Topical use of steroid and antibiotics cause the fungal infection in the middle ear.[3,4]

The most common causal fungal organisms are Aspergillus niger, Candida albicans, Actinomyces, Trichophyton, Aspergillus fumigatus and Candida tropicalis. Common predisposing factors include prolonged treatment with topical antibiotics, hearing aid use, regular swimming in contaminated water, trauma to the ear canal and immunosuppression.[5]

The symptoms of otomycosis are non-specific and include itching, otalgia, otorrhoea, aural fullness, hearing loss and tinnitus. Furthermore, although the classic sign of otomycosis is the presence of waving conidiophores, this is not universally present. Yeasts, such as Candida species, do not form the closely woven mass of hyphae that are formed by moulds, such as Aspergillus.[6]

More common is the finding of generalized inflammatory changes of the external canal (oedema, hyperaemia, granulomatous myringitis and aural discharge of variable colour.[7]

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2. Materials and Methods

For identification of fungal organism, laboratory examination of the discharge was carried out microscopically (in 10% KOH preparations) for the presence of pus cells, budding yeast cells, fungal hyphae (septate or aseptate), etc direct microscopy and culture of the material on SDA with Chloramphenicol.

To the solution of 10%KOH, 10% of glycerol is added to prevent drying. Mix the above ingredients properly and store solution at room temperature. The material was spread on a glass slide over a drop of 10% KOH solution and covered with a cover slip. Slide was examined under the microscope for the presence of fungi.[8]

The swab material was cultured over SDA cultue plate and incubated at 37^0C temperature and was observed daily for fungal growth upto 2 weeks. The growth was observed for the following–

1. Rate of growth
2. Morphology of colony
3. Texture
4. Surface pigmentation

Microscopic examination like LP mount and slide culture were done to identify the fungi.

Gram staining was done for identification of yeast and yeast like cells.

Chlamydospore formation, germ tube tests and Candida CHROM agar were done to identify Candida albicans.

3. Results

In our study, growth of microorganisms was seen in 95% of the processed samples and 5% didn't show any growth.

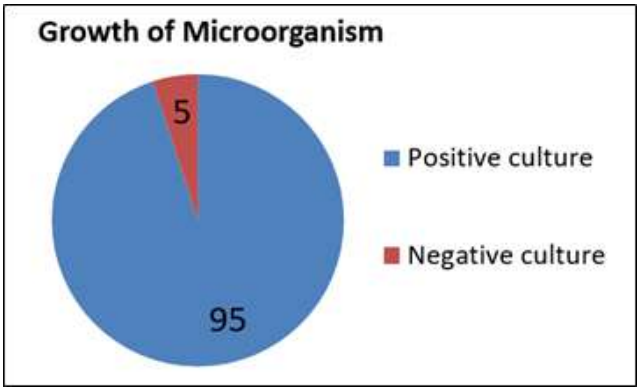

Fig. 1:

In our study Itching was the most common symptom (84.6%), followed by pain (53.8%), decreased hearing (30.7%) and sense of ear blockage (23%).

Total Fungal isolates were found in 13% of cases where Candida species was most common where it was isolated in 10% of cases. Out of total 13 fungal isolates Candida species was most common (76.92%) followed by Aspergillus species which was isolated in 23.07% of samples.

Table 1:

S. No.	Symptom	Percentage (%)
1	Itching	84.6
2	Pain	53.8
3	Decreased Hearing	30.7
4	Sense of blockage	23

Table 2:

Species	Tubotympanic	Atticoantral	Percentage
Aspergillus flavus	00	01	01 (0.99%)
Aspergillus niger	02	00	02 (1.85%)
Candida albicans	02	04	06 (5.55%)
Candida non albicans	01	03	04 (3.76%)

4. Discussion

Fungal infections of the middle ear are common as fungi thrive well in moist pus. In the present study ear discharge was seen in all the patients followed by itching (84.6%), pain (53.7%), decreased hearing (30.7%) and blocking sensation in the ear (23%). These finding were in agreement with study done my Rajpal Singh Punia et al in 2018.[9]

The most commonly found fungi in CSOM are Candida species and Aspergillus species.[10] In the present study, overall 13(13.68%) fungal isolates were obtained, out of which 4 (4.21%) were single fungal isolates. Candida species was most commonly isolated which was in 10% of cases. Out of total 10 (76.92%) candida isolates; 6 were albicans and 4 were non albicans followed by Aspergillus species which was isolated in 23.07% of samples where, Aspergillus niger was isolated in 15.38% and Aspergillus flavus 7.69% of cases. This was in accordance with study done by Harvinder Kumar et al and Prakash et al,[11] where total fungal isolates were 15% and 12.25% and Candida species was most common which was isolated in 60% of samples followed by Aspergillus species which was isolated in 40% cases whereas Prakash et al[11] reported Aspergillus species 70.83% and Candida species 29.17%. Aspergillus is a saprophytic mold and is one of the primary colonizers of the manmade substrata. Its rapid growth and production of a large number of small, dry, easily aerosolized conidia make it a significant contaminant with regards to air quality and potential human exposure-related illness. Aspergilli are common in airborne dust, and their growth is aided by cerumen and the slightly acidic pH of

the ear canal. The difference in the various studies could be due to the difference in the patient population studied and geographical variation.

5. Conclusion

The incidence of Otomycosis in patients of CSOM is high because of indiscriminate use of antibiotic and steroid drops. Discharge of CSOM also favours fungal growth.

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None.

7. Conflict of Interest

None.

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Original Research Article

Bacteriological profile in microbiology surveillance of operation theatres: A retrospective study at a tertiary care teaching hospital in Rajsamand district, Rajasthan

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ABSTRACT

Introduction: Contamination of operation theatres and Intensive care units through air, surface or article vehicle is major cause of surgical site and hospital acquired infections leading to increased morbidity and mortality.

Aims and Objective: The present study was conducted with aim to isolate and identify the nature of microbial contamination through air, surface and equipment of OT in a tertiary care teaching hospital.

Materials and Methods: Six months (August 2019 – January 2020) retrospective analysis of data by random sampling of the six OT's of the hospital was done. Air sampling was done by settle plate method. Surface samples were taken from different sites and equipments from the OT. Bacterial species were isolated and identified by conventional methods.

Results: Total 300 samples were collected and analysed Out of which 116 samples (38.66%) were positive for bacterial growth. The predominant bacterial species isolated from surface or equipment was Bacillus (48.27%), followed by Coagulase Negative Staphylococcus (21.55%), Gram Negative bacilli i.e. Klebsiella (8.62%) and least commonly isolated bacterial species was Staphylococcus aureus 2(1.72%). Air quality analysis showed highest bacterial CFU rate of 75cfu/m3 from general surgical operation theatres and Ophthalmology OT recorded least bacterial cfu rate of 20cfu/m3. Most common isolated species was Baciilus followed by Coagulase Negative Staphylococcii.

Conclusion: The study revealed that the OT's of our hospital showed a low bacterial contamination rate on surface swabbing and air quality CFU count per mm3 were within permissible limits. The present study emphasizes the need for periodic surveillance of OT's and ICU's and highlight the importance of early detection of bacterial contamination levels and prevention of hospital acquired infections.

1. Introduction

Hospital premises is in itself home to many kind of infections and have a potential role in transmission of so called Healthcare Associated Infections (HAI), also known as Noscomial or Hospital Aquired Infections. Hospital environmental hygiene plays very critical role in prevention of Hospital Aquired Infections and effective implementation of Hospital Infection Control programmes. HAIs are known to increases the morbidity, mortality and effective cost of treatment by increase in hospital stay.[1] Microbial contamination poses major risk factor in occurrence of surgical site infection (SSI).[2] Invasive procedures done without proper aseptic measures, irrational antibiotic usage and transmission of microbial infection between patients due to inadequate hospital infection control measures leads emergence and spread of microbial resistance in hot zones like OT's and ICU's.[3]

Microbiological surveillance is an important aspect of Infection control Programme, providing data regarding types and counts of microbial flora from various sites of healthcare facilities.[4] Knowledge of the incidence of

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micro flora in a hospital is important for implementation of planning of adequate cleaning of hospital environment leading to prevention of further infections.

2. Aims & Objective

The present study was conducted to isolate and identify bacteriological profile and to evaluate the level of bacterial contamination found in surveillance of surface, equipment and air samples from various speciality OT's. It also aims at strengthening the Infection control strategy of the hospital towards prevention of HAI.

3. Materials and Methods

This retrospective study was conducted at the Department of Microbiology, Ananta Institute of Medical Sciences and Research Centre, Rajsamand Rajasthan over a period of six months from August 2019 - January 2020. The study is approved by Institutional Ethical Committee. The study includes random Air and Surface sampling from Operation Theatres. Samples were taken without prior information to nursing and cleaning staff so that true picture can be brought out.

Sampling procedures used in the study were surface swabbing and settle plate method.[5] All standard operating procedures were followed while taking samples. Sterile swabs soaked in nutrient broth were used for collecting samples from different sites and equipments (Instrument trolley, Anaesthesia trolley, table top, OT light, Monitor, Suction apparatus, Crash cart, IV infusion pump, door handle) from six OTs of the hospital.[6]

After labelling them properly, samples were transported to microbiology laboratory immediately for further processing. Blood agar and MacConkey agar culture plates were inoculated and incubated at 37 degree centigrade for 24 hours aerobically. Isolated bacterial species were identified by conventional method.[7] Air sampling was done by settle plate method. Blood agar plates were taken in OT and labelled with sample number, site, time and date. Plates were kept at about 1meter above the ground and 1meter from the wall at the center of OT and four corners.[8] Plates were exposed for an hour, at the time when OT's were functional. Exposed plates were sealed in plastic bags and sent to microbiology laboratory. Plates were incubated at 37degree centigrade for 24 hours. Colonies were counted and bacterial isolates were identified by conventional methods. Further, the colony forming unit (cfu) per plate was expressed as cfu/m^3 by Omeliansky formula.[9]

4. Results

Total 300 samples were processed, out of which bacterial species were isolated from 116 (38.66%) samples. Rest swab samples were sterile.

The Bacterial cfu/m^3 counts of air from all OTs ranged from 20cfu/m^3 (isolated from Opthalmology OT) to 75cfu/m^3 (isolated from General Surgery OT).

Table 1: Bacterial colony count on air sampling of various OT's.

Name of OT	Colony count(cfu/m^3)
General Surgery	75 cfu/m^3
Urology	65 cfu/m^3
Gynaecology & Obstetrics	55 cfu/m^3
ENT	25 cfu/m^3
Orthopaedics	23 cfu/m^3
Opthalmology	20 cfu/m^3

Table 2: Various Bacterial isolates from different OTs in Air sampling.

Name of OT	Microbes isolated
Orthopaedics	Bacillus ,CoNS
Urology	CoNS
Gynaecology & Obstetrics	Bacillus, CoNS
General Surgery	Bacillus, CoNS, Micrococci
ENT	Bacillus, CoNS
Opthalmology	Bacillus, CoNS

Bacillus species and Coagulase Negative Staphylococci (CoNS) were the most common isolates from different OTs in air sampling.

Table 3: Number of Bacterial isolates obtained from OTs in Surface Sampling.

Bacterial isolates	Number	% (n=116)
Bacillus	56	48.27%
CoNS	25	21.55%
Klebsiella	10	8.62%
Escherichia coli	08	6.89%
Micrococci	07	6.03%
Acinetobacter species	05	4.31%
Pseudomonas species	03	2.58%
Staphylococcus aureus	02	1.72%

Out of Total Positive Bacterial isolates most common was Bacillus (48.27%), followed by CoNS(21.55%) and least common Staphylococcus aureus (1.72%).

5. Discussion

Microbial contamination in OT leading to post operative infections can have serious implications for patients and their close contacts. A case of suspected HAIs is aggressively investigated by performing cultures from body sites of target patient, other close patients, health care staff working in wards and ICU's and environment.[10]

Specimens must be selected very carefully to obtain authentic and meaningful results. Hospital acquired infections prolongs patients hospital stay, increases morbidity, increase resistance to antimicrobials, represent a additional

financial burden for health system and cause unnecessary deaths.[5]

Prevention measures that need to be practiced to avoid such critical situations rest not only with the operating personnel but also with the entire infection control team. In this context, monitoring and microbiological surveillance can serve as warning system for change in the type and count of microbial flora.[11]

Hygienic condition of operation theatre is reflected by Microbiological quality of its air. Settle plates are believed to be more sensitive in detecting any deterioration in the microbial contamination of air in the operation theatre and conditions that could compromise the quality of the air in OT.[12]

In the present study, the count ranged between 20 – 75 cfu/m^3 of air which is well within permissible limits and correlate well with studies from Dipendra et al and Desai et al,[5,13] where as Anjali et al[11] have reported a high counts from air sampling. Variability in results in different studies can be attributed to various factors like method of surveillance, time of sampling (random /operational), ventilation of OT, disinfectants and method of sterilization used in infection control program. Highest colony forming unit count per cubic meter of air in our study was observed from General Surgery OT and least with Ophthalmology OT which coincides with study by Dipendra et al. High count seen in General Surgery OT's can be directly related to patient load in General Surgery OT and infective profile of patients in General surgery compared to Ophthalmic OT.[5]

In surface sampling, out of total 116 positive samples (38.66%), Bacillus species was most common isolate (48.27%) which is also considered to be environmental contaminant, followed by CoNS(21.55%) which is a common commensal organism and are also an important cause of SSI,[5] and shedding of CoNS from skin of Healthcare workers and patients and its easy cross transmission may be the reason for its presence in the study. This coincides with other studies by Pasquarella et al., and Desai et al.[12,13] In our study least common isolate was Staphylococcus aureus (1.72%) which is a potential pathogen and an important cause of skin and soft tissue infection. The instruments and article which were sterilised by autoclave showed no growth and highly touched surfaces like door handles, IV stand and OT lights also showed no growth of bacteria.

6. Conclusion

Our study shows that the microbiological quality of air and surfaces in OT of our hospital is satisfactory. This data can be used to set regional standards for level of acceptable microbial population and for suggesting guidelines to decrease the microbial population rates in indoor air.

The high prevalence of infective sources in hospital operation theatre environment is alarming and there is a need for strengthening of surveillance and proper implementation of infection control protocol which should be adopted at all levels of health care. Therefore, more extensive studies are required in the field for monitoring, surveillance methods and comparison of compliance between healthcare facilities, along with infection control measures which will be very useful in controlling HAIs.

7. Source of Funding

None.

8. Conflicts of Interest

None.

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Original Research Article

Aerobic Bacteriology of Chronic Suppurative Otitis Media in Rajsamand District of Rajasthan

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ABSTRACT

Objective: The objective of our study was to examine the aerobic bacteriological profile and antibiotic sensitivity pattern to locally available antibiotics in chronic suppurative otitis media (CSOM) in Rajsamand district of Rajasthan state in India.
Materials and methods: This prospective study was conducted in the department of otorhinolaryngology, Ananta Institute of Medical Sciences, Rajsamand for a period of one year from February 2017 to February 2018. Aural swabs were taken on the first day of attendance of the patients to ENT OPD before any local medication was given to the patient, using sterile cotton wool swabs and sterile ear specula and sent for culture and sensitivity.
Results: A total of 150 cases of CSOM were selected for the study out of which 109 cases were of unilateral CSOM and 41 cases were having bilateral disease. Thus, a total of 191 swabs were taken for analysis. Out of 191 swabs processed, microbial growth was seen in 176 samples while 15 samples showed no growth. 121 (68.75%) samples showed mono-microbial growth while 55 (31.25%) samples showed poly-microbial growth. The peak incidence of CSOM was found in the age group 31-45 years (34.66%) followed by age group 16-30 years (27.33%). Females (62%) were more commonly affected than males (38%) and the female: male ratio was 1.6:1. *Pseudomonas aeruginosa (38.63%) was the most commonly isolated bacterial pathogen followed by staphylococcus aureus (35.22%) and klebsiella sp. (10.22%).*
Conclusion: A thorough and precise knowledge of the etiological agents causing CSOM and their antimicrobial susceptibility is of essential importance for an effective and efficient treatment and thus in further prevention of both complications and development of antibiotic resistance which is becoming more common now a days.

Keywords: Chronic suppurative otitis media, antibiotic resistance, staphylococcus aureus, Amikacin

INTRODUCTION

Chronic suppurative otitis media (CSOM) is a major problem globally since prehistoric times with higher incidence in developing countries because of poor socio-economic status and lack of health education. [1]

CSOM is a long standing infection of a part or whole of the middle ear cleft. Clinically, CSOM is divided into two major types: Tubotympanic CSOM i.e. 'Safe' or 'Benign' type of CSOM and Atticoantral i.e. 'unsafe' or 'dangerous' type of CSOM. [2]

CSOM is found to be the single major cause for conductive deafness (66.3%) and it is also responsible for 1.5% of speech disorders. [3]

The indiscriminate, haphazard and half hearted use of antibiotics and poor follow up of the patients have resulted in persistent changes in the bacteriological pattern of the disease, the advent of new antimicrobials, anti-inflammatory and anti-histamine agents make an evaluation of bacterial flora of CSOM important. [4]

The objective of our study was to examine the bacteriological profile and antibiotic sensitivity pattern to locally available antibiotics in CSOM.

MATERIALS AND METHODS

This prospective study was conducted in the department of otorhinolaryngology, Ananta Institute of Medical Sciences, Rajsamand for a period of one year from February 2017 to February 2018.

Aural swabs were taken on the first day of attendance of the patients to ENT OPD before any local medication was given to the patient, using sterile cotton wool swabs and sterile ear specula. The collected samples were enclosed in airtight plastic tubing and then transported to the microbiology test laboratory. The samples were always taken before cleaning/suctioning the ear canals of the excess purulent exudates. Samples from bilaterally discharging ears were collected separately. The material was inoculated on Sheep Blood agar, Mac Conkey's agar, Chocolate agar, Robertson's Cooked meat broth for aerobic and anaerobic bacteria. The swabs were incubated for 48 hr and 72hr. Organisms were identified using standard procedures. [5] Antimicrobial sensitivity testing for aerobic isolates was carried out by Kirby Bauer disc diffusion method on Muller Hinton agar. Results were interpreted in accordance with central laboratory standards institute guide-lines. [6]

RESULTS

A total of 150 cases of CSOM were selected for the study out of which 109 cases were of unilateral CSOM and 41 cases were having bilateral disease. Thus, a total of 191 swabs were taken for analysis.

Out of 191 swabs processed, microbial growth was seen in 176 samples while 15 samples showed no growth. 121 (68.75%) samples showed mono-microbial growth while 55 (31.25%) samples showed poly-microbial growth.

In present study, age of the patients ranges from 10 months to 73 years. The peak incidence of CSOM was found in the age group 31-45 years (34.66%) followed by age group 16-30 years (27.33%). Females (62%) were more commonly affected than males (38%) and the female: male ratio was 1.6:1. (table.1)

Microbiological profile of isolates from patients of CSOM and their antibiotic sensitivity pattern is depicted in table.2 and table.3 respectively.

Table.1 Age wise distribution of patients with CSOM

S.No.	Age-group (years)	Number	Unilateral	Bilateral	Mono-microbial	Poly-microbial	Sterile	Total
1.	0-15	23	11	12	22	9	4	35
2.	16-30	41	34	7	33	12	3	48
3.	31-45	52	44	8	38	17	5	60
4.	46-60	20	12	8	14	13	1	28
5.	61-75	14	8	6	14	4	2	20
	Total	150	109	41	121	55	15	191

Table.2 microbiological profile of aerobic isolates from patients of CSOM

S.No.	Type of organism	Number of samples	Percentage
1.	Pseudomonas aeruginosa	68	38.63
2.	Staphylococcus aureus	62	35.22
3.	Klebsiella sp.	18	10.22
4.	Proteus mirabilis	17	09.65
5.	E.coli	8	04.54
6.	Enterococcus faecalis	3	01.70
	Total	176	100

Table.3 Antibiotic sensitivity pattern of organism isolated in present study

S.No.	Antibiotic	Pseudomonas sp.	Staph. Aureus	Klebsiella sp.	Proteus mirabilis	E. coli	Enterococcus faecalis
1.	Ampicillin	0	11 (17.74%)	0	0	0	0
2.	Cloxacillin	0	18 (27.41%)	0	0	0	0
3.	Amoxicillin + clavulanate	0	48 (77.41%)	0	0	0	0
4.	Amikacin	59 (86.76%)	38 (61.29%)	8 (44.44%)	7 (41.17%)	4(50%)	0
5.	Gentamicin	47 (69.11%)	39 (62.90%)	2 (11.11%)	3 (17.64%)	0	0
6.	Netilmicin	48 (70.58%)	42 (67.74%)	0	1(5.88%)	2(25%)	0
7.	Vancomycin	64 (94.11%)	47 (75.80%)	7 (38.88%)	3 (17.64%)	3(37.5%)	0
8.	Ciprofloxacin	38 (55.88%)	22 (35.48%)	6 (33.33%)	3 (17.64%)	3(37.5%)	1 (33.33%)
9.	Levofloxacin	30 (44.11%)	15 (24.19%)	4 (22.22%)	2 (11.76%)	1(12.5%)	1 (33.33%)
10.	Ceftriaxone	41 (60.29%)	44 (70.96%)	2 (11.11%)	8 (47.05%)	4(50%)	2 (66.66%)
11.	Cefotaxime	27 (39.70%)	26 (41.93%)	1(5.55%)	8 (47.05%)	3(37.5%)	0
12.	Ceftazidime	51(75%)	44 (70.96%)	1(5.55%)	9 (52.94%)	0	0
13.	Piperacillin+ Tazobactam	51(75%)	55 (88.70%)	6 (33.33%)	6 (35.29%)	5(62.5%)	1 (33.33%)

DISCUSSION

CSOM is a long standing infection of a part or whole of the middle ear cleft. Clinically, CSOM is divided into two major types: Tubotympanic CSOM i.e. 'Safe' or 'Benign' type of CSOM and Atticoantral i.e. 'unsafe' or 'dangerous' type of CSOM. [2]

The definitive treatment of CSOM is by surgery (tympanoplasty and/or mastoidectomy), nevertheless, initial treatment by ear toilet and ototopical agents is necessary to prepare the ear for surgery. The selection of local or systemic antibiotic for therapy depends greatly on the type of the organism isolated in such cases.

In present study, microbial growth was seen in 176 (92.14%) samples out of 191 swabs used. 15 samples (7.8%) showed no growth. The culture results are found correlated with previous studies. [7-11] Negative cultures can be attributed to Non-bacterial growth, Anaerobic growth, Prior-antibiotic therapy and/ or Presence of antimicrobial enzymes i.e. lysozyme alone or in combination with immunoglobulins that suppress the bacterial growth. [4,10]

121 (68.75%) samples showed mono-microbial growth while 55 (31.25%) samples showed poly-microbial growth. Our study is correlated with Rama Rao et al. (1980) [3] found equal incidence of mixed and pure culture and Baruah et al. (1972) found predominance of mixed culture. [12]

In present study, most commonly affected age group was 31-45 years (34.66%) followed by age group 16-30 years (27.33%). In most of the earlier studies, the most commonly affected age group is 0-30 years. [13-18] The reason for high prevalence in higher age group in present study may be because of low socioeconomic status and poor awareness of the patients in villages near the hospital.

In the present study, Pseudomonas aeruginosa (38.63%) was the most commonly isolated bacterial pathogen followed by staphylococcus aureus (35.22%) and klebsiella sp. (10.22%).

Pseudomonas is the predominant cause of CSOM in tropical region does not usually inhabit the upper respiratory tract, its presence in the middle-ear cannot be ascribed to an invasion through eustachian tube and it should be considered as secondary invader gaining access to the middle-ear via tympanic membrane perforation. [19] Proteus mirabilis was seen in 9.65%% of the cases and Escherichia coli were isolated from 4.5% cases, and these findings were similar to the reports in earlier studies. [16,18]

In the present study the most effective antibiotic against Pseudomonas aeruginosa was found to be Vancomycin (94.11%) followed by amikacin (86.76%), piperacillin+Tazobactam, ceftazidime, netilmicin, Gentamicin, ceftriaxone and ciprofloxacin. This finding was corroborated by studies of numerous other authors. [13,18,19]

Staphylococcus aureus was found to be the second most common organism in the present study. The antimicrobial susceptibility pattern of Staphylococcus

aureus revealed highest sensitivity to piperacillin+tazobactam (88.70%) followed by amoxicillin+ clavulanate (77.41%), Vancomycin (75.80%), ceftriaxone & ceftazidime (70.96%), Netilmicin (67.74%) and Amikacin (61.29%) and least sensitivity to quinolones. In case of Klebsiella sp, Proteus, E.coli and Enterococcus faecalis-ceftriaxone, Amikacin and piperacillin with Tazobactam were found to be equally effective. These findings are in accordance with previous study done by Gulati et al (1997). [20]

CONCLUSION

A thorough and precise knowledge of the etiological agents causing CSOM and their antimicrobial susceptibility is of essential importance for an effective and efficient treatment and thus in further prevention of both complications and development of antibiotic resistance which is becoming more common now a days.

Conflict of interest:

No conflicts of interest exist for these authors. No relevant financial relationship exists between the authors and procedures or products used in this manuscript.

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Seroprevalence of Hepatitis B Virus Infection among OPD Patients Attending Tertiary Care Hospital

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ABSTRACT

Background: *Hepatitis B infection is a major global health problem. The hepatitis B surface antigen (HBsAg) in serum is the first seromarker to indicate active HBV infection either acute or chronic. The seroprevalence of Hepatitis B surface antigen among general population attending OPD at a tertiary care hospital is useful in assessing true nature of problem, which can help to estimate the magnitude of HBV infection and aid in devising preventive measures. The aim of the study was to determine the seroprevalence of Hepatitis B infection among OPD patients attending a tertiary care hospital.* ***Methods:*** *Data from Dec 2015- April-2017 for OPD patients underwent HBsAg screening were collected and analysed.* ***Results:*** *A total number of 3891 patients were screened for HBsAg among them 1731 (44.48%) were males and 2160 (55.51%) were females. The seroprevalence of HBsAg in total OPD patients was 90(2.31%), was higher in males 46(2.65%) as compared to females 44(2.03%). The highest seroprevalence was found in 60-71 (4%) age group.* ***Conclusions:*** *The seroprevalence of Hepatitis B positive cases was 2.31% among OPD patients. Also, the rising seroprevalence rates of hepatitis B in males need urgent attention.*

Key words: *HBsAg, seroprevalence, OPD patients, tertiary care hospital*

INTRODUCTION

About 30% of the world population has serological evidence of current or past infection with hepatitis B virus. It is known to be the 10th leading cause of death and HBV related hepatocellular carcinoma is the 5th most frequent cancer worldwide.[1] About 2 billion people (or 30% of world population) worldwide have serological evidence of current or past HBV infection, and an estimated 350 million people harbor chronic infection[2]. India has been placed into the intermediate zone of prevalence of hepatitis B (2-7% prevalence rate by WHO).[2] Indian population forms the second largest global pool of chronic HBV infections and the number of HBV carriers in India is estimated to be 50 million.[3] The virus is transmitted by either per-cutaneous or mucous membrane contact with infected blood or other body fluid and is found in highest concentrations in blood and serous exudates. The primary routes of transmission are peri-natal, early childhood exposure, sexual contact, and per cutaneous exposure to blood or body fluids (i.e. injections, needle stick, blood transfusion). The hepatitis B surface antigen (HBsAg) in serum is the first seromarker to indicate active HBV infection, either acute or chronic.[4]

A large population of patients suffering from hepatitis B may be asymptomatic and can transit the disease to healthy population. The patients presenting to the OPDs of a hospital are generally those seeking treatment for mostly community acquired ailments hence the estimation of seroprevalence of hepatitis B surface antigen in such patients can be considered as a surrogate marker to represent the dynamics of virus transmission in the community. Studies have been conducted to estimate the prevalence of hepatitis B virus in selected group of people with higher risk factors such as blood donors, pregnant women, drug addicts and patients with liver disorders.

However, there is paucity of information in India on prevalence of HBV infection among general population. That is why a prevalence based study of patients at a

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tertiary care teaching hospital is helpful in assessing true nature of problem in the community, which can help in assessing the magnitude of HBV infection and aid in devising preventive measures.

Community based seroprevalence studies are difficult to conduct in a developing country like India, because of socioeconomic hurdles and logistics difficulties. More than one half ambulatory and two- thirds outpatients care are catered by private health care in India.[5]

A private tertiary teaching hospital catering to the needs of a large population thus represents an important center for serological surveys. Also, the available data at Rajasthan state level on the seroprevalence and distribution of this blood borne pathogen is limited.

It was against the above backdrop that the present study was undertaken to estimate the seroprevalence of Hepatitis B viral infection among OPD patients attending tertiary care hospital.

METHODS

The present study is a prospective hospital based study conducted in the department of Microbiology, at Ananta Institute of Medical Sciences & Research Center, Rajsamand from December 2015 to April 2017. A total of 3891 blood samples were collected from patients attending different OPDs, for whom HBsAg detection was sought after a written consent. For the evaluation of HBsAg, a one-step rapid immunochromatographic Assay (ICA) was used. The qualitative detection of HBsAg was determined using a rapid Card (Hepacard-Biomed industries). The ICA are rapid and sensitive methods for detecting HBsAg. They are economical and do not require special instrumentation for analysis and have been recommended for use in clinical microbiology laboratories.[6] Immnunochromatoghraphic Assay has high sensitivity and specificity.[7] The reactive samples were retested in duplicates with fresh blood samples, if found reactive were considered as reactive.

RESULTS

We report here a study to assess the epidemiology of HBV prevalence among the OPD patients attending a tertiary care hospital of Rajsamand (Rajasthan).

A total of 3891 serum samples were processed for HBsAg detection over a period of 12 months, among them 1731 (44.48%) were male and 2160 (55.51%) were female. Table 2 shows age and sex distribution of hospital based population. The seroprevalence of HBsAg was 90 (2.31%). It was higher in males 46 (2.65%) as compared to females 44 (2.03%). The highest seroprevalence was found to be among 61-70 age groups which were (4%). The highest seroprevalence among HBsAg positive male was found in 61-70 age group which was 5.47% and among females were in age group 41-50 which was 3.71.

DISCUSSION

The seroprevalence of HBsAg in the present study was found to be 2.31%. India has been placed into the intermediate zone of prevalence of hepatitis B (2-7%) so present study findings correspond to it. HBV prevalence among the hospital based population at Karad, Maharashtra in a tertiary care hospital by Patil et al 2016,[8] the seroprevalence of HBsAg was found to be 2.25%. A study conducted by Tripathi P.c. et al 2015[9] seroprevalence of hepatitis B surface antigen at a tertiary care center in Telangna was 1.69%. Samtha P et al 2014[10] in their hospital based population at Guntur Andhra Pradesh reported prevalence of hepatitis B surface antigen was 2.4%, which approximately coincides with our study. Quadri S.A. at al 2013[11] reported the prevalence of HBsAg to be 1.63%, in a hospital based study at Bijapur, Karnataka. A recent study conducted in Rajasthan by Payal Mathur et al 2016[12] at a tertiary care teaching hospital situated at district Ajmer, the seroprevalence of HBsAg was found to be 0.94% only. Another hospital based population study conducted by Smita Sood 2013[13] at Jaipur district of Rajasthan at a superspeciality private hospital among OPD attendees, the prevalence of hepatitis B surface antigen was observed to be 1.73%. There are several studies conducted on seroprevalence of HBsAg in India. The point of hepatitis B in non-tribal population is 3.07% and among the tribal population is 11.85%. Batham A et al in their review of 54 studies on seroprevalence of HBsAg was observed 2.4% in non-tribal population and 15.9% among tribal population. Another review of hepatitis B prevalence in India by Lodha et al has conducted that it is in between 1-2%[14]. High prevalence of HBsAg (between 2-7%) has been reported in the past, and a community based study carried out in Tamil Nadu reported the prevalence of HBsAg was 5.7%.[15] Another study conducted in Sarkhet Valley, HBsAg prevalence rate was found to be 8.8% in the hospital patients.[16] The prevalence of HBsAg in patients attending surgical OPD at Fauji Foundation hospital, Rawalpindi, Pakistan has been reported as 2.28%.[17] Seroprevalence of Hepatitis B was 2.11% to3.53%[18, 19] in Rawalpindi, and 4% from Jamshoro (Sindh).[20] Very Low prevalence rate of HBsAg also has been observed in few studies Smita Sood and Shirish Malvankar 2010[21] in a study of HBsAg prevalence in hospital based population was noted to be 0.87%. The relative low prevalence in their study could be due to the fact that it was conducted in a private hospital catering usually to economically privileged class patients. Another low prevalence of 0.62% has been reported among blood donors from coastal Karnataka.[22]

Table-1 Gender Distribution of HBsAg Positive Patients

Gender	No. of sera tested	HBsAg positive sera	Percentage
Male	1731	46	2.65
Female	2160	44	2.03

Prevalence of Hepatitis B varies from country to country and depends upon a complex mixture of behavioural, environmental and host factors. In general, it is lowest in countries or areas with high standards of living (eg. Australia, North America, North Europe) and Highest in countries or area where socioeconomic level is lower (eg. China, South-East Asia, South America)[23] Most of the studies have reported high prevalence of HBsAg in males as compared to females, which is also true in our study.

Table -2 Age and Sex distribution of OPD patients with hepatitis B seropositivity

Age Group	Male	Female	HBsAg (+) Male %	HBsAg (+) Female%	Total Patients Tested	Total Patients HBsAg (+)%
0-10	36	18	0(0%)	0(0%)	54	0(0%)
11-20	80	74	2(2.5%)	0(0%)	154	2(1.29%)
21-30	338	739	8(2.36%)	8(1.08%)	1077	16(1.48%)
31-40	392	588	8(2.04%)	14(2.38%)	980	22(2.24%)
41-50	315	296	10(3.17%)	11(3.71%)	611	21(3.43%)
51-60	352	234	9(2.55%)	8(3.41%)	586	17(2.90%)
61-70	146	129	8(5.47%)	3(2.32%)	275	11(4%)
Above 71	72	82	1(1.38%)	0(0%)	154	1(0.64%)
Total	**1731 44.48%**	**2160 55.51%**	**46 2.65%**	**44 (2.03%)**	**3891**	**90 (2.31%)**

Smita sood and Shirish Malvankar have reported the prevalence to be 1.04% and 0.58%in males and females respectively.[21] Tripathi et al reported HBsAg prevalence in males 1.97% and in 1.28% females, Payal Mathur et al reported 1.12% in males and 0.7% in female, Samtha et al reported males 2.5% and 1.13% in females. There has been no plausible explanation for the higher rates in males in the general population but probably due to the higher exposure to occupational HBV, and also probably because females clear the HBV more efficiently as compared to males. In the present study, highest prevalence was found to be among 61-70 yrs age group i.e 4% followed by 41-50 i.e. 3.43% and 51-60 age group with 2.90%. Quadari et al reported relatively higher percentage of subjects in 6^{th}, 3^{rd}, and 2^{nd} decade of life respectively were found with HBsAg in their sera. Smita Sood and Shirish Malvankar reported highest prevalence among 2^{nd}, 5^{th} and elderly patients. Patil et al reported highest HBsAg prevalence among 51-60 yrs age group (5.24%) in both males (5.51%) and females (4.78%). A community based study carried out in Tamil Nadu reported that age specific prevalence for the overall exposure to HBV, HBsAg, HBeAg was not significantly different in different age group.[24] In another population studies, conducted on blood donors the HBsAg carrier rate is observed to increased directly with age up to a peak and then to decline among the older age group.[25]

CONCLUSION

Present study reported Seroprevalence of HBsAg as well as its age and sex wise distribution, our study highlights HBV infection rate in this part of the country and shall provide reference to future studies on the epidemiology of HBV infection, to understand and assess the magnitude of disease in a community and for its control and prevention. This study also shows that the ever rising Seroprevalence rates of hepatitis B among the males, is a cause of alarm in the country which also should be taken into consideration.

Permission obtained from Institution Ethics Committee.

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HAS HAART WON HEART OF HIV/AIDS PATIENTS?

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ABSTRACT

Background: The Human Immunodeficiency Virus (HIV) has changed from life threatening to chronic condition due to the almost universal use and accessibility of antiretroviral treatment (ART) among HIV patients. Antiretroviral (ARV) treatment works by suppressing the viral load and restoring the immune system. Once patients start Highly Active Antiretroviral Therapy (HAART), it is to be continued lifelong in spite of its many adverse side effects. **Objective:** To identify the adverse drug reactions (ADRs) to antiretroviral therapy (ART) and to assess their impact on treatment compliance in patients with HIV/AIDS in western India. **Methods:** A retrospective study was conducted in Gujarat to study the adverse effects after HAART initiation in 1244 patients on HAART who were evaluated retrospectively for their adverse drug reactions (ADRs). **Results:** The most common first line regimen was stavudine+lamivudine+efavirenz (d4T +3TC + EFV)(68.6 %) followed by stavudine + lamivudine + nevirapine (d4T + 3TC + NVP)(17.9%); zidovudine+ lamivudine + nevirapine(AZT+3TC+NVP) (10.9 %); and zidovudine+lamivudine+efavirenz

(AZT + 3TC +EFV) 2.5%. The first line of regimen was modified in 136(10.9%) patients, the most common cause for modifying therapy being development of an adverse effect 721(57.9%) and completion of antituberculous therapy in 510 cases(41.%). The most common cause for modifying therapy was skin rashes due to NVP in 279(22.4%) followed by loss of appetite 195(17.2%). **Conclusion:** A significant proportion of patients had adverse effects of HAART. A significant proportion of those started on NVP-based regimens are more likely to substitute therapy when compared with those on non-NVP-based regimens.

KEYWORDS: HIV, AIDS, ART, HAART, Adverse Drug Reaction (ADR), CD4 Count.

ABBREVIATIONS

HIV – Human Immunodeficiency Virus

AIDS - Acquired immune deficiency syndrome

ART - Antiretroviral Treatment

ARV – Antiretroviral

HAART - Highly Active Antiretroviral Therapy

ADR - Adverse Drug Reaction

INTRODUCTION

The Human Immunodeficiency Virus (HIV) has changed from life threatening to chronic condition due to the almost universal use and accessibility of antiretroviral treatment (ART) among HIV patients [1]. Antiretroviral (ARV) treatment works by providing suppression of viral load and restoring the immune system. It is estimated that out of the 35.3 million people living with HIV worldwide, 10.6 million were receiving ART in 2012 [2]. Nearly, 6.6 million HIV/AIDS related deaths worldwide have been prevented as a result of ART [2]. Despite these gains, adverse reactions to these medicines remain a significant public health concern and may compromise the effectiveness of the ART programmes [3,4].

In India, approximately 2.4 million people were living with human immunodeficiency virus (HIV) in 2009, which is estimated to be the third largest population of HIV affected people in the world.[5] With the availability of new antiretroviral drugs, there has been a decline in morbidity and mortality due to acquired immunodeficiency syndrome (AIDS).

The advent of highly active antiretroviral therapy (HAART) has resulted in significant decreases in HIV-related morbidity and mortality in both the developed and developing

world[6-8] and HAART has been touted as one of the greatest breakthroughs in the response to the HIV pandemic. HAART may be modified or interrupted as a result of many reasons, key among which are adverse effects and virological failure [8-11]. The adverse effects may in themselves result in virological failure or disease progression as a result of sub optimal dosing or treatment interruption.

In a study done in India, 90.6% of all the patients on HAART developed an adverse drug reaction and there were 618 episodes in various systems, the abdominal and central nervous systems were the most affected [12]. Luma and colleagues, studying patients in Cameroun found an adverse drug reaction (ADR) prevalence of 19.5% of which 21.2% were due to peripheral neuropathy. Overall 56.1% of ADR were attributed to the use of stavudine (d4T)[13]. Anaemia was observed as an ADR in many patients on ART, especially whenever the patients took zidovudine (ZDV) [14].

In an effort to scale up HAART to those who needed it most, the WHO in 2003 launched the "3 by 5" initiative with an objective of placing 3 million persons living with HIV on HAART by 2005[15]. In line with this initiative the World Health Organisation (WHO) developed guidelines on antiretroviral therapy for resource poor countries. The guidelines recommended a combination of two nucleoside reverse transcriptase inhibitors (NRTIs) and one non-nucleoside reverse transcriptase inhibitor (NNRTI) as first-line regimens in resource-constrained settings[16].

Access to antiretroviral therapy (ART) has improved tremendously over the last few years due to implementation and enforcement of various strategies by National AIDS Control Organization (NACO). NACO has established ART centres in selected government hospitals which offer free treatment for HIV/AIDS and related opportunistic infections. [17] In India, as of May 2009, there were 174 ART centres and 1,55,000 patients were on therapy. [18] By 2012, National AIDS Control Program III (2007-2012) aims to increase number of ART centres up to 250 where 3,00,000 adults will be given free ART. [17] In addition, 10 centres of excellence responsible for training, research work and mentoring of ART centres linked to them have been established across the country.[19]

HAART is the corner stone of management of patients with HIV/AIDS infection. [20] Consistent use is vital for drugs to be effective and to prevent emergence of resistance. However, ARV drugs are highly toxic and are associated with various adverse

drug reactions (ADRs) due to which many patients require withdrawal of the drug or even discontinue the treatment resulting in treatment failure. [21] Hence, monitoring and reporting of ADRs in HIV/AIDS patients receiving ART assumes great importance. There is paucity of data on ADRs to ART in Indian population. Keeping this in view, the present study was designed to identify the ADRs in patients receiving ART and to assess their impact on the compliance to the prescribed treatment.

MATERIAL AND METHODS

It was a retrospective study conducted at various ART centres of western India. The study was approved by GSACS, Ahmedabad.

A cross sectional retrospective study was conducted reviewing data of 1244 patients initiated on HAART. Univariate analysis was done for the dependent and independent variables. Stepwise logistic regression procedures were used to model the effect of gender on the development of ADRs controlling other variables like age, marital status, weight at baseline and CD4 at baseline.

From the patients records, findings of complete general, physical, systemic examination and all laboratory investigations were recorded. ADR monitoring was done in a systemic manner adopting both spontaneous and intensive monitoring approaches. The WHO definition of an ADR was adopted [22]. A pre-designed and pre-tested proforma had been confidentially used for ADR record keeping.

If the patient developed any ADR, the drug which was most commonly implicated in the causation was challenged by the treating physician and was replaced by another drug from the same class. The patient was then monitored for recovery from the symptoms.

The World Health Organisation (WHO) ADR probability scale was used for causality assessment.

With respect to ADR, following parameters were recorded.

1. Number of adverse drug reactions with different treatment regimens,
2. Nature of adverse drug reactions,
3. Severity of adverse drug reactions,

4. Incidence of each adverse drug reaction-calculated by dividing the number of patients suffereing from a particular adverse drug reaction by the total number of patients taking the same suspected drug,
5. Requirement of de-challenge,
6. Compliance to the prescribed treatment- monitored by pill count at each visit and as reported by the patient, and
7. Number of deaths.

RESULTS AND DISCUSSION

One thousand two hundred forty four (1244) patients who had been on ART were included in the present study, Out of which 1132(90.99%) patients complained of ADRs and few of them even recorded to have multiple ADRs.

Patients received four first line regimens as per the NACO guidelines [Table 1]. Stavudine +Lamivudine + Efavirenz was the most widely used combination [Table 2]. Drugs were given in the following dosages: Stavudine 40 mg B.D., Lamivudine 150 mg B.D., Nevirapine 150 mg B.D., Zidovudine 300 mg B.D. and Efavirenz 600mg H.S.

Out of the 1244 patients enrolled, 1132(90.99%) patients were recorded to report ADRs. About 74.91 % were recorded to develop more than one adverse reaction. A total of 1511 adverse drug reactions affecting various systems were observed in 1132 patients [Table 3]. Majority of adverse reactions were observed related to the gastrointestinal system and central nervous system including loss of appetite and insomnia each accounting for 28 percent. Maximum adverse reactions (872 out of 1511) were observed in patients who were prescribed treatment Ia (Stavudine + Lamivudine + Nevirapine). This was followed by 338 ADRs in patients receiving treatment regimen IIa, 223 ADRs in the patients taking treatment regimen I, and 78 ADRs in the patients taking treatment regimen II.

Irregular menstrual cycle was reported by 10 patients, 3 each in treatment I, II, and IIa. Loss of smell sensation and hearing impairment was observed in 2 patients receiving treatment regimen I and in 3 patients in regimen Ia.

Incidence of ADRs to a particular drug was calculated based on only the dechallenge test. Incidence of peripheral neuropathy and fat redistribution due to stavudine was 6.98% and

2.67%, respectively, and incidence of skin rash due to nevirapine was 7.23%, incidence of hepatitis due to nevirapine and efavirenz was 2.96% and 2.17 % respectively.

Even though HAART showed plenty of adverse drug reactions, at the same time it decreased morbidity and mortality in HIV/AIDS patients, it improved health status, body weight and even CD4 counts in almost about 90 % of the patients who adhere to this treatment strictly [Table 4].

The basic configuration of antiretroviral regimens is unchanged. The most common initial regimens are a non-nucleoside reverse transcriptase inhibitor (NNRTI) or a protease inhibitor (PI) with two nucleoside/nucleotide reverse transcriptase inhibitors (NRTIs). Common toxicities of ART can make adherence to therapy difficult. However, adherence is important to prevent the development of drug resistance. Unlike therapy for other diseases, a strategy of decreasing the dose or switching to a different drug to minimize toxicity and maximize adherence may not be possible with ART; the benefit of suppressing HIV may override other considerations. Identification and awareness of ART toxicity are necessary to facilitate patient adherence and determine when a change in therapy may be needed.

Routine monitoring in patients receiving ART includes a complete blood count and a comprehensive metabolic panel every three to six months. A lipid profile and urinalysis for proteinuria should be performed annually. When ART is changed, a complete blood count, metabolic panel, and lipid profile should be performed two to eight weeks afterward. Abnormal results should prompt more frequent testing based on clinical assessment.

According to Joint United Nations Programme on HIV and AIDS (UNAIDS) and WHO estimates, approximately 1,58,000 people all over the world were receiving ART in 2007[23]. It is well known that anti-retroviral drugs are highly toxic and therefore, early detection of ADRs by continuous monitoring is indispensable for successful treatment. In the present study, 1511 ADRs were observed in 1132 (90.99%) patients. Main risk factors associated with development of ADRs in HIV patients as determined by the researchers in previous studies included illiteracy, female gender, CD4 < 200 cells/µL, and opportunistic infections such as tuberculosis.[24] Earlier studies have also documented that a majority of ADRs were predictable and preventable.[24,25]

We observed that the maximum numbers of ADRs were related to the gastrointestinal system which is in agreement with findings of Modayil *et al*.[24] In our study, apparently maximum ADRs occurred in patients receiving stavudine+lamivudine+efavirenz which may be attributable to larger number of patients receiving this combination; however, it was observed that the incidence of ADRs was highest with the stavudine+lamivudine+nevirapine regimen.

Most cases (18/21) of peripheral neuropathy and all cases of lipodystrophy were observed in patients receiving stavudine therapy. Similar findings have been reported earlier. [24] We observed an incidence of 1.39% of peripheral neuropathy but no case of fat redistribution with stavudine. However, earlier studies have reported an incidence of peripheral neuropathy as 10%, 12% and a prevalence of lipodystrophy as 25%.[26,27.28] Low incidence seen in our study may be contributed to under diagnosis and that the drug is well tolerated in this part of the world. Recently updated WHO guidelines on ART for HIV/AIDS patients do not recommend use of stavudine as a first choice in first-line regimens due to these adverse effects.[20]

Incidence of skin rash (18.46%) and hepatotoxicity (3.19%) due to nevirapine seen in our study was almost the same when compared to that observed by Rotunda *et al*. (skin rash-15%),[29] Martinez *et al*. (hepatotoxicity-12.5%),[30] and Sulkowski *et al*. (hepatotoxicity-15.6%).[31] Latter also reported that the incidence of hepatitis due to efavirenz was 8%, whereas we found an incidence of only 0.43%. Further, in our study dechallenge with nevirapine and efavirenz in these patients resulted in resolution of hepatitis gradually over a period of 3 weeks and 1 month, respectively.

Few ADRs never documented earlier in the literature with use of ART such as irregular menstrual cycle, hearing impairment and loss of smell were also observed in the present study.

Issue of non-compliance is of major concern in management of HIV patients keeping in view that it requires lifelong treatment. Non-compliance causes significant economic implications by complicating disease management and its subsequent healthcare and social costs. Earlier studies have documented that most important factor resulting in non adherence to ART is toxicity.[32] We observed that it was mainly the severe ADRs which affected the patients' compliance. We observed that 22.1% of patients were non-compliant to ART because of

ADRs. These findings are in concordance with that of Monforte *et al.* who reported non compliance in 21.1% of Italian patients due to ADRs to ART.[32]

The risk of adverse drug reactions (ADRs) arises because of the effect of the disease on the immune systems and the safety profiles of the complex ART drugs [3]. There are a number of ADRs related to ART that have been documented, and may be mild to severe; and short to long term depending on the environment[1,5,33]. ADRs in developing countries may differ from those in developed countries because of high prevalence of conditions such as malnutrition, tuberculosis and patients presenting with advanced HIV disease [34]. For instance, it has been found that in Africa, neuropathy, neutropenia and lipodystrophy are the predominant ADRs[35]. Short term ADRs are a potential threat to successful initiation and adherence to ART[36]. The timing of ADRs may also depend on the type of drugs. Studies have shown that patients on Efavirenz, Lamivudine and Zidivudine or Indinavir, Zidovudine and Lamivudine may present with ADRs within the first 12 and 24 weeks, respectively[37]. ADRs may be common or specific to class of drugs [1,36]. Drugs classified as non-nucleoside reverse transcriptase inhibitors (NNRTIs) which include Efavirenz (EFZ) and Nevirapine (NVP) are known to cause rashes and hepatotoxicity. On the other hand, drugs classified as nucleoside reverse transcriptase inhibitors (NRTIs) including Zidovudine (AZT) and Stavudine (d4T) are known to cause anaemia, nausea, rashes, lipoatrophy and lactic acidosis.[1]

Apart from ADR depending on the environment and the type of ART regimen, a number of other risk factors have been identified, that include patient age, gender, duration of treatment, disease biomarkers such as CD4 count and viral load and body mass index (BMI) [38]. These risk factors have been found to interact with type of ADR. For instance, females are more likely to develop rashes and hepatotoxicity[38]; and patients aged 40 years and above are at a higher risk of developing peripheral neuropathy when taking d4T[39]. The longer a patient is on ART the less likely they would experience ADRs; possibly as a result of stability in ARV regimen, coming after many changes and eventually settling on an acceptable regimen [30].

Monitoring safety and toxicity related to ART remains a challenge facing the public health sector. Monitoring is usually done using spontaneous surveillance of HIV patients on treatment. Spontaneous reporting of ADRs is a very inefficient system in detecting drug-related conditions, leading to underestimation of the burden due to ADRs [3,40]. Thus, more systematic and robust surveillance methods including structured surveillance

pharmacovigilance systems, which assess and monitor safety profile and impact of antiretroviral medicines have been advocated. Structured surveillance tracks HIV positive patients who are on ART to assess drug related morbidity and mortality over time. South Africa, a country heavily hit by the HIV epidemic, uses spontaneous surveillance of HIV patients on ART to assess ART-related adverse effects. Though these data are routinely available, the coverage may not be adequate. Thus, for the purposes of this study, data from a structured surveillance system in Western India are used.

The adverse drug reaction events in patients often are of recurrent nature, such that the repetitions tend to cluster more in some patients than in others. Analyses of these data are complicated due to the fact that independence between the recurrent event times cannot be predicted in a subject. In medical studies, time-to-event models have been developed to account for possible dependence between recurrent events data [42]. The aim of this study was to provide a unified analysis of recurrent ADR events data from a structured antiretroviral pharmacovigilance surveillance system.

Table 1: Treatment Regimens as per NACO guidelines.

Treatment Regimens	Drugs in combination	No Patients
I	Zidovudine + Lamivudine + Nevirapine	136
Ia	Stavudine + Lamivudine + Nevirapine	223
II	Zidovudine + Lamivudine + Efavirenz	31
IIa	Stavudine + Lamivudine + Efavirenz	854

Table 2: Patient's characteristic in different treatment groups.

	Treatment regimen I	Treatment regimen Ia	Treatment regimen II	Treatment regimen IIa
No of patients	136	223	31	854
Mean Age(years)	36 + 8.34	40 + 2.87	33 + 7.20	38 + 4.31
Sex(M/F)	92/44	155/68	20/11	532/322
Weight (kg)	50 + 6.65	53 + 9.22	51 + 5.13	58 + 5.22
Current CD4 count				
< 200	43	78	21	247
> 200	93	145	10	607

Table 3: ADRs related to different systems.

System Involved	No. of patients with ADRs (%)
Gastrointestinal system	**678(36.45%)**
Loss of appetite	195(28.76%)
Dyspepsia	154(22.71%)
Abdominal Discomfort	81(11.94%)

Diarrhoea	74(10.91%)
Constipation	54(07.96%)
Nausea	51(07.52%)
Vomiting	43(06.34%)
Abdominal Pain	21(03.10%)
Hepatitis	05(00.59%)
Central Nervous System	**415(22.31%)**
Insomnia	111(28.75%)
Headache	89(21.45%)
Dizziness	78(18.80%)
Anxiety	57(13.73%)
Nightmare	27(06.51%)
Peripheral neuropathy	21(05.06%)
Excessive sleep at night	19(04.58%)
Delusion	14(03.37%)
Dermatological	**287(15.43%)**
Skin rashes & itching	279(97.21%)
Facial discolouration	08(02.79%)
Metabolic	**178(09.57%)**
Fatigue	109(61.24%)
Dyspnea	69(38.76%)
Musculoskeleton	**106(05.70%)**
Body ache	51(48.11%)
Vague chest pain	28(26.41%)
Pain in legs	27(25.47%)
Miscellaneous	**15(00.81%)**
Irregular menstruation	10(66.67%)
Loss of smell sensation	3(20.00%)
Hearing impairment	2(13.33%)

Table 4: Descriptive analysis of socio-demographic and health status of the patients at ART clinic.

	Variables	**n(%), N = 1244**
1	**Socio-demographic**	
(i)	Education (primary and above)	871(70.1)
(ii)	Work status (unemployed)	247 (19.9)
(iii)	Age (≤40 years)	705(56.7)
(iv)	Gender (female)	445(35.8)
(v)	Marital status (married)	1068 (85.9)
(vi)	Residency (urban)	466 (37.5)
2	**Clinical variables**	
(i)	Duration of ART (≤4 years)	495(39.8)
(ii)	Current CD4 level (cells/mm^3)	
a.	< 200	389(31.3)
b.	>200	855(68.7)
(iii)	Non adherence	47(3.8)
3	**General profile**	
	General health at the start of treatment	

(i)	Healthy	257(20.67)
(ii)	Mild to severely ill	987 (79.5)
4	**CD $_4$ count after treatment**	
(i)	Increased	1135 (91.2)
(ii)	Decreased	27(2.1)
(iii)`	No change	82(6.6)
5	**Health status after ART start**	
(i)	Improved	1114(89.5)
(ii)	Not improved	130(10.4)
6	**Body weight**	
(i)	Increased	1009(84.1)
(ii)	Decreased	91(7.3)
(iii)	No change	144(11.6)

CONCLUSION

HAART has decreased morbidity and mortality up to the expectation along with increasing considerable longevity of life of the HIV/AIDS patients. But all these antiretroviral drugs are highly toxic and associated with myriad adverse drug reactions and that too with a very high frequency. These ADRs are adding to the problem of non-compliance which in itself is a very big issue with ART. Hence, it is prudent to recognize these ADRs as early as possible in the course of treatment. This goal can be achieved by regular monitoring and reporting of ADRs which is indispensable for improving the treatment outcome.

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BACTERIOLOGICAL PROFILE AND ANTIBIOTIC SUSCEPTIBILITY PATTERN (ANTIBIOGRAM) OF URINARY TRACT INFECTIONS IN TERTIARY CARE HOSPITAL AT RAJSAMAND

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ABSTRACT

Background: To detect the prevalence rate of bacterial infection among urinary isolates and to determine the antimicrobial susceptibility pattern in the rural area of Rajsamand. **Aim:** of the study was to find prevalence of uropathogen in this part of world along with to study the antibiogram of UTI cases. **Material and Method:** A retrospective analysis of bacterial pathogens and their antimicrobial susceptibility was done on urine sample s at tertiary care hospital. Antimicrobial susceptibility tests were done using disc diffusion technique as per the standard of Kirby-Bauer method. **Results:** Out of total 600 samples, 193 samples were found positive. Out of which males 74(38%) and females119(62%) were positive. Females showed higher prevalence rate of UTI than males. Gram negative bacteria were found in high prevalence rate than gram positive bacteria. E. coli 101(52 %) was the most common organism, followed by Klebsiella 25(13%), CoNs22(11%), Pseudomonas13(7%), CoPs11(6%), Enterococcus12(6%) Candida Sp. 6(3%) and Proteus Sp. 3(2%). **Conclusion:** There is a need for constant monitoring of susceptibility of specific pathogens in different populations to commonly used anti-microbial agents.

KEYWORDS: Urinary tract infection, Antibiotic Susceptibility Pattern, Uropathogenes.

INTRODUCTION

Urinary tract infection (UTI) is an important health-care problem affecting millions every year in the community and tertiary care settings. It is a term applied to a variety of clinical conditions ranging from asymptomatic presence of bacteria in the urine to severe of the kidney with sepsis.[1]

A count of $>10^5$ colony forming units (CFU)/mL of urine is considered as significant bacteriuria.[2] Etiological agents of UTI are variable and usually depend on time, geographical location and age of patients.[3] Most UTIs are caused by Gram-negative bacteria like Escherichia coli (E. coli), Klebsiella spp., Proteus mirabilis, Pseudomonas aeruginosa, Acinetobacter spp., and Serratia spp. and Gram-positive bacteria such as Enterococcus spp. and Staphylococcus spp[3]. E. coli is the single most common pathogen accounting for 70-75% of all cases of UTI.[2]

The antimicrobial agents used in treatment of UTI include cell wall inhibitors like Penicillin, Cephalosporins, DNA gyrase inhibitors like Floroquinolones and Aminoglycosides that are protein synthesis inhibitors. Inappropriate and extensive use of antibiotics has lead to the development of multidrug resistance among the pathogens. To ensure appropriate treatment, knowledge of the organisms that cause UTI and their antibiotic susceptibility pattern is mandatory.

MATERIAL AND METHOD

The study was conducted in a tertiary care hospital, Rajsamand, Rajasthan. All positive urine culture and sensitivity reports of males and females over a period of one year were included in the study. Urine culture and sensitivity reports with more than one causative organism were excluded from the study Sample size. The organism isolated and the antimicrobial susceptibility profiles were collected from the registration records using a standard data collection form.

Culture and Identification

As per the standard operating procedures, clean-catch midstream morning urine specimen were collected under

sterile conditions in a sterile wide mouth container. All samples were completely processed within 1–2 h after arrival, to avoid overgrowth of any contaminating bacteria. Urine samples were plated on Nutrient agar, Blood agar and MacConkey agar using calibrated wire loops and then incubated aerobically at 37 °C for 24 h. From positive cultures, uropathogens were identified based on biochemical reaction.[4]

Antimicrobial susceptibility tests

According to the standard operational procedures, antimicrobial susceptibility tests were done on Mueller-Hinton agar (Oxoid, Hampshire, England) using Kirby-Bauer disk diffusion method[8] antimicrobial agents of variable strength. Resistance data were interpreted according to Clinical laboratory Standards Institute. Reference strains of E. coli ATCC 25922 and Staphylococcus aureus ATCC 25923 (S. aureus) were used for quality control for antimicrobial susceptibility tests.[9] Statistical Analysis: Data entry was done using Microsoft Excel and the data was analysed using SPSS 16.

RESULTS

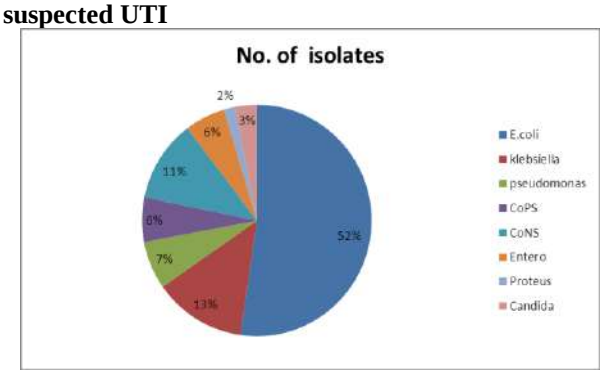
A total of 600 samples were taken during a period of 2015 -2016, out of which 193 were culture positive cases. The identification of bacteria and culture and sensitivity was carried out for the same. Out of 193 cases, males were 74 (38%) and females were 119(62%) and more common in 21-40 age group. The number of organisms isolated from females subjects were more than males (Table 1). E. coli 101(52 %) was the most common organism, followed by Klebsiella 25(13%), CoNs 22(11%), Pseudomonas 13(7%), CoPS 11(6%), Enterococcus 12(6%) Candida Sp. 6(3%) and Proteus Sp.3(2%). Sex-wise distribution of UTI by organism, Out of 74 males E. coli was isolated from 34 and Klebsiella 14 and out of 119 females E. coli was isolated from 65 and Klebsiella 11.E.coli (52%) , followed by Klebsiella (13%) were the commonest in both sexes (Table 4).The antibiotic susceptibility profile of gram negative organisms showed that E.coli and klebsiella were highly susceptible (100%) to imipenem followed by Nitrofurantoin, Amikacin, Piperacillin tazobactum, Ceftazidime/clavulanic acid while its resistance profile showed that they were more resistant to sulphamethoxazoles followed by amoxclav, ampicillin sulbactum, cephalosporins, and ceftriaxone. Staphylococcus aureus and Enterococcus were highly sensitive to Nitrofurantoin followed by Vancomycin, Linezolid, Gentamicin, Ciprofloxacin, Levofloxacin, Cotrimoxazole and Cephalosporins.

Table 1: Age and Sex distribution of patients with suspected UTI.

Age Group	Male	Female	Total
0-20	10	15	25
21-40	20	55	75
41-60	16	33	49
61-80	26	14	40
81-100	02	02	04
Total	74(38%)	119(62%)	193

Out of total 600 urine culture, 193 cases were culture Positive and sensitivity was also carried out for the same. Out of 193 cases, males were 74 (38%) and females were 119(62%) and more common in 21-40 age group. (Table.1).

Bacterial isolates from urine sample of patients with suspected UTI



E. coli 101(52 %) was the most common organism, followed by Klebsiella 25(13%), CoNs22(11%), Pseudomonas 13(7%), CoPs11(6%), Enterococcus 12(6%) Candida Sp. 6(3%) and Proteus Sp. 3(2%).

Table 2: Age- Sex distribution of patients with suspected UTI according to type of uropathogen.

Organisms	0-20		21-40		41-60		61-80		81-100		Total (n=193)
	Male	Female	Male	Female	Male	Female	Male	Female	Male	Female	
E.coli	4	9	8	26	9	20	15	9	-	1	101
Klebsiella	3	2	3	4	4	4	4	1	-	-	25
Pseudomonas	1	-	2	4	-	3	1	1	1	-	13
Proteus sp.	-	-	-	-	-	-	1	2	-	-	3
Cons	-	4	2	9	2	2	2	1	-	-	22
Cops	-	-	-	9	-	1	2	-	-	-	12
Enterococcus	2	-	4	3	-	1	-	-	1	-	11
Candida	-	-	1	-	1	2	1	-	-	1	6

According to Age-Sex distribution of Patients, Out of 74 males E. coli was isolated from 34 and Klebsiella 14 and out of 119 females E. coli was isolated from 65 and Klebsiella 11.(Table 2).

Table 3: Resistant pattern of Antibiotic in bacterial isolates from patients with suspected UTI.

Organisms	E.coli (n=101)	Klebsiella (n=(25)	Pseudo monas (n=13)	Proteus sp. (n=3)	Cons (n=22)	Cops (n=12)	Entero Coccus (n=11)
Amikacin/ Gentamycin	12 (12%)	06(24%)	03(23%)	01(33%)	NA	01(8%)	0
Cefuroxime	80(79%)	22(88%)	11(85%)	03(100%)	12(54%)	05(42%)	11(100%)
Ceftizoxime	71(70%)	20(80%)	10(77%)	02(67%)	15(68%)	05(42%)	11(100%)
Ceftriaxone	70(69%)	19(76%)	10(77%)	02(67%)	10(45%)	05(42%)	11(100%)
Ceftazidime + clavulanic acid	33(33%)	11(44%)	05(38%)	01(33%)	NA	NA	NA
Cefoperazone + sulbactam	22(22%)	11(44%)	04(30%)	01(33%)	NA	NA	NA
Cefixime	75(74%)	22(88%)	13(100%)	02(67%)	17(77%)	05(42%)	11(100%)
Vancomycin	NA	NA	NA	NA	0	0	0
Azithromycin	NA	NA	NA	NA	13(33%)	04(33%)	09(81%)
Amoxycillin + clavulanic acid	84(83%)	22(88%)	13(100%)	03(100%)	10(45%)	05(42%)	07(63%)
Ampicillin + Sulbactam	73(72%)	18(72%)	13(100%)	03(100%)	08(36%)	05(42%)	07(63%)
Piperacillin + tazobactam	18(18%)	07(28%)	05(38%)	01(33%)	NA	NA	NA
Ciprofloxacin	63(62%)	14(56%)	07(54%)	01(33%)	08(36%)	01(8%)	08(73%)
Levofloxacin	51(50 %)	13(52%)	07(54%)	01(33%)	07(32%)	0	08(73%)
Co trimoxazole	78(77%)	17(68%)	13(100%)	03(100%)	13(33%)	04(33%)	08(73%)
Linezolid	NA	NA	NA	NA	0	0	0
Aztreonam	61(60%)	19(76%)	10(77%)	02(67%)	NA	NA	NA
Imipenam	02(2%)	0	0	0	NA	NA	NA
Meropenam	02(2%)	0	0	0	NA	NA	NA
Nitrofurantoin	04(4%)	06(24%)	13(100%)	03(100%)	03(14%)	0	01(9%)
Clindamycin	NA	NA	NA	NA	11(50%)	0	NA

The overall susceptibility profiles of bacterial isolates are shown in Table 3. Amongst gram negative bacilli, amox-clav and cefuroxime had the highest overall resistance followed by Ampicillin -Sulbactam, Cefixime, Ceftizoxime, Co trimoxazole whereas other drugs showed sensitive pattern. Cephalosporins were most resistant drugs in gram positive bacilli followed by amox-clav, Azithromycin, Ampicillin- Sulbactam, Co trimoxazole, Ciprofloxacin, Levofloxacin, Clindamycin, Nitrofurantoin.

DISCUSSION

Urinary tract infection is huge burden on health care due to high prevalence of infection in both community and nosocomial settings. It is caused by variety of pathogens including *E. coli*, *K. pneumoniae* and *P. aeruginosa*. Continuous surveillance of antibiotic susceptibility patterns of uropathogens at local level is crucial in dealing with emerging problems of antibiotic resistance and provides assistance in managing effective initial therapy.[4] In present study, the prevalence of UTI in females is higher than the males which is attributed to factors like close proximity of the uretheral meatus to the anus, shorter urethra. This finding is consistent with other studies done by Jubina Bency et al Prakasam A., K.C et al and Azra S. Akram T et al. There was significant growth of E.Coli, Klebsiella, Enterococci, Staphylococcus and Pseudomonas. Ecoli & Klebsiella infections were most common organisms similar to Jubina Bency et al. *Enterococcus* was sensitive to Vancomycin & Linezolid. *Staphylococcus* was sensitive to Vancomycin.[6] The pattern of antimicrobial resistance of the micro-organisms causing UTIs vary in their susceptibility to antimicrobials from place to place and from time to time. World wide data shows that there is an increasing resistance among UTI pathogens to convential drugs. Resistance has emerged even to newer more potent antimicrobial agents.

E.coli(52 %) was the most common organism, followed by Klebsiella(13%), CoNs(11%), Pseudomonas(7%), CoPs(6%), Enterococcus(6%) Candida Sp. (3%) and Proteus Sp.(2%). This finding patterns were similar with the study of Savitha like E.coli(48.04%), Klebsiella species(8.82%) and Proteus spp.(4.90%).

It has been observed that there is slow but persistent decrease in the sensitivity of gram negative and gram positive bacteria to some quinolones derivative, Ampicillin and Sulphonamides which is alarming because these antibiotics have been one of the best options for treatment of UTI in both outdoor patients and hospitalized patients. Other factors which may influence

the sensitivity of urinary pathogens includes, routes of administration, dosage schedule, choice of antibiotic, misuse of antibiotic and condition of patients and self-medication.[7]

CONCLUSION

In this study, higher prevalence rates of urinary bacterial isolates are observed in females the most commonly found organisms were *E. coli* and *Klebsiella*. There is an emerging resistance of commonly isolated bacteria to routinely used antibiotics, which can be ascribed to inappropriate antibiotic administration. Important infecting organisms are found to be the commensals of perianal and vaginal regions, emphasizing a need to have proper hygienic practices.

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Original Research Article

Spectrum of aerobic bacteria and their antimicrobial pattern in blood stream infections of hospitalised patients: a retrospective study

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ABSTRACT

Background: Bacteria associated with blood stream infections are an important public health problem which results in morbidity and mortality globally. Emergence of multidrug resistant isolates in hospitalized patients is a major problem. Automation techniques play a major role in early identification of the isolate and its drug susceptibility testing which is important for better outcome of the treatment. This study was aimed to detect the blood stream isolates and their drug susceptibility pattern in hospitalized patients.
Methods: This was a retrospective study conducted from 377 records of automated blood culture (bact/alert) and drug susceptibility testing (vitek) results. Positive blood culture bottles were sub cultured to different culture media and the isolates were identified and screened for drug susceptibility testing on Vitek II.
Results: Around 20.68% of samples were positive for blood stream infections caused by different pathogens. A total of 78 microorganisms were isolated from 377 samples. Among which gram negative bacilli was observed in 52.56%, gram positive cocci in 44.87% and yeast in 2.56% samples. Coagulase negative *staphylococci* and *Klebsiella pneumoniae* were the predominant isolates of the study.
Conclusions: Early diagnosis of blood stream infections in hospitalized patients is life saving. Hence a continuous monitoring of isolates and their drug susceptibility is the need of the day.

Keywords: Blood stream infections, Coagulase negative *staphylococcus, Klebsiella pneumoniae*

INTRODUCTION

Blood stream infection (BSI) remains one of the foremost important causes of morbidity and mortality globally. The infection may range from self limiting to life threatening sepsis.[1,2] As case fatality rate is high it requires appropriate and immediate antimicrobial therapy. Different bacteria were associated with (BSI) from time to time at different geographical areas. These bacteria play an important role in causing mortality, increasing the length of hospital stay and also the health care cost.[3]

Drug resistance of these bacteria is an important issue of public health concern. Since many studies have reported that gram negative and gram positive bacteria are associates with these infections which are often drug resistant. Empirical antibiotic therapy is initiated in almost all cases before the blood culture reports are available. Choice of right empirical therapy is important. An early blood culture report may help in selection of appropriate antibiotics.[2,4]

Minimal time is required to get a blood culture report using automated systems. The etiology and antimicrobial pattern of (BSI) may vary at different times in the same region hence a continuous update is essential for epidemiological purpose and also for rational and accurate use of antibiotics by clinicians. The present

study aimed to determine the etiology and antibiotic resistance pattern in blood stream infections.

METHODS

Study design

A retrospective study was conducted from the records of automated blood culture (bact alert) and drug susceptibility testing (vitek) results in the clinical microbiology laboratory from June, 2016 to July, 2018 at Ananta institute of medical sciences and research centre, Rajsamand. This data includes 377 records of hospitalised patients who were admitted to different units of hospital during the study period.

Sampling technique and data collection

Blood cultures were performed for different age groups up to 90 years. Samples were collected by phlebotomist from the patients after disinfection of vein puncture site with 70% alcohol. 3-4ml of blood was inoculated in 30ml BacT/Alert blood culture bottles for paediatrics and 4-5ml blood was inoculated in 30ml BacT/Alert blood culture bottles for adults. These bottles were incubated in BacT/Alert automated system. The bottles which showed positive signal for growth were removed from the automated system and subculture was done on Nutrient agar, blood agar and MacConkey's agar. Smears from the colony of different agar plates were prepared and stained with Gram stain to identify the growth (i.e. gram positive or gram negative bacteria). Then the growth of the bacteria was run on VITEK II automated system for identification of the organism and Antibiotic Sensitivity. If there is no growth of bacteria within five days of inoculation of blood sample into BacT/Alert blood culture bottle then the sample is considered to be negative.

Data regarding the age, sex, isolate and its antimicrobial pattern was collected and statistical analysis of the data was done by Chi square test to study the P value using social science statistics online software.

RESULTS

A total of 377 samples were screened for blood culture from hospitalized patients of different units. 20.68% of samples were positive for blood stream infections caused by different pathogens (Table 1).

A total of 78 microorganisms were isolated from 377 samples. Among which gram negative bacilli was observed in 52.56%, gram positive cocci in 44.87% and yeast in 2.56% samples. The leading isolate among the gram positive cocci were CONS (coagulase negative *staphylococci*) and among the gram negative bacilli, *Klebsiella pneumoniae*. Details of each isolate were mentioned in Table 1. Only two samples were found to be positive for yeast i.e. *Candida tropicalis*.

Table 1: Bacteria and yeast isolated from blood culture samples.

	Isolate	Positive %
Gram negative bacilli (A)	*Acinetobacter baumannii*	4 (9.75%)
	Acinetobacter iwoffii	1 (2.44%)
	Burkholderia cepaciae	1 (2.44%)
	Escherichia coli	10 (24.39%)
	Enterobacter cloacae Complex	2 (4.87%)
	Klebsiella pneumoniae	17 (41.46%)
	Pseudomonas aeruginosa	3 (7.31%)
	Spingomonas paucimobilis	1 (2.44%)
	Stenotrophomonas maltophilia	1 (2.44%)
	Serratia marcescenes	1 (2.44%)
Total		41 (100%)
Gram positive cocci (B)	*Staphylococcus aureus*	3 (8.57%)
	Staphylococcus cohnii#	2 (5.71%)
	Staphylococcus epidermidis#	6 (17.14%)
	Staphylococcus haemolyticus#	4 (11.48%)
	Staphylococcus hominis#	3 (8.57%)
	Staphylococcus lentus#	2 (5.71%)
	Staphylococcus pseudintermedius#	2 (5.71%)
	Enterococcus faecalis	3 (8.57%)
	CONS	10 (28.57%)
Total		35 (100%)
Yeast (C)	*Candida tropicalis*	2(100%)
Total (A+B+C)		78/377* (20.68%)

*Total number of samples tested, CONS-coagulase negative *staphylococcus*, # CONS

Isolates were predominant in males (62.82%) as compared to females (37.18%) (Table 2). Paediatric patients were more (31.57%) exposed to BSI than adult and elderly patients (23.52%). Statistical analysis showed a P value of 0.03. CONS were the leading pathogens in paediatric patients. *Klebsiella pneumoniae* was the leading pathogen among the adult and elderly patients. 83.3% (65) of samples were culture positive in <24hours, 15.4% (12) in between 24 <48hours, 1.3% (1) between 48-72hours.

Table 2: Sex wise and age wise distribution of positive and negative blood culture samples.

Variable	Blood culture result			P value
	Positive	Negative	Total	
Male	49	191	240	X^2=0.03 P=0.86
Female	29	108	137	
Age				
<5 years	25	58	83	X^2=6.88 P=0.03
5 <15 year	5	37	42	
>15 years	48	204	252	

Among the gram-negative isolates, *Escherichia coli* showed 100% sensitivity to colistin and tigecycline, 80% to ertapenem. *Acinetobacter* species showed 80% sensitivity to colistin and 70% to amikacin. *Enterobacter cloacae* showed 100% sensitivity to tigecycline,

Klebsiella pneumoniae showed 100% sensitivity to colistin and 88.3% to tigecycline. *Pseudomonas aeruginosa* showed 66.7% sensitivity to colistin (Table 3). Among gram positive isolates, CONS showed 93.1% sensitivity to linezolid, 89.7% to tigecycline and 86.2% to vancomycin. *Staphylococcus aureus* showed 100% sensitivity to oxacillin, gentamicin, linezolid, vancomycin, tetracycline and tigecycline. E*nterococcus faecalis* showed 100% sensitivity to gentamicin, linezolid and vancomycin (Table 4).

Very low positivity 1 (2.44%) was observed for *Spingomonas paucimobilis, Stenotrophomonas maltophilia, Burkholderia cepaciae* and *Serratia marcescenes.*

Table 3: Antibiotic resistance of gram negative bacilli isolated from blood culture.

Antimicrobial agent	Resistance percentage of gram negative bacilli				
	***Eschericia coli* (n=10)**	***Acinetobacter species* (n=05)**	***Enterobacter cloacae* (n=02)**	***Klebsiella pneumoniae* (n=17)**	***Pseudomonas aeruginosa* (n=03)**
Ampicillin	100	100	NT	100	NT
Amoxicillin/clavulanate	80	100	100	94.1	NT
Piperacillin/tazobactam	80	80	100	94.1	66.6
Cefuroxime	100	100	100	100	NT
Cefuroxime axetil	100	100	100	100	NT
Ceftriaxone	100	80	100	100	NT
Cefaperazone/sulbactum	70	80	100	94.1	100
Ertapenem	20	NT	NT	NT	NT
Cefepime	70	80	100	100	100
Imipenem	50	70	100	35.3	66.6
Meropenem	60	70	100	58.8	66.6
Amikacin	30	30	100	88.2	66.6
Gentamicin	30	80	100	100	66.6
Nalidixic acid	80	80	100	82.3	NT
Ciprofloxacin	80	80	100	82.3	66.6
Tigecycline	0	60	0	11.7	100
Trimethoprim/ sulphamethoxazole	60	80	100	52.9	NT
Colistin	0	20	NT	0	33.3

NT - Not Tested

Table 4: Antibiotic resistance of gram-positive cocci isolated from blood culture.

Antimicrobial agent	Resistance percentage of gram-positive cocci		
	Cons* (n=29)	***Staphylococcus aureus* (n=03)**	***Enterococcus faecalis* (n=03)**
Benzylpenicillin	96.5	100	100
Oxacillin	82.7	0	100
Gentamicin	31.3	0	0
Ciprofloxacin	65.5	33.3	50
Levofloxacin	65.5	33.3	50
Erythromycon	89.6	66.6	100
Linezolid	6.9	0	0
Clindamycin	86.2	66.6	100
Tecoplanin	27.5	80	50
Vancomycin	13.8	0	0
Tetracycline	27.6	0	50
Tigecycline	10.3	0	100
Trimethoprim	51.7	66.6	50

DISCUSSION

The overall frequency of blood culture isolates in present study was (20.68%). This is comparable with studies conducted in India by Pal et al, 2016 (22.3%) and Gill et al, 2016 (24.8%).[5,4] However, some studies have reported high frequency of bacterial pathogens from blood cultures (24.2%-37.1%).[6,7] This may be due to use of different blood culture systems, different sample size, variations in study design and protocols, different geographical locations, variations in causative agents and the policies adopted for infection control between countries. Incidence of gram negative bacilli (GNB) was 52.56% and gram positive cocci (GPC) were 44.87%. Similar findings with high frequency of GNB as compared to GPC were previously reported by an Indian study.[8]

In our study, coagulase negative *staphylococcus* was the leading blood culture isolates (37.1%). Similar results were reported from India (61%) and globally (42%).[9,10] They often occur as skin contaminants during the collection of blood. Cross infections in ICU'S with multidrug resistant CONS can be prevented by use of appropriate antimicrobial agents. There is a need for differentiation between true pathogen and contaminant which can be achieved by correlating clinically the blood culture isolate and time taken for positivity of CONS.[11] Among the GPC group CONS showed high frequency of antimicrobial resistance as compared to others (Table 4). *Staphylococcus* aureus was 100% sensitivite to oxacillin, gentamicin, linezolid, vancomycin, tetracycline and tigecycline. Similarly, an earlier study reported 100% sensitivity to linezolid and vancomycin.[8]

Enterococcus faecalis was observed in (8.5%) of gram positive cocci. Similar findings (8.4%) were reported by an earlier Indian study.[11] It is a normal flora of female genitourinary tract and gastrointestinal tract. Though vancomycin resistance was reported since a decade, in the present study no resistance to vancomycin was observed for *Enterococcus faecalis*. This may be due to differences in the circulating strains. However, an earlier study from north India reported 23% of vancomycin rersistant enterococci.[11]

Gram negative bacteria accounted for more than fifty percent among the total isolates of the blood culture. This is consistent with an earlier study, though there is difference in the range of isolates.[1] Among the non fermenters, *Acinetobacter* species and *psuedomonas aeruginosa* showed high level resistance to cephalosporins and carbapenems. There is increase in the trend of carbapenem resistance to *Acinetobacter* species.[11] This may be because of extensive use of these antimicrobials. The overall antimicrobial resistance of gram negative bacteria and gram positive bacteria varied from 0% to 100% in our study. This is different when compared to a previous study which reported a higher resistance in gram negative bacteria (20-100%) as compared to gram positive bacteria (23.5%-58.8%).[12] Among the *Klebsiella pneumoniae* isolates high level sensitivity was shown by colistin 100% followed by tigecycline 88.3%, imipenem 64.7% and meropenem 41.2%. Singh et al, 2014 reported 100% and 71.4% sensitivity for imipenem and meropenem respectively each.[8] *Eschericia coli* showed high level sensitivity to colistin and tigecycline 100%, followed by ertapenem 80%, amikacin and gentamicin 70%. The sensitivity of gentamicin in our study was much higher as compared to an earlier Indian study 35%.[13]

Differences in antimicrobial resistant pattern in different studies may be due to circulation of different strains in different regions at different times.

Among the yeast isolates *Candida tropicalis* was isolated in two blood culture samples. Both the isolates were 100% sensitive to fluconozole, voriconazole, caspofungi, micafungin, amphotericin-B, and flucytosin. However, studies from different parts of India reported the emergence of *nonalbicans Candida* and resistant to widely used antifungal agents.[14,15]

CONCLUSION

Coagulase negative *staphylococcus* and *Klebsiella pneumoniae* were the predominant isolates of the study. High level multidrug resistance was observed in both GPC and GNB. Tigecycline and colistin remains the choice of antibiotics for gram-negative bacilli. Gentamicin, linezolid, vancomycin and tigecycline are the choice of antibiotics for gram positive cocci. Good antibiotic policy and strict hospital infection control measures may help to curb the emergence of multidrug resistant pathogens. There is a need for continuous monitoring and updating the BSI isolates and their antimicrobial patterns for an early effective approach to treatment.

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ORIGINAL RESEARCH PAPER

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A STUDY ON IDENTIFICATION AND SPECIATION OF MEDICALLY IMPORTANT CANDIDA SPECIES ISOLATED FROM VARIOUS CLINICAL SAMPLES BY USING HICROME CANDIDA.

Microbiology

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ABSTRACT

Candida albicans remains the most frequently isolated species, but an increase in the prevalence of Non-albicans candida is a matter of concern for various laboratories, as NAC show less susceptibility to antifungal agents particularly azoles[1-3]. Routinely used conventional methods are cumbersome and time consuming. Hence the present study aimed at species identification of candida isolated from various clinical specimens and also to evaluate the usefulness of HiCrome Candida differential agar as compared to routine conventional method for speciation of candida. A total of 51 non repetitive clinical isolates of Candida were obtained from various clinical samples. *Candida albicans* was the major species accounting for 23 (45.10%) of the total isolates. *Non albicans Candida* constituted 17 (33.33%) of *C. tropicalis*, 9 (17.64%) of *C. krusei* and 2 (3.92%) of *C. parasilosis*. 49 Candida species which were correctly identified by HiCrome Candida agar except 2 species of C.parasilosis (identified by conventional method) which were identified as C. glabrata by Hicrome Candida agar.

KEYWORDS

Non-albicans Candida, HiCrome Candida differential agar, conventional method, candida speciation.

INTRODUCTION

Candida species particularly Candida albicans remains the most common cause of superficial and deep fungal infections worldwide[1,2]. But an increase in the prevalence of Non albicans Candida (NAC) during the last few decades is a matter of concern for various laboratories, as NAC show less susceptibility to commonly used antifungal agents particularly azoles ie fluconazole[3-5]. Thus species identification of Candida isolates have become very necessary for providing effective antifungal therapy, which will in turn prevent the emergence of drug resistance and also nosocomial infection[6].

A large variety of techniques from conventional to molecular methods are available for yeast identification[4,5]. Routinely used conventional methods like gram staining of smear, germ tube test, colony morphology on Sabouraud's dextrose agar, urease test, growth on corn meal agar, sugar fermentation and assimilation test, growth at 45^{0}C are labour intensive, cumbersome and time consuming ie may take 3-4 days[7].

Now a days, newer methods like several chromogenic media, BiGGYagar system, API system, Vitek 2ID system and molecular methods, have been developed for rapid identification of Candida species[8-10]. HiCrome Candida agar is one of the selective and differential chromogenic media manufactured by Himedia, Mumbia, India. This media contain chromogenic substrates that react with enzymes secreted by microorganisms producing colonies with various pigmentation. These enzymes are species specific, allowing organisms to be identified to the species level by their colour and colony characteristics[11]. They are used for rapid isolation and identification of candida species directly from clinical samples and also where multiple yeast species are present in the sample. On these media results are obtained in less time ie within 48hrs, can be easily interpreted and is also cost effective as compared to other newer methods like API system, Vitek 2ID system and molecular methods which are expensive[12-15].

As many tests from conventional to molecular methods are available, clinical microbiological laboratories are facing an important challenge regarding selection of method that is cost effective, accurate, easily interpreted and also rapid for identification of Candida, which inturn is of great importance for clinicians of our hospital to select appropriate prophylactic and therapeutic antifungal drug. Keeping the above point in view, the present study aimed at species identification of Candida isolated from various clinical specimens and also to evaluate the usefulness of HiCrome Candida differential agar as compared to routine conventional method for speciation of Candida.

MATERIALAND METHOD

Study design and setting – A prospective study was carried out in the department of Microbiology, NIMS Medical College and Hospital, Jaipur (Rajasthan) from January 2017 to May 2017. A total of 50 non repetitive clinical isolates of *Candida* obtained from various clinical samples, which were received from different Wards, ICUs and OPDs of the hospital and were submitted to microbiology laboratory with all aseptic precautions were included in the study.

Specimen processing [7]

1. Direct examination of sample- Direct microscopic examination by 10% KOH mount and Gram staining reveals presence of oval budding yeast cells with / without pseudohyphae[7].

2. Culture – All the clinical samples were inoculated on to Blood agar and SDA , both were incubated at 37C for 48-72 hrs. All the samples which showed growth were identified by colony characteristics and by gram staining. Once the conformation of colonies was done, they were further speciated[7].

3. Speciation of candida isolates (Fig 1-8)

(a) Standard conventional method - Candida isolates were further speciated by standard method which includes germ tube test, growth pattern on Corn Meal agar , sugar fermentation and assimilation test[7].

(b) Growth on chromogenic agar – Isolated Candida species were also inoculated on to the chromogenic media (HiCrome Candida differential agar (M1297A); Himedia, Mumbia, India.) Inoculated plate was incubated at 37^{0}C for 24 hours. These plates were further incubated for 48 hrs to get better well developed colored colonies. The color of the colony was interpretated as per color code provided on chromogenic media (Table 1) by two observer to avoid subjective variation[11]. All the isolates with doubtful morphology were considered unidentified and excluded from the study.

RESULT

In the present study, a total of 51 (4.5%) Candida species were isolated from 1113 clinical specimens. In our study conventional method was considered gold standard method for speciation. Out of 51 Candida isolates, most common isolated species was Non-albicans Candida ie 28 (55%) followed by Candida albicans ie 23 (45%) (Fig 4). Out of 28 Non-albicans Candida, C.tropicalis was most frequently isolated (33%) followed by C.krusei (18%), C.parasilosis (4%) (Fig 9).

These 51 strains were also identified using Hicrome Candida differential agar. 49 Candida species which were correctly identified by Hicrome Candida agar except 2 species of C.parasilosis (identified by conventional method) which were identified as C. glabrata by Hicrome Candida agar (Fig 10). 100% sensitivity and specificity was observed for Candida albicans, Candida tropicalis, Candida krusei. 0% sensitivity and100% specificity for Candida parasilosis (Table 2).

DISCUSSION

In the present study, out of 51 Candida isolates, 23(45.1%) were identified as C. albicans and 28 (54.9%) were NAC species. Our study showed that Non albicans Candida were isolated at higher rate (54.9%) than C. albicans (45.1%), which was in agreement with the studies conducted by Saroj Golia et al[17] and N.Pahwa et al[19] who also showed the Non albicans Candida incidence (64% and 58% respectively) to be higher than that of C. albicans . This change in pattern has been partly attributed to increased immune suppression resulting in higher number of susceptibility in immunocompromised patients and also due to the prophylactic use of antifungal agents in critically ill patients. Hospitalization (especially in ICU), placement of central venous catheters and the other indwelling devices, previous antimicrobial therapies have played significant role in this changing pattern of Candidiasis[22,23].

In our study, the most frequently isolated species was C. albicans in 45.1% of the infections, followed by C. tropicalis 33.3%, C. krusei 17.6% and C. glabrata 3.92% respectively. Hence C. tropicalis (33.3%) was the second most common species reported in the present study. This finding was comparable with other workers like L.Sumitra Devi et al.[18] (22.9%), Divya Dadhich et al.[20] (26.4%), and Khan and Bobade O, et al.[21] (21%) [table3].

In the present study, HiCrome agar showed 100% sensitivity and 100% specificity for C. albicans, C.tropicalis and C. krusei. Our study agrees with that of the studies conducted by D. Dadhich et al[20] and Nayak et al[24].,who also showed cent percent sensitivity and specificity to these Candida species when compared with conventional method.

In our study low sensitivity was reported for C. parasilosis which correlates well with the study conducted by tha of Baradkar et al[11].

These values are in contrast to the study conducted by various other scientists[24,25]. As both the species of C.parasilosis showed characteristic morphology on corn meal agar. Hence a combination of HiCrome and Corn meal agar can identify this Candida species with in 48 hours of culture.

CONCLUSION

On completion of this study it is concluded that *Non- albicans* Candida which was earlier considered to be non-pathogenic has emerged as important pathogen. It can no longer be discarded as a lab contaminant. Hence speciation of *Candida* species is of utmost importance in the present clinical scenario.

Speciation of *Candida* using conventional methods is quite cumbersome and time consuming. Therefore species level identification using HiCrome Candida agar medium is advocated. The advantages of HiCrome Candida agar is that it is easy to prepare i.e. boiling and dispensing in petri plates. It is technically simple and cost effective compared to technically demanding and time consuming conventional methods. It also facilitates identification of two or more different species present in a single clinical sample as is seen in our study. As a result it can be concluded that the use of HiCrome agar Candida is an easy reliable method for presumptive identification of most of the Candida species Furthermore, the species level identification of the Candida isolates along with their antifungal susceptibility patterns can greatly influence the treatment options for the clinician and may have an impact on the patient care.

Table 1: Colour of different Candida species on Hicrome agar

Species	Color of the colony
C. albicans	Light-green
C. dubliniensis	Dark-green
C. glabrata	Cream to white
C. krusei	Pink, fuzzy
C. parapsilosis	White to Cream
C. tropicalis	Blue to purple

Table 2: Sensitivity and specificity of HiChrom agar for identification of various Candida spp.

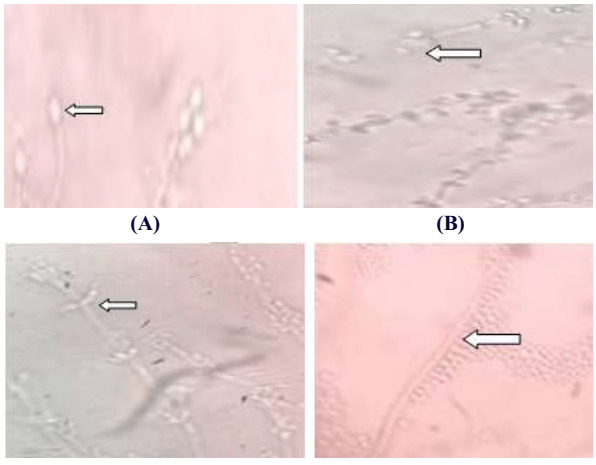
Candida spp	No.of Candida spp. identified by conventional method	No.of Candida spp. identified using HiCrome agar	Sensitivity of HiCrome agar	Specificity of HiCrome agar
C. albicans	23	23	100%	100%
C. tropicalis	17	17	100%	100%
C. krusei	9	9	100%	100%
C. parasilosis	2	0	0	100%

Table- 3 Candida species isolated in various studies

S. No.	Author	Year, Place	C. albicans	C. tropicalis	C. Krusei
1	**Badiee P[16]**	Iran, 2011	48%	1.7%	16.1%
2	Saroj Golia[17]	Karnataka, 2013	35.71%	26.78%	4.46%
3	L. Sumitra Devi[18]	Haryana, 2014	51.6%	25%	16.6%
4	N Pahwa[19]	Indore, 2014	42.2%	22.4%	3.4%
5	Divya Dadhich[20]	Kota, 2016	54%	22%	6%
6	Present Study	Jaipur, 2017	45.1%	33.3%	17.6%

Fig 1 –Microscopic appearance of various Candida species on Corn meal agar

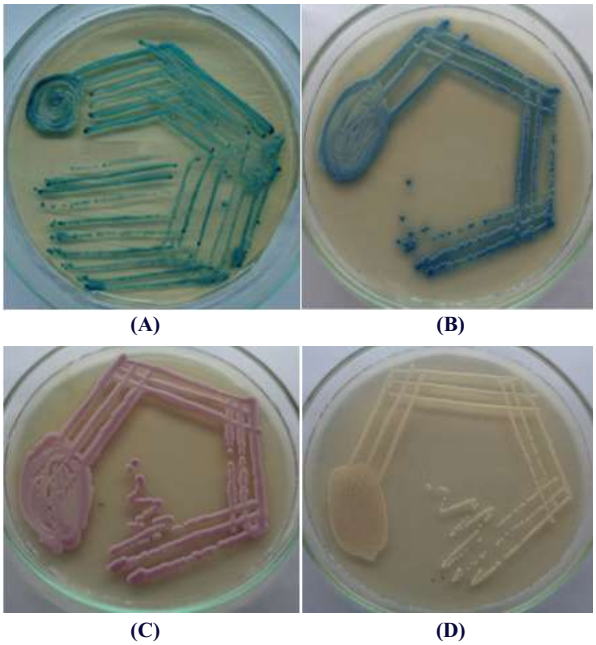
(a) C. albicans - elongated pseudohyphal cells with terminal chlamydospores.
(b) C. tropicalis – blastoconidia formed along the abundant long branching pseudohyphal cells.
(c) C. krusei - chains of blastoconidia extend from the junction of pseudohypal cells.
(d) C. parasilosis - blastoconidia occur singly, in clusters and in short chains along the pseudohyphae.



(A) (B) (C) (D)

Fig 2 Differentiation of various species of Candida on HiCrome agar

(a) C. albicans (b) C. tropicalis (c) C. krusei(d) C. parasilosis



(A) (B) (C) (D)

Figure 9 : Isolation of different species of Candida by Conventional methods

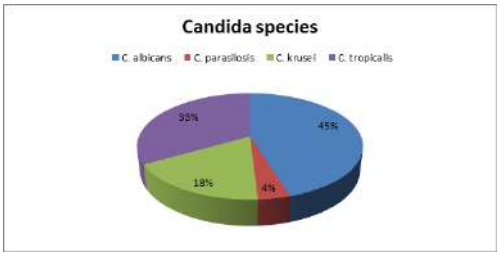
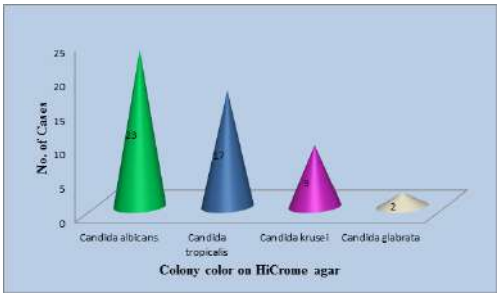


Figure 10 Isolation of different Candida species on HiCrome agar



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A Study on Prevalence and Antibiotic Susceptibility Pattern of Vancomycin Intermediate and Resistant Staphylococcus Aureus in Clinical Specimen in a Tertiary Care Hospital and Detection of their MIC Values by E-test.

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Abstract: *With the increasing incidence of Methicillin Resistant Staphylococcus Aureus(MRSA), Vancomycin Intermediate Staphylococcus Aureus(VISA) & Vancomycin Resistant Staphylococcus Aureus (VRSA) strains now a days. The study was conducted to find out the magnitude of vancomycin resistance in both MRSA and MSSA and antibiotic susceptibility pattern of those isolates in a tertiary care hospital, Jaipur between January 2017 to June 2018.In this cross sectional study,287 Staphylococcus aureus were isolated and identified from various clinical specimens collected from different departments of the hospital.Among these 287 strains,146 were found to be MRSA and 141 MSSA. Subsequently ,the antimicrobial susceptibility test was performed by Kirby Bauer disc diffusion method as per CLSI guidelines. All strains found resistant to vancomycin by disc diffusion method were again grown on BHI-VSA(Brain heart infusion-Vancomycin screen agar) and also recruited to E- Test for confirmation of resistance. Minimum Inhibitory Concentration (MIC) of ≤2 were considered as VSSA,4-8 as VISA.MIC of ≥16 as VRSA. Vancomycin resistance was seen in 9 isolates of S. aureus by disc diffusion method. Among them neither was found to be VISA nor VRSA when confirmed with E-Test with all having MIC <2 .Though there was no incidence of VRSA but MIC of 1.5µg/ml in our study rang an alarm to the infection control committee of this tertiary care hospital.*

Keywords: *MIC, S.aureus, VISA, VRSA, Vancomycin Screen Agar*

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I. Introduction

Staphylococcus aureus is one of the most notorious and important human pathogen that has long been recognized for its ability to cause serious and invasive diseases. Staphylococcus aureus is the most pathogenic member of Staphylococcus genus. This microbe is ubiquitous in nature which resides in the human as a commensally. Some of the commoner infection caused by Staph. aureus include Pyogenic infection (eg. Folliculitis impetigo, breast abscess, post operative wound infection, osteomylitis, septic arthritis, bronchopneumonia, lungs abscess, empyema). Disseminated infection such as Septicemia. Toxic shock syndrome (TSS), staphylococcal scalded skin syndrome(SSSS), staphylococcal food poisoning.[1] A wide range of antibiotics are used to treat the staphylococcal infections including penicillin, cephalosporin, macrolide, fluroquinolone and glycopeptide group of antibiotics.[3] In early 90s,the major treatment available to combat this organism was Penicillin and all isolates were sensitive to penicillin. In the 1960s, a new semisynthetic penicillinase-resistant antimicrobial drugs *methicillin* (formerly named as celbenine) and oxacillin were developed to treat staphylococcal infections caused by β-lactamase-production.[4] But at present, some S. aureus strains also show resistant to methicillin.[2]

Methicillin-resistant Staphylococcus aureus (MRSA)[5] has been recognized as one of the major pathogens in both hospital and community settings. The first case of MRSA was isolated way back in 1961.Since then, there has been an escalating rate of infections caused by MRSA worldwide resulting in increased mortality and morbidity statistics. In India, the prevalence of nosocomial infections caused by MRSA varies between 20 and 40%.*Vancomycin***,** a glycopeptides antibiotics had been considered to be the "gold standard antibiotic" and the drug of choice over the last 3 decades[6]

Apart from vancomycin ,other effective drugs as linezolid and teticolanin are also widely used. Injudicious and infrequent use of vancomycin even in methicillin sensitive Staphylococcal infection has resulted in emergence of the strains with higher vancomycin MIC.[7] At present few vancomycin resistant S.*aureus* strains have been reported. Initially in early twenties,only VISA (Vancomycin intermediate S. *aureus*) strains

were reported by CDC but even now in India, there is emergence of S.aureus strain with higher vancomycin MIC.

This higher vancomycin MIC has been attributed by increased thickness of cell wall as in case of Vancomycin Intermediate Staphylococcus aureus.[8] Vancomycin resistance is acquired by mutation and thickening of cell wall due to accumulation of excess amounts of peptidoglycan.[9]

Keeping the above points in view and also that documented reports of VISA and VRSA in India including Rajasthan are very few ,the present study was planned to find out the prevalence of vancomycin intermediate Staphylococcus aureus and vancomycin resistant staphylococcus aureus among isolates of Staphylococcus aureus in various clinical specimens along with their antibiotic sensitivity pattern so as to guide the clinicians of our hospital to select appropriate antimicrobial agents and also to make them aware ,that if inappropriate use of vancomycin is continued it may lead to impending public health disaster. There fore the present study is designed to find out the prevalence of vancomycin intermediate and resistant Staphylococcus aureus in clinical specimen and to determine the antibiotic susceptibility pattern of vancomycin intermediate and resistant Staphylococcus aureus and to measure the MIC values of vancomycin intermediate and resistant Staphylococcus aureus by E-test.

II. Material And Methods

The present study was conducted in the Department of Microbiology, NIMS Jaipur during the year 2017-2018. A total of 287 non- duplicate Staphylococcus. aureus isolates from various clinical specimens [pus, wound or vaginal swabs, blood, body fluids (csf, pleural fluid, ascitic fluid) urine, sputum, ET secretion etc. were included in the study. Isolates from both in-patients and out-patients were considered. Institutional Ethical clearance was obtained. Data regarding age, sex, etc was obtained from the requisition form submitted to microbiology Department, NIMS, Jaipur.

2.1 Isolation & Identification, of Staphylococcus aureus[10,11]

Smears were prepared from pus, wound swab, sediments of body fluids and respiratory samples, stained by Gram staining and examined for presence of inflammatory cells, epithelial cells and the type of microbial flora. As soon the samples received in the laboratory, Streak culture method was employed for sample inoculation on Blood agar, Nutrient agar. Culture plates were incubated at 37^{o} C aerobically for 24-48 hours .Plates were observed for typical colony characteristics of Staphylococcus aureus on Blood agar (β haemolysis) and Nutrient agar (yellow pigment).For plates with mixed culture growth, sub culture was done on blood agar and incubated for 18-24 hours aerobically at 37^{o}C. Sub culture was also done for Staphylococci colonies more than 48 hours old, where ever required. Gram's staining was performed from representative colonies, and observed for Gram positive cocci in clusters, under oil immersion microscope. Catalase test was performed from Nutrient agar plate. This test is positive for Staphylococcus aureus and differentiates from Streptococci. Slide coagulase test was employed to detect presence of clumping. factor (bound coagulase) which was indicated by prompt clumping in positive isolates. Irrespective of result of slide coagulase test, tube coagulase test was done for presence of coagulase enzyme (Free coagulase). Staphylococcus aureus is positive. For all Staphylococcus aureus strains mannitol fermentation was observed on Mannitol salt agar.

2.2 Antibiotic Sensitivity testing of Staphylococcus aureus[12]

Antibiotic susceptibility to a panel of drugs was tested using (Modified Kirby Bauer's method. Antibiotic discs procured commercially [Hi-media Laboratories, Mumbai] and were placed on inoculated MHA plates using forceps. Plates were incubated at 35±2PC for 18-24 hours. Zone of inhibition of all the antibiotics were measured with scale in reflected light against a black background, to the nearest mm. Interpretation was done according to the guidelines of Clinical Laboratory Standards Institute (2012). All Staphylococcus aureus isolates were subjected to predetermined panel of antibiotics which includes cefoxitin[30ug], Penicillin [10µgm], Cotrimoxazole [1.5/23.75µgm], Erythromycin[15µgm], Ciprofloxacin [5µgm], Clindamycin [2 µgm], Gentamycin [10 µgm], Levofloxacin [5 µgm], Tetracycline [30 µgm], Vancomycin [30 µgm]. Staphylococcus aureus ATCC 25923 was used as control. Cefoxitin disc (30 µgm) was used along with other antibiotics, to detect methicillin resistant isolates as it is a potent inducer of mec A gene mediated resistance[12].

2.3 Detection of Vancomycin resistance

Following 3 methods were used and comparison between modified Kirby -Bauer disc diffusion method using 30μg Vancomycin disc and BHI vancomycin screen agar (6 µg/ml) was done keeping in view E-test as gold standard for detection of vancomycin resistance.

2.3.1 Disc diffusion by Modified Kirby Bauer's Method[13]

It was performed using Vancomycin 30p.g disc. The diameter of-zone of inhibition was measured and interpreted according to CLSI guidelines 2007 [13]. B.BHI vancomycin screen agar[12] BHI-VSA (Hi-Media, India) plates containing 6m/m1 vancomycin were prepared. Inoculum suspensions were prepared by selecting colonies from subcultured colonies on nutrient agar plates. The colonies were transferred to sterile saline to produce a suspension that matches the turbidity of a 0.5 McFarland standard. Using a micropipette, spot of 10-µL drop onto agar surface was done and were incubated aerobically at 35±2°Cfor 24 hrs[14]. Any growth is examined carefully with transmitted light.

2.3.2 Determination of Minimum Inhibitory Concentration (MIC) values[15]

The MIC value of vancomycin was determined by E-test [Epsilometer-test]. Inoculum suspensions were prepared by selecting colonies from overnight growth on nutrient agar plates. The colonies were transferred to sterile saline to produce a suspension that matches the turbidity of a 0.5 McFarland standard and a lawn culture was prepared by pouring the growth suspension on the surface of the BHI agar plate. After drying the surface for half an hour, the E-strips were placed over the surface and incubated over night at 35°C.The plates were read only when sufficient growth was seen and the MIC values were recorded where the ellipse intersects the MIC scale on the strip. If the ellipse intersects the strip in between 2 dilutions MIC was recorded as the value which is nearest to the intersection. For classifying isolates of Staphylococcus aureus with reduced susceptibility to vancomycin based on the laboratory breakpoint published by the clinical and laboratory standards institute [CLSI guidelines][12]

Vancomycin sensitive Staphylococcus aureus [VSSA]: ≤2 µg/ml.
Vancomycin intermediate Staphylococcus aureus [VISA]: 4-8 µg/ml.
Vancomycin resistant Staphylococcus aureus [VRSA]: ≥16 µg/ml.

III. Observation And Results

During the study period, a total of 287 non duplicate Staphylococcus aureus isolates were obtained from variation clinical specimens. Methicillin resistance was detected in 146 (51%) of the total isolates. Isolates that were sensitive to methicillin were 141 (49%) in 287strains.

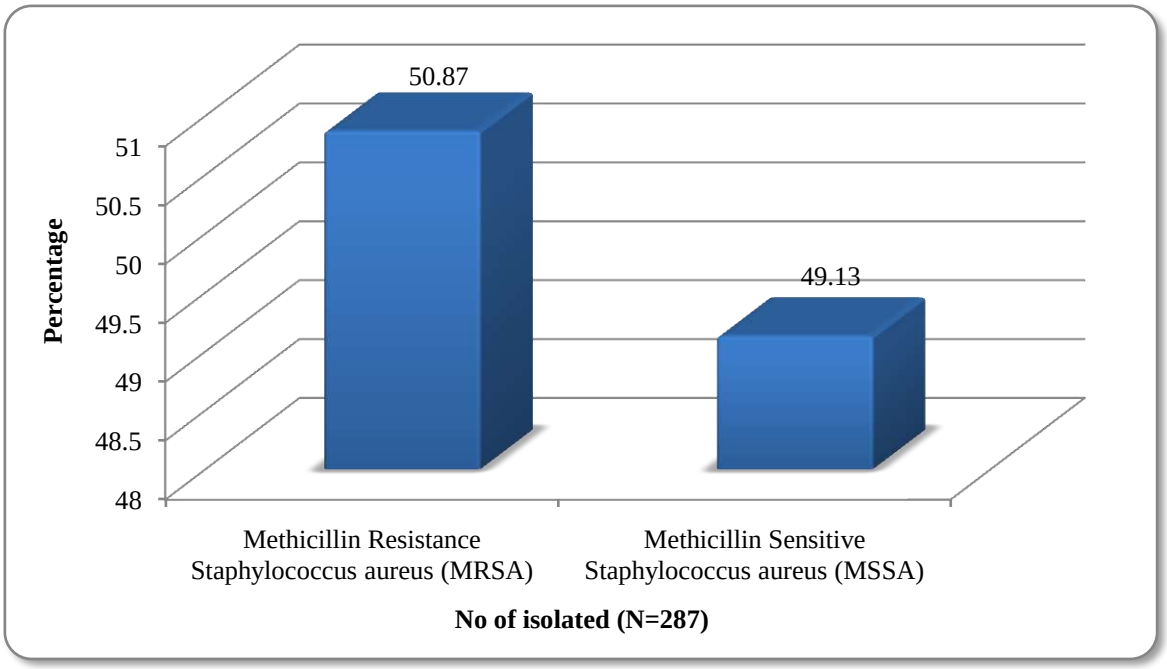

Fig. 1: Prevalence of MRSA and MSSA in total of 287 Staphylococcus aureus isolates

3.1 Vancomycin Resistance

Three phenotypic methods employed in detection of Vancomycin resistance,

3.1.1 Disc Diffusion method

In a total of 287 S.aureus stains, 9 (3%) isolates had shown resistance towards Vancomycin in Disc diffusion.

3.1.2 BHI Vancomycin screen agar (6 ugtn/ ml)

None of the isolates grew on So no resistance is.reported by this method.

3.1.3 Epsilometer [E-testl for Vancomycin

It was considered as Gold Standard. MIC values of all the 287 isolates fall in between range of≤ 2µg /ml, which is category of sensitive. All of the 9 isolates, which were resistant by Vancomycin disc diffusion, are in range of sensitive MIC.

Table No 1: Detection of Vancomycin resistance by different phenotypic methods

Methods	VISA	VRSA	VSSA	Total
Vancomycin disc diffusion (30 ug/disc)	NA	9	278	287
Vancomycin Screen Agar(6ug/ml)	00	00	287	287
Vancomycin E Test	00	00	287	287

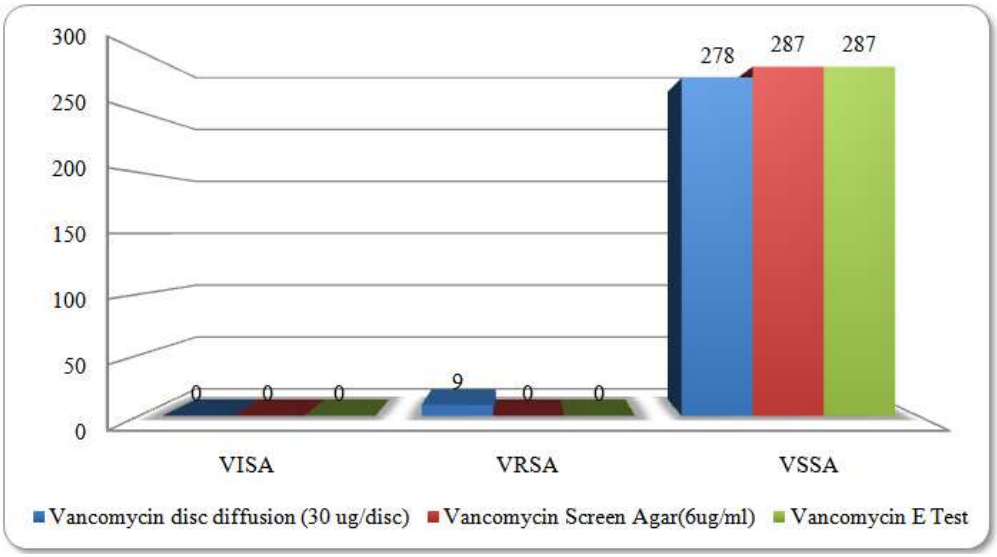

Fig. 2: Detection of Vancomycin resistance by different phenotypic methods

Table No 2: Distribution of the cases according to MIC Values (ugm/ml) against vancomycin

MIC Values (ugm/ml)	Total	
	No	%
0-0.5	169	58.89
>0.5-1	112	39.02
>1-1.5	6	2.09
Total	287	100.00

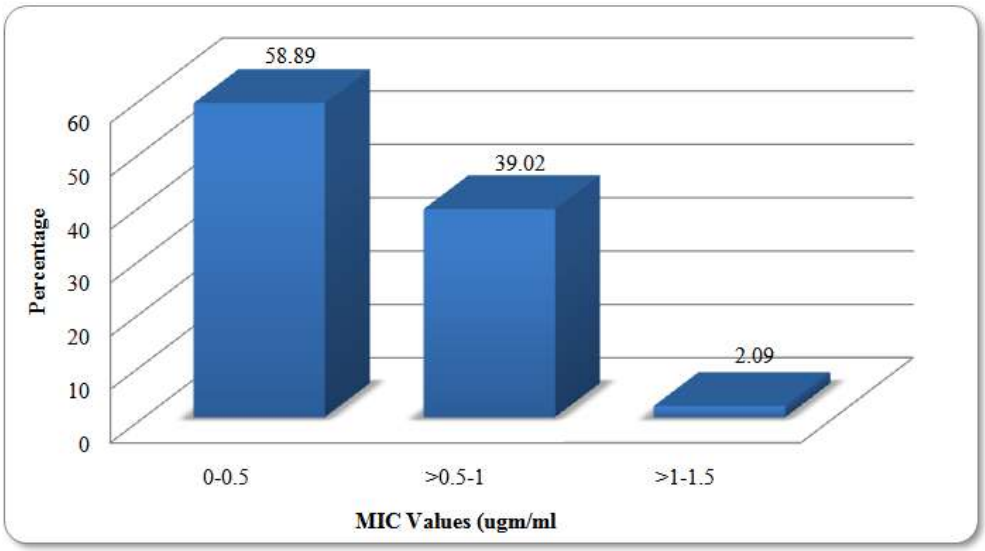

Fig.3: Distribution of the cases according to MIC Values (ugm/ml) against vancomycin

3.2 Antibiogram

All 287 Staphylococcus aureus strains were tested for antibiotic susceptibility pattern against a panel of predefined antibiotics, which was described earlier.

Staphylococcus aureus showed 88% resistance to Pencillin G, followed by 51% resistance to Cefoxitin, 43% each to Co-trimaxazole and Erythromycin, 66% to Ciprofloxacin, 31% to Clindamycin, 16% to Gentarnycin and 28% to Levofloxacin and 3% each for both Tetracycline and Vancomycin.

IV. Discussion

Staphylococcus aureus is a major human pathogen and is one of the commonest causative agent of Community and Hospital acquired infections[11]. The treatment of Staphylococcus aureus infection has become problematic because of emergence of resistance to Penicillin, Methicillin, Vancomycin and many other antibiotics, by acquiring several resistance mechanisms. Increased antimicrobial resistance for such an organism is, therefore a cause of concern.

In the past few decades MRSA has emerged as an important nosocomial pathogen worldwide. In India, prevalence rate varies from 30-85% in different parts and has now become endemic.[16,17,18] A multicentric study done in India involving 17 tertiary care Hospitals reported MRSA prevalence of 41% in 2008-2009.

MRSA is of serious therapeutic, concern not only due to its resistance to Methicillin, but also because of resistance to many other antimicrobials that are used on regular basis in Hospitals. Therefore, the most reliable and sustained therapeutic agerit against methicillin-resiStant Staphylococcus aureus (MRSA) strains is Vancomycin[19]. There is still controversy in clinicians regarding the outcome of Vancomycin treatment in MRSA. Increasing prevalence of MRSA, lead to the extensive use of vancomycin. This inturn lead to the decreased susceptibility to Vancomycin all over the World including India, this was soon followed by strains of Staphylococcus aureus that were totally resistant to vancomycin[20,21]. Such resistance resulted in serious clinical and public health consequences because currently few licenced alternatives are available. to treat vancomycin resistant Staphylococcus aureus infections.

Thus the present study was undertaken to determine the current status of Vancomycin susceptibility in our Hospital setup. to compare the Vancomycin disc diffusion test with BHI- VSA [6µgm/ml] for detecting Vanomycin resistance considering E-Test as gold standard and also to determine the antibiotic susceptibility pattern of these isolates.

In the present study a total of 287 non-duplicate staphylococcus strains were isolated from various clinical specimens. Among all these samples highest isolation was from pus 175 (61%). Harcharan Singh et al in Udaipur (65%)[22], Manu Chaudhary et al in H.P (63%)[23] and Ankur Goyal et at in Agra (66,03%) [24], also reported the highest isolation of Staphylococcus. aureus from pus.

In our study 146 (51%) isolates turned out to be MRSA and 141 (49%) as MSSA. from a total of 287 Staphylococcus aureus strains. The prevalence rate of MRSA in our institute is 51%, which is similar to the studies conducted by S.Vidhani and P.L. Mehndiratta et al in 2001[25] showing a prevalence rate of 51.6% and almost comparable -to the study conducted by Majumdar et al in 2001[26] and Assadullah et al in 2003[27] showing 52.9% prevalence rate. The higher rate in their studies may been attributed to the fact that the studies were conducted at a tertiary care multispecialty center with more and more patients coming from periphery and small nursing homes, where injudious use of antibiotics and inadequate infection control policies are prevalent.

In the present study, maximum MRSA were isolated from pus 89(61%), followed by blood 22(15%), respiratory secretions 15(10%), Swabs and body fluids 7(5%) each and least from Urine 6 (4%). This pattern correlates with studies conducted by Vidya Pai et al in 2010[28] and Nitish Kumar Sharma et al 2013[18]. This is due to the reason that Staphylococcus aureus accounts for most of the skin and soft tissue infections, septicemia and also respiratory tract infection.

Comparatively MRSA prevalence was more in males. (71%) than in females (29%) in our study: Similar findings was also reported by Rao BN et al[29] and Abhishek Mewar et al[30]. The increased rate of MRSA infections among males could be due to their more outdoor activities, inturn exposing them to contaminated environment and also compared to females, accidental injuries are more common among men.

Most of the MRSA strains were isolated from 21-30 yrs of age group (ie 23.69%) and in 31-40yrs (ie 17.77%), indicating MRSA infection is more common in working and old age group. The reason for this may be that younger age group are more involved in outdoor activities inturn exposing them to contaminated environment and in older age group it may be due to waning immunity, hormonal abnormalities and co-morbid conditions. Similar pattern of affected age group. was also reported by Ankur Goyal et al in 2013[24].

In the present study all 287 Staphylococcus aureus strains were screened for vancomycin resistance by Vancomycin disc diffusion method [30g/disc] and BHI-Vancomycin screen agar [6µg/ml]. These were further confirmed by Vancomycin E-test. All 287 Staphylococcus aureus isolates had MIC values ≤ 2µg/ml, hence all were sensitive to Vancomycin and were labeled as VSSA according to the CLSI guidelines 2012[12]. Among

these 169(59%) isolates had MIC of < 0.5µg/ml, 112[39%] had MIC of >0.5-1 µg /ml. Only 6[2%] had MIC of >1-1.5 µg /m1 and none of the isolates had MIC values of >1.5 µg /ml.

In our study no VISA. and VRSA found. This may be due to the fact that the community acquired MRSA (CA-MRSA) unlike the hospital acquired MRSA (HA-MRSA) are known to be sensitive to drugs other than vancomycin. Because of its. high cost, vancomycin may not be in use in the peripheral rural setups, thus decreasing the selection pressure for vancomycin resistance[31].

The current study only indicates the tip of iceberg. More and more studies should be undertaken in future to 'monitor the emergence of resistance to these. antibiotics. This also necessitates to find out better treatment policies and also to use cheaper and effective alternative anti - MRSA drugs so as to reduce the antibiotic pressure on vancomycin. Also clinicians should continue to exercise caution in their use of vancomycin in order to preserve this useful antibiotic and prolong its therapeutic usefulness.

V. Conclusion

To conclude, the result of our present study indicated high antibiotic resistance in commonly used antibiotics by MRSA isolates. The increased use of vancomycin drug has worsened the sensitivity.

We should undertake more and more such studies in future to fight against rising menace of antibiotic resistance, Also more research should be done to find better treatment policies, effective and cheaper alternative antibiotics in developing countries like ours. Even the clinical microbiology laboratories must ensure using detection methods with good sensitivity and specificity. We should also undertake more studies to find out the accurate screening method for VISA and VRSA. The findings of the studies should be shared with hospital infection control committee to help in the formulation of infection control polices and also antibiotic policies. So that the primary care givers can use antibiotics rationally.

However, S. aureus with reduced susceptibility was not observed in the present study. So, as a precautionary measure before starting the patient on vancomycin, the clinicians should seek the help of Clinical Microbiologist to determine the MIC of such strains so that emergence of vancomycin resistance can be prevented. All the laboratories should routinely test the MIC of vancomycin for all Staphylococcus aureus infection for appropriate treatment of patients and also for implementation of infection control.

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Changing Trends in Distribution and Antifungal Susceptibility Pattern of Candida Species Isolated from Various Clinical Samples at A Tertiary Care Hospital, Jaipur

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Abstract

The changing epidemiology from *Candida albicans* to *Non-albicans Candida* along with increasing antifungal resistance is a matter of great concern in health care settings. The studies on *Candida* have largely been carried out by the morphological identification but to the best of my knowledge very little work has been done in Rajasthan to find out antifungal susceptibility pattern of *Candida* species. Keeping in view the above facts, this study was undertaken for identification and evaluation of antifungal susceptibility pattern of *Candida* species isolated from various clinical samples in a tertiary care hospital, Jaipur. A total of 51 candida species were isolated during a period from Jan 2017- May 2017 and identified by standard microbiological procedures. Antifungal susceptibility testing was carried out on the basis of CLSI M44-A guidelines. Out of 51 Candida isolates, 23 were candida albicans and 28 were Non-albicans candida. Among Non – Candida albicans, 17 isolates were C.tropicalis, 9 and 2 isolates were C. krusei and C. glabrata respectively. Candidiasis was more commonly found in female patients and in 20-39 years of age group. Overall, antifungal susceptibility of Candida species to Fluconazole was 57%, Voriconazole 76%, 88% to Amphotericin B and 94 % to Nystatin. Therefore, The changing trends in epidemiology of candidiasis, necessitates the speciation of candida species which inturn facilitate the development of effective measures to prevent and control transmission of resistant pathogen.

Keywords
Changing trends, candida species, candidiasis, antifungal susceptibility.

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INTRODUCTION

The incidence and prevalence of fungal infection due to Candida species are increasing significantly in the recent few decades, so contributing to morbidity and mortality[1]. This increase is mainly due to expanding population of immunocompromised patients that use total parenteral nutrition and intravenous catheters; increasing use of prolonged antibiotic therapy; in organ transplant recipients and also a rise in use of invasive procedures for diagnosis and treatment[2,3].

Candida spp, belonging to yeast like fungi are the normal commensal microflora of skin, mucous membrane of oral cavity, gastrointestinal, genitourinary and respiratory tract[4]. They become pathogenic particularly when the host defense mechanism is lowered and causes an opportunistic infection[5,6].

Genus Candida includes > 500 species, in which only 20 species are recovered from human samples[7]. Among these 20 Candida species, *Candida albicans* is generally considered as major pathogen. But recently published epidemiological data highlights an increase of Non-albicans candida species such as *C. tropicalis, C. parapsilosis, C. glabrata, C. dubliniensis and C. krusei*[8].

In addition, the numbers of new Candida species isolated from clinical samples are increasing continuously every year, which were previously considered "non-pathogenic". The major reason for this could be the use of various commercially available identification methods by clinical microbiology laboratories worldwide to supplement the conventional methods of identification, also a rapid increase in number of immunocompromised patients worldwide in view of the HIV epidemic, organ transplantation and malignancies[9].

Candidiasis is the commonest fungal disease, usually endogenous in origin. All Candida species causes diseases ranging from simple mucosal colonization, superficial infections such as oral thrush to invasive fungal diseases, yet they show difference in disease severity and susceptibility to different antifungal agents[10].

Fluconazole is a triazole most effective and frequently prescribed antifungal drug for treatment of candidiasis, as it has an excellent patient tolerance and minimal side effects. A growing worldwide increase in use of this drug for treatment of candidiasis, in turn lead to drug resistance and also one of the principal causes of recent increase in prevalence of non- candida albicans candidiasis[11].

The changing trends of candidiasis necessitates the speciation of candida species which inturn facilitate the development of effective measures to prevent and control transmission of resistant pathogen. Hence the present study was carried out to detect the clinical distribution of candida species in various clinical specimens along with their antifungal susceptibility pattern.

MATERIAL AND METHOD:

Source of material - The present study was conducted in the department of Microbiology, NIMS Medical College and Hospital, Jaipur (Rajasthan) from January 2017 to May 2017.

Inclusion criteria

- All the *Candida* species isolated from various clinical samples will be included in the study.

Exclusion criteria

- All other fungal isolates except *Candida* species were excluded from the study.

Processing of Samples

During this period all clinical samples suspected of fungal infection, which were received from different Wards, ICUs and OPDs of the hospital and were submitted to microbiology laboratory with all aseptic precautions and processed in the following manner -

1. Direct examination of sample[7]- Direct microscopic examination by 10% KOH mount and Gram staining reveals presence of oval budding yeast cells with / without pseudohyphae.

2. Isolation and Identification of Candida species[7] - This was done by standard conventional method ie inoculation of the sample on to Blood agar and SDA, both were incubated at 37°C for 48-72 hrs. All the samples which showed growth were identified by colony characteristics and by gram staining. Once the conformation of colonies was done, they were further speciated by germ tube test, chlamydospore formation on Corn Meal agar, sugar fermentation and assimilation test.

3. **Antifungal susceptibility pattern[12,13]**- This was done by agar disc diffusion method as recommended by CLSI (M-44A) guidelines. Mueller - Hinton agar with 2% glucose and 0.5ug/ml methylene blue and antifungal agents like Fluconazole, Voriconazole, Nystatin and Amphotericin B were used.

RESULT:

In the present study, a total of 51 (4.5%) Candida species were isolated from 1113 clinical specimens (Fig-1). Maximum Candida were isolated from patients in the age group of 20-39 yrs (33.3%) followed by extremes of age ie 60-79 yrs (23%) and <19 yrs (22%) (Fig-2). Candidiasis was more common in female patients ie 28 (55%) than in males' patients ie 23(45%). Female: Male ratio was 1.2:1 (fig 3).

Out of 51 Candida isolates, most common isolated species was non - Candida albicans ie 28 (55%) followed by Candida albicans ie 23 (45%) (Fig 4). Out of 28 Non-albicans candida, C.tropicalis was most frequently isolated (33%) followed by C.krusei (18%) and C.glabrata (4%) .

Majority of Candida species were isolated from urine samples (51%) followed by sputum (22%), HVS (10%), ear swab (8%), 2% each from foleys catheter, blood, stool, ET secretion and throat swab (Fig 5). Among the isolates derived from urine, C.tropicalis (42%) was predominant followed by C.albicans (27%) and C.krusei (23%), where as C.albicans(82%) was most frequently isolated from sputum sample followed by C.krusei (18%) (Fig 6).

Overall, antifungal susceptibility of Candida species to Fluconazole was 57%, Voriconazole - 76%, 88% to Amphotericin B and 94 % to Nystatin. Hence among the 4 antifungal drugs highest susceptibility was observed for Nystatin and highest level of resistance to Fluconazole 43%. Candida albicans was 100% sensitive to Nystatin and Amphotericin B, 87% and 78 % sensitive to Fluconazole and Voriconazole respectively, where as C.tropicalis was 88%, 82%, 65% and 59% sensitive to Nystatin, Amphotericin B, Voriconazole and Fluconazole. 100 % resistance was seen in C. glabrata against Fluconazole, followed by 100% sensitivity to Nystatin and Voriconazole. In case of C.krusei, 89% resistance was reported for fluconazole, followed by 11%, 22% and 33% resistance to Nystatin, Amphotericin B and voriconazole respectively. (graph 1,2,3,4).

Figure 1: Isolation rate of Candida species from various clinical samples

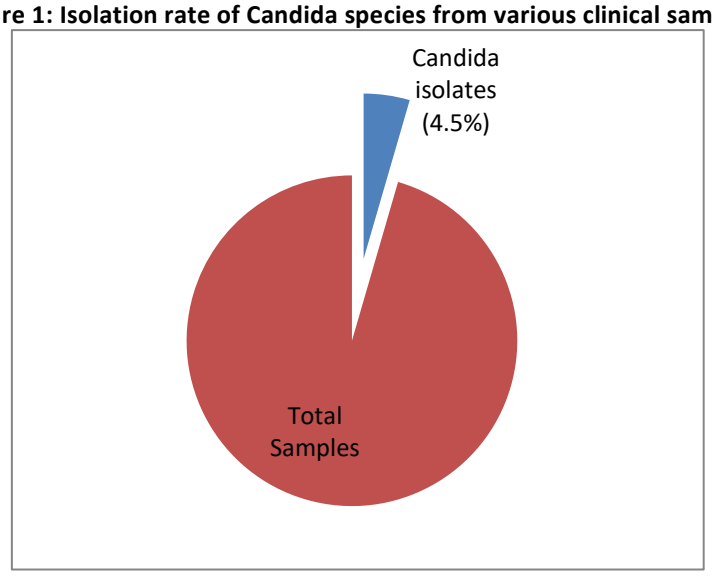


Figure 2: Age wise distribution of patients with Candida infection

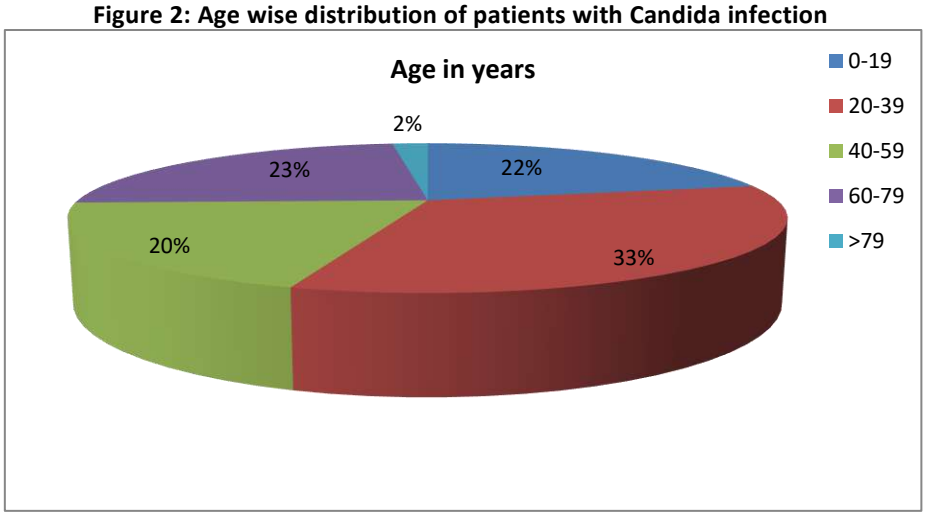


Figure 3: Sex wise distribution of patients with Candida infection

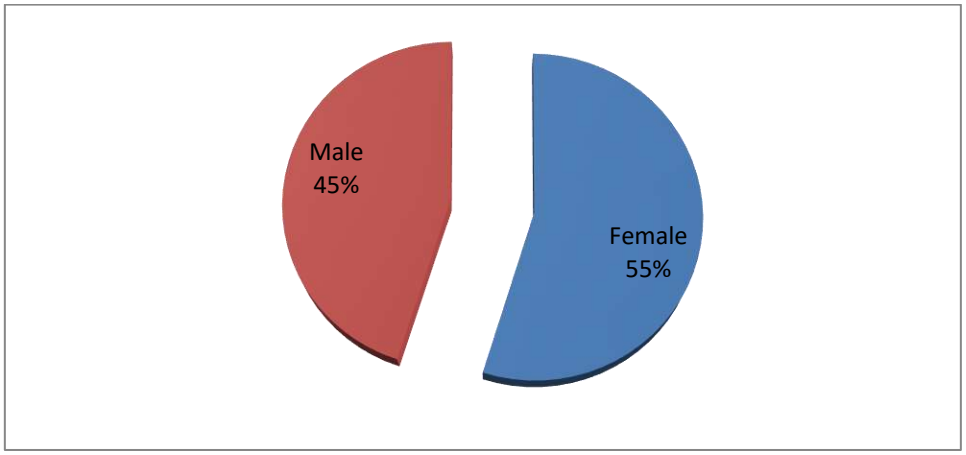


Fig 4: Distribution of Candida species

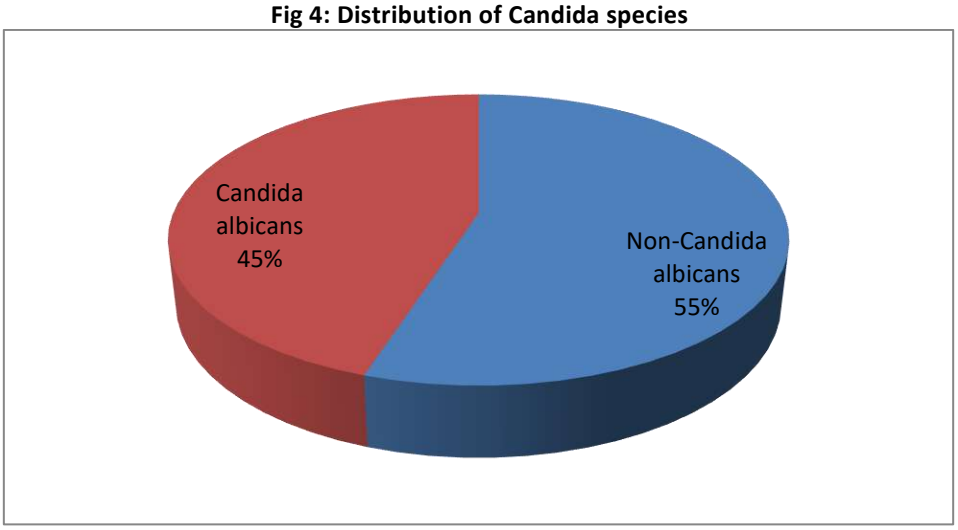


Figure 5: Specimen wise distribution of Candida Species

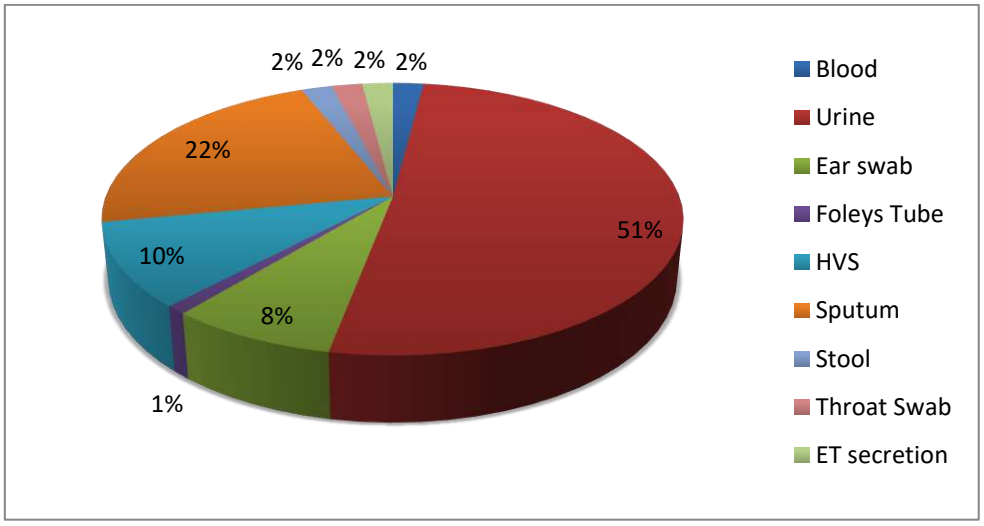
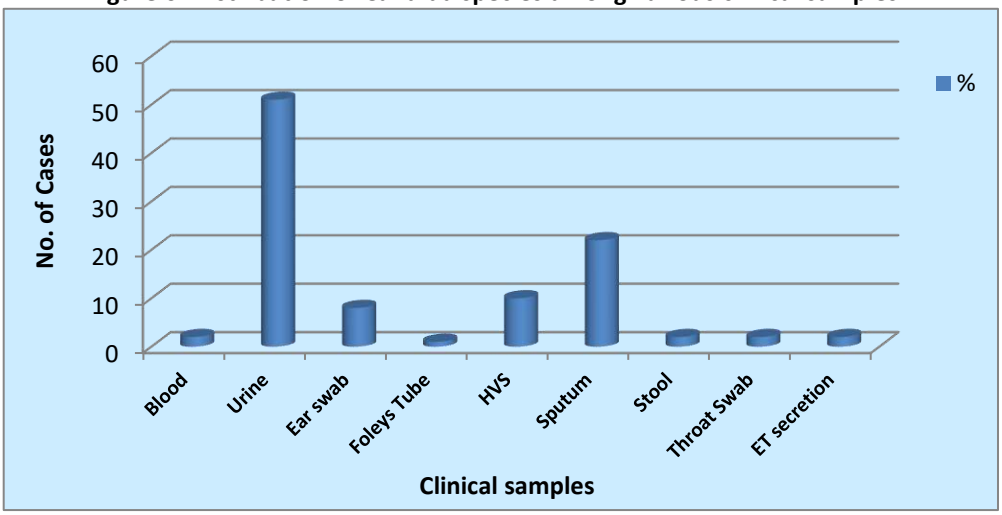
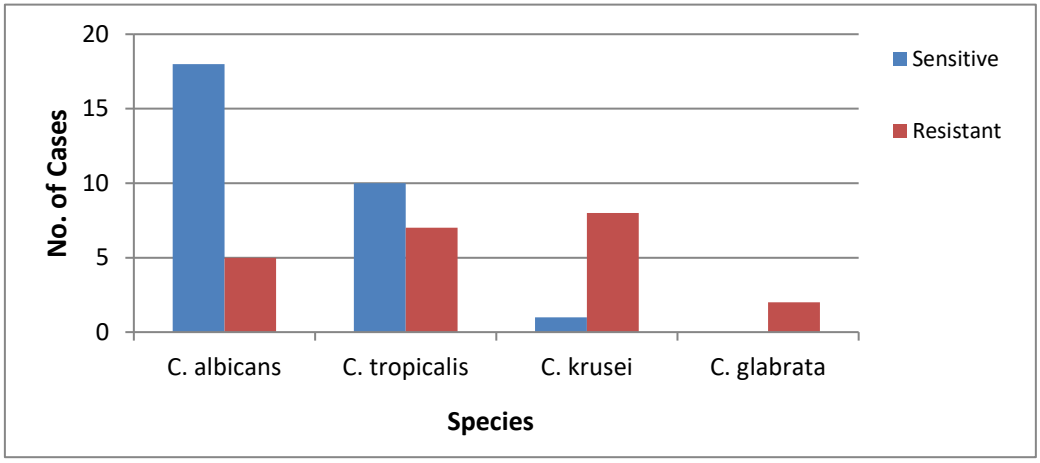


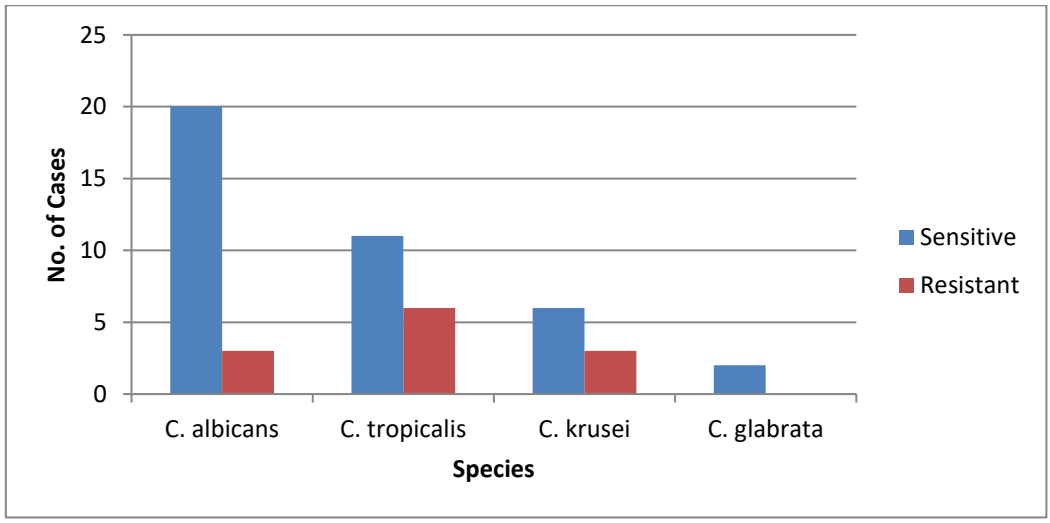
Figure 6: Distribution of Candida species among various clinical samples



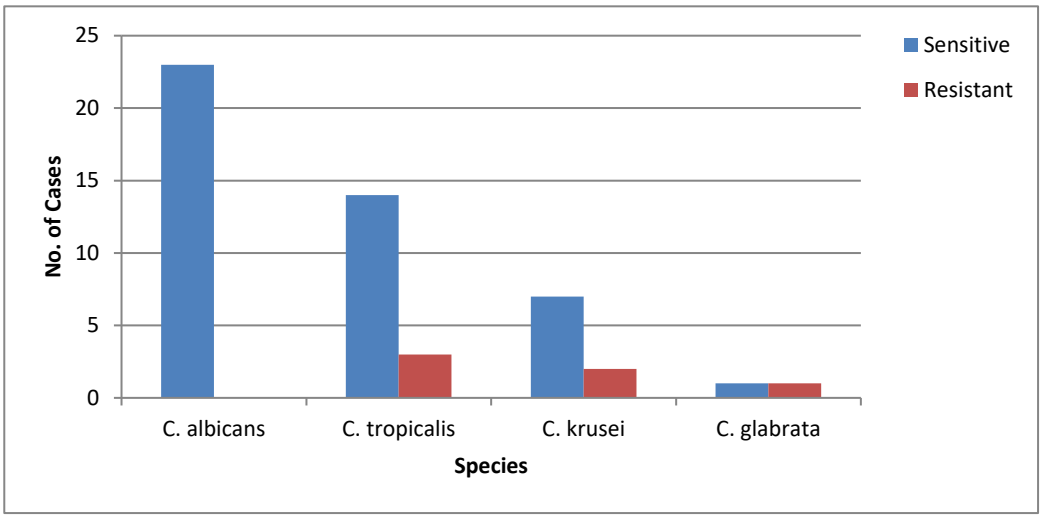
Graph 1: Antifungal susceptibility of Candida isolates to Fluconazole



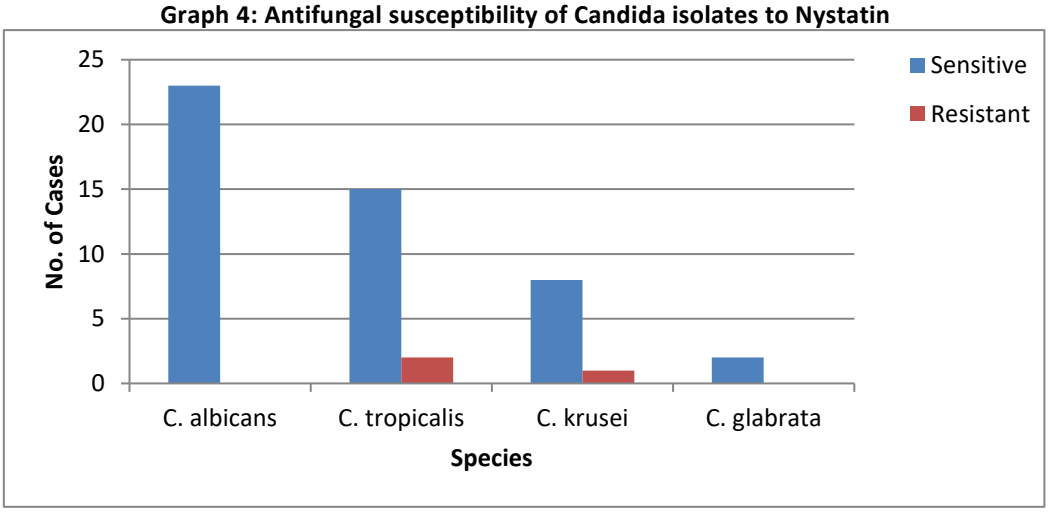
Graph 2: Antifungal susceptibility of Candida isolates to Voriconazole



Graph 3: Antifungal susceptibility of Candida isolates to Amphotericin B



Graph 4: Antifungal susceptibility of Candida isolates to Nystatin



DISCUSSION:

Over the past two decades, a significant increase in the incidence of mycosis in general and Candidiasis in particular is reported in various studies[14]. Also, in recent years non- Candida albicans, emerged as a major pathogen causing serious diseases in humans as they are resistant to commonly used antifungal agents[15]. To tackle this grave situation, the present study was under taken to provide a detailed analysis of the distribution and antifungal susceptibility of 51 isolates of Candida species in various clinical samples and in patients of different age group and gender.

In the present study maximum number of Candida species were isolated from urine samples followed by sputum samples. This is similar to the study conducted by Sukumaran et. al.[16] and Agarwal et. al.[17], in which more no of Candida isolates were found in urine samples. Similarly, a study conducted by Sundar Khadka et. al.[18] isolated maximum number of Candida species from urine (48%) and sputum (42%) samples. These studies indicate increased incidence and isolation of Candida species in Urinary tract and respiratory tract infection.

In the present study Non-albicans candida were isolated at a higher rate (55%) than C.albicans (45%),which was in agreement with the studies conducted by Ragini et al.[19],Chakrabarthi et al.[9] and Agarwal et al.[21] These studies indicate that Non-albicans candida are emerging as a major pathogen and they are treat for future. This change in pattern has been partly attributed to increased immune suppression resulting in higher number of susceptibilities in immunocompromised patients and also to the prophylactic use of antifungal agents in critically ill patients. Hospitalization (especially in

ICU), placement of central venous catheters and the other indwelling devices, previous antimicrobial therapies have played significant role in this changing pattern of Candidiasis.

Among the non- Candida albicans, C.tropicalis(33%) was most frequently isolated followed by C.krusei(18%) and C.glabrata(4%).These findings are comparable to the studies conducted by different researchers like Divya Dadhich et al.[22] and L. Sumitra deviet al.[23] while a study carried out by Mokadas et al.[24] reported C.parasilosis as the most common Non-albicans candida species. In our study the most common isolate in Urine and blood samples was C. tropicalis which correlates well with the study of L. Sumitra Devi et al.[23] C. albicans was the most common isolate in Sputum which is in accordance with the studies of B. Madhumati et al.[25]

In the present study, it was found that Candidiasis can occur at all ages. The youngest in our study was one-year old baby while the eldest was 85 years. The mean age was found to be 43 years. The highest incidence was seen in the age group of 20-39 years. This is similar to the study conducted by Lata R Patel et al, Dalal et al.[100], Jayalaxmi et al[101] showing maximum cases in the age group of 21-40 years.

Comparatively Candida isolation was more in female patients (55%) than in male patients (45%) in our study. Similar finding was also reported by Megha Pawar et al and Sujatha R et al with female predominance. The possible reason is that Candiduria and genital Candidiasis is more common in females during reproductive age group.

In this study, Candida species were more susceptible to Nystatin, followed by Amphotericin B (88%), Voriconazole (76%) and Fluconazole (57%). Hence Nystatin and Amphotericin B emerged as most efficacious drug for the treatment of Candidiasis and also 43% Candida isolates demonstrated resistance to fluconazole which is similar to study done by Deorukhkar et al. Highest resistance to fluconazole was reported by Non – Candida albicans.

CONCLUSION:

To conclude, the present study highlights the predominance of Non- Candida albicans in various clinical specimens. Among commonly used antifungal drugs Nystatin, Amphotericin B, Voriconazole showed high rates of sensitivities while Fluconazole was least effective for candidiasis. This study in our set up will help in recognizing the emerging candida species along with their increasing drug resistance. Therefore, the changing trends of candidiasis, necessitates the speciation of candida species along with their antifungal susceptibility pattern, this will enable the clinicians to choose appropriate antifungal agents, which will inturn decrease the patient's morbidity and mortality.

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Blood Culture of Neonates in Paediatric Department and their Antimicrobial Susceptibility Pattern in and around Nims University, Jaipur, India

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A B S T R A C T

Blood stream infections are very common in the paediatric age group and these are one of the common causes of morbidity and mortality in neonates and children. Objectives of the study are to isolate the different organisms from Blood cultures of Neonates by BACTEC method and know their Antibiotic susceptibility patterns. We processed 100 Blood samples of the Neonates from PICU of NIMS Medical College and Hospital between January and June 2016 (06 months). Samples were collected in BACTEC PEDS PLUS vials with all aseptic precautions. The vials were placed in the BACTEC 9050 and cultured. The positive vials were further plated on BA, MacConkey Agar looked for the growth and identified by necessary biochemical reactions and antibiotic susceptibility is done by Kirby-Bauer method. Out of 100 blood culture samples, 58 were positive. Out of 58, 18 yielded CoNS (31.03%), 12- *Klebsiella* spp (20.68%), 04 - *Staphylococcus aureus* (6.89%), 06 - *Enterococcus* spp (10.34%), 12- *Enterobacter* spp (20.68%), and 02 each of *E. coli* (3.44%), *Citrobacter* (3.44%) and *Acinetobacter* (3.44%). Significantly high rates of Gram Negative bacterial infections were seen followed by Gram Positives. Automated Blood Culture systems significantly reduced the time required for processing of samples and also facilitated the yield of diverse organisms. Antibiotic Susceptibility patterns also showed Gram Negative bacteria to be less sensitive than Gram Positive bacteria.

Introduction

Blood stream infections are very common in the paediatric age group and these are one of the common causes of morbidity and mortality in neonates and children. The incidence of sepsis is increasing all over the world leading to high morbidity and mortality rates (Kavitha *et al*., 2010). Detection of Bacteremia by blood culture is critical in managing patients with infection, and directs the appropriate selection of antimicrobials. Blood culture is a common laboratory investigation where blood is inoculated into culture medium and continuously monitored for positive growth. Media used in the blood culture bottles support the growth of most medically important bacteria. Manual culture techniques often take a longer duration for detection and isolation of organisms (Tarai *et*

al., 2012). Blood culture technology has changed from tube or bottles of liquid culture medium requiring frequent inspection, microscopic or blind plating on to solid culture medium to see if growth has occurred to modern, closed, computer based systems, which assess changes in CO2 indicating growth every 10-15 minutes (the BacT/ALERT microbial detection system, Organon Teknika Corporation, Durham, North Carolina, USA) (Butterly, 2002). The BacT/ ALERT method is reported to more rapidly detect positive blood culture results in pediatric and newborn patients than other systems (Kumer *et al.*, 2001).

Sepsis is a commonly encountered and potentially life threatening problem in Neonatal intensive care units (NICU's), it is not easy to establish a definite diagnosis of Sepsis in the neonates. Early clinical signs are mostly non-specific and in conclusive (Khadija *et al*., 2011). Current study was undertaken to find out the common bacterial pathogens and their susceptibility pattern in neonates with sepsis in a tertiary care hospital providing neonatal intensive care services. Improvement in outcome and successful treatment depends on early initiation of appropriate antibiotic therapy (Srinivasa *et al*., 2014). It is estimated that 26% of newborn infants who die do so as a result of infections that occur around birth. After the first week of life, infections are the main cause of neonatal death in many countries. Most published data are from hospitals where *Klebsiella* species, *Escherichia coli* (*E. coli*), and *Staphylococcus aureus* (*S. aureus*) are the most common causes of infection (Shrestha *et al*., 2013). The early symptoms of sepsis are non-specific, and the outlook is considered to be worst in babies in whom antibiotics are started late. Antibiotics are therefore generally given to all babies with clinical or laboratory indicators of infection and babies at high risk of early onset sepsis. A large number of babies who are evaluated for sepsis do not have proven infection. This means that most of the antibiotics given to babies on the neonatal unit are given to babies without infection. Inappropriate use of antibiotics has been implicated in the development of multi-resistant bacteria in hospitals, Recently published studies suggest that antibiotic courses may be safely reduced to 24–36 hours in asymptomatic term babies (Kumar *et al*., 2001; Khadija *et al*., 2011).

Thus the Objective of this study was to measure the time required for the bacteria to be detected in blood cultures taken from suspected sepsis newborns by the BACTEC microbial detection system (Waricha *et al*., 2006) and also to establish an anti-biogram pattern in and around NIMS University, Jaipur.

Materials and Methods

NIMS Medical College and Research Centre is a 950 bedded hospital located in Jaipur. There is a dedicated team of 05 doctors at Central Laboratory handling approximately 600-650(includes pathology, microbiology and biochemistry samples) samples per day. Microbiology lab is equipped with BACTEC 9050 Blood Culture System (BD).

In this study we used BACTEC PEDS PLUS vials (Yellow top- paediatric aerobic) from the neonates suspected of Septicaemia from PICU. We analyzed 100 blood cultures collected during January to June 2016 after approval of the Hospital ethical committee.

Blood Collection: Under strict aseptic conditions, disinfect the venepuncture site using chlorhexidine with 70% alcohol swabs, allowing the site to completely dry. Draw 0.5-1.0ml of blood and place it in paediatric aerobic bottle. Fill the necessary requisition forms. All the paediatric aerobic bottles were sent to Microbiology laboratory.

Sample processing, identification and sensitivity

BD BACTEC 9050 System was used for incubation and the bottles were incubated until microbial growth was detected (BACTEC). BACTE 9050 is an automated blood culture system, which contains a sensor which responds to the concentration of CO_2 produced by the metabolism of micro organisms or the consumption of O_2 needed for the growth of micro organisms. The sensor is monitored by the instrument every ten minutes for an increase in its fluorescence, which is proportional to the increasing amount of CO_2 or the decreasing amount of O_2 present in the vial. BACTEC 9050 bottles that showed growth were plated onto sheep BA and MacConkey Agar and further incubated at 35+/- 2^0 C. Growth's were stained by Gram's method (WHO; Koneman's Color Atlas and Textbook of Diagnostic Microbiology, 5th edn). The positive growth was further processed by routine biochemical reactions and Antibiotic Susceptibility was put up by modified Kirby Bauer's method (Lalitha, 2004). CLSI guidelines were followed for interpretation of results (Collins *et al*., 1995; Forbes *et al*., 2002; Evans *et al*., 1996; WHO, 1980).

Results and Discussion

Our study analyzed the blood cultures from 1st January to 30th June 2016. A total of 100 Blood cultures were received from Pediatric ICU. Total blood cultures that came positive were 58. Out of 58, 28 samples yielded Gram Positive cocci (CONS-18, *S. aureus*-04, and *Enterococcus*-06) and 30 samples yielded Gram Negative Bacilli (*Klebsiella*-12, *E. coli*-02, *Citrobacter* -02, *Enterobacter*-12 and *Acinetobacter*-02). Most of the blood cultures grew within 72 hrs of incubation.

Table.1 Antibiotic used in the study

S.NO	Antibiotic	Potency	Abbreviations
1.	Amoxiclav	30mcg	AMC
2	Penicillin	10Units	P
3	Linezolid	30mcg	LZ
4	Vancomycin	30mcg	VA
5	Ampicillin	10mcg	AMP
6	Azithromycin	15mcg	AZM
7	Pipercillin/Tazobactum	100/10mcg	PIT
8	Cefoperazone/Sulbactum	30/15mcg	CFS
9	Cefoxitin	30mcg	CTN
10	Ceftriaxone	30mcg	CTR
11	Chloramphenicol	30mcg	C
12	Ofloxacin	5mcg	OF
13	Cefepime	30mcg	CPM
14	Amikacin	30mcg	AK
15	Imipenem	10mcg	IPM
16	Ceftazidime-Clavulanic acid	30/10mcg	CAC

Table.2 Number of organism isolates from culture positive neonates

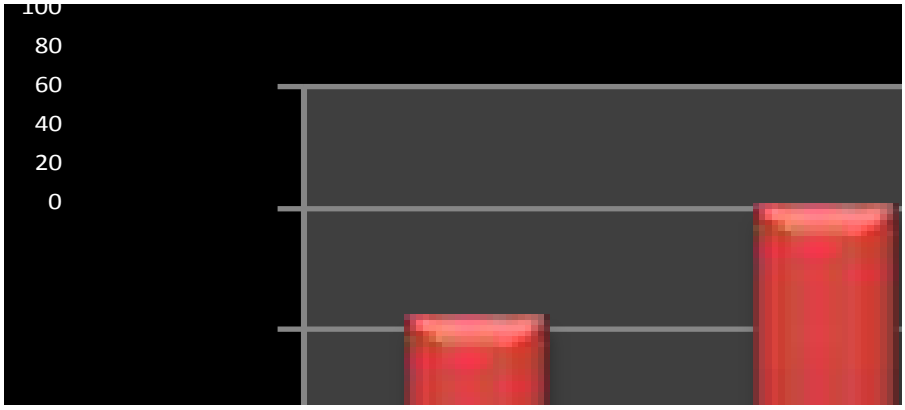
Isolates	Frequency of isolates (%)
CoNS	18 (31.03%)
Klebsiella spp.	12 (20.68%)
S.aureus	04 (6.89%)
Enterococcus	06 (10.34%)
E.coli	02 (3.44%)
Citrobacter	02 (3.44%)
Enterobacter	12 (20.68%)
Acinetobacter	02 (3.44%)

Fig.1 BACTEC 9050 Blood culture system

Graph.2 No. of organism isolates from blood culture positive neonates

Graph.3 Gram positive and Gram negative organisms in blood sample- total isolates (n=58)

Graph.4 Antibiotic sensitivity patterns of blood sample (n=58)



Graph.6 Antibiotic sensitivity of Gram Negative organism in blood sample (n=30)

Neonatal septicemia refers to generalized bacterial infection documented by positive blood culture in first five weeks of life. It is the major cause of mortality and morbidity accounting for 30-50% neonatal deaths in developing countries. In India a lot of neonatal mortality is accountable by septicemia and its treatment failure due to emergence of drug resistance. The fact is that the isolated organisms have developed increased drug resistance over the last few years. Most of the Laboratories in India use conventional Glucose broth/BHI broth for Blood culture routinely. Use of BACTEC PEDS PLUS bottles is intended to maximize the yield of obligate aerobes and anaerobes. BACTEC BD bottles not only yielded Gram Positive cocci, but also Gram Negative bacilli, they also showed positive cultures in patients with single dose of Antibiotics, since the Antimicrobial activity is neutralised by resins present in the bottles. Blood cultures remain a valuable microbiological test for diagnosis of Septicaemia. Automated blood culture methods significantly reduced the time required for processing of samples and also facilitated yield of GPC and GNB.

Neonatal septicemia remains a major clinical problem with high morbidity and mortality rate, especially in developing countries like India. The present study showed that gram negative bacteria were the most prevalent cause of infections in neonates in our hospital. *Klebsiella* spp. was the most commonly isolated gram negative organism whereas CONS were the most commonly isolated from gram positive organism. Drug resistance to conventional antibiotics is a common problem. As neonatal septicemia is considered a life threatening Emergency condition, prompt treatment with antibiotics is necessary. WHO has recommended the use of pencillin or ampicillin plus an aminoglycoside for neonates. The present study showed Imipenem, piperacillin tazobactum, Cefaperazone sulbactum and Ceftazidime-clavulunic acid are more effective drug for the treatment of gram negative organisms. Linzeolid, Vancomycin shows 100% susceptibility for gram positive organisms and more effective drugs for the treatment of gram positive isolates. So, it will important to continue surveillance of neonatal sepsis in order to follow closely changing in trends and risk factor to obtained information for empiric antibiotic therapy and to react rapidly in case of major changes in susceptibility patterns and occurrence of outbreaks.

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Original Research Article

Evaluation of different phenotypic methods for the detection of methicillin resistant *Staphylococcus aureus* and antimicrobial susceptibility pattern of MRSA

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ABSTRACT

Background: Rapid and accurate detection of methicillin resistant *Staphylococcus aureus* (MRSA) is an important role of clinical microbiology laboratories to avoid treatment failure. The aim of this study was to compare conventional methods against the cefoxitin disc diffusion method to determine the best phenotypic method.
Methods: Study was carried out in the Department of Microbiology, National Institute of Medical Sciences & Research, Jaipur (India), between July 2016 – December 2016. The methods included were Oxacillin E-test MIC, Oxacillin screen agar, Oxacillin disk diffusion, Cefoxitin disk diffusion and CHROMagar- MRSA methods. Antimicrobial susceptibility performed as per CLSI guidelines.
Results: Out of 142 isolates of *S. aureus*, fifty three (37.32%) strains of MRSA were isolated from clinical specimen. E-MIC test was selected as gold standard method. The sensitivity and specificity of Oxacillin screen agar and CHROMagar-MRSA were same 98.07% and 97.80%, respectively. The sensitivity and specificity of oxacillin disk diffusion were 94.23% and 98.89%. Fifty three strains of *S. aureus* were MRSA by cefoxitin disk diffusion method and Oxacillin Ezy MIC test. The sensitivity and specificity of cefoxitin disk diffusion method and Oxacillin Ezy MIC method was 100% and 100% respectively. All isolates including MRSA were susceptible to Vancomycin and Linezolid.
Conclusions: All phenotypic methods had high sensitivity and specificity for detection of MRSA. However, cefoxitin disk diffusion method in comparison to other methods had higher sensitivity and specificity.

Keywords: Oxacillin resistant *S. aureus*, Cefoxitin resistant *S. aureus*, Oxacillin ezy strip, Oxacillin screen agar, MeReSa chrom agar

INTRODUCTION

Staphylococcus aureus is an important etiological agent of hospital and community acquired infections.[1,2] The organism has a potential to spread and is reason of outbreaks particularly in hospitals.[3] Methicillin resistant *S. aureus* (MRSA) was first reported in 1961. Now a day matter of concern for microbiologist and clinician is how to overcome methicillin resistance problem.[4] The importance of MRSA as a nosocomial as well as community acquired pathogen is well documented.[5,6] Emerging of MRSA worldwide has led to the overuse of glycopeptides antibiotics, and to the emergence of Vancomycin resistant *S. aureus*.[7] Methicillin resistance in *S. aureus* is mediated by the *mecA gene* which codes for an additional penicillin binding protein, PBP2 or PBP2a.[8] MRSA strains are frequently resistant to many different classes of antibiotics, second and third-line antimicrobial

resistance is a growing concern.[9] Considering the increasing rate of infections caused by MRSA, performance of reliable, accurate and rapid testing for detection MRSA is essential for both antibiotic therapy and infection control measures.[10] There are many molecular and conventional phenotypic methods are available for detection of MRSA in clinical microbiology laboratories. Molecular methods are not affordable by every laboratory especially in India, so it is essential to evaluate an accurate sensitive method which can provide equivocal results with molecular methods.

The aim of this study was to determine the incidence of methicillin resistance and to compare various methods for detection of methicillin resistance with Cefoxitin disc diffusion method at National Institute of Medical Sciences and Research located in Jaipur. E-MIC test was selected as gold standard method.

METHODS

Sample processing

This is a prospective study and the clinical isolates of *S. aureus* from different specimens including tracheal aspirates, wound and soft issue, urine, blood and other specimens between July 2016 to December 2016 in National Institute of Medical Sciences & Research, Jaipur, 142 strains of *S. aureus* isolated from patients admitted to our hospital were included. The majority of patients were hospitalized patients. Briefly, the samples were cultured aerobically in blood and MacConkey agar. The plates were incubated overnight at 37ºC. All isolates were identified using gram stain, biochemical tests including catalase, coagulase. Antimicrobial susceptibility testing of MRSA isolates by Modified Kirby Bauer disk diffusion method (MKBDDM) as per CLSI Guidelines 2016.[11]

Methicillin resistance detection

1. *Cefoxitin disk diffusion*

All strains of *S. aureus* were tested with 30 mg cefoxitin discs (Hi-Media) on Mueller–Hinton agar plates. For each strain, a bacterial suspension adjusted to 0.5 McFarland was used. The zone of inhibition was determined after 16–18 h incubation at 37^{0}C. Zone size was interpreted according to CLSI (2016) criteria: susceptible, >22 mm; resistant, <21 mm.[12]

2. *Oxacillin disk diffusion*

All strains of *S. aureus* were tested with 1 mg oxacillin discs (Hi-Media) on Mueller–Hinton agar with an addition of 4% NaCl. For each strain, a bacterial suspension adjusted to 0.5 McFarland was used. The zone of inhibition was determined after 16-29 h incubation at 35^{0}C. Zone size was interpreted according to CLSI (2016) criteria: susceptible, >13 mm; intermediate, 11–12 mm; and resistant <10 mm.[12]

3. *E-test method (Ezy MIC strip OXA 0.016 – 256 mcg/ml Hi-media)*

The conditions for testing include Muller- Hinton with 2% NaCl. The inoculum density was adjusted equivalent to 0.5 to 1.0 McFarland standards. The plates were swabbed accordingly. By the help of an applicator MIC strip on each plates was placed and were kept at 35^0 C for 24 hrs. The MIC less than 2 ug were considered sensitive and more than 4 ug as resistant.[13]

4. *Oxacillin screening Agar (Oxacillin resistance screening agar base Hi-media)*

This method requires suspending test organism to the density of 0.5 McFarland and inoculating MH agar containing 4% NaCl and 6 mg/ml oxacillin with a spot or a streak of the organism. Plates were incubated at 35^0 C for 24hrs. Any growth other than a single colony was considered as resistant.[14]

5. *MRSA CHROMagar (Hi Crome MeReSa agar Hi-media)*

CHROMagar (Hi-Media) is a new chromogenic medium for the identification of MRSA. For each strain, a bacterial suspension adjusted to 0.5 McFarland was used. Subsequently, a swab was dipped in the suspension and streaked onto a CHROMagar plate. The plates were incubated at 35^0 C for 18-24 hrs. The growth of any green color colony was considered to be MRSA positive.[15]

S. aureus ATCC 25923 was used as a control strains for quality control.

RESULTS

Out of 142 isolates of *S. aureus*, fifty three (37.32%) strains of MRSA were isolated from clinical specimen. E-MIC test was selected as gold standard method. All isolates of MRSA were 100% susceptible to vancomycin and linezolid.

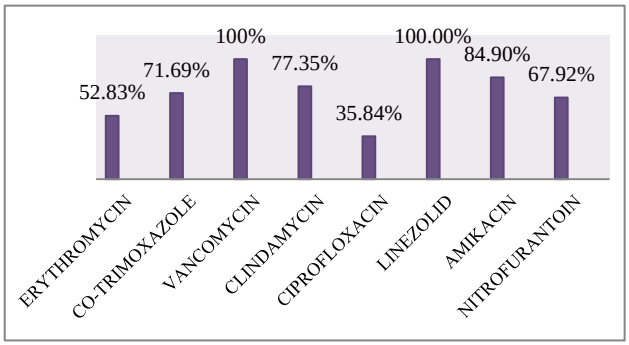

Figure 1: Susceptibility of MRSA isolates.

Table: 1 Sensitivity and Specificity of different methods.

Methods	Total No of MRSA	False -VE	False +VE	Sensitivity (%)	Specificity (%)	PPV	NPV
E-test	53	00	00	100.00	100.00	100	100
CHROMagar	50	01	02	98.07	97.80	96.36	98.89
OXA. Screen AGAR	50	01	02	98.07	97.80	96.36	98.89
Cefoxitin disk diffusion	53	00	00	100	100.00	100	100
Oxacillin disk diffusion	49	03	01	94.23	98.89	98.15	96.74

Sensitivity and specificity of different methods is illustrated in Table 1. The result of susceptibility testing of MRSA isolates to other antibiotics is shown in Figure 1.

Table 1 show the E-test method and Cefoxitin disk diffusion method gives 100% sensitivity and specificity comparison to other tests for the MRSA detection.

Figure 1 shows the vancomycin and linezolid drugs are higher sensitive comparison to other drugs and both are drug of choice for the treatment of MRSA patients.

Figure 2: Cefoxitin disk diffusion method for MRSA detection.

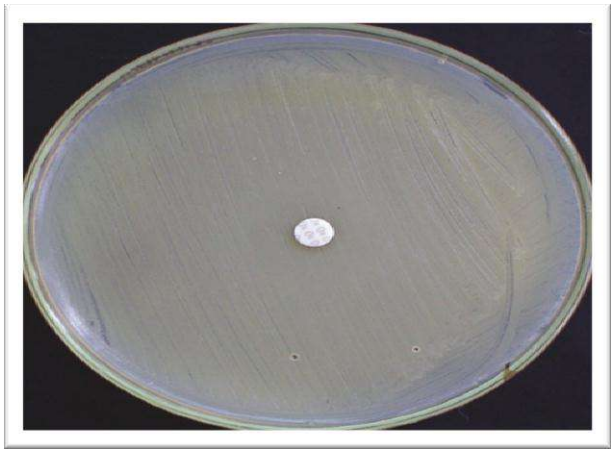

Figure 3: Oxacillin disk diffusion method for MRSA detection.

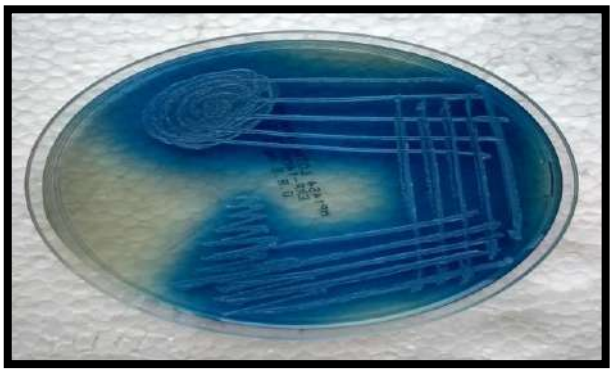

Figure 4: Oxacillin screen agar method for MRSA detection.

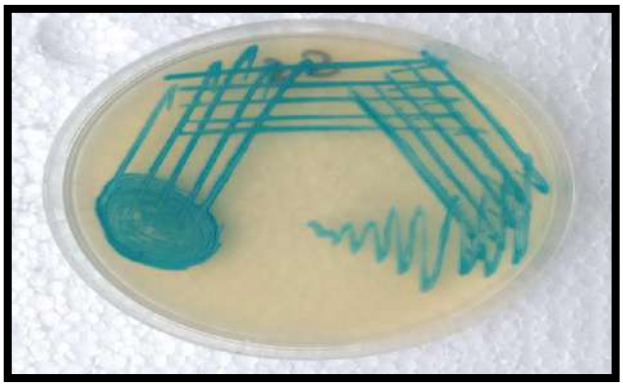

Figure 5: MeReSa Chrome agar method for MRSA detection.

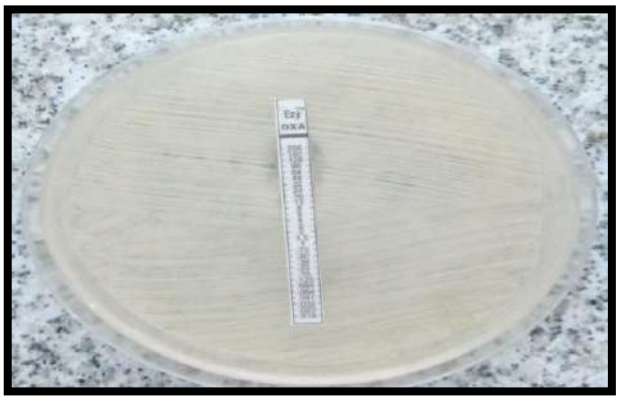

Figure 6: Oxacillin E- strip (E-test) method for MRSA detection.

DISCUSSION

Testing of methicillin resistance in *S. aureus* has been a challenge for clinical laboratories for many years. Several studies have shown that detection of *mecA* gene is a gold standard method for diagnosis of MRSA in clinical microbiology laboratories, but most of the developing countries cannot afford molecular methods in routine due to its high cost, so it is essential to evaluate an easy, cost effective, accurate and sensitive method for MRSA detection that can be used in routine lab and also which can give equivocal results with molecular method.

In the present study, we evaluated five different phenotypic methods for the detection of MRSA. A total 142 *S. aureus* were isolated from different clinical samples. All of the 142 *S. aureus* isolates were processed for methicillin detection by the cefoxitin disc diffusion test as described above in material method section. 53 (37%) were observed as Methicillin Resistant *S. aureus* (MRSA) by cefoxitin disc test with 100% sensitivity and 100% specificity.

These 53 MRSA strains were then compared with oxacillin disc diffusion test, oxacillin screen agar, MRSA chrome agar and E-test strip method, we observed 49 strains as true MRSA, 3 as false negative MRSA and 1 isolate as false positive MRSA by oxacillin disc diffusion test with 94.23% sensitivity and 98.89% specificity. 50 strains detected as true MRSA, 1 false negative MRSA and 2 false positive MRSA by oxacillin screen agar with 98.07% sensitivity and 97.80% specificity. Similarly 50 strains were detected as true MRSA, 1 false negative MRSA and 2 false positive MRSA by chrome agar method with 98.07% sensitivity and 97.80% specificity. The E- test strip method gave equivocal results to cefoxitin disc diffusion test i.e. 53 strains were confirmed as true MRSA with 100% sensitivity and 100% specificity.

There is variation among the results reported regarding sensitivity of different conventional methods used for detection of MRSA by number of authors.[16] However, most of the studies reported 100% sensitivity and 100% specificity with cefoxitin disc diffusion method which is in accordance with our results.[17] Karami et al depicted 100% sensitivity and 100% specificity with E Test MIC which is also similar to our observation.[18]

Our observation does not suggest oxacillin disc diffusion, oxacillin screen agar and MRSA chrome agar to be used in routine as there are chances of misinterpretation ultimately risk of treatment failure which is not acceptable and affordable at any cost. E test MIC detected all of 53 isolates as true MRSA that can also be an alternate to molecular method also it is easy to perform in routine.

Recently CLSI has replaced oxacillin with cefoxitin for detection of MRSA. Regarding cefoxitin disk diffusion, many studies reported that the results of cefoxitin disk diffusion tests correlate better with the presence of *mecA* than do the results of disk diffusion tests using oxacillin. In a study by Anand et al, results of cefoxitin disk diffusion method for detection of MRSA were in concordance with the PCR for *mecA* gene.[17] Another study by Anupurba et al, showed a high correlation between MICs of cefoxitin and presence of *mecA* in staphylococcus spp. Recently it is shown that cefoxitin disk diffusion method is more reliable than oxacillin disk diffusion method for detection of MRSA.[19]

In our hospital, 37.32% of all *S. aureus* infections are caused by MRSA. Susceptibility test profiles revealed a higher level of resistance to commonly prescribed antimicrobial agents among MRSA. All isolates were sensitive to Vancomycin and Linezolid. These results were comparable to studies carried out by others (Anupurba et al).[19] In the present study the antibiotic sensitivity pattern of MRSA included Erythromycin (52.83%), Co-trimoxazole (71.69%), Clindamycin (77.35%), Ciprofloxacin (35.84%), Nitrofurantoin (67.92%) and Amikacin (84.90%). Vancomycin and Linezolid are (100%) susceptible to all MRSA isolates. In other study conducted by Datta et al, also found (100%) MRSA strains were sensitive to Vancomycin and Linezolid.[12]

CONCLUSION

In our study we found that the cefoxitin disc is a good method for MRSA detection but it should be supplemented with some other method so that no MRSA is missed. No other method (oxacillin disc diffusion, MRSA chrome agar and oxacillin screen agar method) was as sensitive and specific as cefoxitin disc diffusion test and Oxacillin E test strip was so it is advisable to combine two methods, one with high sensitivity and the other with high specificity. According to our results, the best combination is the cefoxitin disc diffusion method and the Oxacillin E- strip test. Since the Oxacillin E- strip test is expensive it cannot be applied to all tests. Therefore, isolates that give a zone diameter of less than 20 mm can be easily reported as MRSA and only those with zone diameters of 20–22 mm need to be confirmed by Oxacillin E- strip.

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ORIGINAL RESEARCH PAPER
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AN ANALYSIS OF VARIOUS CLINICAL PRESENTATION, ETIOLOGICAL AND RISK FACTORS AMONG ACUTE ISCHEMIC STROKE PATIENTS ADMITTED AT A TERTIARY CARE HOSPITAL, IN NORTH INDIA.

Neurosurgery

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ABSTRACT

Background: South Asian countries constitute 22% of world population and 40% of developing world and account for more than 40% of global burden of stroke death[1]. There are insufficient studies available on ischemic stroke in Asian countries including India.

Aims: The present study aimed at evaluating risk factors, clinical profile and stratification of ischemic Stroke subtypes based on TOAST categories among patients admitted in a tertiary care hospital, in North India.

Methods and Material: An Observational prospective hospital based Study was carried out on patients of acute Ischemic stroke admitted within 7 days of symptom onset to a tertiary care hospital during June 2015 to December 2016 who were suitable as per our inclusion and exclusion criteria.

Results: A total of 164 acute ischemic stroke patients were enrolled during the study period. Acute ischemic stroke was found comparatively more in Male patients [71%] than in females [29%]. More than one fourth of patients were between 61-70 years (28%) followed by 51-60 (23.8%). The most common risk factors were Hypertension (56.1%) followed by Diabetes (40.2%). The most common clinical presentation was limb weakness in (70.7%) of patients followed by dysarthria (58.5%).The most common subtypes of acute ischemic stroke was undetermined etiology (UDE) in 34.7% followed by Stroke of other determined etiology in 24.3% .

Conclusions: The present study suggests that male and middle aged individuals are at increased risk of having acute ischemic stroke. The commonest risk factor in our study was Hypertension, followed by diabetes, CAD, smoking and tobacco chewing. The most common etiology of ischemic stroke was stroke of undetermined etiology.

KEYWORDS

Ischemic stroke, risk factors, clinical presentation, hypertension, North India.

INTRODUCTION

Stroke is the 2nd leading cause of death and third leading cause of disability worldwide[2]. Globally, 70% of strokes and 87% of both stroke-related deaths and disability-adjusted life years occur in low- and middle-income countries (LMIC)[3-5]. The disability in LMIC like India, largely driven by demographic changes and further enhanced by the increasing prevalence of the key modifiable risk factors. So there is double whammy for LMIC as both primary prevention and stroke treatment is not up to the mark.

Hence the present study aimed at Stratification of ischemic Stroke subtypes and to identify the common modifiable and non- modifiable risk factors along with clinical presentation among ischemic stroke patients in North India.

Subjects and Methods

Study Population:-

The present study was undertaken after obtaining permission from the institution's research and ethical committee. Patients of acute Ischemic stroke admitted within 7 days of symptom onset to a tertiary care hospital during June 2015 to 31stDecember 2016 who were suitable as per our inclusion and exclusion criteria were included in the study.

Inclusion criteria:

- Patients of all age group diagnosed as having acute ischemic stroke within 7 days of symptom onset, based on the imaging study (MRI or CT scan) during the study period.

Exclusion criteria:

- All other patients not willing to give an informed consent, stroke mimics and ICH were excluded from the study.

Study Design:-Observational prospective hospital based Study

Sample Size

For the margin of error at 2% and confidence level of study at 99%, a minimum of 136 patients (calculated using Raosoft sample size calculator and based on similar previous studies reported prevalence of stroke is 83%)[6] were required for Evaluation of clinical in different subtypes of ischemic stroke and to Assess Prognosis of patients in different sub types of ischemic strokes. So the sample size in our study was minimum of 136 patients.

Methodology-

- An informed consent of each patient studied prospectively was obtained.
- A detail history in terms of name, age, sex, chief complaints, past and family history was taken. History related to etiological factor like smoking, diabetes, hypertension, previous stroke, history of atrial fibrillation, dyslipidemia, malignancy etc. was noted.
- Diabetics- Patients who are known diabetics, or newly diagnosed (HbA1C ≥6.5%)
- Hypertension- Patients on antihypertensive medication or having previous history of hypertension.
- Dyslipidemia- Total cholesterol >200mg/dl and /or LDL cholesterol >100mg/dl.
- Smoking- 10 or more cigarette or Bidi per day for at least 6 months
- Alcoholic- on average ≥ 2 drinks/day for males and ≥ 1 drinks for females (previous drinker: ex drinker for more than 1 year).
- Tobacco Chewer – History of tobacco chewing
- Hypothyroidism- History of hypothyroidism or newly diagnosed
- Renal disease- History of chronic kidney disease (Stage I-V) or newly diagnosed.
- CAD- History of angiographically proven CAD.

Subtypes of ischemic stroke

Clinical examination of patient was done including general physical and neurological examination with parameters like baseline NIHSS**,** Pupils, Cranial nerves examination, Muscle Tone, Power in limbs, Deep tendon reflexes, Sensory examination, Cerebellar signs. Based on clinical and radiological findings patients were classified in different TOAST categories

Data processing and analysis

All the analysis was carried out on SPSS 16.0 version (Chicago, Inc., USA) with statistical significance at <0.05.

Results

A total 164 acute ischemic stroke patients were enrolled during June2015 to December 2016 and were evaluated for risk factors, clinical presentation and stroke subtype.

Demographic profile

In the current study, acute ischemic stroke patients was found comparatively more in Male patients i.e. 117 [71%] than in female

patients 47 [29%]. The male to female ratio was 2.49:1. The mean age was 57.77±15.16 years for males and 62.19±14.54 years for females, More than one fourth of patients were between 61-70 years (28%) followed by 51-60 (23.8%), >70 (22%), <40 (14%) and 41-50 (12.2%) years. (Figure 1-3)

Risk factor profile

Among ischemic stroke patients, 92 (56.1%) were hypertensive, 66 (40.2%) were diabetic and 24 (14.6%) had dyslipidemia. History suggestive of coronary artery disease was present in 36 (22%) patients, atrial fibrillation was present in 16 (9.8%) patients, and 10 (6.1%) patients each had rheumatic heart disease and Renal disease. Family history suggestive of stroke was present in 23(14%) patients and previous history of stroke was found in 14% patients. Smoking habit was seen in 12.8% patients and tobacco chewing habit was seen in 6.1%. Alcoholic were 3%. (Figure 4-6)

Figure 7 is showing distribution of patients with recurrent stroke according to the time interval from the previous stroke. Maximum (39.1%) patients had previous stroke between 1-5 years followed by 30.4% of patients within 3months to 1 year and 26.1% before 5 year. Only 4.3 % of patients were having stroke within 3 months of previous stroke.

Clinical presentation

Figure 8 is showing distribution of symptoms in acute ischemic stroke. Acral weakness was the most common symptom present in 70.7% of patients followed by dysarthria (58.5%), aphasia (22.6%) and ataxia (11.6%). Other uncommon symptoms were Loss of consciousness (11%), headache (7.3 %), vertigo (1.8%), seizure (1.2%), visual loss (1.2%), and altered sensorium (0.6%).

Ischemic stroke subtype

An important objective of our study was to classify the patients in to subtypes of acute ischemic stroke. Despite extensive evaluation , etiology remained undetermined in 34.7% (UDE). Stroke of other determined etiology in 24.3%, small vessels (20.7%), large artery atherosclerotic disease in12.8% and Cardio-embolic in 7.3 % patients were seen. Stroke of other determined etiology was identified in 40 patients (24.3%), which included hyperhomocysteinemia in 33 (82.5%), malignancy in 4(10%), Antiphospholipid syndrome in 1 (2.5%), dissection in 2(5%) patients. (Figure 9-10)

DISCUSSION

The present observational prospective hospital based Study provides advance and unique data on clinical presentation, etiological and risk factors of ischemic stroke in a section of Indian population. Out of 164 acute ischemic stroke patients, 117 [71%] were male and 47 [29%] were female (p =0.08). Male to female ratio in our study was 2.49:1. This gender differentiation is similar to other studies reported by Raghuvanshi S. et al[7], Marulaiah S.K. et al[8] and Kashinkunti et al[9]. The male to female ratio is comparable to other studies conducted by Raghuvanshi S. et al[7]., from Bhopal and Parvaiz A Shah et al[10]., from Kashmir showing a M:F ratio of 2.89:1 and 2.4:1 respectively. The above studies concluded that stroke is more common among men than women. Male sex is one of the strong risk factor for stroke. Women have lower stroke incidence than men because of genetic factors, positive effects of estrogen on the cerebral circulation, and low blood pressure levels. Moreover, ischemic heart disease, peripheral artery disease and cigarette smoking are more prevalent among male stroke patients[11].This gender difference probably resulted from inherent social bias, in which female patients are less likely to be admitted to hospital compared to male patients which is less likely in urban setting. This observation is in contrast to the study done by Yadav R.S. et al[12] in which there was female predominance in ischemic stroke patients; may be due to disorders related to pregnancy, excess use of contraceptive pills and also stroke in females due to migraine in these studies.

In our study, the mean age of patients of acute ischemic stroke at presentation was 57.77±15.16 years for males and 62.19±14.54 years for females. More than half of the patients were in the age group of 51–70 years (51.8%).Young patients with ischemic stroke (age ≤50 years) comprised of 26% of the cohort while 7.3% were in age group of >80 year.The above mentioned observations are similar to studies conducted by Grau AJ et al[13], Acciarresi M et al[14], in which ischemic stroke mean age for males was lower females (59.3±13.6 versus 66.85±14.9).This is dissimilar to studies conducted by Al-Rajeh S et al[15],El Sayed MM et al[16]., in which stroke occurred at a younger age in women than men. The age distribution in our study is similar to studies carried out by Yadav R.S. et al[12] and Marulaiah S.K. et al[8], with 45.5% were 51-70 years, and 51% patients in 51-70 years, respectively. The data of young ischemic stroke is comparable with the studies done by Misbach and Wendra et al[17], and Eapen et al[18], with incidences of young patients with ischemic stroke were 12.9% and 15.4% respectively. Stroke at earlier age has been shown by various studies conducted in India[7].

The mean age of stroke in present study was 59.04±15.07 years which is comparable to study conducted by Raghuvanshi S. et al[7] (Indians) 53.02±12.45 years versus (Americans) 71 ± 13 years. In comparison with the studies carried out by Kissela et al[19], and Baidya et al[20], the mean age of the patients with stroke is relatively lower in our study. It is possibly because of lack of preventive strategies in place regarding various risk factors of stroke at the population level.

In the present study, hypertension was the most common risk factor among the stroke patients (56.1%). Diabetes was the second most common (40.2%) and CAD was the third most common disease (22%). This is similar to study conducted by Nadia Aquil et al[21], in which hypertension was most common with (55%), diabetes mellitus (49%), CAD in (30%) and dyslipidemia in 22% patients. Similar trend was seen in study conducted by N.A. Syed[22], in which hypertension was reported as the most commonest risk factor (66.2%), followed by diabetes mellitus in 41.5% patients. In study by Marwat et al[23], hypertension was the most common risk factor (75%) followed by diabetes mellitus (54.5%), IHD (36.3%), hyperlipidemia (13.6%) and valvular heart disease (6.8%).

In contrast to the present study, Vaidya et al[24], reported that the most common risk factor was hypertension with (30.1%) incidence, second most commonest was CAD (16.1%), dyslipidemia (15.6%) and diabetes mellitus in 10.8% patients. A study by Misbach and Wendra et al[17]., hypertension was the most important risk factor for ischemic stroke, as other risk factors were hyperlipidemia, diabetes mellitus, IHD and atrial fibrillation.

Hypertension has been observed the most common risk factor of ischemic stroke in various studies. This alarmingly high prevalence of hypertension in patients with ischemic stroke calls for need of treatment of major public health problems and indicates the need to incorporate treatment of hypertension into health care policy measures in order to reduce morbidity and mortality of stroke. Also the risk of stroke in diabetic patients is about double than that found in non-diabetic individuals[25].

Out of 164 patients, 21 (12.8%) were smokers,6.1% patients were tobacco chewer and only 3% patients were alcoholic.This is comparable to the study done by Deepa Dash et al[26] and Azra Zafar et al[27], who found smoking in 9.5% and 7.2% patients respectively but is in contrast to studies conducted by Raghuvanshi S et al[7] and Yadav RRS et al[12], in which the smoking rate was much higher ie 44% and 23.8% respectively. The observation of tobacco chewing habit is comparable to the study conducted by Raghuvanshi S et al[7]., in which 10% patients were tobacco chewer, a slight high rate of tobacco chewing is noticed in study conducted by Yadav RRS et al[12], ie 14.8%. The alcoholics (3%) are comparable to the study done by Vaidya C et al[25], with 6.6%. This is much lower than the studies conducted by Eapen RP et al[18], and Naik M et al[28], who found 35.3% and 30.5% alcoholics respectively. The current study had a reduced frequency of smoking, tobacco chewing and alcoholics compared to previous Indian studies. A bias due to suppression of history of addiction may be responsible for some reduction.

In the present study, previous history of stroke was found in 14% patients. This figure is generally in agreement with studies conducted by Raghuvanshi S et al[7], and Yadav RSS et al[12]., with history of stroke in 13.7%, and 9.8% patients respectively. Maximum (39.1%) patients had previous stroke between 1-5 years followed by 30.4% of patients within 3 months to 1 year and 26.1% before 5 year. Only 4.3 % of patients were having stroke within 3 months of previous stroke in the present study.

The most common stroke subtype in the present study was undetermined etiology(34.7%)followed by stroke of other determined cause (24.3%), small vessel disease (20.7%), large vessel disease

(12.8%) and cardioembolic stroke (7.3%). This is comparable with the study done by Yatsu FM et al[29] and Kunitz SC et al[30] in which 33% and 33% patients were remained in stroke of undetermined etiology. This is much higher than the previous studies done by Kaul S. et al[31] in 27%, Raghuvanshi S et al[7] in 21.7% and Nadia et al[21] in 18% patients. The most common reason for categorizing these patients as having an undetermined etiology was due to fact that a large number of patients had two or more etiological possibilities and some patients could not be evaluated extensively for stroke subtypes on account of various reasons. (Table1)

Stroke of other determined etiology was identified in 40 patients (24.3%).The most common etiology in this group was hyperhomocysteinemia in 33(82.5%), followed by cancer in 4(10%), Antiphospholipid syndrome in 1 (2.5%), dissection in 2(5%) patients. Similar to the study conducted by Kaul S et al[31]., in which Stroke of other determined etiology was identified in 17 patients (4%), in which hyperhomocysteinemia was the most common etiology ie in 8 (47.1%) patients, followed by anticardiolipin antibody in 4(23.5%) and dissection in 2(11.7%).A study conducted by Kumar SSS et al[32]., hyperhomocystenemia (55%) was predominantly seen followed by Protein S deficiency, Protein C deficiency and antithrombin III deficiency in 21%, 14% and 7% patients respectively and Antiphospholipid antibody (APLA) was positive in 3% . In contrast to the study conducted by Deepa Dash et al[26]., reported the most common etiology in patients with ODC to be dissection (51.3%). Increased incidence of hyperhomocysteinemia in our study is probably due to slight higher incidence of smoking.

Third most common cause of ischemic stroke was small vessels etiology (20.7%).This is comparable to 18% reported previously by Parvaiz AS.etal[10], however, lower than 43% and 42.7% reported by Nadia et al[21] and Syed NA[22] et al respectively.

The frequency of cardioembolic stroke was 7.3% in this study. This is much lower than that reported from Sacco RL et al[33] (19%) and Raghuvanshi S et al[7] (16%) but comparable to 6% by Syed et al[22] and 10% by Kaul et al[31].

Most common symptom at presentation amongst patients of acute ischemic stroke was hemiperesis (70.7%) followed by dysarthria (58.5%)which was similar to the findings in study done by Vaidya.etal[24] . Weakness and dysarthria (58.5%) were also the most common symptoms in the study performed by Kumar NSSetal[32] where they found motor weakness in 94% of cases and dysarthria in 72% of cases. The higher occurrence of these symptoms in this study may be related to the higher percentage of anterior circulation stroke (86%) of patients. Other uncommon symptoms were aphasia (22.6%) loss of consciousness (11%), headache (7.3 %), vertigo (1.8%), seizure (1.2%), visual loss (1.2%) and altered sensorium (0.6%). Headache ataxia, vetigo and visual loss were associated with posterior circulation stroke.

Strength and limitations of the study

This is a prospective study with a relatively large sample size and also ensured uniform data collection of various risk factors related to stroke ,we obtained reliable information about clinical characteristics risk factors to achieve the goals of our study. This will in turn help the health care authorities to formulate the preventive strategies for management of risk factors and will also decrease the gravies effect of stroke by having overview knowledge about clinical characteristics of stroke.

There are certain limitations of our study. First, this study was confined to a single tertiary care hospital and thus represents a limited population. Moreover, this Hospital is a specialized neurology and neurosurgery hospital of India. The patients treated here are usually in a more critical condition as these patients are referred from the adjacent peripheral areas including rural and urban areas in and around metropolitan city, also referred from other neighbouring states and this may result in selection bias.

CONCLUSION

Our study suggests that acute ischemic stroke was maximum in male and middle aged patients. The most common preventable stroke risk factors were smoking, HTN, diabetes and CAD. The most common clinical presentation was limb weakness and dysarthia. Our study showed that most common subtype of acute ischemic stroke was stroke of undetermined etiology.

Considering the high morbidity and mortality associated with stroke, a large scale community based health awareness programme should be launched with the help of social group, local political leaders and healthcare workers. So that stroke can be recognized at its early stage and available treatment should be offered to the patients. It is also important for the local health care workers to know the acute ischemic stroke treatment guidelines.

To conclude, further similar studies on ischemic stroke, its clinical profile, risk factors should be encouraged, so that local risk factors of the defined area could be identified and shared with frontline healthcare workers, so that screening and management of common risk factors can be executed at the community level.

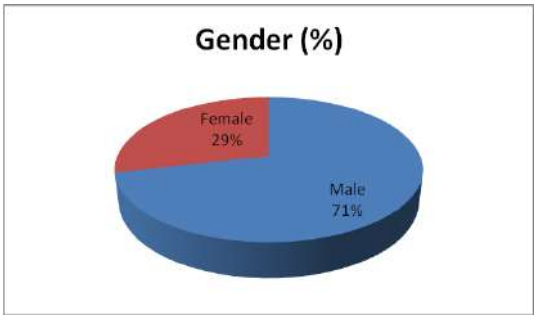

Figure -1: Gender distribution of acute ischemic stroke patients

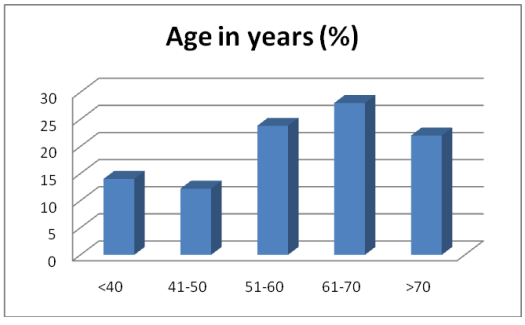

Fig. 2: Age distribution of acute ischemic stroke patients

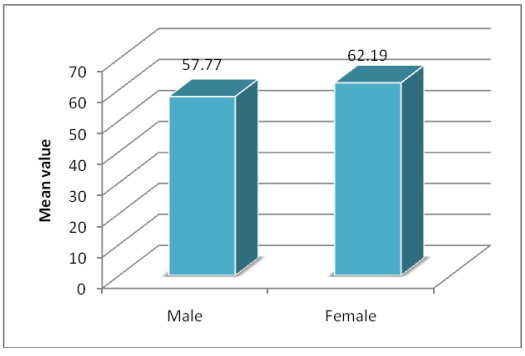

Fig. 3: Mean and SD of age according to gender

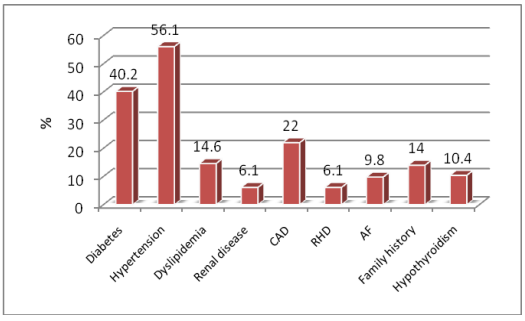

Fig. 4: Distribution of patients according to comorbid illness and other risk factors

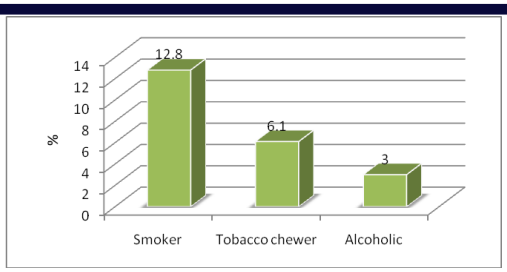

Fig. 5: Distribution of patients according to addiction habit

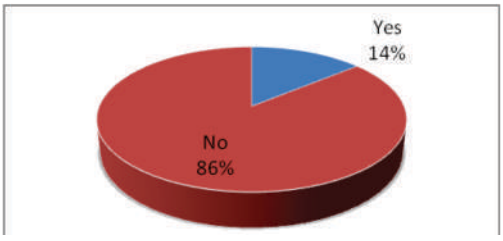

Fig. 6: Distribution of patients according to previous history of stroke

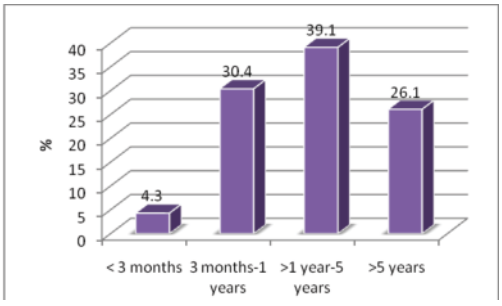

Figure 7 Distribution of the patients according to the time interval of the previous stroke

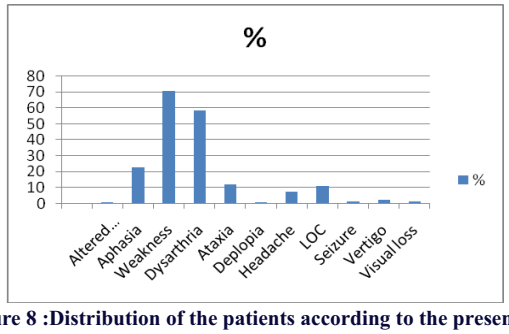

Figure 8 :Distribution of the patients according to the presenting symptoms

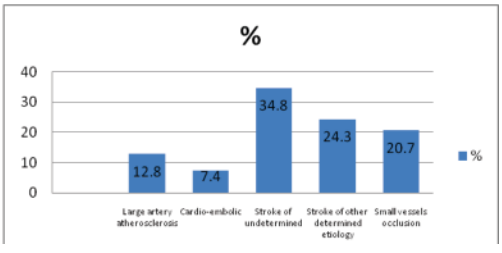

Fig. 9: Stroke Subtype by TOAST criteria

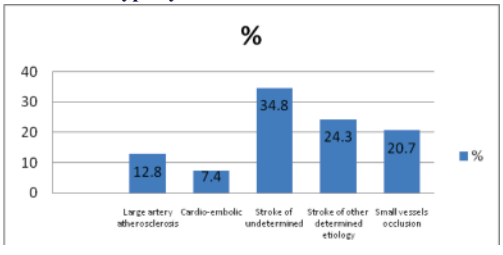

Figure-10: Distribution of stroke of other determined etiology

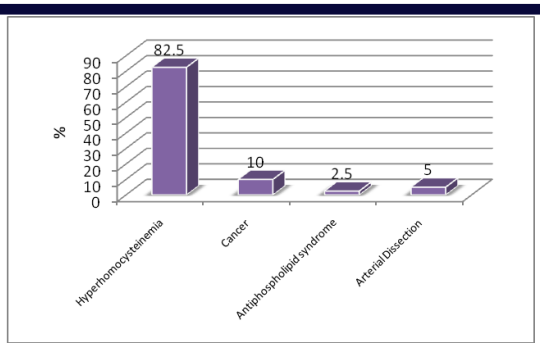

Table 1-Comparative analysis of present studies Vs previous studies

Study	Patient No	Large Vessel Disease (%)	Small Vessel Disease (%)	Cardioembolic (%)	Other Determined Etiology (%)	Undetermined Etiology (%)
Sacco RL et al[34]	1273	14	27	19	-	40
Yatsu FM et al[29]	3727	50	-	-	17	33
Kunitz SC et al[30]	708	24	14	-	28	33
Kaul S. et al[31]	392	41	18	10	4	27
Raghuvanshi S et al[7]	175	41.1	15.4	16	2.2	25.1
Syed NA et al[22]	393	26.9	42.7	6.1	-	20.3
Nadia et al[21]	100	31	43	8	1	18
Parvaiz AS.et al[10]	3837	1.6	17.9	2.3	25.1	1.5
Present study	164	12.8	20.7	7.3	24.3	34.8

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A Prospective Study on the Prevalence and Antibiotic Sensitivity Pattern of Methicillin Resistant *Staphylococcus aureus* isolated from Various Clinical Specimen at a Tertiary Care Post Graduate Teaching Institute

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A B S T R A C T

In recent times, the treatment of Staphylococcus aureus infection has become problematic because of emergence of resistance to antibiotics which is a cause of concern for all the clinicians and microbiologists worldwide. Infections caused by MRSA have been associated with high morbidity and mortality rates. Hence this study was conducted to know the prevalence of Methicillin resistant Staphylococcus aureus [MRSA] isolates in various clinical specimens and to determine the sensitivity of these isolates to different antimicrobial agents. Among the 161 clinical isolates of S. aureus, highest isolation was from pus samples (64%), followed by blood (13%) and respiratory secretions (13%). 82 (51%) were identified as MRSA by Cefoxitin disc diffusion method and maximum MRSA were again isolated from pus (61%). Comparatively MRSA prevalence is more in males (73%) and most common affected age group was 21-30 years. All MRSA strains were resistant to penicillin (100%), followed by ciprofloxacin (93%) and erythromycin (61%). We found statistically significant differences in the drug susceptibility pattern of MRSA & MSSA for Penicillin, Clindamycin, Erythromycin, Ciprofloxacin, Co-trimoxazole and Levofloxacin. MDR-MRSA strains in our study is 45%. Hence we suggest, more and more studies in future are needed to fight against rising menace of antibiotic resistance among Staphylococcus aureus

Introduction

Staphylococcus aureus, the most clinically significant species of Staphylococci has been recognized as an important cause of human disease for more than 100 years (Ankur *et al*., 2013). It is one of the pathogens of greatest concern because of its intrinsic virulence factors, its ability to cause diverse array of life threatening infections, it's competency to adapt to different environmental conditions and its nasal carriage, which accounts for possible spread and re infection (Anupurba *et al*., 2003). Infections by *Staphylococcus aureus* are continuously challenging the clinicians despite the availability of antibiotics from nearly 70 yrs. This was due to the emergence of various types of antibiotic

resistance mechanisms especially to methicillin and vancomycin, which was the theme of several epidemiological studies (Arora *et al*., 2010; Assadullah *et al*., 2003).

With the introduction of Penicillin in 1940, it was thought that we can escape from the deadly threats of Staphylococcal infections, but no sooner in 1944 first strain of *Staphylococcus aureus* resistant to penicillin G appeared in London, mediated by the presence of penicillinase enzyme which hydrolyses the β-lactam ring of penicillin (Astagneau *et al*., 1996). By 1950s, penicillinase producing strains of *Staphylococcus aureus* were so common that penicillin became useless against Staphylococcal infections. To resolve this issue, in 1960 semi-synthetic penicillin (penicillinase stable penicillin) - like Methicillin came in picture, but availability of these agents did not stem the tide of resistance as within a year the first MRSA was reported from U.K. This was mediated by the presence of PBP-2a which is expressed by an exogenous gene, *mecA* (Bandaru, 2010).

In the past few decades MRSA has emerged as an important nosocomial pathogen worldwide. In India, prevalence rate varies from 30-85% in different parts and has now become endemic (Barber, 1961; Boucher, 2010). A multicentric study done in India involving 17 tertiary care Hospitals reported MRSA prevalence of 41% in 2008-2009 (Clinical and Laboratory Standards Institute, 2012), MRSA is of serious therapeutic concern not only due to its resistance to Methicillin, but also because of resistance to many other antimicrobials that are used on regular basis in Hospitals. Therefore, the most reliable and sustained therapeutic agent against methicillin-resistant *Staphylococcus aureus* (MRSA) strains is Vancomycin. Increasing prevalence of MRSA has lead to the extensive use of vancomycin. This inturn has lead to the decreased susceptibility to vancomycin. Such resistance is a serious clinical and public health consequences because currently few licenced alternatives are available to treat vancomycin resistant *Staphylococcus aureus* infections.

The association of Multidrug resistance with MRSA adds to the problem and the presence of MDR strains in the hospital cannot be neglected. Several studies are prevailing for Methicillin resistance from India but few have worked on Multi-drug resistance. MRSA strain showing resistance towards ≥ 3 antibiotics is defined as MDR strain and its prevalence ranges from 23% - 60% in India (Diep *et al*.,). The emergence of MDR MRSA infections is worrisome in the present therapeutic scenario. Keeping the above points in view, the present study was planned to find out the prevalence of MRSA among isolates of *Staphylococcus aureus* in various clinical specimens along with their antibiotic sensitivity pattern so as to guide the clinicians of our hospital to select appropriate antimicrobial agents and also to make them aware, that if inappropriate use these antibiotics is continued it may lead to impending public health disaster.

Materials and Methods

Source of material

The present study was conducted in the Department of Microbiology, GMCH, Udaipur, during the year 2013-2014. A total of 161 non- duplicate *Staphylococcus aureus* isolates from various clinical specimens [pus, wound or vaginal swabs, blood, body fluids (csf, pleural fluid, ascitic fluid) urine, sputum, ET secretion etc] were included in the study. Isolates from both in-patients and out-patients were considered. Institutional Ethical clearance was obtained. Data regarding age, sex, patient location, history of any clinical

illness etc. was obtained from the requisition form submitted to Microbiology Department, GMCH.

Inclusion criteria

All *Staphylococcus aureus* strains isolated from various clinical specimens, were included in the study.

Exclusion criteria

Clinical specimen's yielding growth of Gram positive cocci other than *Staphylococcus aureus* and all gram negative bacteria were excluded.

Isolation and identification of *Staphylococcus aureus*

All the isolates were identified by standard procedures (gram staining, catalase test, mannitol fermentation, Hugh-Leifson OF media, slide coagulase and tube coagulase test). Tube coagulase was taken as the main criteria of identification and was performed by diluting plasma in freshly prepared normal saline (1:6). Three to four colonies were emulsified in 1 ml of diluted plasma and the tubes were incubated at 37ºC. Readings were taken at 1, 2, 3 and 4 h and further incubated at room temperature if no clot formation was observed (Yogesh *et al*., 2013).

Determination of antibiotic susceptibility

All *Staphylococcus aureus* isolates were then subjected to antimicrobial susceptibility testing by modified Kirby–Bauer disc diffusion method. Antibiotics tested were Penicillin [10 units], cefoxitin (30 µg), Vancomycin [30µg], Linezolid [30µg], Pristinomycin (Quinupristin/Dalfopristin) [15µg], Gentamicin [10µg], Tetracycline [30µg], Chloramphenicol [30 µg], Ciprofloxacin [5µg], Levofloxacin [5µg], Erythromycin [15µg], Clindamycin [2µg], Rifampicin [5µg] and Cotrimoxazole [1.5/23.75µg]. *Staphylococcus aureus* ATCC 25923 was used as control strain. Zone of inhibition of all the antibiotics were measured with scale in reflected light against a black background, to the nearest mm. Interpretation was done according to the guidelines of Clinical Laboratory Standards Institute.

Detection of methicillin resistance

Cefoxitin disc (30 µgm) was used to detect methicillin resistant isolates as Cefoxitin, which is a potent inducer of the mecA regulatory system, is being widely used as a surrogate marker for detection of mecA gene-mediated methicillin resistance. MRSA strains exhibiting inducible resistance to methicillin grow much more readily in the presence of cefoxitin than oxacillin, due to an enhanced induction of PBP 2a by cefoxitin. Isolates with zone diameter of ≤21 mm were considered resistant to methicillin and zone of ≥22 mm were sensitive (Harcharan *et al*., 2014).

Results and Discussion

In the present study, a total of 161 non duplicate *Staphylococcus aureus* isolates were obtained from various clinical specimens. *Staphylococcus aureus* infection was found comparatively more in Male patients i.e. 115 [71%] than in female patients 46 [29%]. The male to female ratio was 2.5:1. Age group of 21-30 yrs and 51-60 yrs were predominantly affected. [Figure 1 and figure 2]. Among all *Staphylococcus aureus* isolates, majority contribution was from Pus samples 103 (64%), followed with blood 23(15%), respiratory secretion 18 (11%) and body fluids 7 (4%). Swabs and Urine samples grew only 7 (4%) and 3 (2%) respectively.[Table1] Out of total 161 Staphylococcus aureus strains, 82 (51%) were found to be MRSA

and79 (49%) were MSSA. Pus shown the highest prevalence of resistance towards methicillin i.e. (61%) followed by Blood (15%), Respiratory secretions (10%), body fluids (5%), Swabs (5%), and Urine (4%).[Figure 3, Figure 4] Comparatively MRSA prevalence is more in males (73%) and most common affected age group was 21-30 years.

Out of 161 *Staphylococcus aureus*, only 19 (12%) strains were sensitive to all antibiotics.[Table 2] Maximum resistance was shown by MRSA isolates. All the MRSA isolates were resistant to penicillin (100%) and all were sensitive to Linezolid, Pristinomycin, Chloramphenicol and Rifampicin. Among the MRSA strains, least sensitivity was showed by Ciprofloxacin (93%) followed by erythromycin (66%), Co-trimaxazole (54%), Levofloxacin (46%), Clindamycin (46%) and Gentamicin (30%). Tetracycline (6%), Vancomycin (3%) showed good efficacy.

Table.1 Distribution pattern of *Staphylococcus aureus* isolates in various clinical specimens

Clinical specimen	No of isolates	Percentage
Pus	103	64
Blood	23	15
Sputum/ ETsecretion / Bronchial aspirate	18	11
Body fluids (csf, pleural fluid, ascitic fluid)	7	4
Swabs (Vaginal/wound)	7	4
Urine	3	2
Total	**161**	**100**

Table.2 Antibiogram of *Staphylococcus aureus* strains

Drugs	***Staphylococcus aureus* strains**			
	Sensitive	**%**	**Resistant**	**%**
Penicillin G	19	12	142	88
Cefoxitin	79	49	82	51
Ciprofloxacin	54	34	107	66
Levofloxacin	116	72	45	28
Gentamycin	136	84	25	16
Erythromycin	91	57	70	43
Clindamycin	111	69	50	31
Co-trimaxazole	91	57	70	43
Tetracycine	156	97	5	3
Rifampicin	161	100	0	0
Chloramphenicol	161	100	0	0
Vancomycin*	156	97	5	3
Linezolid	161	100	0	0
Quinipristin/dalphopristin	161	100	0	0

Vancomycin* - According to CLSI guidelines 2007[66]

Table.3 Antibiogram of MRSA and MSSA

Drugs	MRSA [n=82]		MSSA [n=79]	
	Sensitive (%)	Resistance (%)	Sensitive (%)	Resistance (%)
Penicillin G	0 (0)	82 (100)	19 (24)	60 (76)
Ciprofloxacin	6 (7)	76 (93)	48 (61)	31 (39)
Levofloxacin	44 (54)	38 (46)	72 (91)	7 (9)
Gentamycin	57 (70)	25 (30)	79(100)	0 (0)
Erythromycin	28 (34)	54 (66)	63 (80)	16 (20)
Clindamycin	44 (54)	38 (46)	67 (85)	12 (15)
Co-trimaxazole	38(46)	44(54)	53(67)	26(33)
Tetracycine	77 (94)	5 (6)	79 (100)	0 (0)
Rifampicin	82 (100)	0 (0)	79 (100)	0 (0)
Chloramphenicol	82 (100)	0 (0)	79 (100)	0 (0)
Vancomycin*	82 (100)	5(3)	79 (100)	0 (0)
Linezolid	82 (100)	0 (0)	79 (100)	0 (0)
Quinipristin/dalphopristin	82 (100)	0 (0)	79(100)	0 (0)

Vancomycin* - According to CLSI guidelines 2007[66]

Table.4 Statistical analysis of antibiotic resistance pattern of MRSA and MSSA by using software SPSS

Drugs	MRSA Resistance (%)	MSSA Resistance (%)	p value	Statistical Significance
Penicillin G	82 (100)	60 (76)	<0.001	Significant
Ciprofloxacin	76 (93)	31 (39)	<0.001	Significant
Levofloxacin	42 (51)	15 (19)	<0.001	Significant
Erythromycin	50 (61)	20 (25)	<0.001	Significant
Clindamycin	38 (46)	10 (13)	<0.001	Significant
Co-trimoxazole	44(54)	26(33)	<0.001	Significant

Figure.1 Sex wise distribution of patients with *Staphylococcus aureus* infection

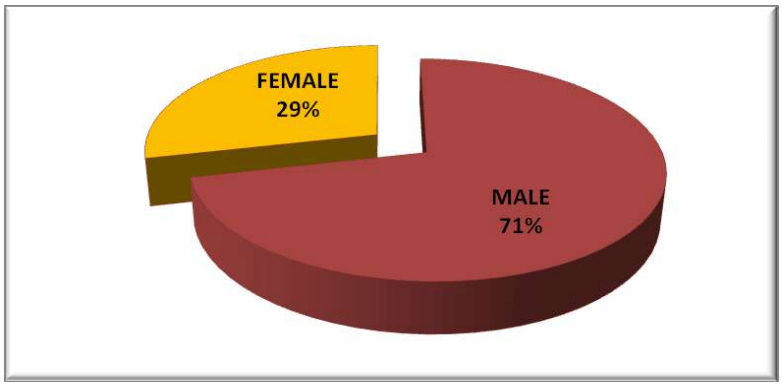


Figure.2 Age wise distribution of patients with *Staphylococcus aureus* infection

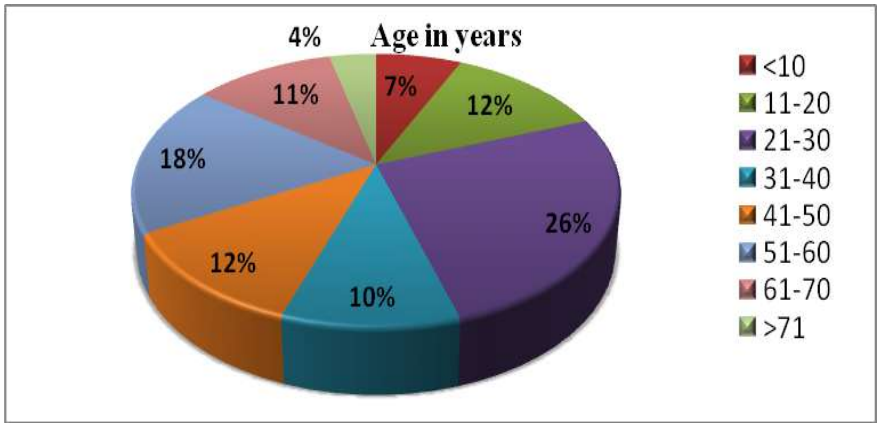


Figure.3 Total number of MRSA and MSSA in *Staphylococcus aureus* isolates

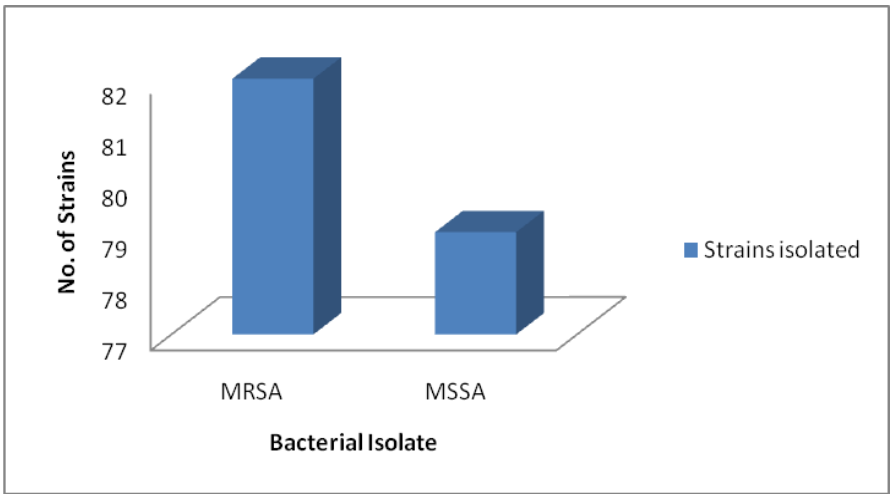
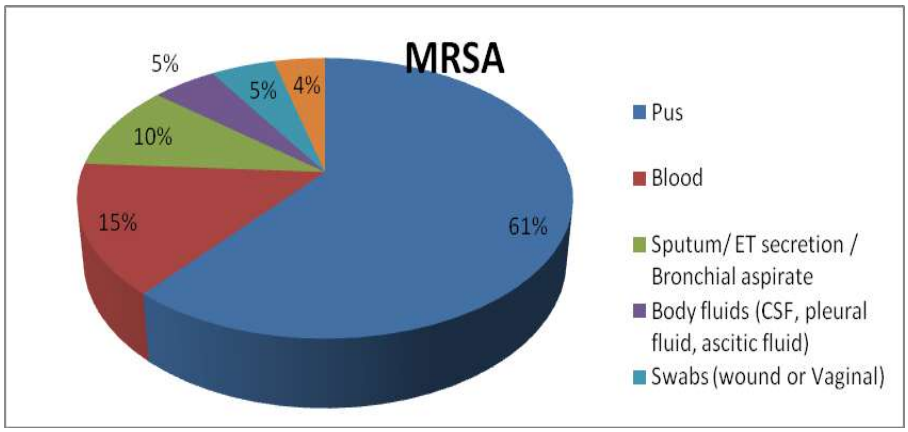


Figure.4 Specimen wise distribution of MSSA



The sensitivity pattern of MSSA was quite different from the MRSA strains. All the MSSA strains showed cent percent sensitivity to Gentamicin, Tetracycline, Vancomycin, Linezolid, Pristinomycin, Chloramphenicol and Rifampicin. Levofloxacin showed the highest sensitivity (91%) among MSSA strains followed by Clindamycin (85%), Erythromycin (80%), Co-trimoxazole (67%), Ciprofloxacin (61%) and showed least sensitivity to penicillin (24%).(Table 3) Among all above mentioned drugs, antibiotic resistance for MRSA and MSSA was statistically significant only for Pencillin, Clindamycin, Erythromycin, Ciprofloxacin, Co-trimozole and Levofloxacin.(Table 4).

Staphylococcus aureus is a major human pathogen and is one of the commonest causative agent of Community and Hospital acquired infections. The treatment of *Staphylococcus aureus* infection has become problematic because of emergence of resistance to Penicillin, Methicillin, Vancomycin and many other antibiotics, by acquiring several resistance mechanisms. Increased antimicrobial resistance for such an organism is, therefore a cause of concern.

In the past few decades MRSA has emerged as an important nosocomial pathogen worldwide. In India, prevalence rate varies from 30-85% in different parts and has now become endemic (Lowy, 1998). A multicentric study done in India involving 17 tertiary care Hospitals reported MRSA prevalence of 41% in 2008-2009 (Mallick *et al*., 2010). MRSA is of serious therapeutic concern not only due to its resistance to Methicillin, but also because of resistance to many other antimicrobials that are used on regular basis in Hospitals. Therefore, the most reliable and sustained therapeutic agent against methicillin-resistant *Staphylococcus aureus* (MRSA) strains is Vancomycin. Extensive use of this antibiotic inturn lead to the emergence of Vancomycin intermediate *Staphylococcus aureus* [VISA] and Vancomycin resistant *Staphylococcus aureus* [VRSA] strains in various parts of the world (Manu *et al*., 2013).

In the present study a total of 161 non-duplicate *Staphylococcus aureus* strains were isolated from various clinical specimens. Among all these samples highest isolation was from pus 103 (64%). Harcharan singh *et al.,* (2014) in Udaipur (65%), Manu Chaudhary *et al.,* (2013) in H.P (63%) and Ankur Goyal *et al.,* in Agra (66.03%), also reported the highest isolation of *Staphylococcus aureus* from pus.

All the *Staphylococcus aureus* strains were screened for Methicillin resistance using Cefoxitin disc diffusion method. Since it is a potent inducer of *mecA* gene, hence considered as a surrogate marker for detection of methicillin resistance by CLSI 2012, in our study 82 (51%) isolates turned out to be MRSA and 79(49%) as MSSA, from a total of 161 *Staphylococcus aureus* strains. The prevalence rate of MRSA in our institute is 51%, which is similar to the studies conducted by Vidhani and Mehndiratta *et al*., in 2001 showing a prevalence rate of 51.6% and almost comparable to the study conducted by Majumdar *et al*., in 2001 and Assadullah *et al*., in 2003 showing 52.9% prevalence rate. The higher rate in their studies may been attributed to the fact that the studies were conducted at a tertiary care multispecialty center with more and more patients coming from pheriphery and small nursing homes, where injudious use of antibiotics and inadequate infection control policies are prevalent. Verma *et al*., in 2000 reported a higher prevalence rate of 80.89% in Indore and Mehta *et al*., in 2007 reported a lower prevalence rate of 24% in Chandhigarh. This variation in prevalence may be because of several factors like different Geographical and

environmental conditions, population group under study, healthcare facilities available in the particular hospital, implementation and monitoring of infection control committee, rationale antibiotic usage which varies from hospital to hospital. We have 51% prevalence rate of MRSA in our hospital setup. It therefore calls in for better vigilance and implementation of more effective MRSA surveillance programme complemented with improved infection control practices.

In the present study, maximum MRSA were isolated from pus 50 (61%), followed by blood 13(15%), respiratory secretions 8 (10%), Swabs and body fluids 4(5%) each and least from Urine 3(4%). This pattern correlates with studies conducted by Vidya Pai *et al.,* in 2010 and Nitish Kumar Sharma *et al.*, 2013. This is due to the reason that *Staphylococcus aureus* accounts for most of the skin and soft tissue infections, septicemia and also respiratory tract infection.

Comparatively MRSA prevalence was more in males (73%) than in females (23%) in our study. Similar findings was also reported by Rao *et al*., (2010) and Abhishek Mewar *et al*., The increased rate of MRSA infections among males could be due to their more outdoor activities, inturn exposing them to contaminated environment and also compared to females, accidental injuries are more common among men.

Most of the MRSA strains were isolated from 21-30 yrs of age group (ie 32%) and in 51-60yrs (ie 26%), indicating MRSA infection is more common in working and old age group. The reason for this may be that younger age group are more involved in outdoor activities inturn exposing them to contaminated environment and in older age group it may be due to waning immunity, hormonal abnormalities and co-morbid conditions. Similar pattern of affected age group was also reported by Ankur Goyal *et al*., in 2013. Isolation was more from the IPD patients (88.8%) than from the OPD patients (11.2%). Among IPD patients, highest prevalence was seen in orthopedics, oncology and surgical wards. Similarly Mallick and Basak reported 84.8% MRSA from IPD patients, in which maximum strains were isolated from surgical and orthopedics ward. This might be because the patients in these wards are usually with open wounds and are debilitated. They undergo multiple interventions in the hospital which further increases the risk of MRSA infection due to multiple people involvement as well as prolonged stay in the wards. Along with these factors, the patient is usually on multiple antibiotics.

Resistance of MRSA to a wide range of antibiotics is well documented[35]. In the present study antibiotic resistance is significantly more in MRSA strains of *Staphylococcus aureus* as compared to MSSA strains. Statistically significant difference was observed for Penicillin, Fluoroquinolones, Erthromycin, Clindamycin and Co-trimoxazole. Such similar statistically significant difference between the sensitivity pattern of MRSA and MSSA was also reported by Vidhani *et al*., (2013), Shilpa Arora *et al*., (2013) Majumder *et al*., (2013).

For Penicillin 100% resistance was observed for MRSA strains in our study and such similar finding was also reported by Gupta *et al*., (2010), Anupurba *et al*., The resistance rate of Ciprofloxacin in MRSA strains was high [93%], consistent with the resistance rate of Pulimood *et al*., [90%] and Udaya Shankar *et al*., [95.8%]. Our study had also showed high degree of resistance to Erythromycin and Co-trimoxazole. Such high resistance pattern observed for these antibiotics in our study may be due to the differential clonal expansion and indiscriminate empirical use of these drugs. The present study also showed a low level of resistance to Clindamycin, similar to the study conducted by Ankur

Goyal *et al*., (2013). This may be due to the antibiotic recycling and the dependence of the clinicians more on beta lactam drugs. In the light of the present study, we would recommend use of Clindamycin for the management of soft tissue infections, with MRSA strains that are sensitive to Clindamycin since it has better soft tissue penetration and no renal dosing adjustments and thus by reserving Vancomycin for life threatening infections.

The association of Multidrug resistance with MRSA adds to the problem and the presence of MDR strains in the Hospital can't be neglected. Several studies are prevailing for Methicillin resistance from India but few have worked on Multi-drug resistance. MRSA strain showing resistance towards ≥ 3 antibiotics is defined as MDR strain. MDR MRSA strains in our study is 45%, a study conducted by Majumder *et al*., (2013) reported 23.2% MDR- MRSA, 32% by Anupurva *et al*., and as high as 63.6% by Rajaduraipandi *et al*., (2000). The emergence of MDR MRSA infections is worrisome in the present therapeutic scenario, hence a continuous antibiotic surveillance is required for all the *Staphylococcus aureus* isolates. This inturn will help in formulation of effective antibiotic policies in the health care set-up or else the threat will increase.

In the present study 3% resistance was observed for Vancomycin by disc diffusion test, Harcharan Singh *et al*., (2013) conducted a study in Udaipur and observed a higher resistance of 13% to Vancomycin by using Disc diffusion method only. Similarly Yogesh Kumar Gupta *et al*., and Ankur Goyal *et al*., had reported no vancomycin resistance by Disc diffusion in Rajasthan and Agra respectively.

To conclude, the result of our present study indicated high antibiotic resistance to commonly used antibiotics by MRSA isolates. The increase in vancomycin resistance among MRSA and MDR- MRSA and excessive use of antimicrobial agents has worsened the sensitivity. Hence prudent and responsible usage of newer antibiotics is advocated to preserve their continued effectiveness in the management of difficult to treat infections caused by MRSA and VRSA. We should undertake more and more such studies in future to fight against rising menace of antibiotic resistance. Also more research should be done to find better treatment policies, effective and cheaper alternative antibiotics in developing countries like ours. The findings of the studies should be shared with hospital infection control committee to help in the formulation of infection control polices and also antibiotic policies. So that the primary care givers can use antibiotics rationally.

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Original Research Paper Medical Science

Incidence and Antibiotic Resistance patterns of nosocomial Infections caused by *Pseudomonas aeruginosa* in a Tertiary Hospital, Nashik, India: A Epidemiological Study during 2015-2016

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ABSTRACT

Backgrounds: *P. aeruginosa* is major causative organism of Nosocomial infections. The emergence of drug resistance and its transmission from patients to patients and from healthy persons to patients in ICU is major health concerns before the health workers in India. Moreover the accumulation of number of drug resistance genes in the this organism gives limited options for treatment of infections caused by it. Therefore, continued surveillance of drug resistance in this opportunistic pathogen is necessary to plan effective anti-microbial treatment against the infections caused by it.

Materials and Methods: From different clinical samples, *P.aeruginosa* was isolated and identified and tested for drug resistances on suitable media using standard procedures before the start and at the end of Stewardship Program. Statistical analysis was done using R statistical package in Linux system.

Results: All the drug tested for drug susceptibility testing show decreased in incidence of drug resistance after a one year time span. Gentamycin show highest decrease of 16.58% followed by ceftazidime at 13.92% and carbenacillin at 12.38%. whereas, the reduction in drug resistance to penicillin and and piperacillin is very low, i.e. only 1.19%.

Conclusions: Imipenem, with incidence of drug resistance of 4.13%, was found to be most effective drug and piperacillin and ciprofloxacin , both with incidence of drug resistance of 41.66% were least effective drug against P. aeruginosa in our study in the year 2016.

KEYWORDS : Antimicrobial Stewardship program, Nosocomial infections, Antimicrobial resistance, P. aeruginosa.

Introduction:

Pseudomonas aeruginosa, which is quintessentially ubiquitous opportunistic pathogen found in soil and water, causes number of post-operative and medical devices associated nosocomial infections in Indian hospital settings.

Spread of *Pseudomonas* infections through contaminated water is most common route of infection in hospital settings[1]. Lung infection of *Pseudomonas* is acquired by inhalation of aerosols of *Pseudomonas* contaminated water[1].

Moreover, due to high particulate pollution caused by soil dust, infections caused by Pseudomonas present in the dust is also high. Persons carry millions of dust particles and hence Pseudomonas present in them, which them easily transmit to inpatients.

The multi-drug resistance to number of routinely used anti-microbial drugs in this organism is matter of concerns among health workers in controlling and treating the infections caused by this organism, especially in hospital inpatients.

10% of the infections contracted during hospital stay of patients are caused by *Pseudomonas aeruginosa*[2].

Although the Pseudomonas infections are third leading causes of nosocomial infections that prolong the ICU stay, multi-drug resistance in this pathogen contributes to higher morbidity and mortality as compared to other pathogens in tertiary health care settings[3,4,5].

Number of studies in India have reported high prevalence of drug resistance in *Pseudomonas aeruginosa* isolated from various samples from 8.43% to 32.1%[6,7,8,9]

The higher drug resistance observed in *Pseudomonas aeruginosa* is due to presence of intrinsic drug resistance to number of drugs used against them, the selection pressure because of higher amount of antibiotics use inappropriately adds to the total drug resistance increasing incidence it many folds in this opportunistic pathogen.

To minimize the transmission of drug resistance and halt accumulation of drug resistance genes in *P. aeruginosa,* number of researchers suggested implementation of Stewardship programs[10]

One of the causes of emergence of drug resistance in bacteria, is higher selection pressure by use of higher amount of antibiotic inappropriately in hospital settings.

Stewardship program is defined as efforts of prescribing appropriate antimicrobial agents, its route, dosing and duration of its use in inpatient settings in order and reduce or prevent emergence of antimicrobial resistance, adverse consequences of its use, improve patients' health and provide cost effective therapy. Cochrane suggested one year period of the assessment of stewardship Programs on incidence of drug resistance in bacteria[10].

In the present study, researchers have studied the epidemiology of trends of drug resistance and incidence of infections caused by *Pseudomonas aeruginosa* with respect to the antimicrobial Stewardship programs for a period of one year.

Materials and Methods:

Sampling :

The number of clinical samples such as pus, urine, blood, sputum and body fluids were collected, as per standard procedures, from inpatients who developed infections after some kind of surgery or after some invasive medical procedures in order to investigate nosocomial infections, their causative organisms and incidence of drug resistance among them. The patients who have already have infections caused by *Pseudomonas aeruginosa* on admission to the hospital were excluded from this research study. Total 250 samples were processed for culture identification and drug susceptibility during each years of 2015 and 2016.

Culturing and identification of Pseudomonas isolates:

The isolates, for *Pseudomonas aeruginosa,* were cultured aerobically in Muller-Hinton broth for 16 to 24 hours at 37°C. The isolates were Gram stained and inoculated first into brain-heart infusion medium and then onto cetrimide agar. The Gram-negative bacteria from

isolated colony from cetrimide agar were confirmed as *Pseudomonas aeruginosa* by biochemical tests. The isolated were tested for oxidative fermentation and ability to grow at 42°C[11].

Implementation of Stewardship Program:
The above mentioned samples were microbiologically processed, drug susceptibility testing of isolated *Pseudomonas aeruginosa* was carried out in order to find out incidence of antibiotic resistance in this organism before the start and at the end ,after one year, of antimicrobial Stewardship program.

The antimicrobial Stewardship program was carried out between between January 2015 to December 2016 and continued thereafter also.

In the present Stewardship program, appropriate antimicrobial drug selection and its dosing was implemented. Antimicrobial therapy was started only after the culture identification and drug susceptibility testing were carried out. The antibiotic therapy was stopped as soon as a targeted infection is subsided.

Drug Susceptibility Testing:
Antibiotic susceptibility testing was carried out by Kirby-Bauer disk diffusion method as per CLSI guidelines[12,13] using antibiotics, gentamycin, piperacillin, carbenicillin, ciprofloxacin, amikacin, ceftazidime and imipenem.

Frequencies of drug resistance for each drug tested were recorded sample wise, gender wise and age group wise. Proportion and P-value was calculated using R-package of statistical analysis[14].

Results and discussion:
Results :
The total 250 various samples were selected randomly during January 2015 to December 2015, processed for drug resistance and data such as type of samples, type of infections and incidence of drug resistance was analyzed sample wise, gender wise and age-groups wise. Same procedure was followed for the 250 samples processed during January 2016 to December 2016. Sample-wise, gender-wise and age-groups wise incidences of nosocomial infections caused by *Pseudomonas aeruginosa* were recorded in **table No.1, 2** and **3** respectively.

Table No. 1 Sample-wise incidence of *Pseudomonas aeruginosa isolates* in 2015 and 2016 (sample size = 250)

Sr. No.	Specimen	Number of Samples in 2015	Number of Samples in 2016	proportions (%) in 2015	Proportions (%) in 2016
1	Wound Swab/Pus	20	14	57.14	58.33
2	Urine	10	5	28.57	20.83
3	Sputum	3	3	8.57	12.50
4	Body fluid	2	2	5.71	8.33
Total		35	24	100	100

Table No. 2 Gender-wise incidence of *Pseudomonas aeruginosa* infections in 2015 and 2016.

Sr. No.	Gender	Number in 2015	Number in 2016	Proportion(%) in 2015	Proportion(%) in 2016
1	Male	21	14	60	58.33
2	Female	14	10	40	41.66
Total		35	24	100	100

Table No. 3 Age-groups wise incidence of *Pseudomonas aeruginosa* infections in 2015 and 2016

Sr.No.	Age in years	No. of Patients in 2015	No. of patients in 2016	proportion (%) in 2015	Proportions (%) in 2016
1	0-21	3	2	8.57	8.33
2	21-40	5	8	14.28	33.33
3	41-60	17	12	48.57	50
4	61-80	10	2	28.57	8.33
Total		35	24	100	100

The data of incidence of drug resistance in *Pusedomonas aeruginosa* for year 2015 and 2016 was tabulated in **table No. 4.**

Table No. 4 Incidence of drug resistance in *Pseudomonas aeruginosa* isolates in 2015 and 2016 (Sample size = 250)

Sr. No.	Drugs (Mcg)	No. Of Sensitive Samples In 2015(%)	No. Of Sensitive Samples In 2016(%)	No. Of Resistant Samples In 2015(%)	No. Of Resistant Samples In 2016(%)	P-values
1	Gentamycin (10)	19(54.28)	17(70.83)	16(45.71)	7(29.13)	0.06391
2	Carbenicillin (100)	19(54.28)	16(66.66)	16(45.71)	8(33.33)	0.1516
3	Piperacillin (100)	20(57.14)	14(58.33)	15(42.85)	10(41.66)	0.5413
4	Amikacin (30)	20(57.14	16(66.66)	15(42.85)	8(33.33)	0.1516
5	Ciprofloxacin (5)	18(51.42)	14(58.33)	17(48.57)	10(41.66)	0.5413
6	Ceftazidime (30)	17(48.57)	15(62.5)	18(51.42)	9(37.50)	0.3075
7	Imipenem (10)	32(91.42)	23(95.83)	3(8.57)	1(4.13)	2.98e-06

Proportion of Wound and pus samples were remarkably high followed by urine samples both in years 2015 and 2016.

Male inpatients recorded higher incidence of pseudomonas infections than female patients both in the years 2015 and 2016.

The lowest resistance was observed for imipenem both for 2015 and 2016 of 8.57% and 4.13% respectively.

During the period of one year, all the drugs tested for drug susceptibility show remarkably high drug resistance.

Ceftazidime show highest resistance of 51.42%, followed by ciprofloxacin with resistance of 48.57%, in 2015 among all the drug tested whereas imipenem show lowest resistance of 8.57% in 2015.

In 2016, imipenem show lowest drug resistance of 4.13%, whereas other drugs show resistance between 29.13%(Gentamycin) to 41.66%(ciprofloxacin and piperacilin).

Discussion :
The incidence of Pseudomonas isolates and infections were 14% and 9.6% in the years, 2015 and 2016 respectively, sample-wise, gender-wise and age-group wise.

All the drugs tested for drug resistance, though show remarkably high resistance during 2015, the incidence of drug resistance has come down by 10% to 12% in 2016. During 2015, incidence of drug resistance for ceftazidime was 51.42% which observed to be 37.50% in 2016; thus incidence of drug resistance for this drug reduced by 16.58%. which is highest decrease in incidence of resistance. Penicillin, piperacillin show very negligible reduction of drug resistance, 1.19%, during a year period.

Incidence of drug resistance for Imipenem was recorded 8.57% in 2015 whereas it come down to 4.13% in 2016; a marginal reduction of 4.44%.

Thus the reduction in incidence of drug resistance is proportionate to initial incidence of the previous year, i.e. 2015; higher the incidence more is its down fall as results of various practices

followed in Stewardship program in this research work. However, the reduction in drug resistance to penicillin and and piperacillin is very low, i.e. only 1.19%, despite their remarkably high resistance in 2015; this might be due to presence of number of mutations governing a single drug resistance which take time to revert back to normal genes and this inferences can be supported by the facts that chromosomal β lactamase and MexAB-OprM MDR system are required for drug resistance to β lactam antibiotics[15]. This type of cooperative mutations show very low mutability rate in the organism[16] resulting in low decrease in incidence of drug resistance.

The high incidence of drug resistance among patients visiting this hospital might be because of accumulation of drug resistant strains of Pseudomonas aeruginosa among patients, most of who are living in dusty environment and frequently followed antibiotics regimes for acute respiratory system's illness; this inferences are drawn from oral communications by the patients since the history of such patients can not be recorded, which is the limitation of this research work.

Some significant outcomes of this research work are that that avoiding inappropriate use of anti-microbial drug, combination of more that one antibiotic use and implementation of good sanitary and aseptic practices in hospital environment help controlling spread of drug resistance in *Pseudomonas aeruginosa.*

Since the said hospital is situated in dusty environment and the dust being the major source of Pseudomonas infections, the researchers have suggested the air handling system to the administration of the hospital. The air handling system would provide microbe-free air to the modular operation theater, thus substantially reducing the microbial loan in the hospital air. The researchers, therefore, suggested to the said hospital administration to install pure air handling system in their hospital. The researchers also suggested to stop prescribing those antibiotics with high incidence of drug resistance, e.g. penicillin, piperacillin, ciprofloxacin and ceftazidime.

Conflicts of Interests:

The authors have no any kind of affiliations or financial involvement with any organization or department of government or private body with a financial interest in or conflict with the subject matter or materials discussed in the manuscript apart from those disclosed.

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Original Research Article.

Study of *Pseudomonas Aeruginosa* Clinical Isolates with Special Reference To Drug Resistance and Biofilm Formation

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ABSTRACT

Background: *Pseudomonas aeruginosa* is a Gram negative, motile rod shaped bacterium. Production of different virulence factors make the *P.aeruginosa* more virulent. About 65% hospital acquired infections are associated with biofilms.

Objectives: To study incidence, antimicrobial susceptibility pattern and biofilm formation of *P.aeruginosa* clinical isolates.

Materials and Methods: Total 400 various clinical samples from different wards received for routine culture and sensitivity tests in the microbiology laboratory were processed during January 2015 to June 2015. Blood agar, MacConkey agar and nutrient agar plates were used for culture. Confirmed *P. aeruginosa* Isolates were screened for antimicrobial susceptibility pattern and biofilm formation. Muller-Hinton agar plates were used to study antimicrobial susceptibility pattern. Biofilm formation was studied by tube method.

Results: Total 6.25% (25/400) clinical samples were positive for *P.aeruginosa*. Out of 25, 18 (72%) isolates were from pus, 5/25(20%) urine and 2/25(8%) sputum. Twenty out of 25 (20/25, 80%) isolates were from male patients and 5/25 (20%) form female patients. Higher incidence was found in 41- 60 years of age group (19/25, 76%). *P.aeruginosa* found highly resistant to ceftazidime (48%) and 100% susceptible to imipenem. Fourteen out of 25 (14/25, 56%) isolates showed biofilm production and 11/15 (73.33%) MDR *P.aeruginosa* isolates showed biofilm production.

Conclusion: Most effective drug was Imipenem. Antibiotic resistance was higher among biofilm producers. This study showed strong association between biofilm formation and drug resistance.

Key words: *Pseudomonas aeruginosa*, Biofilm Formation, Imipenem.

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INTRODUCTION

Pseudomonas aeruginosa *(P.aeruginosa)* is a gram negative, opportunistic pathogen. It causes acute and chronic infections.[1]

Moist sites in the hospital environment are known reservoirs of *P.aeruginosa* strains. They are often multidrug resistant due to intrinsic and acquired determinants.[2] It can survive with low levels of nutrients and grow in temperatures ranging from 4 – 42°C.[3]

P.aeruginosa is one of the members of normal flora of nasopharynx and is capable of colonizing the respiratory tract.[4]

Biofilm formation, development of drug resistance and production of different virulence factors make the *P.aeruginosa* more virulent.[5] It can cause Urinary tract infections, respiratory tract infections, dermatitis, soft tissue infections, bacteremia, bone and joint infections and gastrointestinal infections. They are more common in immunocompromised patients and in cystic fibrosis patients.[6]

Because of different metabolic and virulence properties, *P.aeruginosa* is capable of surviving in different environmental conditions.[7]

Biofilm production is an important determinant of pathogenicity in infections caused by *P.aeruginosa*. Biofilm presents strong resistance to the immune system and antibiotics. *P.aeruginosa* forms biofilm that contribute to acute, chronic and persistent infections.[8] *P.aeruginosa* is one of the main pathogenic organisms responsible for drug-resistant nosocomial infections and is becoming day-by-day very common pathogen. It may colonise healthy human without causing disease. Injudicious administration

of broad spectrum antibiotics, instrumentation and intrinsic resistance of microorganisms contribute to make *P.aeruginosa* a nosocomial pathogen.[9] Keeping these facts in mind, this study was undertaken to study the prevalence, antimicrobial susceptibility pattern and detection of biofilm formation among the *P.aeruginosa* clinical isolates.

AIMS AND OBJECTIVES

To determine prevalence, antimicrobial susceptibility pattern and to study biofilm formation of *P.aeruginosa* clinical isolates.

MATERIALS AND METHODS

This study was conducted at the Department of Microbiology in Dr. D. Y. Patil Medical College, Hospital and Research centre, Pimpri, Pune-411018. The study was conducted during January 2015 to June 2015.

Total 400 various clinical samples received from different wards of all ages and both sexes for routine culture and sensitivity tests were processed and confirmed *P.aeruginosa* isolates were screened for antimicrobial susceptibility pattern and biofilm formation.

Isolation and Identification of *P. aeruginosa*

All clinical samples were inoculated on Blood agar, MacConkey agar and Nutrient agar plates. The inoculated plates were incubated for 24 hours at 37°C. Isolates were confirmed as *P.aeruginosa* by colony morphology, grape like odour, pigment production (Figure-1), growth at 42°C, Gram staining, motility, and biochemical tests like catalase, oxidase, nitrate reduction test and citrate utilization tests.[10]

Antimicrobial Resistance Pattern

Antimicrobial resistance pattern was studied on Muller-Hinton (MH) agar by standard disc diffusion method (Kirby-Bauer) as recommended by Clinical and Laboratory Standards Institute.[11] Bacterial inoculum was prepared by using 16-24 hours old culture. Bacterial suspension was prepared using 4-5 isolated colonies. Standard inoculum size was prepared using turbidity standards (0.5 Mcfarland=$1.5x10^8$ CFU/ml) as a reference to adjust the turbidity of bacterial suspensions so that the number of bacteria will be within a given range.[12]

Bacterial suspension was inoculated on Muller-Hinton agar plates by using sterile swab on entire surface of agar plates. Antimicrobial agents used to study resistance pattern were amikacin (30µg), ceftazidime (30µg), ceftazidime/ clavulanicacid (30/10µg), ceftazidime/ tazobactum (30/10µg), carbenicillin (100µg), ciprofloxacin (5µg), gentamicin (10 µg), imipenem (10 µg) and piperacillin (100 µg).The antibiotic discs were placed on the surface of the inoculated plates and gently pressed with sterile forcep. Plates were incubated at 37°C for 18-24 hours. (Figure-2).

The diameter of inhibition zone was measured in millimetres and isolates were scored as sensitive or resistant by comparing with values recommended on standard charts.

Pseudomonas aeruginosa ATCC 27853 was used as the quality control organism in antimicrobial susceptibility determination.

Evaluation of Biofilm Formation by Tube Method

This is a qualitative method used for detection of biofilm formation. This test was carried out as described by Christensen et al.[13] A loopful of test organisms from overnight culture plates were inoculated in 10 ml of trypticase soy broth with 1% glucose in test tubes. Inoculated tubes were incubated at 37°C for 24hrs. Then tubes were decanted, washed with phosphate buffer saline (pH 7.3). Then tubes were dried and stained with crystal violet (0.1 %). Excess stain was removed and after washing with distilled water, tubes were dried in inverted position. Then dried tubes were observed for biofilm formation. A visible thick film lined the wall and the bottom of the tube was considered biofilm positive. The amount of biofilm formed was graded and recorded as a positive and negative biofilm formation (Figure -3A and 3B).

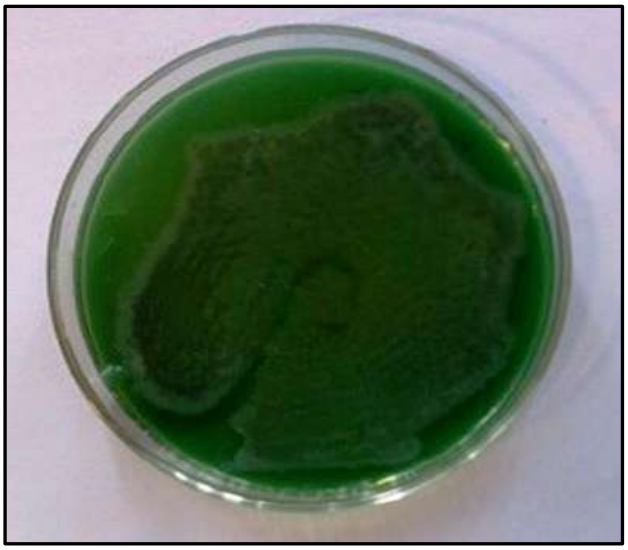

Figure 1: Growth of *P.aeruginosa* on nutrient agar.

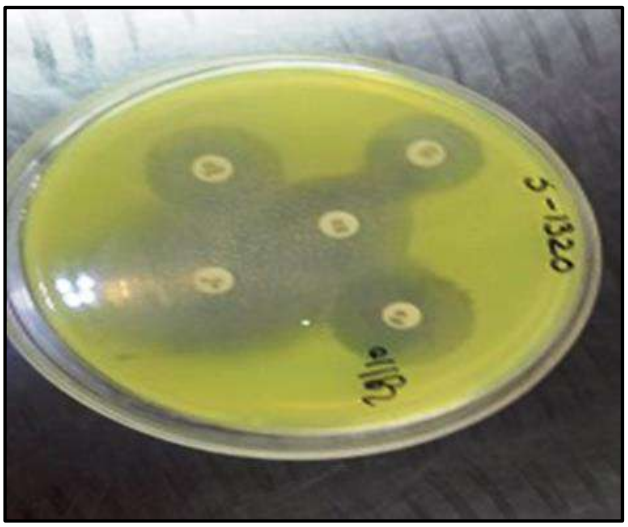

Figure 2: Antibiotic susceptibility test.

RESULTS

Out of 400 various clinical samples, 25 (6.25%) were positive for *P.aeruginosa.* Out of 25, 20 (80%) were from male patients and 5 (20%) were female patients (table 1).

Higher rate (19/25, 76%) of *P.aeruginosa* was found in 41-60 years of age group (table 2)

Out of 25 *P.aeruginosa* isolates, 18 (72%) were from pus followed by urine 5 (20%) and sputum 2 (8%) (table 3).

All Isolates were sensitive to imipenem (25/25, 100%) and antibiotic resistance was higher in ceftazidime (12/25, 48%). A total of 60% (15/25) *P. aeruginosa* were Multidrug resistance.

Out of total 25, 14 (56%) *P.aeruginosa* showed biofilm formation. Out of 15 MDRPA, 11 (73.33%) showed biofilm formation.

Figure 3A: Positive biofilm formation.

Figure 3B: Negative biofilm formation

Table 1: Gender-wise distribution of clinical isolates of *P.aeruginosa* (n=25).

Gender	n	%
Male	20	80%
Female	05	20%
Total	25	100%

Table 2: Prevalence of *P.aeruginosa* based on age.

Age in years	n	%
0-20	01	04%
21-40	05	20%
41-60	19	76%
Total	25	100%

Table 3: Distribution of specimens of *P.aeruginosa* clinical isolates.

Specimen	n	%
Pus/wound swab	18	72%
Urine	05	20%
Sputum	02	8%
Total	25	100%

Table 4: Antimicrobial susceptibility pattern

Antibiotic	Sensitivity (%)	Resistance (%)
Amikacin (30mcg)	19 (76%)	6 (24%)
Ceftazidine + Clavulinic acid (30 + 10mcg)	16 (64%)	9 (36%
Ceftazidime + tazobactum (30 mcg + 10 mcg)	14 (56%)	11(44%)
Ceftazidime (30 mcg)	13 (52%)	12 (48%
Carbenicillin (100mcg)	14 (56%)	11 (44%)
Ciprofloxacin (5mcg)	17 (68%)	8 (32%)
Gentamicin (10mcg)	18 (72%)	7 (28%)
Imipenem (10mcg)	25 (100%)	0 (0%)
Piperacillin (100mcg)	16 (64%)	9 (36%)

DISCUSSION

The aim and objectives of this study were to determine prevalence, antimicrobial susceptibility pattern and to study biofilm formation of *P.aeruginosa* clinical isolates. The researcher processed total 400 various clinical samples received in Microbiology laboratory during January 2015 to June 2015.

Out of 400 clinical samples processed, 25 (6.25%) were positive for *P. aeruginosa.* In India, other researchers in similar studies have reported 2.76%, 8.2% prevalence of *P.aeruginosa* clinical isolate respectively.[14,15]

Prevalence of *P.aeruginosa* in pus was found to be 72 % (18/25) followed by 20% prevalence of the organism in urine. The higher prevalence (50.7%, 55.3%) of this pathogen in pus was also reported by other researchers respectively.[16,17]

The higher prevalence of *P.aeruginosa* isolates was observed in male patients (80%) than female (20%). Similarly, in other studies also the researchers reported the higher prevalence of *P.aeruginosa* in male than in female patients.[18] This shows that the male patients are more exposed to this pathogen than the female patients due to their occupational risks.

Higher prevalence of *P.aeruginosa* was found in 41-60 years age group (19/25, 76%) both in male and female patients. The other studies have also reported similar finding in India.[19]

P.aeruginosa clinical isolates were most sensitive to imipenem (100%) followed by Amikacin (76%) and least sensitive to ceftazidime (52%). These results are in agreement with other similar studies where researchers found that the pathogen was 90% sensitive to imipenem.[20] Thus imipenem is the most effective antibiotic and there is no resistance to this antibiotic; therefore this antibiotic should be used very judiciously so that least or no drug resistance develop in this pathogen. Out of 25 *P.aeruginosa* clinical isolates, 60% (15/25) showed MDR pattern. The higher MDR in this pathogen suggests that there is urgent need to implement the antibiotics stewardship program so that no further increase in the drug resistance appears in this pathogen. Further research is needed to find out the best antibiotic combinations to minimise the emergence and transmission of drug resistance in *P. aeruginosa.* In this study, 14/25 (56%) *P.aeruginosa* isolates showed biofilm production. This finding is in agreement with the 53.3%.[21] A total of 73.33% (11/15) MDR *P.aeruginosa* showed biofilm formation. The high proportion of biofilm markers among MDR *P.aeruginosa* strains suggest that the biofilm production play

some significant roles in showing drug resistant in agreement with same results shown in different studies.[22,23] This also suggests that there is strong association between biofilm formation and drug resistance. The association of biofilm production with MDR *P. aeruginosa* should be further investigated. Many times, the biofilm producing strains showing the drug resistance, clinically, is not true drug resistance but due to poor penetration of the drug in the biofilm showing the drug resistance in this pathogen.

CONCLUSION

Most effective drug was imipenem. Antibiotic resistance was higher among the biofilm forming strains of *P.aeruginosa*. Biofilm formation in MDR *P. aeruginosa* clinical isolate was recorded as 73.33%. This study showed strong association between biofilm formation and drug resistance. There should be continuous surveillance of drug susceptibility testing among *P. aeruginosa* strains in hospital setup. Further research is needed to find out the best antibiotic combinations to minimise the emergence and transmission of drug resistance in *P. aeruginosa.*

ETHICAL STATEMENT

The present study was approved by Institutional Ethical Committee of Dr. D. Y. Patil Medical College, Hospital and Research Center, Pimpri, Pune-411018.

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Conflict of Interest: None Declared.

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Study of detection of *plcH gene* and its phenotypic expression in *Pseudomonas aeruginosa* isolated from various clinical samples.

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Abstract:
Background: *Pseudomonas aeruginosa (P.aeruginosa) is an opportunistic pathogen and can infect almost all tissues. After multiplication and colonization, P.aeruginosa spreads within cells. Toxins and enzymes produced by P.aeruginosa are key factors that invade host cells and produce disease. P. aeruginosa harbours virulence genes like plcH, plcN, plcB, exoS, exoT, exoU, lasB, pilB, exoS, algD, nanI, pvdA. These virulent genes colonize the host cells and play important role in causation of disease. Phospholipases C involve in pathogenicity. P.aeruginosa produces two types of phospholipases C, haemolytic phospholipase C and non-haemolytic* phospholipase *C encoded by plcH and plcN genes respectively. Haemolytic phospholipase C is responsible for haemolysin production and show haemolytic activity. Phospholipases C are secreted via a micro machine known as Type -2 secretion system. Phosphate deficiency induces production of haemolytic phospholipase C. This study was focussed on study of detection of plcH gene and its and phenotypic expression in P.aeruginosa strains isolated from various clinical samples obtained at Tertiary Care Hospital.*
Objectives: *Detection of plcH gene and its phenotypic expression in P. aeruginosa isolated from various clinical samples received in a Tertiary Care Hospital.*
Materials and methods: *Thirty strains of P. aeruginosa isolated from clinical specimens were identified using standard laboratory methods. Gene plcH were detected by polymerase chain reactions and gel electrophoresis technique. Production of haemolysins was studied on 5% sheep blood agar plates.*
Results: *PCR amplification results showed presence of plcH genes in 22 (73.33%) out of 30 P.aeruginosa strains and 21 (70%) of the isolates showed haemolysin production.*
Conclusion*: Gene plcH of p. aeruginosa is one of the important virulent factors and plays key role in development of disease. It is concluded that plcH gene can be a striking pathogenic factor shown by presence of 73.33% and expressed phenotypically by 70% of P. aeruginosa strains isolated from clinical samples. The proved role of plcH virulent gene in the causation of disease would help in geeting clue of the prognosis of infections caused by Pseudomonas and scheming successful therapy and designing suitable vaccine against the prevention of infections caused by Pseudomonas.*
Key words: *P.aeruginosa, plcH, Haemolysin, PCR.*

Date of Submission: 20-12-2020 Date of Acceptance: 03-01-2021

I. Introduction

P. aeruginosa is Gram negative, motile, rod shaped opportunistic pathogen. It causes chronic and acute infections in human. Infections caused by *P. aeruginosa* play major role in cystic fibrosis, sepsis and in burn patients. Infections caused by *P. aeruginosa* are commonly observed in immune suppressed patients. [1-5].

A serious issue in infections caused by *P.aeruginosa* is multi-drug resistance to routinely used antibiotics to treat patients [6-7]. These high and multi-drug resistance is acquired due to genetic, intrinsic and acquired resistance [8]. *P.aeruginosa* is more virulent as it produces large number of cellular and extracellular virulence factors regulated by quorum sensing system. These virulence factors contribute in causation of disease in humans [9].

Virulence factors produced by *P.aeruginosa* play an important role in pathogenicity are exotoxins and exoenzyme U, exoenzyme S, exoenzyme T secreted by T3 secretion system encoded by *exoU, exoS* and *exoT* virulent genes respectively and elastage B encoded by *lasB. P.aeruginosa* produces haemolytic phospholipase C and non-haemolytic phospholipase C which are encoded by *plcH* and *plcN* virulence genes respectively. Phospholipid present in surfactans may be hydrolysed by phospholipases C [10-11].In India, very few researchers have worked on virulence factors like haemolytic phospholipase C and its allied *plcH* gene produced by *P. aeruginosa*. Considering these facts in mind, this research study was designed to detect and study the

distribution of *plcH* virulence gene and its phenotypic expression in *P. aeruginosa* isolated from various clinical samples obtained at Tertiary Care Hospital.

Aims and objectives: Aims and objectives were detection of *plcH* gene and its phenotypic expression in *P. aeruginosa* isolated from various clinical samples received in a Tertiary Care Hospital.

II. Materials And Methods:

This study was carried out at the Department of Microbiology, in Dr.D.Y.Patil Medical College, Hospital and Research Cenre, Pune-411018.

Various clinical samples like urine, sputum, pus, blood and body fluids, were received from different clinical wards including of all ages and both sexes for routine culture and sensitivity tests. All different clinical samples received were processed and confirmed strains of *P.aeruginosa* were screened for detection of *plcH* gene by Polymerase chain reactions technique and production of haemolysins was studied on 5% sheep blood agar plates.

Ethical statement

This research study was approved by Institutional Ethical Committee of Dr.D.Y.Patil Medical College, Hospital and Research Centre (Dr.D.Y.Patil Vidyapeeth), Pune.

Source of Funding: None.

Coflict of Interest: None.

Isolation and Identification of *P.aeruginosa*

All different clinical samples received were inoculated onto nutrient agar, blood agar and MacConkey agar plates. After inoculation and incubation 37ºC for 24 hrs, plates were examined for presence of growth. *P.aeruginosa* was confirmed by studying colony morphology, pyocyanin pigments production, typical grape like odour, tendency to growth at 42ºC, Gram staining, motility test, positive citrate and oxidase tests [12].

Detection of haemolysin production of *P.aeruginosa* isolated from various clinical samples

Detection of Hemolysins: All 30 strains of *P.* aeruginosa isolated from various clinical samples under this study were screened for detection of haemolysin production activity. *P.aeruginosa* grown for 18 hours at 37ºC in nutrient broth were plated on blood agar containing 5% (vol/vol) sheep blood to obtain isolated colonies. Plates were incubated at 37ºC for 24 hours. The clear zone around the colonies (total lysis of red blood cells around the colonies) was considered as positive reaction for production of haemolysins [13, 14].

Detection of *plcH* gene of *P.aeruginosa* isolated from various clinical samples

Extraction of DNA:

For the screening of *plcH* virulence genes of *P.aeruginisa,* Chromosomal DNA from the 30 clinical strains of *P.aeruginosa* clinical isolates under this study was extracted. Purification of extracted DNA was carried out using (Ganeaid-Presto™ Mini gDNA bacteria Kit) a commercial available DNA extraction kit following the manufacturer's guidelines.

Polymerase Chain Reaction: The sequences of the primers used in polymerase chain reactions for detection of *plcH* gene and its molecular weight are shown in Table No.1.

Table No.1: The Primer sequence used for the screening of *plcH* genes.

Gene	Primer sequence	Amplicon size	Length(bp)	References
plcH	Forward 5'-GAAGCCATGGGCTACTTCAA-3' Reverse 5'-AGAGTGACGAGGAGCGGTAG-3'	20 20	307	15, 16

The chromosomal DNAs extracted from *P.aeruginosa* strains under study were used as templates for polymerase chain reactions. Polymerase chain reactions were carried out in 25ul mixture containing 7.5ul distilled water, 1.5ul forward primers, 1.5ul reverse primers, 2.0ul DNA template and 12.5ul mastermix (Geneaid-Presto™Mini gDNA bacteria Kit).

The Polymerase chain reactions were carried out using conditions as shown in Table No.2

Table 2: Conditions used for Polymerase Chain Reactions.

Gene	Initial denaturation	No.of Cycles	Denaturation in each cycle	Annealing	Primer extention	Final extention
plcH	95ºC, 2 min	30	95ºC, 30 sec	55ºC,30 sec	72ºC, 30 sec	72ºC,5 min

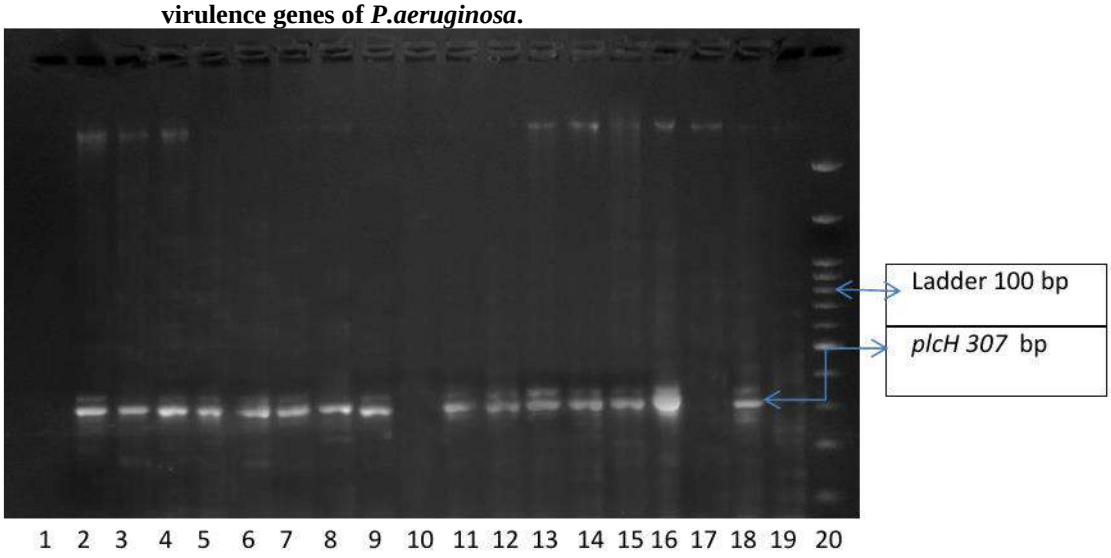
Gel electrophoresis

Polemerase chain reaction products of *P.aeruginosa* were used for gel electrophoresis. For a gel preparation, 250 ml agarose quantity was required. Agarose gel was prepared with 2% agarose and ethidium bromide as it shows good resolution for small fragments. Images of PCR products were detected using transillumator by UV illumination as shown in image No.1. For the estimation and to compare size of PCR products, the 100bp DNA molecular size markers were used [17].

III. Results:

This research study was carried out using 30 strains of *P.aeruginosa* isolated from various clinical samples in respect to sites of infections as shown in Table No.3

Image No.1: Images of Gel Electrophoresis and amplification Products of *plcH* virulence genes of *P.aeruginosa*.



No.1= Negative control (Distilled water),Nos,2,3,4,5,6,7,8,9,11,12,13,14,15,16,18 showing *plcH* gene of *Pseudomonas aeruginosa*. .Nos 10, 17, &19= showing no *plcH* gene. & No.20 is ladder100 bp

Table No.3 Distribution of *plcH* genes of 30 *P.aeruginosa* clinical Isolates in respect to sites of Infections.

S.N	Sample	case	*plcH*		S.N	sample	Case	*plcH*
1	Pus	Maxilla	+		**16**	Urine	UTI	-
2	Pus	CSOM	+		**17**	pus	CSOM	+
3	Pus	NHTU	+		**18**	pus	CSOM	-
4	Pus	Hydrocele	+		**19**	urine	UTI	+
5	Urine	CUTI	+		**20**	blood	Fever	+
6	Urine	UTI	+		**21**	pus	Leg abscesses	-
7	Pus	Leg Cellulitis	+		**22**	pus	NF	+
8	Pus	DFU	+		**23**	pus	NF	+
9	Fluid	COPD	-		**24**	sputum	RTI	+
10	Pus	NF	+		**25**	pus	TA	-
11	Pus	DFU	+		**26**	pus	DFU	-
12	Pus	CSOM	+		**27**	pus	DFU	-
13	Urine	UTI	+		**28**	sputum	RTI	+
14	Sputum	RTI	+		**29**	blood	Pneumonia	+
15	Sputum	RTI	+		**30**	pus	DFU	-

CSOM = chronic suppurative otitis media, NHTU=Non Healing Tropic Ulcer, UTI=Urinary Tract Infection, NF=Necrotizing fascitis, COPD=Chronic Obstructive Pulmonary Disease, DFU=Diabetes Foot Ulcer, RTI=Respiratory Tract infection, TA=Traumatic Amputation, CAUTI =Catheter Associated UTI.

Out of 30 strains of *P.aeruginosa* clinical isolates, 22(73.33%) showed amplification of *plcH* gene and haemolysin production was seen in 21 (70%) as shown in Table No.4,

Table No.4 Showing specimen-wise distribution of PlcH gene and its phenotypic expression (haemolysin production).

S.N	Source	*plcH* gene (%)	Hemolysis (%)
1	Pus	12(66.66)	11(61.11)
2	Urine	04 (80)	04(80)
3	Sputum	04(100)	04(100)
4	Blood	02(100)	02(100)
5	Fluids	00(00)	0(0)
6	Total	22(73.33)	21(70)

IV. Discussion

The aims and objectives of this research were to detect *plcH* virulence gene and its phenotypic expression in *P.aeruginosa* isolated from different clinical samples. In this research study, 30 strains of *P.aeruginosa* clinical isolates were included.

P.aeruginosa possesses number of quarum sensing genes which encode for number of exotoxins and exoenzymes. These exotoxins and exoenzymes are virulence factors playing their active roles in pathogenicity of various infections caused by the organism.

There are total 23 so far known bacterial virulence genes, namely *lasl, lasB, lasA, lasR, rhlR, rhIl, rhlAB, fliC, aprA, plcN, plcH, toxA, ExoT, ExoS, ExoY, ExoU, phzI, phzll, phzS, phzM, pilA, pilB* and *pvdA* [18].

The present paper discuss only the *plcH gene* encoding for haemolysin proteins. *plcH* is an important virulence genes encoding for haemolytic phospholipase C. Hemolytic phospholipase C play an important role in spreading type of infections caused by *P.aeruginosa*. Finding out its prevalence is important, as an epidemiological marker in pathogenic *P.aeruginosa.*

In this study, out of 30, 22 (73.33%) *P.aeruginosa* clinical strains were positive for *plcH* gene. This finding is in agreement with similar studies where the prevalence of *plcH* was documented as 70.42% and 75% respectively [19, 20]. Other researchers have reported high incidence of *plcH* gene in *P.aeruginosa* strains isolated from different clinical specimen in hospitals [21, 22, 23]. In pus samples, 66.66% isolates showed presence of *plcH* gene and 80% *P.aeruginosa* strains obtained from urine samples were positive for *plcH* gene. All *P.aeruginosa* strains were positive for *plcH* gene isolated from blood and sputum. Therefore, detection of *plcH* gene can be conveniently used as one of the important markers of virulence in epidemiological study.

The presence of *plcH* and its encoded product determine the prognosis of infections caused by *P. aeruginosa* and also predict the possibility of development of spreading type of infections. In the present study, 70% (21/30) of *P.aeruginosa* clinical isolates showed haemolysin production.Haemolysin production was found highest (100%) in blood and sputum isolates showing expression of *plcH* gene and suggesting that the haemolysin virulence factor is highest in spreading and systemic type of infections caused by *P. aeruginosa*. In other research studies showed that in majority of infections caused by *P.aeruginosa*, the *plcH* and its phenotypic expression were reported at 100 proportion [24, 25]. Such spreading type infections caused by *plcH gene* possessing strains of the organism had high morbidity and were more difficult to treat. The multi-drug resistance in such strains further aggravate infections resulting in high morbidity and mortality. Researchers, therefore suggest that the *Pseudomonas aeruginosa* clinical isolates having *plcH* gene, must always to subject to drug susceptibility testing in order to manage the infections effectively.

Statistical analysis:

By using Fisher exact test, the 'P' value is 0.00001. As the $P < 0.05$, result is significant and hence, there is strong association between *plcH* genes and its phenotypic expression.

Therefore either the detection of presence of *plcH* gene or its phenotypic expression can be used to determine the development and prognosis of spreading type of infections caused by *P. aeruginosa.*

V. Conclusion

We found that majority of the *P.aeruginosa* strains isolated from patients having spreading type of infections possessed *plcH* gene and its corresponding phenotypes.

We also found that since there is strong correlation between the presence of *plcH* gene and its phenotypic expression ($P<0.05$); either of the in-vitro detection of *plcH* gene or its phenotypic expression can be used to determine the severity and prognosis of pseudomonas infections in patients.

The *plcH* gene detection by polymerase chain reaction is rapid method than the detection of its phenotypic expression and therefore would be more helpful in epidemiological study and in deciding the treatment course for the infections caused by *P. aeruginosa.*

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Original Research Article

Profile of pathogens isolated from different clinical samples and their antimicrobial pattern: a retrospective study

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ABSTRACT

Background: Since there is a significant rise in resistant bacteria to different antimicrobial agents, there is a need to study the resistance pattern of different isolates from different clinical samples for effective use of available antimicrobials by clinicians. The aim of the present study was to detect the resistance pattern of various antimicrobials against different clinical isolates in hospitalised patients in out setting.
Methods: This is a retrospective study involving the collection of the data from the records of microbiology laboratory. All clinical specimens were processed as per standard microbiological procedures. Antibiotic susceptibility testing was performed by Kirby Bauer disc diffusion method on Mueller Hinton agar plate as per CLSI guidelines.
Results: A total of 153 isolates were recovered from 219 clinical samples accounting for 69.86% of total positivity. Which includes gram negative bacilli 107/153 (69.93%) gram positive cocci 36/153 (23.53%) and yeast 10/153 (6.54%). Among the total isolates gram negative bacilli account for major number of isolates 69.93% followed by gram positive cocci 23.53% and yeast 6.54%. Gram positive cocci and gram-negative bacilli showed a significant level of antimicrobial resistance. Nitrofurantoin is highly effective against urinary isolates of *Escherichia coli.* vancomycin and linezolid are most effective antimicrobials against gram positive cocci. Among gram negative bacilli meropenem and amikacin are most effective antimicrobials. Statistical significance of occurrence of *Escherichia coli* as predominant isolate as compared to other isolates were analysed by chi square test by using GraphPad online calculator. A p value<0.001 was obtained.
Conclusions: Significant rise in antimicrobial resistant pathogens were observed. Local antimicrobial policy should be developed for effective selection of available antimicrobials which are the need of the day to reduce the burden of diseases on global health care system.

Keywords: Antimicrobial resistance, Gram negative bacilli, Gram positive cocci

INTRODUCTION

Infections with microbes has a drastic effect on human health.[1] Microbial infections are important cause of morbidity and mortality across the globe with increase resistance of pathogens to different antimicrobial agents posing great concern to public health.[2] Antimicrobials are being used to overcome the drastic effect of microbial agents. Their wide spread use has led to emergence of multidrug resistant (MDR) pathogens. Antimicrobial resistance (AMR) may be due to natural, acquired/clinical resistance.[1]

High morbidity and mortality are seen in infections caused by drug resistant pathogens. The pattern of resistance to various antimicrobial agents may change over a period of time.[3] Nosocomial infections pose a great challenge to the well fare of the patient

management, since most of them are MDR strains. This increases the hospital stay of in patients and increases the health care cost.[1]

AMR is a great health care problem in India.[4] The burden of infectious disease is more in India because of increased drug resistant bacteria due to indiscriminate use of antimicrobials. Frequent cause of hospitalisation is associated with different microbial infections. The choice of selecting an effective antimicrobial agent has been reduced because of their resistance to different pathogens causing hospital and community acquired infections.[5]

Patients infected with drug resistant pathogens are at high risk of serious clinical outcomes and require more heath care services. Resistance to different antimicrobials is seen because of indiscriminate use of different antimicrobial agents, which in turn leads to mutations and results in drug resistance. MDR bacteria pose great threat for patients. since, it becomes very difficult to treat such patients and requires use of broad-spectrum antibiotics.[6]

METHODS

This was a retrospective study which involves analysis of medical microbiology test results of different clinical samples collected over a period of 6 months between July 2019 to December 2019. Only IPD patients were included in the study. The study was carried out at Ananta Institute of Medical sciences and research center, Rajsamand. This is a tertiary care hospital.

Data collection and testing

Type of clinical samples, isolates, age, sex and their antimicrobial susceptibility pattern were collected from the records. All clinical specimens were processed as per standard microbiological procedures. The isolates were first identified by standard biochemical techniques and then subjected to antibiotic susceptibility testing by Kirby Bauer disc diffusion method on Mueller Hinton agar plate as per CLSI guidelines.[5]

Antibiotic discs

The following antibiotic discs containing amikacin AK 30 mcg, amoxycillin/clavulanic acid AMC 30 mcg, ampicillin/sulbactam A/S 10/10 mcg, azithromycin AZM 15 mcg, aztreonam AT 30 mcg, cefoxitin CX 30 mcg, ceftizoxime CZX 30 mcg, ceftriaxone CTR 30 mcg, cefuroxime CXM 30 mcg, ciprofloxacin CIP 5 mcg, clindamycin CD 2 mcg, colistin CL 10 mcg, erythromycin E 15 mcg, gentamicin GEN 10 mcg, imipenem IPM 10 mcg, levofloxacin LE 5 mcg, linezolid LZ 30 mcg, meropenem MRP 10 mcg, piperacillin/ tazobactum PIT 100/10 mcg, polymyxin-B PB 300 units, trimethoprim TR 5 mcg, vancomycin VA 30 mcg, cefoperazone/ sulbactam CFS 75/10 mcg, ceftazidime/clavulanic acid CAC 30/10 mcg, nitrofurantoin NIT 300 mcg were used as per manufacturer (Himedia) instructions.

Statistical analysis

Statistical analysis was done by using GraphPad online calculator. Chi square test was employed. P value<0.05 is considered as statistically significant

RESULTS

A total of 153 isolates were recovered from 219 clinical samples accounting for 69.86% of total positivity. Which includes gram negative bacilli 107/153 (69.93%) gram positive cocci 36/153 (23.53%) and yeast 10/153 (6.54%). Among the total isolates gram negative bacilli account for major number of isolates 69.93% followed by gram positive cocci 23.53% and yeast 6.54% (Table 1).

Among the gram-negative bacilli, the major isolates are *Escherichia coli* 35.29% followed by *Klebsiella* species 12.41% and *Pseudomonas aeruginosa* 12.41%. Among the gram-positive cocci, the major isolates are coagulase negative *Staphylococcal species* (CONS) 12.41% followed by coagulase positive *Staphylococcus* (*Staphylococcus aureus*) 6.53% and *Enterococcus faecalis* 4.57%. Among the yeast the major isolate is *Candida albicans* 4.57% followed by *Candida tropicalis* 1.96% (Antifungal agents were not tested).

Among different clinical samples received urine samples account for highest number of isolates 62/119 (52.10%). Among which gram-negative bacilli accounts for 53/62 (85.48%) followed by gram positive cocci 5/62 (08.06%) and yeast 4/62 (06.45%). *Acinetobacter* species were predominant in clinical aspirates 10/21 (47.61%). *Pseudomonas aeruginosa* was predominant in pus 11/48 (22.91%) (Table 1). A total of 10 co-infections were detected among the total isolates (Table 1).

Antimicrobial resistance

Antimicrobial resistance pattern of gram-negative bacilli and gram-positive cocci varied from nil to 100% for different isolates. The details of each isolate and their antimicrobial resistance pattern is given in Table 2 and 3.

Among gram negative isolates, meropenem and amikacin are more effective against *E-coli* with 9.25% and 18.51% resistance respectively each. Meropenem and piperacillin/ tazobactam are more effective against *Klebsiella* species with 36.84% and 47.36% resistance respectively each. Amikacin and ciprofloxacin are more effective against *P. aeruginosa* with 15.78% and 31.57% resistance respectively each. Amikacin, ampicillin/sulbactam and levofloxacin are more effective against *Acinetobacter* species with 41.66% resistance respectively each. Polymyxine-B and colistin showed no resistance when used against *P. aeruginosa* and *Acinetobacter* species. Piperacillin/ tazobactam is more effective against proteus species with 33.33% resistance (Table 2).

Among gram positive isolates ampicillin/sulbactam, cefoxitin/clindamycin are more effective against cons with 21.05% and 26.31% resistance respectively each. Clindamycin and trimethoprin/ sulphamethoxazole are more effective against *S. aureus* with 30% and 60% resistance respectively each. Gentamicin and Trimethoprin/ sulphamethoxazole more effective against *Enterococcus faecalis* with 14.28% and 57.14% resistance respectively each. Gentamicin is nil resistant to CONS and *S. aureus*. Linezolid and vancomycin are nil resistant to *Enterococcus faecalis*, CONS and *S. aureus* (Table 3). Among total number of clinical isolates, males accounted for (54.25%) positivity and females accounted for (45.75%) positivity. Among the male patients the predominant isolates are *E-coli* (30.12%), followed by *P. aeruginosa* (16.86%) and *Acinetobacter species* (14.45%). Among the female patients the predominant isolates are *E-coli* (41.42%), CONS (15.71%) and *Klebsiella* species (12.85%). Details of each isolate in males and females are mentioned in Table 4.

Statistical significance of occurrence of *Escherichia coli* as predominant isolate as compared to other isolates were analysed by chi square test by using GraphPad online calculator. A p value<0.001 was obtained.

Table 1: Different microbial agents isolated from various clinical samples.

Isolated micro-organism (%)		Clinical sample	Single infection	Co-infection	Total
Gram negative Bacilli (A)	*Acinetobacter* species (7.84)	Aspirates	9/21	1	10/21
		Pus	2/48	-	2/48
	Escherichia coli (35.29)	Stool	1/3	-	1/3
		Others (tips)	1/2	-	1/2
		Urine	39/119	1	40/119
		Vaginal swab	4/15	-	4/15
		Pus	7/48	-	7/48
		Drain fluid	1/1	-	1/1
	Klebsiella species (12.41)	Aspirates	3/21	1	4/21
		Pus	-	1	1/48
		Sputum	3/5	-	3/5
		Stool	1/3	-	1/3
		Urine	7/119	-	7/119
		Vaginal swab	3/15	-	3/15
	Pseudomonas aeruginosa (12.41)	Aspirates	2/21	2	4/21
		Pus	10/48	1	11/48
		Others (tips)	1/2	-	1/2
		Urine	2/119	1	3/119
	Proteus species (1.96)	Urine	3/119	-	3/119
	Total (%)		99/107* (92.52)	08/107* (7.48)	107/153 (69.93)
Gram positive cocci (B)	Coagulase negative *Staphylococci* (12.41)	Aspirates	1/21	-	1/21
		Pus	11/48	-	11/48
		Stool	1/3	-	1/3
		Urine	2/119	-	2/119
		Vaginal swab	4/15	-	4/15
	COPS (6.53)	Pus	10/48		10/48
	Enterococcus faecalis (4.57)	Urine	3/119	-	3/119
		Vaginal swab	4/15	-	4/15
	Total (%)		36/36# (100)	-	36/153 (23.53)
Yeast (C)	*Candida albicans* (4.57)	Aspirates	-	1	1/21
		Pus	1/48	-	1/48
		Sputum	1/5	-	1/5
		Urine	3/119	-	3/119
		Vaginal swab	1/15	-	1/15
	Candida tropicalis (1.96)	Aspirates	-	1	1/21
		Urine	1/119		1/119
		Vaginal swab	1/15		1/15
	Total (%)		08/10@ (80)	2/10@ (20)	10/153 (6.54)
	Total (A+B+C) (%)		143/219$ (65.30)	10/219$ (4.56)	153/219$ (69.8)

*Total number of gram-negative bacilli isolated, # Total number of gram-positive *cocci* isolated, @Total number of yeast isolated, $ Total number of samples tested, COPS-Coagulase positive *Staphylococci* p<0.001

Table 2: Antibiotic resistance pattern of gram-negative bacilli isolated from different clinical samples.

Antimicrobial agent	Resistance percentage of gram-negative bacilli				
	Escherichia coli, (n=54)	*Klebsiella* species, (n=19)	*Pseudomonas aeruginosa*, (n=19)	*Acinetobacter* species, (n=12)	*Proteus* species, (n=3)
Ceftizoxime	85.18	68.42	84.21	100	66.66
Piperacillin/ tazobactam	29.62	47.36	42.10	75	33.33
Cefuroxime	92.59	73.68	100	100	100
Polymyxin B	NT	NT	0	0	NT
Ceftriaxone	83.33	73.68	73.68	83.33	100
Cefaperazone/ sulbactum	59.25	63.15	73.68	66.66	66.66
Levofloxacin	79.62	63.15	47.36	41.66	66.66
Aztreonam	75.92	73.68	42.10	100	66.66
Imipenem	68.51	52.63	42.10	66.66	100
Meropenem	9.25	36.84	26.31	58.33	66.66
Amikacin	18.51	78.94	15.78	41.66	66.66
Ampicillin/ sulbactam	51.85	73.68	84.21	41.66	66.66
Amoxicillin/ clavulanic acid	90.74	78.94	73.68	75	100
Ciprofloxacin	81.48	52.63	31.57	58.33	66.66
Trimethoprim/ sulphamethoxazole	68.51	63.15	84.21	66.66	100
Colistin	NT	NT	0	0	NT
Ceftazidime/ clavulanic acid	42.59	63.15	57.89	91.66	66.66

NT-Not tested

Table 3: Antibiotic resistance pattern of gram-positive cocci isolated from different clinical samples.

Antimicrobial agent	Resistance percentage of gram-positive cocci		
	CONS, (n=19)	*Staphylococcus aureus*, (n=10)	*Enterococcus faecalis*, (n=07)
Gentamicin	0	0	14.28
Ciprofloxacin	36.48	60	85.71
Levofloxacin	42.10	60	85.71
Erythromycon	47.36	60	100
Linezolid	0	0	0
Clindamycin	26.31	30	100
Vancomycin	0	0	0
Cefuroxime	42.10	70	100
Ceftizoxime	42.10	70	100
Ceftriaxone	47.36	80	100
Azithromycin	89.47	70	100
Cefoxitin	26.31	70	NT
Ampicillin/sulbactam	21.05	80	85.71
Amoxicillin/clavulanic acid	73.68	80	85.71
Trimethoprim/ sulphamethoxazole	47.36	60	57.14

Table 4: Different clinical isolates in males and females.

Isolate	Male	Female	Total
Acinetobacter species	12	-	12
Escherichia coli	25	29	54
Klebsiella species	10	9	19
Pseudomonas aeruginosa	14	5	19
Proteus species	1	2	3

Continued.

Isolate	Male	Female	Total
Coagulase negative *Staphylococci*	8	11	19
COPS	7	3	10
Enterococcus faecalis	1	6	7
Candida albicans	4	3	7
Candida tropicais	1	2	3
Total (%)	83/153, (54.25)	70/153, (45.75)	153, (100.00)

DISCUSSION

Different pathogens are associated with human infections. Management of this infectious diseases by timely identification and selection of effective antimicrobials against the causative agents help in early recovery of the patients and also helps in reducing the hospital costs as well as the stay time in hospital. Emergence and spread of MDR pathogens are a major challenge for better health care management. MDR pathogens increase morbidity and mortality in hospitalised patients. This study present various pathogens isolated from different clinical samples and their antimicrobial activity in hospitalised patients.

The total positivity of the clinical isolates of the present study were 69.86% with predominance of gram-negative bacilli 69.93% as compared to gram positive cocci 23.53%. An earlier study has reported a total positivity of 64.70% which correlates with our study.[7] Abebe et al and Masyeni et al reported gram-negative bacilli as the most predominant isolate. Similar findings are observed in the present study. Most of the nosocomial infections are associated with gram negative bacilli causing severe form of the disease. These strains are mostly MDR.[3,8]

The present study has reported a high-level resistance to various class of antimicrobials against gram negative bacilli and gram-positive cocci. Antibiotic resistance is a threat to the world and is a major public problem in India. since, India harbours great burden of bacterial diseases. Emergence of MDR strains from India for gram negative bacilli and gram-positive cocci has been reported.[9] This coincides with the present study which shows high resistance of bacteria to various antimicrobials.

Urine samples accounted for majority (54.33%) of the samples in the present study. similar findings have been observed with other studies.[1,5] The most common pathogen isolated from all clinical samples in our study was *Escherichia coli* 35.29% with predominance of females (57.05%) as compared to males (42.95%). This is followed by *Klebsiella* species, CONS and *Pseudomonas aeruginosa* 12.41% each. These findings are in correlation with other studies.[2,9,10] Among the uropathogens isolated, *Escherichia coli* and *Klebsiella* species were the predominant isolates in our study which correlates with earlier studies.[5,12]

Among the antimicrobials used against *Escherichia coli*, meropenem showed 09.25% resistance, amikacin showed 18.51% resistance and piperacillin/ tazobactam showed 29.62% resistance. Nitrofurantoin showed nil resistance against *Escherichia coli* isolates from urine. similar findings were also reported by other studies with decreased potency of ciprofloxacin and co-trimoxazole among uropathogens.[5,6,10] Among *Klebsiella* species isolated meropenem is more effective which showed 36.84% resistance. This finding is different from an earlier study which reported 100% resistance.[4] In *Pseudomonas aeruginosa* nil resistance was observed for polymyxine-B and colistin. Amikacin showed least resistance 15.78% to *Pseudomonas aeruginosa* followed by meropenem 26.31%. Higher rate of resistance for amikacin (78.00%) and meropenem (100.00%) was reported by an earlier study.[4] *Acinetobacter* species showed nil resistance to polymyxine-B and colistin and 41.66% resistance to amikacin, ampicillin/ sulbactam and levofloxacin respectively each. Piperacillin/tazobactam was the most effective antimicrobial against proteus species with 33.33% resistance. This finding is different from a previous study which reported 100.00% resistance to piperacillin/ tazobactam.[4]

Among the gram-positive isolates nil resistance was observed for vancomycin, linezolid. Gentamicin showed nil resistance against CONS and *Staphylococcus aureus* but showed 14.28% resistance against *Enterococcus faecalis*. Among CONS, ampicillin/sulbactam was the most effective antimicrobial with a resistance of 21.05% followed by cefoxitin and clindamycin with 26.31% resistance. This finding is different from an earlier study which reported 100% sensitivity to cefoxitin and clindamycin.[5] *Staphylococcus aureus* showed least resistance to clindamycin (30%). This finding is different from an earlier study which reported 100% resistance to Clindamycin.[5] Trimethoprin/ sulphamethoxazole showed a least resistance of 57.14% when used against *Enterococcus faecalis*. Khatun et al reported a higher resistance of 75% to trimethoprin/ sulphamethoxazole. The difference in the resistance pattern of different antimicrobials for gram negative bacilli and gram-positive cocci in different studies may be attributed to the usage of that particular antimicrobial in different settings.

High rate of resistance to various antimicrobials in our study may be due to inclusion of only hospitalised patients. Since nosocomial infections are seen in hospitalised patients and the strains are generally resistant to most of the commonly used antimicrobials. Similar findings were observed by earlier studies which included IPD and OPD patients.[5,6] The high rate of antimicrobial

resistance in IPD patients may indicated the need for surveillance studies on nosocomial infections to identify the source of infection. Incorrect diagnosis may lead to irrational use of antibiotics which may lead to overuse or misuse of antimicrobials resulting in dissemination of antibiotic resistance.

CONCLUSION

The most predominant isolate from different clinical samples in our study was *Escherichia coli*. Among gram negative isolates in the present study, the most effective antimicrobials are colistin, meropenem, amikacin, piperacillin/tazobactam, ampicillin/ sulbactum. Among urinary isolates of *Escherichia coli*, nitrofurantoin is very effective. Gentamicin, vancomycin and linezolid are most effective antimicrobials against gram positive cocci in our study. Significant rise in resistance to antimicrobials was observed in this study. Local antimicrobial policy should be developed for effective selection of available antimicrobials which are the need of the day to reduce the burden of diseases on global health care system.

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Original Article

Microbiology Section

Prevalence of *exoT* Gene in *Pseudomonas aeruginosa* Isolated from Various Clinical Samples: A Cross-sectional Study

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ABSTRACT

Introduction: *Pseudomonas aeruginosa (P.aeruginosa)* is one of the most frequently co-infecting bacteria reported. Development of drug resistance, biofilm formation, cell associated factors make the *P.aeruginosa* more virulent. Type III secretion system controls expression of genes. *P.aeruginosa* chromosome harbours *exoT, exoS, exoU*, and *exoY* virulent genes. Gene *exoT* plays an important role in causation of infection. The identification of virulent markers of pathogens for identification of acute and chronic infections at early stage remains a critical area and still need large research.

Aim: To study the prevalence of *exoT* gene encoding exotoxin T in *P.aeruginosa* from clinical samples.

Materials and Methods: A descriptive cross-sectional research was conducted during January 2015 to March 2016 at the Department of Microbiology in Dr. D.Y. Patil Medical College, Pimpri, Pune, Maharashtra, India. Various clinical samples were processed using standard laboratory methods. The statistical analysis was done by using Chi-square test. Strains of *P.aeruginosa* isolated from various clinical samples were identified using standard laboratory methods, and *exoT* gene was detected by Polymerase Chain Reaction (PCR) and gel electrophoresis technique.

Results: Out of 30 strains of *P. aeruginosa*, 20 (66.67%) were isolated from male and 10 (33.33%) from female patients. Most of them belonged to the age group 41-60 years (46.67%). The *exoT* gene occurred in 20/30 (66.67%) isolates of *P.aeruginosa*, while 10/30 (33.33 %) showed negative amplification results. Out of 20 *exoT* genes in *P.aeruginosa*, 17/20 (85%) were detected from male and 3/10 (15%) from female patients.

Conclusion: Gene *exoT* of *P. aeruginosa* plays the crucial role in causation of disease. It is concluded that *exoT* gene can be a notable virulent element expressed by 66.67% of *P.aeruginosa* clinical isolates. The proven role of *exoT* virulence gene in the pathogenicity of *P.aeruginosa* would help in understanding the prognosis of *Pseudomonas* infection and designing an effective treatment and vaccine against the *Pseudomonas* infections to prevent them.

Keywords: Exotoxin T, Gram negative bacteria, Polymerase chain reaction

INTRODUCTION

Pseudomonas aeruginosa (*P.aeruginosa*) is an actively motile, biofilm forming Gram negative human opportunistic pathogen. It exhibits multidrug resistance and is widely connected with hospital acquired infections [1]. They are resistant to multiple antibiotics due to acquired or inherent determinants. It can cause acute and chronic infections [2]. *P.aeruginosa* causes serious infections such as endocarditis, pneumonia, septicaemia, wound infections, cystitis [3], blood stream infections, urinary tract infection and surgical site infections [4]. Biofilm formation, development of drug resistance, various secreted toxins, proteases, pyocyanin, exotoxins and different cell associated factors make *P.aeruginosa* more virulent [5]. *P.aeruginosa* has the ability to colonise the respiratory tract and is one of the members of normal flora of nasopharynx [6]. *P.aeruginosa* infections are more frequently observed in cystic fibrosis and in weakened immune patients. In a recent study, researcher documented *P.aeruginosa* as a common co-infecting pathogen in patients [7].

P.aeruginosa continues to exist in different environmental states because of different virulence factors and metabolic properties [8]. Toxins are released by passive transport from the cells secreted by one of the three secretion systems namely, Type I Secretion System (T1SS), Type II Secretion System (T2SS) and Type III Secretion System (T3SS). Type III secretary system plays a key role in determining virulence [9]. The Gram negative bacteria have a complex T3SS which is an essential machinery of *P.aeruginosa* to inject exotoxin T (*exoT*), exotoxin S (*exoS*) and exotoxin U (*exoU*) virulence factors directly into host cells [10] and can evoke different responses from the host suitable for spreading of infection [11]. Exotoxin produced during release and escape of pathogen mainly attacks host kinases and is responsible for adhesion, phagocytosis, with spreading type of infection from lung to the liver in experimental animal [9,12].

Very few researchers in India have focussed on *exoT* gene encoding exotoxin T, virulence factor of T3SS of *P.aeruginosa*. In previous similar study in India, the researcher documented 84% prevalence of *exoT* gene in *P.aeruginosa* strains obtained from various clinical samples [13]. Keeping these facts in mind, this study was designed to study the prevalence of *exoT* gene in *P.aeruginosa* obtained from different clinical samples in a tertiary care hospital.

MATERIALS AND METHODS

Present descriptive cross-sectional research was conducted during January 2015 to March 2016 at the Department of Microbiology in Dr DY Patil Medical College, Hospital and Research Centre, Pimpri, Pune, Maharashtra, India. Different clinical samples (pus, urine, sputum, blood and body fluids) were received from various wards irrespective of age and gender for routine culture and sensitivity tests. The isolates were processed and confirmed *P.aeruginosa* strains were screened for detection of *exoT* gene by PCR and gel electrophoresis techniques. The study was done after approval from Institutional Ethical Committee of Dr DY Patil Medical College, Hospital and Research Centre, Pimpri, Pune, Maharashtra, India.

Inclusion criteria: Samples showing *P.aeruginosa* as single causative agent of infection were included in this study. Total 30 strains were included in this research study.

Exclusion criteria: Samples showing mixed growth were excluded from this study.

Isolation and identification of *P.aeruginosa*: All clinical samples were inoculated onto MacConkey agar, Nutrient agar and Blood agar plates. Inoculated plates were incubated at 37ºC for 24 hours. After obtaining the growth, *P.aeruginosa* was identified by studying colony characteristics, production of pyocyanin pigments, grape like odour, growth at 42ºC, motility test, Gram staining, and positive oxidase, citrate, and catalase tests [14].

Extraction of DNA: For the detection of *exoT* gene, chromosomal DNA from the 30 clinical strains of *P.aeruginosa* clinical isolates was extracted and DNA purification was carried out using a commercial available DNA extraction kit (Ganeaid-Presto™ Mini gDNA bacteria Kit) as indicated by manufacturer's instructions.

Polymerase Chain Reaction (PCR): The sequences of the primers used in PCR for detection of *exoT* gene and its molecular weight are shown in [Table/Fig-1] [15,16].

Gene	Primer sequence	Amplicon size	Length (bp)
exoT	Forward 5'-AATCGCCGTCCAACTGCATGCG-3'	22	152
	Reverse 5'-TGTTCGCCGAGGTACTGCTC-3'	20	

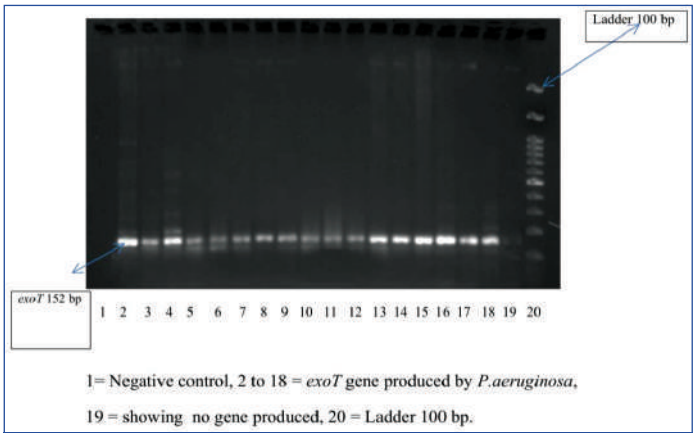
[Table/Fig-1]: The Primer sequence used for the detection of exoT genes.

For all PCRs, the DNA extracted from *P.aeruginosa* under study was used as templates. PCRs were carried out in 25 µL mixture containing 12.5 µL mastermix (Geneaid-Presto™Mini gDNA bacteria Kit), 1.5 µL forward primers, 1.5 µL reverse primers, 2.0 µL DNA template and 7.5 µL distilled water [Table/Fig-2].

Gene	Initial De-naturation	No.of Cycles	Denaturation in Each Cycle	Anneal-ing	Primer Extention	Final Extention
exoT	95ºC, 2 min	36	95ºC, 30 sec	58ºC,30 sec	72ºC, 30 sec	72ºC,5 min

[Table/Fig-2]: Polymerase Chain Reaction (PCR) conditions.

Gel electrophoresis: Electrophoresis was done using PCR products of *P.aeruginosa*.To prepare agarose gel, 2% agarose with ethidium bromide was used, as it shows clear resolution for small fragments. The quantity of agarose used for a gel preparation was around 250 mL. Images of PCR products were detected using transillumator by UV illumination is shown [Table/Fig-3]. PCR products were estimated by comparing with the 100bp DNA molecular size markers [17].



[Table/Fig-3]: Showing gel electrophoresis and amplification products of virulence gene (*exoT*) of *Pseudomonas aeruginosa* clinical isolates.

STATISTICAL ANALYSIS

The statistical analysis was done by using Chi-square test on line by graphpad prism 9.2.0.332. The calculated p-value was 0.0093 which is significant.

RESULTS

Out of 30 strains of *P.aeruginosa*, 20 (66.67%) were isolated from male and 10 (33.33%) from female patients. Most of the subjects belonged to 41-60 years of age group (46.67%). Out of 20 *exoT* genes in *P.aeruginosa*, 17/20 (85%) were detected from male and 3/10 (15%) from female patients [Table/Fig-4].

Age group (years)	Male	Female
0-20	00	00
21-40	02	01
41-60	12	02
61-80	03	00
Total	17	03

[Table/Fig-4]: Age and gender wise distribution of prevalence of *exoT* gene in *P.aeruginosa* (N=20).
Chi square 6.769, df-1, p-value=0.0093, p-value is statistically significant

The prevalence of *exoT* gene was 66.67%. Out of 30 strains of *P.aeruginosa* clinical isolates, 20 (66.67%) showed amplification of *exoT* gene and 10 (33.33%) strains showed negative amplification [Table/Fig-5].

S.N	Sample	Case	*exoT*	S.N	Sample	Case	*exoT*
1	Pus	Maxilla	+	16	Urine	UTI	+
2	Pus	CSOM	+	17	Pus	CSOM	+
3	Pus	NHTU	+	18	Pus	CSOM	-
4	Pus	Hydrocele	+	19	Urine	UTI	-
5	Urine	CUTI	+	20	Blood	Fever	-
6	Urine	UTI	+	21	Pus	Leg abscesses	+
7	Pus	Leg cellulitis	+	22	Pus	NF	-
8	Pus	DFU	+	23	Pus	NF	-
9	Fluid	COPD	+	24	Sputum	RTI	+
10	Pus	NF	+	25	Pus	TA	-
11	Pus	DFU	+	26	Pus	DFU	-
12	Pus	CSOM	+	27	Pus	DFU	-
13	Urine	UTI	+	28	Sputum	RTI	+
14	Sputum	RTI	+	29	Blood	Pneumonia	-
15	Sputum	RTI	+	30	Pus	DFU	-

[Table/Fig-5]: Distribution of *exoT* genes of 30 *Pseudomonas aeruginosa* clinical Isolates in respect to sites of Infections.
CSOM: Chronic suppurative otitis media; NHTU: Non healing tropic ulcer; UTI: Urinary tract infection; NF: Necrotizing fascitis; COPD: Chronic obstructive pulmonary disease; DFU: Diabetes foot ulcer; RTI: Respiratory tract infection; TA: Traumatic amputation; CAUTI: Catheter associated UTI

Out of 30 strains of *P.aeruginosa* 11/30 (61.11%) isolates from pus detected *exoT* gene followed by urine 4/5 (80%), sputum 4/4 (100%), body fluid 1/1 (100%) and blood 0/2 (0%) [Table/Fig-6].

Sr.No.	Source	*exoT* (%)
1	Pus	11(61.11)
2	Urine	4 (80)
3	Sputum	4 (100)
4	Blood	0 (0)
5	Body fluids	1 (100)
6	Total	20 (66.67)

[Table/Fig-6]: Showing distribution of *exoT* genes *Pseudomonas aeruginosa* Clinical Isolates (Pus n=18, Urine n=5, Sputum n=4, Blood n=2, Fluid n=1) in different samples, Total n=30).

DISCUSSION

P.aeruginosa is one of the major and well identified nosocomial pathogen. It has capability to survive and multiply with minimal nutrients. It can cause severe infection in hospitalised patients. *P.aeruginosa* is one of the most common co-infecting pathogen and exotoxin T is virulence factor that make *P.aeruginosa* more virulent for host cells. This descriptive research study was undertaken to detect *exoT* gene encoding exotoxin T in *P.aeruginosa* clinical isolates. T3SS is a basic and important weapon of *P.aeruginosa* and several other Gram negative

organisms for survival and causation of disease. The T3SS is a needle like sharp tiny machine that carry and deliver effector proteins (exotoxins) directly into targeted cells of the host to start disease. These delivered exotoxin precipitate and continue progress of infection by changing normal functions of target cells, such as constant movement of network of protein filaments and microtubules in the cytoplasm, reactions of cells to inflammatory stimuli, signalling pathways and secretory trafficking [18]. T3SS complex cellular nano machine is a key weapon of several pathogenic Gram negative bacteria which works in a systematic planned mode of action and can alter the target cell in number in irregular manner. T3SS has gradually developed because of the pressure of the survival within infected cells.

Virulence factors injected by T3SS into host cells play important role for *P.aeruginosa* to be more virulent [19,20]. The gene *exoT*, modify the actin cytoskeleton, inhibit migration and multiplication of cell. Exotoxin T prevents adhesion, phagocytosis, excessive multiplication and stop epithelial barrier that help *P.aeruginosa* to cause spread type of infections [21]. Gene *exoT* is an important virulence gene encoding exoenzyme T. Therefore, detection of *exoT* gene is important while determining pathogenicity of *P.aeruginosa* in different type of infections.

In this research study, authors aimed to determine the prevalence of *exoT* virulent gene in 30 strains of *P.aeruginosa* isolated from various clinical samples in a Tertiary Care Hospital. PCR and gel electrophoresis technique was used for the detection of *exoT* gene in *P.aeruginosa* under study. In this study, the prevalence of *exoT* gene was 66.67%. Out of 30 strains of *P.aeruginosa* clinical isolates from the different clinical conditions, 20 (66.67%) detected *exoT* gene in all spreading type of infections caused by *P.aeruginosa. P.aeruginosa* isolates from pus (61.11%), sputum (100%), urine (80%) and bodyfluids (100%) samples showed presence *exoT* gene. Out of 30, 10 (33.33%) strains were found to be negative for *exoT* gene.

In other similar study in southern India, the prevalence of *exoT* was recorded as 84% [13]. Many researches all over the world studied the prevalence of *exoT* genes as an epidemiological marker in pathogenic *P.aeruginosa* causing different type of infections. The prevalence of *exoT* genes has been found to be variable in *P. aeruginosa* isolates obtained from different infections in the world. Prevalence of *exoT* gene recorded in Iran was 36.27% [22] and in Egypt and Romania, prevalence of *exoT* in *P.aeruginosa* clinical isolates were recorded as 100% [12,23].

Role of *exoT* gene is crucial in the causation of spreading type infections. T3SS virulence factors are responsible for seriousness of the infections with raised death rate [24]. The proven role of *exoT* virulence genes in the pathogenicity of *P.aeruginosa* would help in understanding the prognosis of *Pseudomonas* infections and designing an effective vaccine against the pseudomonas infections to prevent them. This may help in epidemiological study, deciding the treatment course for the infections caused by *P.aeruginosa*. These findings may help in identifying virulent gene targets for immune intervention which could regulate the severity of the host response and its effect on impairment caused by *P.aeruginosa*.

The identification of virulent markers of pathogens for identification of acute and chronic infections at early stage remains a critical area and still need large research. Such type of research studies and findings facilitate the prevention of infections caused by bacteria and can be very useful to control the *Pseudomonas* infections.

Limitation(s)

All the *P.aeruginosa* strains under study were obtained from In Patient Department (IPD) only. Therefore, prevalence of *exoT* gene in *P.aeruginosa* could not be studied in Out Patient Department (OPD) patient. Larger sample size of both IPD and OPD patients would have provided better status of prevalence of *exoT* virulent gene marker as well as difference and significance.

CONCLUSION(S)

Gene *exoT* encoding ExotoxinT plays a very crucial role in the causation of disease. The proven role of *exoT* virulence genes in the pathogenicity of *P.aeruginosa* would help in understanding the prognosis of *Pseudomonas* infections and designing an effective vaccine against the *Pseudomonas* infections to prevent them. This may help in epidemiological study, deciding the treatment course for the infections caused by *P.aeruginosa*. In future trends in diagnostic microbiology, focus should be on development of rapid tests required for detection of virulence factors which are important epidemiological markers apart from identification and antimicrobial susceptibility tests.

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Brief Communication

Trends of Respiratory Syncytial Virus Sub-types in Children Hospitalised at a Tertiary Care Centre in Jaipur during 2012–2014

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Abstract

Respiratory syncytial virus (RSV) causes high mortality and morbidity in infants. The study was planned to determine the trends of RSV sub-types in hospitalised children. Nasopharyngeal aspirate and throat swabs were collected from the hospitalised children up to 5 years of age. Viral nucleic acid was extracted using easyMAG automated extraction system, and real-time reverse transcription polymerase chain reaction was performed. Total positivity for RSV was found to be 25.40%, predominantly for RSV B (20.03%), followed by RSV A (2.90%) and RSV AB mixed infections (2.47%). Palivizumab prophylaxis can be planned to be given to infants from post-monsoon to end of winter.

Keywords: Palivizumab, real-time reverse transcription polymerase chain reaction, Respiratory syncytial virus A, respiratory syncytial virus B

Introduction

Respiratory syncytial virus **(**RSV) is an important cause of acute respiratory infections (ARIs) in children; about 60% of children get infected with RSV by the 1st year and 100% by the 2nd year of life.[1] As per the World Health Organization, RSV is responsible for 4 million deaths around the world annually in children <5 years of age.[2] The virus is mostly seen in children with bronchiolitis and pneumonia.[3] Repeated infections and yearly outbreaks of RSV possibly occur due to the antigenic variability of the virus which is a challenge for designing and development of vaccine.[3] To optimise the prophylaxis, it is important to forecast the trends of RSV infection in a given area for better prevention and control.

Materials and Methods

Study duration

The study was conducted over a period of 28 months, i.e., between September 2012 and December 2014.

Ethical clearance

The study was carried out subsequent to clearance from the Institutional Ethics Committee vide letter no MC/EC/2011/227.

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Sample collection and transportation

A total of 689 nasopharyngeal aspirates and throat swab samples were collected from patients of ARI by a trained technician, using sterile nylon flocked swabs, and placed in viral transport medium, labelled and transported on ice at the earliest to advanced research laboratory (ICMR Grade-I Virology Lab) of Sawai ManSingh Medical College, Jaipur, for further processing and storage of the samples.

Nucleic acid extraction

One hundred and ten microlitres of viral nucleic acid was extracted from 400 µl of sample using NucliSENS easyMAG automated nucleic acid extractor (BioMerieux) as per the manufacturer's instructions.

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Real-time reverse transcription polymerase chain reaction

Initial screening for the presence of RSV was done using previously published primer probes for RSV by real-time reverse transcription polymerase chain reaction amplification[4] (synthesised by Applied Biosystems Inc., USA). Samples positive for RSV were retested separately for RSV A and RSV B on ABI 7500 fast (Applied Biosystems Inc., USA). The primer probe for sub-typing of RSV A and RSV B was synthesised (TIB MOL, from TIB MOLBIOL, Berlin, Germany) as per the published literature.[5]

Results

Six hundred and eighty-nine samples from hospitalised children of age ≤ 5 years were screened for possible RSV infection. The total positivity for RSV was found to be 175/689 (25.40%), 133/490 (27.14%) in males and 42/199 (21.10%) in females. RSV B was found positive in 20.03% (138/689) patients, RSV A in 2.90% (20/689) patients and RSV AB in 2.47% (17/689) patients. Correlation of RSV sub-types in relation to signs, symptoms and clinical syndromes is mentioned in Table 1.

Age-wise distribution of Respiratory syncytial virus A, Respiratory syncytial virus B and Respiratory syncytial virus AB

The occurrence of RSV infections varied in different age groups. Maximum positivity was observed in age group 1–12 months (36.13%), which was statistically significant ($P < 0.001$) (Chi-square test), followed by 13–24 months age group (18.34%); very low positivity was found in other age groups (2.33%–8.82%).

Seasonal distribution of Respiratory syncytial virus A, Respiratory syncytial virus B and Respiratory syncytial virus AB

In the 1st year of the study from September 2012 to August 2013, the only circulating type of RSV was the RSV A with its peak in March 2013, at the end of winter season. In the 2nd year of study from September 2013 to August 2014, both the types and mixed infections, i.e., RSV A, RSV B and RSV AB, were found to be circulating. All the RSV types were found to be circulating mainly during winter months and post-monsoon season [Figure 1].

Discussion

RSV is an important cause of mortality and morbidity requiring hospitalisation in the first few years of life. The present study was first to report the trends of RSV A and RSV B from Jaipur and Rajasthan in the hospitalised children ≤5 years of age. During the study period of 27 months, total positivity of RSV was found to be 25.40%. This is in correlation with an earlier study which reported a positivity of 26%.[6] On RSV typing of positive samples in the present study, predominance of RSV B (78.85%) was observed as compared to RSV A and RSV AB mixed infections. This is consistent with an earlier Indian study from Delhi (64.44%)[7] and other studies globally, from Malaysia (73.36%),[8] Zagreb (83.60%)[9] and Brazil (92.07%).[6] A study from Kolkata (India) reported predominance of RSV B (95%) in the 1st year, which was replaced by RSV A (94.84%) in the consequent years of the study.[10]

In the present study, RSV was positive predominantly (36.13%) in the hospitalised children <12 months of age. RSV is known to be an important cause of hospitalisation in children younger than 1 year of age.[6] This may be due to low levels of immunity in infants.

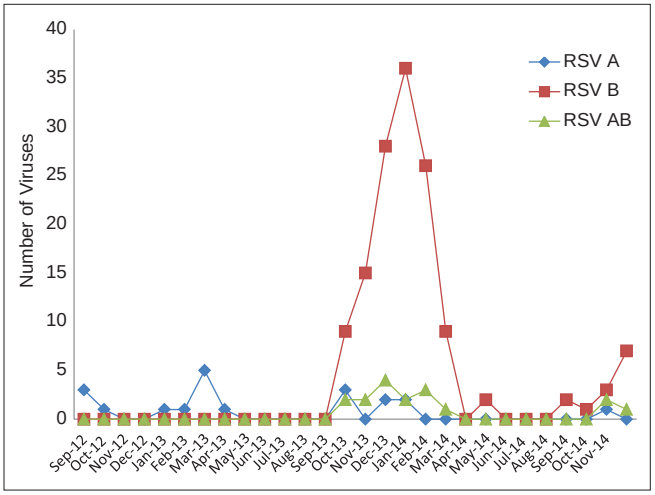

Figure 1: Seasonal variations in Respiratory syncytial virus A and Respiratory syncytial virus B along with Respiratory syncytial virus AB mixed infection.

Table 1: Correlation of Respiratory syncytial virus sub-types in relation to signs, symptoms and clinical syndromes

	RSV A, *n* (%)	RSV B, *n* (%)	RSV AB, *n* (%)	Total RSV
Total	20 (11.43)	138 (78.85)	17 (9.71)	175 (100.00)
Signs and symptoms				
Fever	3 (15.0)	115 (83.33)	16 (94.11)	134 (76.57)
Cough	20 (100.0)	137 (99.27)	17 (100.0)	174 (99.42)
Sore throat	9 (45.0)	3 (2.17)	1 (5.88)	13 (7.42)
Shortness of breath	16 (80.0)	127 (92.02)	16 (94.11)	159 (90.85)
Wheezing	2 (10.0)	2 (1.45)	-	4 (2.28)
Clinical syndrome				
Pneumonia	3 (15.0)	76 (55.07)	11 (64.70)	90 (51.42)
Bronchiolitis	1 (5.0)	20 (14.49)	1 (5.88)	22 (12.57)

RSV: Respiratory syncytial virus

In the present study, pneumonia was observed in 51.42% and bronchiolitis in 12.57% of RSV-positive patients. Earlier studies reported bronchiolitis in 47.1% to 82%[1,11] and pneumonia in 36.2%–76%[1,11] in RSV-positive patients. RSV B was the predominant RSV type detected in the present study in the hospitalised children of ≤5 years of age. RSV B was reported to be a more common cause of bronchiolitis and pneumonia than sub-type A.[9]

During the 1st year of our study, only RSV A was the type of RSV circulating whereas, during the 2nd and 3rd year of the study, all the two types and mixed infections, i.e., RSV A, RSV B and RSV AB, were found to be co circulating. The exact reason for this variation in the circulation patterns of RSV during different years of the study is not known. Similarly co-circulation of RSV A and RSV B has been found in other studies from India and Germany with the predominance of RSV A sub-group.[12,13]

Conclusion

RSV B was the most predominant type circulating in our area with co-circulation of RSV A and RSVAB. Peak positivity was seen in winters and lower positivity in post-monsoon season. Palivizumab can be planned to be given post-monsoon till winters are over. Only hospitalised patients were studied in present study which is a limitation but provides information on trends in serious patients and can provide guidance to plan prevention and control policies.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Aetiological Study of Viruses Causing Acute Encephalitis Syndrome in North West India

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Abstract

Context: Acute encephalitis syndrome (AES) is a serious public health problem, caused mainly by viruses. However, the profile of viruses causing AES in Rajasthan is not well characterised. **Aims:** The present study was undertaken to identify the viruses causing AES and develop diagnostic algorithm so as to help in improved diagnosis, treatment, prevention and control. **Settings and Design:** The present study is a hospital-based descriptive, observational study. Samples were processed at Grade-1 DHR/ICMR Viral Research and Diagnostic Laboratory at SMS, Jaipur. **Subjects and Methods:** Cerebrospinal fluid (CSF) samples were processed for IgM antibody detection by enzyme-linked immunosorbent assay (ELISA) for mumps virus (MPV), measles virus (MV), Rubella virus (RV), Japanese encephalitis virus (JEV), West Nile virus (WNV) and Dengue virus using commercial kits. Nucleic acid was extracted from CSF using automated extraction system. Real-time polymerase chain reaction was done using specific primers and probes for Herpes simplex virus (HSV), Varicella-zoster virus (VZV), Epstein-Barr virus (EBV), cytomegalovirus (CMV) and enterovirus (EV). **Statistical Analysis Used:** Statistical analysis was done using ANOVA. **Results:** Among 3088 patients, 702 (22.7%) patients were positive for one or more viruses. HSV (261;8.45%) was the most common followed by EBV (173;5.6%), VZV (97;3.1%), CMV (68;2.2%), EV (32;1.03%), MPV (27;0.9%), DV (28;0.9%), MV (19;0.6%) and RV (6;0.2%). **Conclusions:** AES occurred sporadically in Rajasthan, samples should be tested first for herpes group of viruses followed by EV or/and for arboviruses depending on season or measles, mumps and RVs in children.

Keywords: Acute encephalitis syndrome, cerebrospinal fluid, enzyme-linked immunosorbent assay, herpes simplex virus, Japanese encephalitis, polymerase chain reaction

Introduction

Acute encephalitis syndrome (AES) is defined as the acute-onset of fever and a change in mental status and/or new-onset of seizures in a person of any age at any time of the year. AES is an emerging public health problem, claiming thousands of lives[1] and the disease most commonly affects children and young adults and can lead to considerable morbidity and mortality.[2]

Although bacteria, viruses and protozoan parasites may cause encephalitis, among these the viruses are the most common and important cause of encephalitis. Cases of AES have been reported from many states of India, but the aetiological agent has been identified in only 20%–30% cases.[3] Among all, viral encephalitis that is encountered in India, JE appears to be of greater significance during outbreaks as well as in sporadic cases. Herpes group of viruses, enterovirus (EV), measles virus (MV), mumps virus (MPV) and Rubella virus (RV) also constitute significant numbers in sporadic and outbreak cases in India. However, the profile of agents causing AES varies from place to place. Clinically and neurodiagnostic tests can usually establish the presence of encephalitis but do not necessarily establish the aetiologic cause, which often remains unknown.[4]

There is only one report from Rajasthan on aetiology of AES cases, where only HSV was tested.[5] Rajasthan has its own geographic characteristics, and till recently, the state has

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been considered to be non-Japanese encephalitis (JE) area. With better irrigation and paddy cultivation in the state, the vector for Japanese encephalitis virus (JEV) is available, and the risk has consequently increased. The present study was undertaken to identify the viruses causing AES in patients. These results are likely to help in proper diagnosis, treatment, planning prevention and control strategies and in developing diagnostic algorithm in our state. The findings of our study are also likely to help clinicians in the management of AES.

Subjects and Methods

Study design

The present study is a hospital-based descriptive, observational study.

Source population

This study was carried out on patients admitted to SMS and attached group of hospitals, Jaipur.

Period

The study period was November 2011 to December 2016.

Place of study

Samples were processed at Virology Laboratory, Jaipur. Institutional Ethics Committee permission was obtained before initiating the study.

Sample size

The minimum sample size for this study was calculated as 375 with an estimated 0.42 true proportion rate[6] at a confidence level of 95% assuming desired precision rate of 5% using the formula from EpiTools epidemiological calculators $n = (Z^2 \times P\ [1 - P])/e^2$ (where Z is value from standard normal distribution corresponding to desired confidence level ($Z = 1.96$ for 95% confidence interval), 'P' is expected true proportion and 'e' is desired precision (5%). However, to study the trends, all samples meeting criteria and tested over 5 years were included in the study.

Inclusion criteria

Patients presenting with fever of <15 days duration with or without altered sensorium, seizures, headache, vomiting, abdominal pain and paralysis.

Exclusion criteria

Patients suffering from bacterial meningitis, head injury, simple febrile seizures, seizure disorder, heat stroke, metabolic disorders and papilloedema.

Sample collection and transportation

A total of 3088 cerebrospinal fluid (CSF) samples were collected from patients suspected of AES. All samples were received with prior informed consent from the patients/parents/guardians. Detailed pro forma was filled; samples were labelled and sent to lab. Each sample was processed in accordance with established SOPs in the laboratory.

Serological detection

IgM antibody detection by enzyme-linked immunosorbent assay (ELISA) for MPV, MV, RV, JEV, West Nile virus (WNV) and Dengue virus (DV) were done in patient CSF using commercial ELISA kits [Table 1] as per manufacturer's instructions.

Polymerase chain reaction-based detection

Nucleic acid extraction

Briefly, nucleic acid (NA) was extracted by an automatic nucleic acid extractor (NucliSENS easyMAG-Biomerieux) according to the manufacturer's instructions. A total of 300 µl of each CSF sample was loaded in the instrument for on-board lysis, and 60 µl of magnetic silica were added to each specimen after 10 min incubation and mixed well. The NA was extracted in a final volume of 100 µl to be used in real-time polymerase chain reaction (PCR) and an aliquot was stored at 80°C for further use.

Standardisation of real-time polymerase chain reaction

Standardizations were done for real-time PCR by using the positive controls. The cell culture supernatant of Herpes simplex virus (HSV), Varicella-zoster *virus* (VZV), Epstein-Barr virus (EBV), Cytomegalovirus (CMV) and EV were used as positive control which was provided by Manipal Center for Virus Research, Kasturba Medical College (KMC), Manipal.

Amplification and detection of viruses was done on Light Cycler 480 instrument (Roche) as per manufacturer's instructions using their master mix and primer probes as per previously published sequences as given in Table 2.[7-10] Briefly for DNA viruses 10 µl of Light Cycler 480 Probes Master ready mix (Roche), 2 µl of primer probe mix [Table 2], 3 µl of PCR grade water and 5 µl of DNA were added, cycling profile for PCR was; preincubation at 95°C for 10 min followed by 45 cycles of denaturation at 95°C for 10 s, annealing at 55°C for 30 s and extension at 72°C for 1 s.

For the detection of RNA viruses, 20 µl RNA Master Mix (Roche) was used comprising of 0.3 µl enzyme blend,

Table 1: Enzyme linked immunosorbent assay kits used for the detection of viruses causing acute encephalitis syndrome

Serial number	Test done	Kit used
1	JEV IgM	InBios International, Inc., Seattle, Washington, USA
2	WNV IgM	InBios International, Inc., Seattle, Washington, USA
3	Mumps virus IgM	Calbiotech Inc., Austin Dr, Spring Valley, CA
4	Measles virus IgM	Calbiotech Inc., Austin Dr, Spring Valley, CA
5	Rubella virus IgM	Diagnostic Bioprobes s.r.l Altunizade Uskudar Istanbul, Turkey
6	Dengue virus IgM	Standard Diagnostics, Inc., Korea/NIV Pune

JEV: Japanese encephalitis virus, WNV: West Nile virus

Table 2: Customized primers and probes for the detection of viruses causing acute encephalitis syndrome using real time polymerase chain reaction

Virus	Primer or probe	Gene target	Sequence (5' - 3')	References
HSV	Forward	gD	CGGCCGTGTGACACTATCG	Weidmann *et al*., 2003[7]
	Reverse		CTCGTAAAATGGCCCCTCC	
	Probe		FAM-CCATACCGACCACACCGACGAACC	
EBV	Forward	p143	GGAACCTGGTCATCCTTTGC	Niesters *et al*., 200[8]
	Reverse		ACGTGCATGGACCGGTTAAT	
	Probe		FAM-CGCAGGCACTCGTACTGCTCGCT	
VZV	Forward	DNA polymerase	CGGCATGGCCCGTCTAT	Weidmann *et al*., 2003[7]
	Reverse		TCGCGTGCTGCGGC	
	Probe		FAM-ATTCAGCAATGGAAACACACGACGCC	
CMV	Forward	MIE protein	AAC TCA GCC TTC CCT AAG ACC A	Ramamurthy *et al*., 2011[9]
	Reverse		GGG AGC ACT GAG GCA AGT TC	
	Probe		FAM-CAA TGG CTG CAG TCA GGC CAT GG	
EV	Forward	5' UTR	CCCTGAATGCGGCTAATCC	Piqueur *et al*., 2009[10]
	Reverse		ATTGTCACCATAAGCAGCCA	
	Probe		FAM-AACCGACTACTTTGGGTGTCCGTGTTTC	

HSV: Herpes simplex virus, VZV: Varicella zoster virus, EBV: Epstein-Barr virus, CMV: Cytomegalovirus, EV: Enterovirus

3 µl reaction buffer plus 2 µl primer-probe mix, 9.7 µl PCR grade water and 5 µl RNA. Reverse transcription was done at 50°C for 10 min. The cycling profile of PCR was initial denaturation at 95°C for 30 s, followed by 45 cycles of denaturation at 95°C for 1 s, annealing at 55°C for 20 s and extension at 72°C for 1 s. Each assay was run using a positive control and a negative control.

Results

Virus identification, serologically or by molecular testing, was possible in 22.7% of AES suspected patients. The positivity for viruses in male (27.62%) and female (26.85%) was not statistically significant ($P = 1.00$). The positivity in children (41.10%) was significantly higher ($P = 0.0001$) as compared to adults (21.51%) [Table 3].

Most common virus identified in AES suspects in our study was HSV (8.4%) followed by EBV (5.6%), VZV (3.1%), CMV (2.2%), EV (1.0%), MPV (0.9%), DV (0.9%), MV (0.6%) and RV (0.2%). None of the samples were found positive for JE and WNV. Coinfection was seen in nine (0.3%) patients with two viruses each, HSV and VZV in four (0.1%) patients, and HSV and EBV in five (0.16%) patients. Age- and sex-wise distribution for different viruses in positive cases is given in Table 4. Positivity in males was higher than females for HSV and EBV but for other viruses, it was either similar or slightly more in males. The HSV, VZV, EBV, CMV, EV and DV were found more in adults compared to children whereas MPV, MV and RV were found only in children [Table 4].

The most common clinical presentation was fever followed by altered sensorium, seizures, headache, vomiting and abdominal pain [Table 5]. No seasonal variation was observed for all viruses except DV in the present study [Figure 1].

Table 3: Positivity for viruses in patients suspected of acute encephalitis syndrome

Sample	Patients	Male	Female	Children	Adult
Tested	3088	1926	1162	1433	1655
Positive	702	532	312	589	356
Percentage	22.73	27.62	26.85	41.10	21.51

Discussion

There is a wide variation in the viral aetiological agents causing CNS infections across the globe and even in the same continent, and a country.[11] For better management of patients, it is important to know the profile of viruses causing AES in the given area so that immediate action can be taken before laboratory results are available.

In the present study, viral confirmation of AES was documented in only 702 (22.73%) patients. Similarly, other Indian studies have reported positivity from 17.20% to 29.81%, at Odisha (17.2%),[12] at Uttar Pradesh (21.83%),[2] at West Bengal (29.81%)[13] but other studies from India reported higher positivity from 50% to 71.92% at Uttar Pradesh (58.36%),[14] at Karnataka (60%)[9] and at New Delhi (71.92%)[11] Positivity from other countries ranged from 4% to 69% in AES suspected patients.[15-19]

The positivity varies from place-to-place and depends on the number of viruses included in the detection panel; samples included in the study; detection techniques; geographical location; occurrence of any epidemic/outbreak during the study period, etc.

Among the positive cases, Herpes group of viruses were the most common (84.24%) causative agent of AES in the present study. Wide variation in positivity has been reported for Herpes group in India from 13% to 59.10% at Karnataka,[9] Eastern India,[12] and

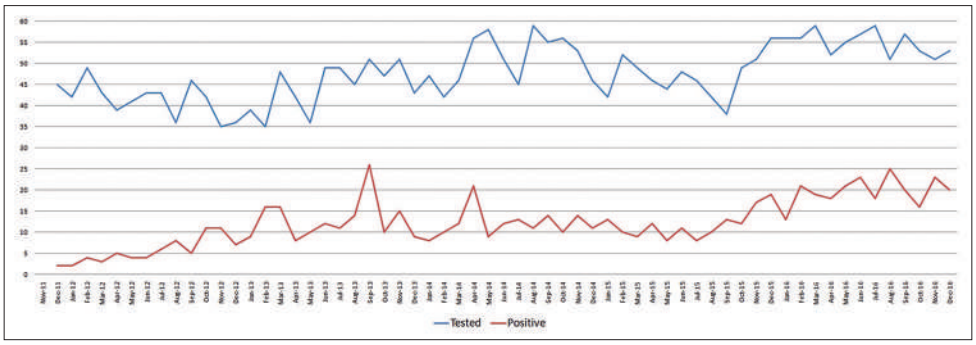

Figure 1: Seasonal trends of acute encephalitis syndrome

Table 4: Sex and age group wise occurrence of different viruses in positive cases

Viruses	Positive (%)	Children	Adults	Males	Females
		Total (%)	Total (%)	Positive (%)	Positive (%)
HSV	261 (36.71)	89 (12.52)	172 (24.19)	155 (21.80)	106 (14.91)
VZV	97 (13.64)	35 (4.92)	62 (8.72)	62 (8.72)	35 (4.92)
EBV	173 (24.33)	51 (7.17)	122 (17.16)	116 (16.32)	57 (8.02)
CMV	68 (9.56)	23 (3.23)	45 (6.33)	38 (5.34)	30 (4.22)
EV	32 (4.50)	24 (3.38)	8 (1.13)	23 (3.23)	9 (1.27)
MPV	27 (3.80)	27 (3.80)	0	22 (3.09)	5 (0.70)
MV	19 (2.67)	19 (2.67)	0	13 (1.83)	6 (0.84)
RV	6 (0.84)	6 (0.84)	0	5 (0.70)	1 (0.14)
DV	28 (3.94)	9 (1.27)	19 (2.67)	19 (2.67)	9 (1.27)
JEV	0	0	0	0	0
WNV	0	0	0	0	0
Total	711 (100)	283 (39.80)	428 (60.20)	453 (63.71)	258 (36.29)

HSV: Herpes simplex virus, VZV: Varicella zoster virus, EBV: Epstein-Barr virus, CMV: Cytomegalovirus, EV: Enterovirus, MPV: Mumps virus, MV: Measles virus, RV: Rubella virus, DV: Dengue virus, JEV: Japanese encephalitis virus, WNV: West Nile virus

Table 5: Clinical profile of acute encephalitis syndrome in suspected patients (n=3088)

Clinical features	Cases (%)
Fever	2653 (85.91)
Altered sensorium	1968 (63.73)
Seizures	1596 (51.68)
Headache	1021 (33.06)
Vomiting	653 (21.15)
Abdominal pain	234 (7.58)

UP[2,14] and abroad also from 7.19% to 55%.[16-21] Herpes group remains the most common causative agent in acute sporadic encephalitis cases in the developed world and in India too. All these viruses have specific antiviral therapy available (acyclovir), and early diagnosis can alert the clinician for timely initiation of specific therapy and prevent the high mortality and morbidity which can occur in absence or delay in treatment.

Additional viruses identified in positive cases in our study were EV (4.50%), DV (3.94%), MPV (3.80%), MV (2.67%) and RV (0.84%). EV-71 is an important emerging encephalitogenic virus. Similar to our study, low positivity was observed to these viruses from 0.19% to 2.6% from Eastern India,[12] but higher positivity to all these viruses from one study from Western UP (EV 71 in 42.1%, MV in 21.1%, and MPV in 10.5%).[2] Whereas EV was not reported in another study from UP.[14] On the other hand, very high positivity was reported for EV 71 (35.1%) from New Delhi.[11]

Before the start of nationwide, MMR vaccination programs, mumps and measles were most common causative agents detected in encephalitis suspected children. From developed countries, these organisms have almost disappeared; however, they continue to be most common causative agents of AES in developing countries like India, probably because of suboptimal immunisation rates.[14]

In the present study, none of the samples were found positive for JEV and WNV. Similarly, other studies from India and abroad also did not report JEV, from Western UP,[2] Andhra Pradesh,[22] Taiwan,[20] and Malaysia.[4]

JEV is a big public health problem in India causing frequent outbreaks and high mortality[23-25] but Rajasthan belongs to non-JE endemic area, and even now, no case was reported in our study also. However, there may be some limitations in our study, the kit used of JE was from Inbios and not from NIV moreover majority of our samples belonged to about 22 districts of Rajasthan. There is a need to systematically test samples from all the districts of Rajasthan, especially those where there

has been change in ecosystem due to buildings of dams and canals and presence of JE vector has been reported.

In the present study, co-infection was seen in nine samples with two viruses each HSV and VZV in four samples and HSV and EBV in five samples. Similarly, other studies also reported coinfection. A study from Sweden[15] detected coinfection in two samples with two viruses each; HSV and EBV in one sample and VZV and EBV in the other sample. Authors from Italy[26] reported coinfection in four samples with two viruses each HSV1 and VZV in two samples, HSV1 and HSV2 in one sample and EBV and HSV2 in one sample. Herpes group of viruses may be positive due to reactivation of latent viruses in the setting of a primary central nervous system infectious agent.[27]

In the present study, positivity for AES was found in both children and adults, but it was significantly higher in children ($P = 0.0001$) as compared to adults. Similar findings have been reported in Lucknow, UP, which also showed higher positivity in children.[14] However, many studies conducted for AES in India were limited to children only.[2,11,13,28,29]

The MPV, MV and RV were found positive in children only; whereas other viruses occurred both in children and adults but predominantly in adults. MMR has been reported to mainly affect older teens and young adults, which include the unvaccinated population; this population has probably not developed immunity through exposure to virus because of decreased circulation of the virus after the implementation of childhood immunisation program.[11]

In the present study, the number of males enroled was higher but positivity in both sexes was similar. Although none of the CNS infections are known to have a male predominance, this apparent male predominance can be attributed to the male-dominated social system where a sick male gets preferential medical attention.

In the present study, post-monsoon presence of DV was observed which coincides with seasonal increase in DV infection post-monsoon. However, no distinct seasonal variation was observed for other viruses. Similarly, Jain *et al*. from UP[14] observed a definite seasonality for DV and JEV in monsoon and post-monsoon seasons. While from Gorakhpur, UP[30] reported AES cases throughout the year, but the incidence peaked in post-monsoon period. The seasonal trends depend on the predominant agent involved in each study. Fever with altered mental state was the most common symptom complex in our patients as reported earlier.[31]

Diagnostic algorithm

The diagnostic algorithm which can be followed in our setting is as follows; first panel HSV, EBV and VZV; second panel CMV, EV and DV; third panel MPV, MV and RV; fourth panel JE, WNV and other viruses as per clinical history.

Conclusions

AES occurred sporadically in Rajasthan, samples should be tested first for herpes group of viruses followed by EV or/and for arboviruses depending on season or measles, mumps and RVs in children.

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Conflicts of interest

There are no conflicts of interest.

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Original Article

Profile of Respiratory Pathogens Causing Acute Respiratory Infections in Hospitalised Children at Rajasthan a 4 Year's Study

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Abstract

Introduction: Various pathogens cause respiratory tract infections in children of <5 years of age causing severe morbidity and mortality. The profile of causative agents varies from place to place. **Aims:** The objectives of our study were to detect the profile and trends of respiratory pathogens causing acute respiratory tract infection in children using a custom multiplex real-time polymerase chain reaction (RT-PCR) and to develop a diagnostic algorithm. **Materials and Methods:** A total of 997 children with clinical manifestations of respiratory infections were included in the study. Their nasopharyngeal aspirate and throat swab samples were subjected to nucleic acid extraction followed by multiplex RT-PCR for eighteen viruses and six bacteria. **Statistical Analysis Used:** Chi-square test was employed to study the *P* value of different viruses and bacteria. **Results:** A total of 765 (76.73%) samples were found to be positive for one of the respiratory pathogens. Viruses were detected in 598 (59.98%) and bacteria in 167 (41.85%) samples, respectively. The prevalence of single and co-infections among viruses and bacteria were 77.76% and 22.24%, 81.44% and 18.56% each, respectively. Respiratory syncytial virus (RSV) A/B and *Streptococcus pneumoniae* were the most predominant pathogens detected in the study and were associated with lower respiratory tract infections. **Conclusion:** RSV and *S. pneumoniae* were the most common pathogens detected, higher prevalence was observed in children <1 year of age. Viruses were predominant during winter months. The study helped to prepare diagnostic algorithm which will help in reducing diagnostic costs. However, further studies are required to assess whether viruses are bystander or real pathogens and include larger panel of bacteria and viruses for diagnosis.

Keywords: Acute respiratory infection, hospitalised children, multiplex real-time polymerase chain reaction, viruses

Introduction

Respiratory infections pose major public health problem worldwide. About 13 million children of <5 years of age, die every year, 95% of them are from developing countries and one-third of the total deaths are due to acute respiratory infections (ARIs).[1] ARI accounts for 30%–50% of the total paediatric outpatient visits and 20%–30% of the paediatric admissions.[2] ARIs are mainly self-limited, but can lead to complications requiring hospitalisation due to severe acute respiratory infections (SARI) which can be fatal at times,[3] cause high economic burden on health care systems and to family of patients.

The causative agents include mainly viruses, up to 60%, (e.g., Respiratory syncytial virus (RSV), Influenza A, Rhinovirus, Adenovirus); bacteria (e.g., *Streptococcus pneumoniae*, *Mycoplasma pneumoniae* and *Staphylococcus aureus*) and fungi (e.g., *Pneumocystis jirovecii*).[4,5] The severity of the disease can be affected by type of infecting agent and predisposing factors such as age, immune status of the host, single or mixed infections and virulence mechanisms of the viral agents.[6] It is important to know the profile and trends of various agents causing RTI in children so as to initiate appropriate therapy. Moreover, due to lack of identification of viruses antibiotics are given which cause undue side effects and also increase antimicrobial drug resistance. There are only few studies enumerating the profile of pathogens causing

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ARI in hospitalised patients.[2] Most of the respiratory pathogens produce similar symptoms as a result it is difficult to identify them clinically. Various commercial and in-house multiplex real-time polymerase chain reaction (RT-PCR) assays are being used for simultaneous amplification of multiple pathogens in a single-reaction mixture, which makes them rapid and cost-effective.[7,8] Hence, the present study was undertaken to identify the profile and trends of various respiratory pathogens in hospitalised children using a validated customised multiplex RT-PCR.

Materials and Methods

Setting

This study was conducted at the Indian Council of Medical Research (ICMR)/DHR Grade-I Virology reference Laboratory-Advanced Research Laboratory, Department of Microbiology and Immunology, S. M. S. Medical College, Jaipur during 2012–2016. The study was approved by Institutional Ethics Committee.

Patient's enrolment

All the patients enroled in the study were freshly diagnosed and hospitalised cases. Any previous history of respiratory infections was excluded from the study to prevent the detection of residual nucleic acid. Written consent was obtained from the parent/guardian. Clinical signs and symptoms of children enroled in the study were noted in pro forma for fever, cough, nasal catarrh, shortness of breath, sore throat, wheezing, bronchiolitis and pneumonia.

Sample collection and transportation

Nasopharyngeal aspirate and throat swabs from 997 children (age range 1–60 months) with acute respiratory illness were collected in 3 ml of viral transport media. Samples were labelled and transported on ice packs at the earliest to the laboratory. On reaching the laboratory, samples were registered and given a unique identification number before aliquoting for processing and storage.

Nucleic acid extraction

Nucleic acid from samples was extracted using NucliSENSE EasyMAG (Biomeurex) automated extractor according to the manufacturer's instructions, 110 µl of nucleic acid was eluted from a volume of 400 µl sample.

Previously standardised customised multiplex PCR was used for identification of various viruses,[7] bacterial PCR standardisation was done using the same protocol but tested in duplex in samples negative for any virus [Table 1].

Statistical analysis

Chi-square test was employed to study the *P* value of different viruses and bacteria.

Results

Viruses detected in children

Out of 997 children enroled, 598 (59.98%) children were positive for at least one of the respiratory viruses of which co-infections were detected in 133 (22.24%) children. Single infection was observed in 465 (77.76%) children [Table 2]. The most common virus detected in the study (including single and co-infection) was RSV A/B in 279 (37.35%), followed by human rhinoviruses (HRV) 106 (14.19%) and HAdV 83 (11.11%). The profile of viruses causing ARIs is mentioned in Table 2. Details of co-infections of different viruses are mentioned in Table 3.

Clinical features and association with respiratory viruses

Cough and fever were the most common clinical manifestation followed by shortness of breath, pneumonia and bronchiolitis [Table 4]. The RSV A/B was predominant in cases presenting with pneumonia and bronchiolitis.

Viruses among different age groups

Positivity for respiratory viruses was found to be more in the age group of 1–12 months; 495 (66.26%) cases, followed by 13–24 months' age patients with 101 (13.52%) cases and 25–36 months' age patients, 65 (8.70%). Most of the viruses were found predominantly in the age group of 1–12 months as compared to other age groups [Table 2].

Seasonal trends of respiratory viruses

During the study, respiratory viruses were predominant during the winter months [Figure 1], RSV A/B had its high peaks in December and January while human

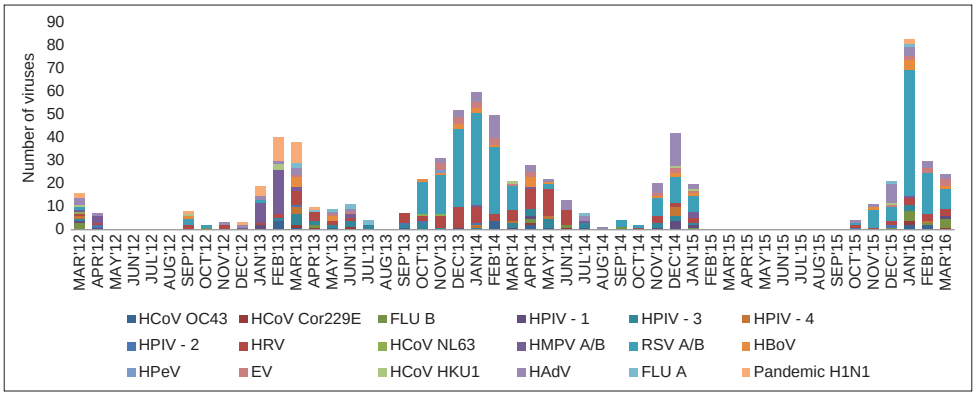

Figure 1: Month-wise activity of different respiratory viruses from March-2012 to March 2016

Table 1: Customised primers and probes for the detection of respiratory viruses and bacteria using real time reverse transcription - polymerase chain reaction (multiplex and duplex)

Virus	Forward (5' - 3')	Reverse (5' - 3')	Probe (5' - 3')	References
		PANEL-1		
HCoV 229E	CAgTCAAATgggCTgATgCA	AAAgggCTATAAAgAgAATAAggTATTCT	VIC - CCCTgACgACCACgTTgTggTTCA	Hammit *et al*., 2011[9]
HCoV OC43	CgATgAggCTATTCCgACTAggT	CCTTCCTgAgCCTTCAATATAgTAACC	NED-TCCgCCTggCACggTACTCCCT	Hammit *et al*., 2011[9]
Flu B	GAgACACAATTgCCTACCTgCTT	TTCTTTCCCACCgAACCAAC	FAM - AgAAgATggAgAAggCA AAg CAgA ACTAgC	Esposito *et al*., 2010[10]
		PANEL-2		
HPIV 1	gTgATTTAAACCCggTAATTTCTCA	CCTTgTTCCTgCAgCTATTACAgA	VIC- ACCTATgACATCAACgAC	Hammit *et al*., 2011[9]
HPIV 3	CCAgggATATAYTAYAAAggCAAAA	CCgggRCACCCAgTTgTg	NED - TggRTgTTCAAgACCTCCATAYCCgAgAAA	Hammit *et al*., 2011[9]
HPIV 4	CAgAYAACATCAATCgCCTTACAAA	TgTACCTATgACTgCCCCAAARA	FAM - CCMATCACAAgCTCAgAAATYCAAAgTCgT	Hammit *et al*., 2011[9]
		PANEL-3		
HRV	TggACAgggTgTgAAgAgC	CAAAgTAgTCggTCCCATCC	VIC - TCAAAgTAgTCggTCCCATCC	Hammit *et al*., 2011[9]
HPIV 2	ATgAAAACCATTTACCTAAgTgATggA	CCTCCYggTATRgCAgTgACTgAAC	NED - TCAATCgCAAAAgC	Hammit *et al*., 2011[9]
Pandemic H1N1	gTgCTATAAACACCAgCCTYCCA	CgggATATTCCTTAATCCTgTRgC	FAM-CAgAATATACA"T"CCRgTCACAATTggARAA	WHO, 2009[11]
		PANEL-4		
HCoV NL63	ACgTACTTCTATTATgAAgCATgATATTAA	AgCAgATCTAATgTTATACTTAAAACTACg	VIC -ATTgCCAAggCTCCTAAACgTACAggTgTT	Hammit *et al*., 2011[9]
HCoV HKU1	AgTTCCCATTgCTTTCggAgTA	CCggCTgTgTCTATACCAATATCC	NED - CCCCTTCTgAAgCAA	Cui *et al*., 2011[12]
RSV A/B	GGAAACATACGTGAACAAGCTTCA	RSV-A: CATCGTCTTTTTCTAAGACATTGTATTGA RSV-B: TCATCATCTTTTTCTAGAACATTGTACTGA	FAM - TGTGTATGTGGAGCCTT	Kwofie *et al*., 2012[13]
		PANEL-5		
HPeV	gTAACASWWgCCTCTgggSCCAAAAg	ggCCCCWgRTCAgATCCAYAgT	VIC- CCTRYgggTACCTYCWgggCATCCTTC	Nix *et al*., 2008[14]
HBoV	TgCAgACAACgCYTAgTTgTTT	CTgTCCCgCCCAAgATACA	NED - CCAggATTgggTggAACCTgCAAA	Sanghavi *et al*., 2012[6]
EV	CCCTgAATgCggCTAATCC	ATTgTCACCATAAgCAgCCA	FAM- AACCgACTACTTTgggTgTCCgTgTTTC	Wolffs *et al*., 2011[15]

Contd...

Table 1: Contd...

Virus	Forward (5' - 3')	Reverse (5' - 3')	Probe (5' - 3')	References
		PANEL-6		
HAdV	gCCCCAgTggTCTTACATgCACATC	gCCACggTggggTTTCTAAACTT	VIC - TgCACCAgACCCgggCTCAggTACTCCgA	Hammit *et al.*, 2011[9]
HMPV A/B	CATCAggTAATATCCCACAAAATCAg	gTgAATATTAAggCACCTACACATAATAARA	NED - TCAgCACCAgACACAC	Sanghavi *et al.*, 2012[6]
Flu A	GACCRATCCTgTCACCTCTgAC	AgggCATTYTggACAAAKCgTCTA	FAM - TgCAgTCCTCgCTCACTgggCACg	WHO, 2009[11]
Bacteria	**Forward (5' - 3')**	**Reverse (5' - 3')**	**Probe (5' - 3')**	**References**
		PANEL-1		
Streptococcus pneumoniae	AgCgATAgCTTTCTCCAAgTg	CTTAgCCAAATCgTTTACCg	FAM - ACCCCAgCAATTCAAgTgTTCgCg	Greiner *et al.*, 2011[16]
Mycoplasma pneumoniae	AAgAAgCTTATggTACAggTTggTTAA	TggAggTTggTAgCTAAgTAAgCA	NED - TgACTggAAggA"T"gTTAAgCAggACAACAAATTT	Kodani *et al.*, 2011[17]
		PANEL-2		
Moraxella catarrhalis	gTgAgTgCCgCTTTTACAACC	TgTATCgCCTgCCAAgACAA	FAM - TgCTTTTgCAgCTgTTAgCCAgCCTAA	Greiner *et al.*, 2003[18]
Staphylococcus aureus	gTTgCTTAgTgTTAACTTTAgTTgTA	AATgTCgCAggTTCTTTATgTAATTT	NED - AAgTCTAAgTAgCTCAgCAAATgCA	Chien *et al.*, 2013[19]
		PANEL-3		
Chlamydophila pneumoniae	gggCTATAAAggCgTTgCTTT	AgACTTTgTTCCAgTAgCTgTTgCT	FAM - CCTTgCCAACAgACgCTggCg	Mitchell *et al.*, 2009[20]
Legionella pneumophila	gTACTAATTggCTgATTgTCTTgACC	CCTggCgATgACCTACTTTCg	NED - ATCgTgTAAACTCTgACTCTTTACCAAACCTgTgg	Yang *et al.*, 2010[21]

Flu A: Influenza A, Flu B: Influenza B, EV: Enterovirus, RSV A/B: Respiratory syncytial virus, HMPV A/B: Human metapneumovirus, HRV: Human rhinovirus, HPeV: Human parechovirus, HBoV: Human bocavirus, HAdV: Human adenovirus, HPIV: Human parainfluenza virus, HCoV: Human coronaviruses

Table 2: Age-wise distribution of the respiratory viruses and the incidence of single and co-infections

Virus	1-12 months	13-24 months	25-36 months	37-48 months	49-60 months	Single infections (%)	Co-infections (%)	Total (%)	*P*
HCoV OC43	8	3	6	2	-	8 (1.72)	11 (3.90)	19 (2.54)	0.0708
HCoV Cor229E	3	3	3	-	-	3 (0.64)	6 (2.13)	9 (1.20)	0.1085
Flu B	11	4	3	1	1	15 (3.22)	5 (1.77)	20 (2.68)	0.5155
HPIV - 1	7	3	3	-	1	9 (1.93)	5 (1.77)	14 (1.87)	0.3944
HPIV - 3	25	9	3	3	1	28 (6.02)	13 (4.60)	41 (5.49)	0.9309
HPIV - 4	5	3	-	2	2	7 (1.50)	5 (1.77)	12 (1.60)	0.1767
HPIV - 2	3	-	3	-	1	6 (1.29)	1 (0.35)	7 (0.93)	0.4248
HRV	66	12	13	3	12	52 (11.18)	54 (19.15)	106 (14.19)	0.7062
HCoV NL63	2	-	-	1	-	1 (0.21)	2 (0.71)	3 (0.40)	0.9344
HMPV A/B	7	11	5	7	14	36 (7.74)	8 (2.83)	44 (5.89)	0.001*
RSV A/B	243	25	4	-	7	209 (44.95)	70 (24.82)	279 (37.35)	0.0001*
HBoV	18	6	5	-	-	10 (2.15)	19 (6.74)	29 (3.88)	0.9454
HPeV	1	-	-	-	-	-	1 (0.35)	1 (0.13)	0.4569
EV	26	3	-	1	-	9 (1.93)	21 (7.44)	30 (4.01)	0.0167*
HCoV HKU1	5	-	1	2	1	3 (0.64)	6 (2.13)	9 (1.20)	0.8364
HAdV	57	7	8	2	9	39 (8.39)	44 (15.60)	83 (11.11)	0.4647
Flu A	3	5	-	2	1	7 (1.50)	4 (1.42)	11 (1.47)	0.0165*
Pandemic H1N1	5	7	8	6	4	23 (4.94)	7 (2.48)	30 (4.01)	0.0022*
Total	495	101	65	32	54	465 (100)	282 (100)	747 (100)	-
Samples									
Positive	384	89	50	28	47	465 (77.76)	133 (22.24)	598 (59.98)	-
Negative	258	62	41	15	23	-	-	399 (40.02)	-
Total	642	151	91	43	70	-	-	997 (100)	-

*P<0.05. Flu A: Influenza A, Flu B: Influenza B, EV: Enterovirus, RSV A/B: Respiratory syncytial virus, HMPV A/B: Human metapneumovirus, HRV: Human rhinovirus, HPeV: Human parechovirus, HBoV: Human bocavirus, HAdV: Human adenovirus, HPIV: Human parainfluenza virus, HCoV: Human coronaviruses

metapneumovirus (HMPV) A/B and Pandemic H1N1 had only single peak in February 2013 and for HAdV in December 2014 and 2015 only. HRV was found to be circulating throughout the year irrespective of the seasons, having high peaks in March, May and December.

Statistical analysis

On Chi-square test, *P* value was found to be significant for some viruses such as RSV ($P < 0.0001$), HMPV A/B ($P = 0.001$), pandemic H1N1 ($P = 0.0022$), Flu A ($P = 0.0165$) and EV ($P = 0.0167$) when age-wise intergroup comparisons were made for each virus.

Bacteria causing ARI

Among samples negative for respiratory viruses, 167 (41.85%) were positive for bacteria. Among these, *S. pneumoniae* was the most common, positive in 127 (62.18%) cases followed by *Moraxella catarrhalis* in 60 (29.85%) cases, [Table 5]. Predominance of bacterial agents was also found in the age group of 1–12 months. $P < 0.05$ was observed for *S. pneumoniae* and *M. catarrhalis*.

Diagnostic algorithm

Based on the viruses/bacteria detected in the study and the severity of the disease that they cause, a diagnostic algorithm was developed [Figure 2].

Table 3: Incidence of co-infections of respiratory viruses

Co-infection	Total, *n* (%)
RSV A/B + HRV	17 (12.78)
RSV A/B + HAdV	16 (12.03)
RSV A/B + EV	12 (9.02)
HRV + HAdV	15 (11.28)
HBOV + RSV A/B	8 (6.02)
HBoV + HAdV	2 (1.50)
HRV + HPIV-4	3 (2.26)
HPIV3 + HAdV	2 (1.50)
HCoV − HKU1 + HCoV − OC43	2 (1.50)
HCoV - 229E + HPIV-1	1 (0.75)
RSV A/B + HCoV-229E	1 (0.75)
RSV A/B + Flu B	1 (0.75)
HAdV + HPIV-4	1 (0.75)
HCoV-OC43 + HRV	2 (1.50)
HCoV-OC43 + EV	1 (0.75)
HBoV + HPIV-3	1 (0.75)
HBoV + HRV	1 (0.75)
HRV + pandemic H1N1	1 (0.75)
Flu B + HRV	1 (0.75)
EV + pandemic H1N1	1 (0.75)
HAdV + pandemic H1N1	1 (0.75)

Contd...

Table 3: Contd...

Co-infection	Total, *n* (%)
HMPV A/B + HAdV	1 (0.75)
HMPV A/B + HPIV-1	1 (0.75)
HCoVHKU1 + HAdV	1 (0.75)
HMPV A/B + RSV A/B	1 (0.75)
HRV + HPIV3	2 (1.50)
HCoV-229E + HRV	1 (0.75)
HCoV-HKU1+HRV	1 (0.75)
HCoVOC43 + HBoV	1 (0.75)
HMPV A/B + Flu A	1 (0.75)
EV + Flu A	1 (0.75)
HPIV3 + Flu A	1 (0.75)
HCoV229 E + pandemic H1N1	2 (1.50)
EV + HRV	3 (2.26)
HCoV-NL 63 + HRV	1 (0.75)
RSV A/B + HPeV	1 (0.75)
HBoV + pandemic H1N1	2 (1.50)
RSV A/B + HPIV-3	3 (2.26)
RSV A/B + HCoV-OC43	3 (2.26)
HCoV-NL 63 + RSV A/B	1 (0.75)
HBoV + HPIV-3 + HRV	2 (1.50)
HCoV-OC43 + HRV + RSV A/B	1 (0.75)
HCoV-229E + Flu B + HMPV A/B	1 (0.75)
HAdV + RSV A/B + Flu B	1 (0.75)
HPIV-3 + HAdV + HMPV A/B	1 (0.75)
RSV A/B + HCoV-HKU1 + EV	1 (0.75)
Flu B + HMPV A/B + HAdV	1 (0.75)
HPIV2 + HPIV1 + HMPV A/B	1 (0.75)
RSV A/B + HCoV-OC43 + HAdV	1 (0.75)
RSV A/B + EV + HRV	1 (0.75)
RSV A/B + HPIV-1 + HRV	1 (0.75)
EV + HBoV + Flu A	1 (0.75)
HPIV-3 + HAdV + HRV	1 (0.75)
HPIV4 + HPIV-1 + HBoV + HCoV-HKU1	1 (0.75)
Total	133 (100)

Flu A: Influenza A, Flu B: Influenza B, EV: Enterovirus, RSV A/B: Respiratory syncytial virus, HMPV A/B: Human metapneumovirus, HRV: Human rhinovirus, HPeV: Human parechovirus, HBoV: Human bocavirus, HAdV: Human adenovirus, HPIV: Human parainfluenza virus, HCoV: Human coronaviruses

Discussion

Respiratory infections claim many lives globally every year. Profile and trends of pathogens causing respiratory infection varies from place to place and as per season and geographic conditions, data from India are very limited hence the present study was done.

In the present study, the overall positivity for viral and bacterial pathogens was found to be 76.73%, whereas a study from Dhaka[5] reported a positivity of 82.5%. This could be due to many reasons such as low-sample size etc. Predominant virus detected in the present study was RSV A/B (37.35%), as also reported from New Zealand (39%),[22] while wide variation was reported from China (13.06%)[23] and Malaysia (70.6%).[24] The variations in detection rates by various studies may be due to sampling methods, genetic variability among the populations, number of samples enroled in the study, samples collected during different seasons of the year and the method used for detection. RSV is known to be an important cause of hospitalisation in children younger than 1 year of age,[25] this may be due to lower immunity in infants.[26,27]

Higher numbers of HRV infections were seen in children of 1–12 months in our study than other age groups as also reported from Latin America.[28] Tregoning and Schwarze 2010[29] reported that RSV and HRV are the most common causes of acute respiratory viral infections as also seen in present study. The positivity of other respiratory viruses, i.e., HAdV, HMPV, HPIV-1 to HPIV-4, HCoV-OC43, HCoV-229E, HCoV-NL 63, HCoV-HKU1, EV, HBoV, Pandemic H1N1, Flu A, Flu B and HPeV were between 11.11%–0.13% [Table 2]. An Indian study by Singh *et al.*, 2014[25] reported no positivity of HPIV 1–4 and 1.10% for HBoV and 7.74% for Influenza (Flu A and Flu B) in hospitalised children with ALRI.

The prevalence of respiratory pathogens were found to be higher in the age group of <1 year with more predilection to RSV A/B and S. *pneumoniae* and higher co-infection as also reported by Bhuyan *et al.*, 2017.[5] Most of the viruses in our study were associated with both upper and lower respiratory tract infections. However, RSV A/B and *S. pneumoniae* were mostly associated with lower respiratory tract infections (i.e. bronchiolitis and pneumonia) in our study and at Dhaka too.[5] On comparing seasonal variation, in our study RSV A/B showed its highest peak in winters, during January similarly a study from Madagascar reported RSV A/B peak in February.[30] HMPV A/B also had highest peak in February as reported from Karachi also.[31] Thereafter, no peaks of HMPV A/B were observed and HMPV A/B was replaced by RSV A/B as the predominant virus which continued in the entire study as the major virus. Continuous positivity with a peak of pandemic H1N1 was observed from December 2012 to April 2013. This may be due to the high prevalence of pandemic H1N1 in the study region. HRV was found to be circulating almost entire year with peaks in March, May and December.

Positivity of the respiratory viruses was not continuous throughout the years. Some studies reported circulation of the respiratory viruses throughout the year, whereas others show distinct seasonality,[24] which could be due to seasonal variations of host immune response, climatic changes, which may promote the viral growth.[25] Low temperatures may favour the circulation of the viruses. The information on seasonal positivity of respiratory pathogens can help public and clinicians to take necessary preventive measures to control respiratory infections.

Timely identification of virus etiology in such patients can prevent misuse of antibiotics and emergence of multidrug-resistant bacteria. Moreover, the detection of fastidious bacteria by RT-PCR could help patient by initiating appropriate therapy timely. *S. pneumoniae* was the predominant bacterial agent as also reported from Dhaka,[5] who report it to be an important cause of mortality in children <5 years of age.[5] The overall positivity

Table 4: Clinical features in association with different respiratory viruses

Virus	Fever (*n*=989)	Cough (*n*=993)	Shortness of breath (*n*=609)	Sore throat (*n*=115)	Nasal catarrh (*n*=121)	Pneumoniae (*n*=307)	Bronchiolitis (*n*=103)	Wheezing (*n*=11)
HCoV-OC43	17	19	15	6	1	4	1	-
HCoV-229E	9	9	2	3	3	2	1	-
Flu B	18	20	13	1	4	10	1	-
HPIV-1	14	14	10	4	1	2	1	-
HPIV-3	38	41	23	8	4	10	2	-
HPIV-4	12	12	8	1	3	-	1	1
HPIV-2	7	7	3	2	1	2	-	1
HRV	101	106	67	12	11	28	8	-
HCoV-NL 63	3	3	3	1	1	-	-	-
HMPV A/B	44	43	18	23	23	1	-	-
RSV A/B	247	277	243	8	8	140	72	-
HBoV	27	29	22	6	4	10	3	-
HPeV	1	1	1	-	-	-	1	-
EV	28	30	23	2	1	8	2	-
HCoV-HKU1	9	9	6	3	3	-	-	-
HAdV	81	79	44	6	10	24	4	-
Flu A	9	11	2	3	1	-	-	-
Pandemic H1N1	29	30	8	15	20	-	-	-

Flu A: Influenza A, Flu B: Influenza B, EV: Enterovirus, RSV A/B: Respiratory syncytial virus, HMPV A/B: Human metapneumovirus, HRV: Human rhinovirus, HPeV: Human parechovirus, HBoV: Human bocavirus, HAdV: Human adenovirus, HPIV: Human parainfluenza virus, HCoV: Human coronaviruses

Table 5: Age-wise distribution of the respiratory bacteria and the incidence of single and co-infections

Bacteria	1-12 months	13-24 months	25-36 months	37-48 months	49-60 months	Single infections (%)	Co-infections (%)	Total (%)	*P*
Streptococcus pneumoniae	101	10	8	2	4	95 (69.85)	30 (46.15)	125 (62.18)	0.0001*
Mycoplasma pneumoniae	3	1	-	-	-	2 (1.47)	2 (3.07)	4 (1.99)	0.6638
Staphylococcus aureus	8	1	-	-	1	2 (1.47)	8 (12.31)	10 (4.97)	0.2359
Moraxella catarrhalis	49	5	4	1	1	35 (25.74)	25 (38.46)	60 (29.85)	0.0045*
Chlamydophila pneumoniae	2	-	-	-	-	2 (1.47)	-	2 (0.99)	0.7591
Legionella pneumophila	-	-	-	-	-	-	-	-	-
Total	163	17	12	3	6	136 (100.0)	65 (100.0)	201 (100.0)	-
Samples									
Positive	134	14	11	3	5	136 (81.44)	31 (18.56)	167 (41.85)	-
Negative	124	48	30	12	18	-	-	232 (58.15)	-
Total	258	62	41	15	23	-	-	399 (100.0)	-

for the bacterial agents was found to be 41.85%. Although the detection rate of *Mycoplasma pneumoniae* was only 1.99% out of which 1.49% were associated with pneumonia. Even though *M. catarrhalis* was second-most predominant bacteria detected in the study its role in respiratory infections needs to be evaluated further as it is a known commensal. In children, <5 years high prevalence of both bacterial and viral pathogens was observed. Immature immune system may be the reason behind this. Although bacteria cause secondary infections after viral infections, they should not be excluded from screening.

A diagnostic algorithm was prepared based on the severity of the disease caused and frequency of detection of pathogens. This will help in rapid economic diagnosis. However, there were some limitations in our study, only viral negative samples were screened for bacteria, screening of all samples would have given better picture; moreover, only limited panel of bacteria were tested and antibiotic sensitivity testing was also not done. Further studies are required including these parameters to answer all questions.

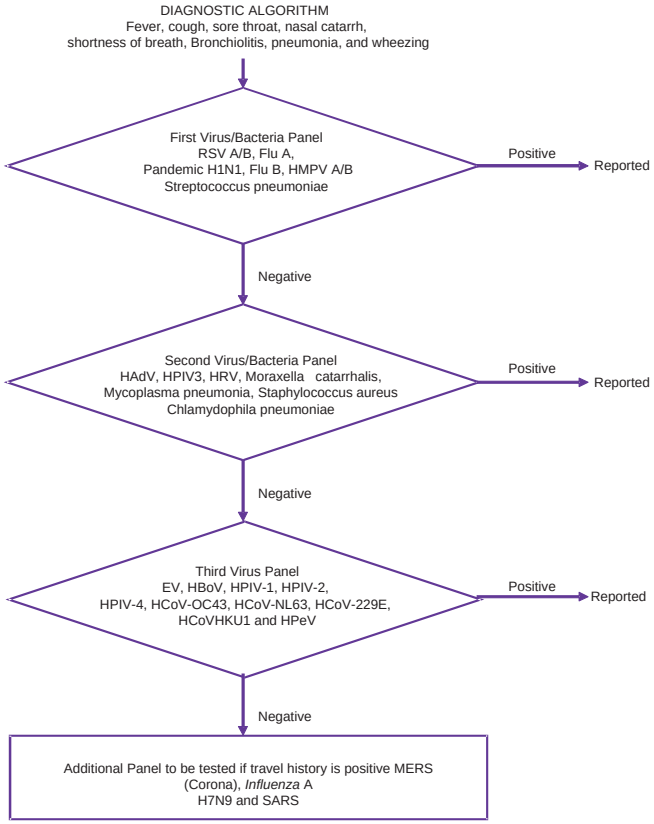

Figure 2: Flow chart of diagnostic algorithm

Conclusion

The RSV A/B, HRV, HAdV and HMPV A/B respiratory viruses were more prevalent than others and that too in winter months. Children aged <1 year were more vulnerable to respiratory viruses and bacteria, diagnostic algorithm developed can help provide rapid economic diagnosis. Rapid early identification of viruses and fastidious bacteria by PCR can help start proper therapy timely and prevent misuse of antibiotics and development of antimicrobial drug resistance. However, inclusion of all bacteria responsible for respiratory infections and the drug resistance markers can further help in patient care, additional studies are required to know whether the agent identified is a bystander or a true pathogen. This will also help in planning strategies for vaccination.

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Conflicts of interest

There are no conflicts of interest.

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Original Research Article

Profile of pathogens isolated from different clinical samples and their antimicrobial pattern: a retrospective study

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ABSTRACT

Background: Since there is a significant rise in resistant bacteria to different antimicrobial agents, there is a need to study the resistance pattern of different isolates from different clinical samples for effective use of available antimicrobials by clinicians. The aim of the present study was to detect the resistance pattern of various antimicrobials against different clinical isolates in hospitalised patients in out setting.
Methods: This is a retrospective study involving the collection of the data from the records of microbiology laboratory. All clinical specimens were processed as per standard microbiological procedures. Antibiotic susceptibility testing was performed by Kirby Bauer disc diffusion method on Mueller Hinton agar plate as per CLSI guidelines.
Results: A total of 153 isolates were recovered from 219 clinical samples accounting for 69.86% of total positivity. Which includes gram negative bacilli 107/153 (69.93%) gram positive cocci 36/153 (23.53%) and yeast 10/153 (6.54%). Among the total isolates gram negative bacilli account for major number of isolates 69.93% followed by gram positive cocci 23.53% and yeast 6.54%. Gram positive cocci and gram-negative bacilli showed a significant level of antimicrobial resistance. Nitrofurantoin is highly effective against urinary isolates of *Escherichia coli.* vancomycin and linezolid are most effective antimicrobials against gram positive cocci. Among gram negative bacilli meropenem and amikacin are most effective antimicrobials. Statistical significance of occurrence of *Escherichia coli* as predominant isolate as compared to other isolates were analysed by chi square test by using GraphPad online calculator. A p value<0.001 was obtained.
Conclusions: Significant rise in antimicrobial resistant pathogens were observed. Local antimicrobial policy should be developed for effective selection of available antimicrobials which are the need of the day to reduce the burden of diseases on global health care system.

Keywords: Antimicrobial resistance, Gram negative bacilli, Gram positive cocci

INTRODUCTION

Infections with microbes has a drastic effect on human health.[1] Microbial infections are important cause of morbidity and mortality across the globe with increase resistance of pathogens to different antimicrobial agents posing great concern to public health.[2] Antimicrobials are being used to overcome the drastic effect of microbial agents. Their wide spread use has led to emergence of multidrug resistant (MDR) pathogens. Antimicrobial resistance (AMR) may be due to natural, acquired/clinical resistance.[1]

High morbidity and mortality are seen in infections caused by drug resistant pathogens. The pattern of resistance to various antimicrobial agents may change over a period of time.[3] Nosocomial infections pose a great challenge to the well fare of the patient

management, since most of them are MDR strains. This increases the hospital stay of in patients and increases the health care cost.[1]

AMR is a great health care problem in India.[4] The burden of infectious disease is more in India because of increased drug resistant bacteria due to indiscriminate use of antimicrobials. Frequent cause of hospitalisation is associated with different microbial infections. The choice of selecting an effective antimicrobial agent has been reduced because of their resistance to different pathogens causing hospital and community acquired infections.[5]

Patients infected with drug resistant pathogens are at high risk of serious clinical outcomes and require more heath care services. Resistance to different antimicrobials is seen because of indiscriminate use of different antimicrobial agents, which in turn leads to mutations and results in drug resistance. MDR bacteria pose great threat for patients. since, it becomes very difficult to treat such patients and requires use of broad-spectrum antibiotics.[6]

METHODS

This was a retrospective study which involves analysis of medical microbiology test results of different clinical samples collected over a period of 6 months between July 2019 to December 2019. Only IPD patients were included in the study. The study was carried out at Ananta Institute of Medical sciences and research center, Rajsamand. This is a tertiary care hospital.

Data collection and testing

Type of clinical samples, isolates, age, sex and their antimicrobial susceptibility pattern were collected from the records. All clinical specimens were processed as per standard microbiological procedures. The isolates were first identified by standard biochemical techniques and then subjected to antibiotic susceptibility testing by Kirby Bauer disc diffusion method on Mueller Hinton agar plate as per CLSI guidelines.[5]

Antibiotic discs

The following antibiotic discs containing amikacin AK 30 mcg, amoxycillin/clavulanic acid AMC 30 mcg, ampicillin/sulbactam A/S 10/10 mcg, azithromycin AZM 15 mcg, aztreonam AT 30 mcg, cefoxitin CX 30 mcg, ceftizoxime CZX 30 mcg, ceftriaxone CTR 30 mcg, cefuroxime CXM 30 mcg, ciprofloxacin CIP 5 mcg, clindamycin CD 2 mcg, colistin CL 10 mcg, erythromycin E 15 mcg, gentamicin GEN 10 mcg, imipenem IPM 10 mcg, levofloxacin LE 5 mcg, linezolid LZ 30 mcg, meropenem MRP 10 mcg, piperacillin/ tazobactum PIT 100/10 mcg, polymyxin-B PB 300 units, trimethoprim TR 5 mcg, vancomycin VA 30 mcg, cefoperazone/ sulbactam CFS 75/10 mcg, ceftazidime/clavulanic acid CAC 30/10 mcg, nitrofurantoin NIT 300 mcg were used as per manufacturer (Himedia) instructions.

Statistical analysis

Statistical analysis was done by using GraphPad online calculator. Chi square test was employed. P value<0.05 is considered as statistically significant

RESULTS

A total of 153 isolates were recovered from 219 clinical samples accounting for 69.86% of total positivity. Which includes gram negative bacilli 107/153 (69.93%) gram positive cocci 36/153 (23.53%) and yeast 10/153 (6.54%). Among the total isolates gram negative bacilli account for major number of isolates 69.93% followed by gram positive cocci 23.53% and yeast 6.54% (Table 1).

Among the gram-negative bacilli, the major isolates are *Escherichia coli* 35.29% followed by *Klebsiella* species 12.41% and *Pseudomonas aeruginosa* 12.41%. Among the gram-positive cocci, the major isolates are coagulase negative *Staphylococcal species* (CONS) 12.41% followed by coagulase positive *Staphylococcus* (*Staphylococcus aureus*) 6.53% and *Enterococcus faecalis* 4.57%. Among the yeast the major isolate is *Candida albicans* 4.57% followed by *Candida tropicalis* 1.96% (Antifungal agents were not tested).

Among different clinical samples received urine samples account for highest number of isolates 62/119 (52.10%). Among which gram-negative bacilli accounts for 53/62 (85.48%) followed by gram positive cocci 5/62 (08.06%) and yeast 4/62 (06.45%). *Acinetobacter* species were predominant in clinical aspirates 10/21 (47.61%). *Pseudomonas aeruginosa* was predominant in pus 11/48 (22.91%) (Table 1). A total of 10 co-infections were detected among the total isolates (Table 1).

Antimicrobial resistance

Antimicrobial resistance pattern of gram-negative bacilli and gram-positive cocci varied from nil to 100% for different isolates. The details of each isolate and their antimicrobial resistance pattern is given in Table 2 and 3.

Among gram negative isolates, meropenem and amikacin are more effective against *E-coli* with 9.25% and 18.51% resistance respectively each. Meropenem and piperacillin/ tazobactam are more effective against *Klebsiella* species with 36.84% and 47.36% resistance respectively each. Amikacin and ciprofloxacin are more effective against *P. aeruginosa* with 15.78% and 31.57% resistance respectively each. Amikacin, ampicillin/sulbactam and levofloxacin are more effective against *Acinetobacter* species with 41.66% resistance respectively each. Polymyxine-B and colistin showed no resistance when used against *P. aeruginosa* and *Acinetobacter* species. Piperacillin/ tazobactam is more effective against proteus species with 33.33% resistance (Table 2).

Among gram positive isolates ampicillin/sulbactam, cefoxitin/clindamycin are more effective against cons with 21.05% and 26.31% resistance respectively each. Clindamycin and trimethoprin/ sulphamethoxazole are more effective against *S. aureus* with 30% and 60% resistance respectively each. Gentamicin and Trimethoprin/ sulphamethoxazole more effective against *Enterococcus faecalis* with 14.28% and 57.14% resistance respectively each. Gentamicin is nil resistant to CONS and *S. aureus*. Linezolid and vancomycin are nil resistant to *Enterococcus faecalis*, CONS and *S. aureus* (Table 3). Among total number of clinical isolates, males accounted for (54.25%) positivity and females accounted for (45.75%) positivity. Among the male patients the predominant isolates are *E-coli* (30.12%), followed by *P. aeruginosa* (16.86%) and *Acinetobacter species* (14.45%). Among the female patients the predominant isolates are *E-coli* (41.42%), CONS (15.71%) and *Klebsiella* species (12.85%). Details of each isolate in males and females are mentioned in Table 4.

Statistical significance of occurrence of *Escherichia coli* as predominant isolate as compared to other isolates were analysed by chi square test by using GraphPad online calculator. A p value<0.001 was obtained.

Table 1: Different microbial agents isolated from various clinical samples.

Isolated micro-organism (%)		Clinical sample	Single infection	Co-infection	Total
Gram negative Bacilli (A)	*Acinetobacter* species (7.84)	Aspirates	9/21	1	10/21
		Pus	2/48	-	2/48
	Escherichia coli (35.29)	Stool	1/3	-	1/3
		Others (tips)	1/2	-	1/2
		Urine	39/119	1	40/119
		Vaginal swab	4/15	-	4/15
		Pus	7/48	-	7/48
		Drain fluid	1/1	-	1/1
	Klebsiella species (12.41)	Aspirates	3/21	1	4/21
		Pus	-	1	1/48
		Sputum	3/5	-	3/5
		Stool	1/3	-	1/3
		Urine	7/119	-	7/119
		Vaginal swab	3/15	-	3/15
	Pseudomonas aeruginosa (12.41)	Aspirates	2/21	2	4/21
		Pus	10/48	1	11/48
		Others (tips)	1/2	-	1/2
		Urine	2/119	1	3/119
	Proteus species (1.96)	Urine	3/119	-	3/119
	Total (%)		99/107* (92.52)	08/107* (7.48)	107/153 (69.93)
Gram positive cocci (B)	Coagulase negative *Staphylococci* (12.41)	Aspirates	1/21	-	1/21
		Pus	11/48	-	11/48
		Stool	1/3	-	1/3
		Urine	2/119	-	2/119
		Vaginal swab	4/15	-	4/15
	COPS (6.53)	Pus	10/48		10/48
	Enterococcus faecalis (4.57)	Urine	3/119	-	3/119
		Vaginal swab	4/15	-	4/15
	Total (%)		36/36# (100)	-	36/153 (23.53)
Yeast (C)	*Candida albicans* (4.57)	Aspirates	-	1	1/21
		Pus	1/48	-	1/48
		Sputum	1/5	-	1/5
		Urine	3/119	-	3/119
		Vaginal swab	1/15	-	1/15
	Candida tropicalis (1.96)	Aspirates	-	1	1/21
		Urine	1/119		1/119
		Vaginal swab	1/15		1/15
	Total (%)		08/10@ (80)	2/10@ (20)	10/153 (6.54)
	Total (A+B+C) (%)		143/219$ (65.30)	10/219$ (4.56)	153/219$ (69.8)

*Total number of gram-negative bacilli isolated, # Total number of gram-positive *cocci* isolated, @Total number of yeast isolated, $ Total number of samples tested, COPS-Coagulase positive *Staphylococci* p<0.001

Table 2: Antibiotic resistance pattern of gram-negative bacilli isolated from different clinical samples.

Antimicrobial agent	Resistance percentage of gram-negative bacilli				
	Escherichia coli, (n=54)	*Klebsiella* species, (n=19)	*Pseudomonas aeruginosa*, (n=19)	*Acinetobacter* species, (n=12)	*Proteus* species, (n=3)
Ceftizoxime	85.18	68.42	84.21	100	66.66
Piperacillin/ tazobactam	29.62	47.36	42.10	75	33.33
Cefuroxime	92.59	73.68	100	100	100
Polymyxin B	NT	NT	0	0	NT
Ceftriaxone	83.33	73.68	73.68	83.33	100
Cefaperazone/ sulbactum	59.25	63.15	73.68	66.66	66.66
Levofloxacin	79.62	63.15	47.36	41.66	66.66
Aztreonam	75.92	73.68	42.10	100	66.66
Imipenem	68.51	52.63	42.10	66.66	100
Meropenem	9.25	36.84	26.31	58.33	66.66
Amikacin	18.51	78.94	15.78	41.66	66.66
Ampicillin/ sulbactam	51.85	73.68	84.21	41.66	66.66
Amoxicillin/ clavulanic acid	90.74	78.94	73.68	75	100
Ciprofloxacin	81.48	52.63	31.57	58.33	66.66
Trimethoprim/ sulphamethoxazole	68.51	63.15	84.21	66.66	100
Colistin	NT	NT	0	0	NT
Ceftazidime/ clavulanic acid	42.59	63.15	57.89	91.66	66.66

NT-Not tested

Table 3: Antibiotic resistance pattern of gram-positive cocci isolated from different clinical samples.

Antimicrobial agent	Resistance percentage of gram-positive cocci		
	CONS, (n=19)	*Staphylococcus aureus*, (n=10)	*Enterococcus faecalis*, (n=07)
Gentamicin	0	0	14.28
Ciprofloxacin	36.48	60	85.71
Levofloxacin	42.10	60	85.71
Erythromycon	47.36	60	100
Linezolid	0	0	0
Clindamycin	26.31	30	100
Vancomycin	0	0	0
Cefuroxime	42.10	70	100
Ceftizoxime	42.10	70	100
Ceftriaxone	47.36	80	100
Azithromycin	89.47	70	100
Cefoxitin	26.31	70	NT
Ampicillin/sulbactam	21.05	80	85.71
Amoxicillin/clavulanic acid	73.68	80	85.71
Trimethoprim/ sulphamethoxazole	47.36	60	57.14

Table 4: Different clinical isolates in males and females.

Isolate	Male	Female	Total
Acinetobacter species	12	-	12
Escherichia coli	25	29	54
Klebsiella species	10	9	19
Pseudomonas aeruginosa	14	5	19
Proteus species	1	2	3

Continued.

Isolate	Male	Female	Total
Coagulase negative *Staphylococci*	8	11	19
COPS	7	3	10
Enterococcus faecalis	1	6	7
Candida albicans	4	3	7
Candida tropicais	1	2	3
Total (%)	83/153, (54.25)	70/153, (45.75)	153, (100.00)

DISCUSSION

Different pathogens are associated with human infections. Management of this infectious diseases by timely identification and selection of effective antimicrobials against the causative agents help in early recovery of the patients and also helps in reducing the hospital costs as well as the stay time in hospital. Emergence and spread of MDR pathogens are a major challenge for better health care management. MDR pathogens increase morbidity and mortality in hospitalised patients. This study present various pathogens isolated from different clinical samples and their antimicrobial activity in hospitalised patients.

The total positivity of the clinical isolates of the present study were 69.86% with predominance of gram-negative bacilli 69.93% as compared to gram positive cocci 23.53%. An earlier study has reported a total positivity of 64.70% which correlates with our study.[7] Abebe et al and Masyeni et al reported gram-negative bacilli as the most predominant isolate. Similar findings are observed in the present study. Most of the nosocomial infections are associated with gram negative bacilli causing severe form of the disease. These strains are mostly MDR.[3,8]

The present study has reported a high-level resistance to various class of antimicrobials against gram negative bacilli and gram-positive cocci. Antibiotic resistance is a threat to the world and is a major public problem in India. since, India harbours great burden of bacterial diseases. Emergence of MDR strains from India for gram negative bacilli and gram-positive cocci has been reported.[9] This coincides with the present study which shows high resistance of bacteria to various antimicrobials.

Urine samples accounted for majority (54.33%) of the samples in the present study. similar findings have been observed with other studies.[1,5] The most common pathogen isolated from all clinical samples in our study was *Escherichia coli* 35.29% with predominance of females (57.05%) as compared to males (42.95%). This is followed by *Klebsiella* species, CONS and *Pseudomonas aeruginosa* 12.41% each. These findings are in correlation with other studies.[2,9,10] Among the uropathogens isolated, *Escherichia coli* and *Klebsiella* species were the predominant isolates in our study which correlates with earlier studies.[5,12]

Among the antimicrobials used against *Escherichia coli*, meropenem showed 09.25% resistance, amikacin showed 18.51% resistance and piperacillin/ tazobactam showed 29.62% resistance. Nitrofurantoin showed nil resistance against *Escherichia coli* isolates from urine. similar findings were also reported by other studies with decreased potency of ciprofloxacin and co-trimoxazole among uropathogens.[5,6,10] Among *Klebsiella* species isolated meropenem is more effective which showed 36.84% resistance. This finding is different from an earlier study which reported 100% resistance.[4] In *Pseudomonas aeruginosa* nil resistance was observed for polymyxine-B and colistin. Amikacin showed least resistance 15.78% to *Pseudomonas aeruginosa* followed by meropenem 26.31%. Higher rate of resistance for amikacin (78.00%) and meropenem (100.00%) was reported by an earlier study.[4] *Acinetobacter* species showed nil resistance to polymyxine-B and colistin and 41.66% resistance to amikacin, ampicillin/ sulbactam and levofloxacin respectively each. Piperacillin/tazobactam was the most effective antimicrobial against proteus species with 33.33% resistance. This finding is different from a previous study which reported 100.00% resistance to piperacillin/ tazobactam.[4]

Among the gram-positive isolates nil resistance was observed for vancomycin, linezolid. Gentamicin showed nil resistance against CONS and *Staphylococcus aureus* but showed 14.28% resistance against *Enterococcus faecalis*. Among CONS, ampicillin/sulbactam was the most effective antimicrobial with a resistance of 21.05% followed by cefoxitin and clindamycin with 26.31% resistance. This finding is different from an earlier study which reported 100% sensitivity to cefoxitin and clindamycin.[5] *Staphylococcus aureus* showed least resistance to clindamycin (30%). This finding is different from an earlier study which reported 100% resistance to Clindamycin.[5] Trimethoprin/ sulphamethoxazole showed a least resistance of 57.14% when used against *Enterococcus faecalis.* Khatun et al reported a higher resistance of 75% to trimethoprin/ sulphamethoxazole. The difference in the resistance pattern of different antimicrobials for gram negative bacilli and gram-positive cocci in different studies may be attributed to the usage of that particular antimicrobial in different settings.

High rate of resistance to various antimicrobials in our study may be due to inclusion of only hospitalised patients. Since nosocomial infections are seen in hospitalised patients and the strains are generally resistant to most of the commonly used antimicrobials. Similar

findings were observed by earlier studies which included IPD and OPD patients.[5,6] The high rate of antimicrobial resistance in IPD patients may indicated the need for surveillance studies on nosocomial infections to identify the source of infection. Incorrect diagnosis may lead to irrational use of antibiotics which may lead to overuse or misuse of antimicrobials resulting in dissemination of antibiotic resistance.

CONCLUSION

The most predominant isolate from different clinical samples in our study was *Escherichia coli*. Among gram negative isolates in the present study, the most effective antimicrobials are colistin, meropenem, amikacin, piperacillin/tazobactam, ampicillin/ sulbactum. Among urinary isolates of *Escherichia coli*, nitrofurantoin is very effective. Gentamicin, vancomycin and linezolid are most effective antimicrobials against gram positive cocci in our study. Significant rise in resistance to antimicrobials was observed in this study. Local antimicrobial policy should be developed for effective selection of available antimicrobials which are the need of the day to reduce the burden of diseases on global health care system.

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Original Research Article

Spectrum of aerobic bacteria and their antimicrobial pattern in blood stream infections of hospitalised patients: a retrospective study

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ABSTRACT

Background: Bacteria associated with blood stream infections are an important public health problem which results in morbidity and mortality globally. Emergence of multidrug resistant isolates in hospitalized patients is a major problem. Automation techniques play a major role in early identification of the isolate and its drug susceptibility testing which is important for better outcome of the treatment. This study was aimed to detect the blood stream isolates and their drug susceptibility pattern in hospitalized patients.
Methods: This was a retrospective study conducted from 377 records of automated blood culture (bact/alert) and drug susceptibility testing (vitek) results. Positive blood culture bottles were sub cultured to different culture media and the isolates were identified and screened for drug susceptibility testing on Vitek II.
Results: Around 20.68% of samples were positive for blood stream infections caused by different pathogens. A total of 78 microorganisms were isolated from 377 samples. Among which gram negative bacilli was observed in 52.56%, gram positive cocci in 44.87% and yeast in 2.56% samples. Coagulase negative *staphylococci* and *Klebsiella pneumoniae* were the predominant isolates of the study.
Conclusions: Early diagnosis of blood stream infections in hospitalized patients is life saving. Hence a continuous monitoring of isolates and their drug susceptibility is the need of the day.

Keywords: Blood stream infections, Coagulase negative *staphylococcus, Klebsiella pneumoniae*

INTRODUCTION

Blood stream infection (BSI) remains one of the foremost important causes of morbidity and mortality globally. The infection may range from self limiting to life threatening sepsis.[1,2] As case fatality rate is high it requires appropriate and immediate antimicrobial therapy. Different bacteria were associated with (BSI) from time to time at different geographical areas. These bacteria play an important role in causing mortality, increasing the length of hospital stay and also the health care cost.[3]

Drug resistance of these bacteria is an important issue of public health concern. Since many studies have reported that gram negative and gram positive bacteria are associates with these infections which are often drug resistant. Empirical antibiotic therapy is initiated in almost all cases before the blood culture reports are available. Choice of right empirical therapy is important. An early blood culture report may help in selection of appropriate antibiotics.[2,4]

Minimal time is required to get a blood culture report using automated systems. The etiology and antimicrobial pattern of (BSI) may vary at different times in the same region hence a continuous update is essential for epidemiological purpose and also for rational and accurate use of antibiotics by clinicians. The present

study aimed to determine the etiology and antibiotic resistance pattern in blood stream infections.

METHODS

Study design

A retrospective study was conducted from the records of automated blood culture (bact alert) and drug susceptibility testing (vitek) results in the clinical microbiology laboratory from June, 2016 to July, 2018 at Ananta institute of medical sciences and research centre, Rajsamand. This data includes 377 records of hospitalised patients who were admitted to different units of hospital during the study period.

Sampling technique and data collection

Blood cultures were performed for different age groups up to 90 years. Samples were collected by phlebotomist from the patients after disinfection of vein puncture site with 70% alcohol. 3-4ml of blood was inoculated in 30ml BacT/Alert blood culture bottles for paediatrics and 4-5ml blood was inoculated in 30ml BacT/Alert blood culture bottles for adults. These bottles were incubated in BacT/Alert automated system. The bottles which showed positive signal for growth were removed from the automated system and subculture was done on Nutrient agar, blood agar and MacConkey's agar. Smears from the colony of different agar plates were prepared and stained with Gram stain to identify the growth (i.e. gram positive or gram negative bacteria). Then the growth of the bacteria was run on VITEK II automated system for identification of the organism and Antibiotic Sensitivity. If there is no growth of bacteria within five days of inoculation of blood sample into BacT/Alert blood culture bottle then the sample is considered to be negative.

Data regarding the age, sex, isolate and its antimicrobial pattern was collected and statistical analysis of the data was done by Chi square test to study the P value using social science statistics online software.

RESULTS

A total of 377 samples were screened for blood culture from hospitalized patients of different units. 20.68% of samples were positive for blood stream infections caused by different pathogens (Table 1).

A total of 78 microorganisms were isolated from 377 samples. Among which gram negative bacilli was observed in 52.56%, gram positive cocci in 44.87% and yeast in 2.56% samples. The leading isolate among the gram positive cocci were CONS (coagulase negative *staphylococci*) and among the gram negative bacilli, *Klebsiella pneumoniae*. Details of each isolate were mentioned in Table 1. Only two samples were found to be positive for yeast i.e. *Candida tropicalis*.

Table 1: Bacteria and yeast isolated from blood culture samples.

	Isolate	Positive %
Gram negative bacilli (A)	*Acinetobacter baumannii*	4 (9.75%)
	Acinetobacter iwoffii	1 (2.44%)
	Burkholderia cepaciae	1 (2.44%)
	Escherichia coli	10 (24.39%)
	Enterobacter cloacae Complex	2 (4.87%)
	Klebsiella pneumoniae	17 (41.46%)
	Pseudomonas aeruginosa	3 (7.31%)
	Spingomonas paucimobilis	1 (2.44%)
	Stenotrophomonas maltophilia	1 (2.44%)
	Serratia marcescenes	1 (2.44%)
Total		41 (100%)
Gram positive cocci (B)	*Staphylococcus aureus*	3 (8.57%)
	Staphylococcus cohnii#	2 (5.71%)
	Staphylococcus epidermidis#	6 (17.14%)
	Staphylococcus haemolyticus#	4 (11.48%)
	Staphylococcus hominis#	3 (8.57%)
	Staphylococcus lentus#	2 (5.71%)
	Staphylococcus pseudintermedius#	2 (5.71%)
	Enterococcus faecalis	3 (8.57%)
	CONS	10 (28.57%)
Total		35 (100%)
Yeast (C)	*Candida tropicalis*	2(100%)
Total (A+B+C)		78/377* (20.68%)

*Total number of samples tested, CONS-coagulase negative *staphylococcus*, # CONS

Isolates were predominant in males (62.82%) as compared to females (37.18%) (Table 2). Paediatric patients were more (31.57%) exposed to BSI than adult and elderly patients (23.52%). Statistical analysis showed a P value of 0.03. CONS were the leading pathogens in paediatric patients. *Klebsiella pneumoniae* was the leading pathogen among the adult and elderly patients. 83.3% (65) of samples were culture positive in <24hours, 15.4% (12) in between 24 <48hours, 1.3% (1) between 48-72hours.

Table 2: Sex wise and age wise distribution of positive and negative blood culture samples.

Variable	Blood culture result			P value
	Positive	Negative	Total	
Male	49	191	240	X^2=0.03 P=0.86
Female	29	108	137	
Age				
<5 years	25	58	83	X^2=6.88 P=0.03
5 <15 year	5	37	42	
>15 years	48	204	252	

Among the gram-negative isolates, *Escherichia coli* showed 100% sensitivity to colistin and tigecycline, 80% to ertapenem. *Acinetobacter* species showed 80% sensitivity to colistin and 70% to amikacin. *Enterobacter cloacae* showed 100% sensitivity to tigecycline,

Klebsiella pneumoniae showed 100% sensitivity to colistin and 88.3% to tigecycline. *Pseudomonas aeruginosa* showed 66.7% sensitivity to colistin (Table 3). Among gram positive isolates, CONS showed 93.1% sensitivity to linezolid, 89.7% to tigecycline and 86.2% to vancomycin. *Staphylococcus aureus* showed 100% sensitivity to oxacillin, gentamicin, linezolid, vancomycin, tetracycline and tigecycline. E*nterococcus faecalis* showed 100% sensitivity to gentamicin, linezolid and vancomycin (Table 4).

Very low positivity 1 (2.44%) was observed for *Spingomonas paucimobilis, Stenotrophomonas maltophilia, Burkholderia cepaciae* and *Serratia marcescenes.*

Table 3: Antibiotic resistance of gram negative bacilli isolated from blood culture.

Antimicrobial agent	Resistance percentage of gram negative bacilli				
	***Eschericia coli* (n=10)**	***Acinetobacter species* (n=05)**	***Enterobacter cloacae* (n=02)**	***Klebsiella pneumoniae* (n=17)**	***Pseudomonas aeruginosa* (n=03)**
Ampicillin	100	100	NT	100	NT
Amoxicillin/clavulanate	80	100	100	94.1	NT
Piperacillin/tazobactam	80	80	100	94.1	66.6
Cefuroxime	100	100	100	100	NT
Cefuroxime axetil	100	100	100	100	NT
Ceftriaxone	100	80	100	100	NT
Cefaperazone/sulbactum	70	80	100	94.1	100
Ertapenem	20	NT	NT	NT	NT
Cefepime	70	80	100	100	100
Imipenem	50	70	100	35.3	66.6
Meropenem	60	70	100	58.8	66.6
Amikacin	30	30	100	88.2	66.6
Gentamicin	30	80	100	100	66.6
Nalidixic acid	80	80	100	82.3	NT
Ciprofloxacin	80	80	100	82.3	66.6
Tigecycline	0	60	0	11.7	100
Trimethoprim/ sulphamethoxazole	60	80	100	52.9	NT
Colistin	0	20	NT	0	33.3

NT - Not Tested

Table 4: Antibiotic resistance of gram-positive cocci isolated from blood culture.

Antimicrobial agent	Resistance percentage of gram-positive cocci		
	Cons* (n=29)	***Staphylococcus aureus* (n=03)**	***Enterococcus faecalis* (n=03)**
Benzylpenicillin	96.5	100	100
Oxacillin	82.7	0	100
Gentamicin	31.3	0	0
Ciprofloxacin	65.5	33.3	50
Levofloxacin	65.5	33.3	50
Erythromycon	89.6	66.6	100
Linezolid	6.9	0	0
Clindamycin	86.2	66.6	100
Tecoplanin	27.5	80	50
Vancomycin	13.8	0	0
Tetracycline	27.6	0	50
Tigecycline	10.3	0	100
Trimethoprim	51.7	66.6	50

DISCUSSION

The overall frequency of blood culture isolates in present study was (20.68%). This is comparable with studies conducted in India by Pal et al, 2016 (22.3%) and Gill et al, 2016 (24.8%).[5,4] However, some studies have reported high frequency of bacterial pathogens from blood cultures (24.2%-37.1%).[6,7] This may be due to use of different blood culture systems, different sample size, variations in study design and protocols, different geographical locations, variations in causative agents and the policies adopted for infection control between countries. Incidence of gram negative bacilli (GNB) was 52.56% and gram positive cocci (GPC) were 44.87%. Similar findings with high frequency of GNB as compared to GPC were previously reported by an Indian study.[8]

In our study, coagulase negative *staphylococcus* was the leading blood culture isolates (37.1%). Similar results were reported from India (61%) and globally (42%).[9,10] They often occur as skin contaminants during the collection of blood. Cross infections in ICU'S with multidrug resistant CONS can be prevented by use of appropriate antimicrobial agents. There is a need for differentiation between true pathogen and contaminant which can be achieved by correlating clinically the blood culture isolate and time taken for positivity of CONS.[11] Among the GPC group CONS showed high frequency of antimicrobial resistance as compared to others (Table 4). *Staphylococcus* aureus was 100% sensitivite to oxacillin, gentamicin, linezolid, vancomycin, tetracycline and tigecycline. Similarly, an earlier study reported 100% sensitivity to linezolid and vancomycin.[8]

Enterococcus faecalis was observed in (8.5%) of gram positive cocci. Similar findings (8.4%) were reported by an earlier Indian study.[11] It is a normal flora of female genitourinary tract and gastrointestinal tract. Though vancomycin resistance was reported since a decade, in the present study no resistance to vancomycin was observed for *Enterococcus faecalis*. This may be due to differences in the circulating strains. However, an earlier study from north India reported 23% of vancomycin rersistant enterococci.[11]

Gram negative bacteria accounted for more than fifty percent among the total isolates of the blood culture. This is consistent with an earlier study, though there is difference in the range of isolates.[1] Among the non fermenters, *Acinetobacter* species and *psuedomonas aeruginosa* showed high level resistance to cephalosporins and carbapenems. There is increase in the trend of carbapenem resistance to *Acinetobacter* species.[11] This may be because of extensive use of these antimicrobials. The overall antimicrobial resistance of gram negative bacteria and gram positive bacteria varied from 0% to 100% in our study. This is different when compared to a previous study which reported a higher resistance in gram negative bacteria (20-100%) as compared to gram positive bacteria (23.5%-58.8%).[12] Among the *Klebsiella pneumoniae* isolates high level sensitivity was shown by colistin 100% followed by tigecycline 88.3%, imipenem 64.7% and meropenem 41.2%. Singh et al, 2014 reported 100% and 71.4% sensitivity for imipenem and meropenem respectively each.[8] *Eschericia coli* showed high level sensitivity to colistin and tigecycline 100%, followed by ertapenem 80%, amikacin and gentamicin 70%. The sensitivity of gentamicin in our study was much higher as compared to an earlier Indian study 35%.[13]

Differences in antimicrobial resistant pattern in different studies may be due to circulation of different strains in different regions at different times.

Among the yeast isolates *Candida tropicalis* was isolated in two blood culture samples. Both the isolates were 100% sensitive to fluconozole, voriconazole, caspofungi, micafungin, amphotericin-B, and flucytosin. However, studies from different parts of India reported the emergence of *nonalbicans Candida* and resistant to widely used antifungal agents.[14,15]

CONCLUSION

Coagulase negative *staphylococcus* and *Klebsiella pneumoniae* were the predominant isolates of the study. High level multidrug resistance was observed in both GPC and GNB. Tigecycline and colistin remains the choice of antibiotics for gram-negative bacilli. Gentamicin, linezolid, vancomycin and tigecycline are the choice of antibiotics for gram positive cocci. Good antibiotic policy and strict hospital infection control measures may help to curb the emergence of multidrug resistant pathogens. There is a need for continuous monitoring and updating the BSI isolates and their antimicrobial patterns for an early effective approach to treatment.

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Original Article

Microbiology Section

Prevalence of *exoT* Gene in *Pseudomonas aeruginosa* Isolated from Various Clinical Samples: A Cross-sectional Study

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ABSTRACT

Introduction: *Pseudomonas aeruginosa (P.aeruginosa)* is one of the most frequently co-infecting bacteria reported. Development of drug resistance, biofilm formation, cell associated factors make the *P.aeruginosa* more virulent. Type III secretion system controls expression of genes. *P.aeruginosa* chromosome harbours *exoT, exoS, exoU*, and *exoY* virulent genes. Gene *exoT* plays an important role in causation of infection. The identification of virulent markers of pathogens for identification of acute and chronic infections at early stage remains a critical area and still need large research.

Aim: To study the prevalence of *exoT* gene encoding exotoxin T in *P.aeruginosa* from clinical samples.

Materials and Methods: A descriptive cross-sectional research was conducted during January 2015 to March 2016 at the Department of Microbiology in Dr. D.Y. Patil Medical College, Pimpri, Pune, Maharashtra, India. Various clinical samples were processed using standard laboratory methods. The statistical analysis was done by using Chi-square test. Strains of *P.aeruginosa* isolated from various clinical samples were identified using standard laboratory methods, and *exoT* gene was detected by Polymerase Chain Reaction (PCR) and gel electrophoresis technique.

Results: Out of 30 strains of *P. aeruginosa*, 20 (66.67%) were isolated from male and 10 (33.33%) from female patients. Most of them belonged to the age group 41-60 years (46.67%). The *exoT* gene occurred in 20/30 (66.67%) isolates of *P.aeruginosa*, while 10/30 (33.33 %) showed negative amplification results. Out of 20 *exoT* genes in *P.aeruginosa*, 17/20 (85%) were detected from male and 3/10 (15%) from female patients.

Conclusion: Gene *exoT* of *P. aeruginosa* plays the crucial role in causation of disease. It is concluded that *exoT* gene can be a notable virulent element expressed by 66.67% of *P.aeruginosa* clinical isolates. The proven role of *exoT* virulence gene in the pathogenicity of *P.aeruginosa* would help in understanding the prognosis of *Pseudomonas* infection and designing an effective treatment and vaccine against the *Pseudomonas* infections to prevent them.

Keywords: Exotoxin T, Gram negative bacteria, Polymerase chain reaction

INTRODUCTION

Pseudomonas aeruginosa (*P.aeruginosa*) is an actively motile, biofilm forming Gram negative human opportunistic pathogen. It exhibits multidrug resistance and is widely connected with hospital acquired infections [1]. They are resistant to multiple antibiotics due to acquired or inherent determinants. It can cause acute and chronic infections [2]. *P.aeruginosa* causes serious infections such as endocarditis, pneumonia, septicaemia, wound infections, cystitis [3], blood stream infections, urinary tract infection and surgical site infections [4]. Biofilm formation, development of drug resistance, various secreted toxins, proteases, pyocyanin, exotoxins and different cell associated factors make *P.aeruginosa* more virulent [5]. *P.aeruginosa* has the ability to colonise the respiratory tract and is one of the members of normal flora of nasopharynx [6]. *P.aeruginosa* infections are more frequently observed in cystic fibrosis and in weakened immune patients. In a recent study, researcher documented *P.aeruginosa* as a common co-infecting pathogen in patients [7].

P.aeruginosa continues to exist in different environmental states because of different virulence factors and metabolic properties [8]. Toxins are released by passive transport from the cells secreted by one of the three secretion systems namely, Type I Secretion System (T1SS), Type II Secretion System (T2SS) and Type III Secretion System (T3SS). Type III secretary system plays a key role in determining virulence [9]. The Gram negative bacteria have a complex T3SS which is an essential machinery of *P.aeruginosa* to inject exotoxin T (*exoT*), exotoxin S (*exoS*) and exotoxin U (*exoU*) virulence factors directly into host cells [10] and can evoke different responses from the host suitable for spreading of infection [11]. Exotoxin produced during release and escape of pathogen mainly attacks host kinases and is responsible for adhesion, phagocytosis, with spreading type of infection from lung to the liver in experimental animal [9,12].

Very few researchers in India have focussed on *exoT* gene encoding exotoxin T, virulence factor of T3SS of *P.aeruginosa*. In previous similar study in India, the researcher documented 84% prevalence of *exoT* gene in *P.aeruginosa* strains obtained from various clinical samples [13]. Keeping these facts in mind, this study was designed to study the prevalence of *exoT* gene in *P.aeruginosa* obtained from different clinical samples in a tertiary care hospital.

MATERIALS AND METHODS

Present descriptive cross-sectional research was conducted during January 2015 to March 2016 at the Department of Microbiology in Dr DY Patil Medical College, Hospital and Research Centre, Pimpri, Pune, Maharashtra, India. Different clinical samples (pus, urine, sputum, blood and body fluids) were received from various wards irrespective of age and gender for routine culture and sensitivity tests. The isolates were processed and confirmed *P.aeruginosa* strains were screened for detection of *exoT* gene by PCR and gel electrophoresis techniques. The study was done after approval from Institutional Ethical Committee of Dr DY Patil Medical College, Hospital and Research Centre, Pimpri, Pune, Maharashtra, India.

Inclusion criteria: Samples showing *P.aeruginosa* as single causative agent of infection were included in this study. Total 30 strains were included in this research study.

Exclusion criteria: Samples showing mixed growth were excluded from this study.

Isolation and identification of *P.aeruginosa*: All clinical samples were inoculated onto MacConkey agar, Nutrient agar and Blood agar plates. Inoculated plates were incubated at 37ºC for 24 hours. After obtaining the growth, *P.aeruginosa* was identified by studying colony characteristics, production of pyocyanin pigments, grape like odour, growth at 42ºC, motility test, Gram staining, and positive oxidase, citrate, and catalase tests [14].

Extraction of DNA: For the detection of *exoT* gene, chromosomal DNA from the 30 clinical strains of *P.aeruginosa* clinical isolates was extracted and DNA purification was carried out using a commercial available DNA extraction kit (Ganeaid-Presto™ Mini gDNA bacteria Kit) as indicated by manufacturer's instructions.

Polymerase Chain Reaction (PCR): The sequences of the primers used in PCR for detection of *exoT* gene and its molecular weight are shown in [Table/Fig-1] [15,16].

Gene	Primer sequence	Amplicon size	Length (bp)
exoT	Forward 5'-AATCGCCGTCCAACTGCATGCG-3'	22	152
	Reverse 5'-TGTTCGCCGAGGTACTGCTC-3'	20	

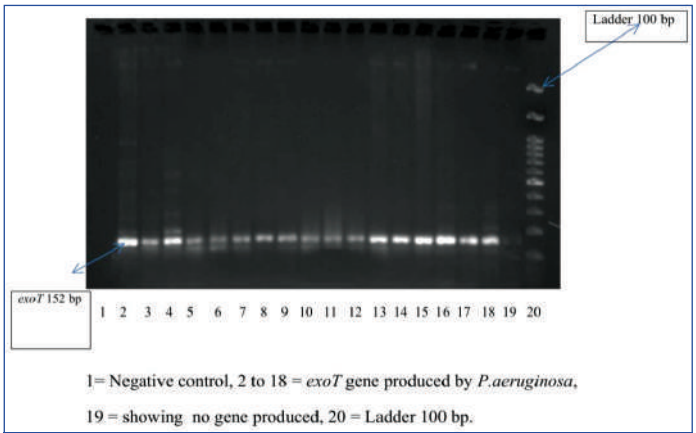
[Table/Fig-1]: The Primer sequence used for the detection of exoT genes.

For all PCRs, the DNA extracted from *P.aeruginosa* under study was used as templates. PCRs were carried out in 25 µL mixture containing 12.5 µL mastermix (Geneaid-Presto™Mini gDNA bacteria Kit), 1.5 µL forward primers, 1.5 µL reverse primers, 2.0 µL DNA template and 7.5 µL distilled water [Table/Fig-2].

Gene	Initial De-naturation	No.of Cycles	Denaturation in Each Cycle	Anneal-ing	Primer Extention	Final Extention
exoT	95ºC, 2 min	36	95ºC, 30 sec	58ºC,30 sec	72ºC, 30 sec	72ºC,5 min

[Table/Fig-2]: Polymerase Chain Reaction (PCR) conditions.

Gel electrophoresis: Electrophoresis was done using PCR products of *P.aeruginosa*.To prepare agarose gel, 2% agarose with ethidium bromide was used, as it shows clear resolution for small fragments. The quantity of agarose used for a gel preparation was around 250 mL. Images of PCR products were detected using transillumator by UV illumination is shown [Table/Fig-3]. PCR products were estimated by comparing with the 100bp DNA molecular size markers [17].



[Table/Fig-3]: Showing gel electrophoresis and amplification products of virulence gene (*exoT*) of *Pseudomonas aeruginosa* clinical isolates.

STATISTICAL ANALYSIS

The statistical analysis was done by using Chi-square test on line by graphpad prism 9.2.0.332. The calculated p-value was 0.0093 which is significant.

RESULTS

Out of 30 strains of *P.aeruginosa*, 20 (66.67%) were isolated from male and 10 (33.33%) from female patients. Most of the subjects belonged to 41-60 years of age group (46.67%). Out of 20 *exoT* genes in *P.aeruginosa*, 17/20 (85%) were detected from male and 3/10 (15%) from female patients [Table/Fig-4].

Age group (years)	Male	Female
0-20	00	00
21-40	02	01
41-60	12	02
61-80	03	00
Total	17	03

[Table/Fig-4]: Age and gender wise distribution of prevalence of *exoT* gene in *P.aeruginosa* (N=20).
Chi square 6.769, df-1, p-value=0.0093, p-value is statistically significant

The prevalence of *exoT* gene was 66.67%. Out of 30 strains of *P.aeruginosa* clinical isolates, 20 (66.67%) showed amplification of *exoT* gene and 10 (33.33%) strains showed negative amplification [Table/Fig-5].

S.N	Sample	Case	*exoT*	S.N	Sample	Case	*exoT*
1	Pus	Maxilla	+	16	Urine	UTI	+
2	Pus	CSOM	+	17	Pus	CSOM	+
3	Pus	NHTU	+	18	Pus	CSOM	-
4	Pus	Hydrocele	+	19	Urine	UTI	-
5	Urine	CUTI	+	20	Blood	Fever	-
6	Urine	UTI	+	21	Pus	Leg abscesses	+
7	Pus	Leg cellulitis	+	22	Pus	NF	-
8	Pus	DFU	+	23	Pus	NF	-
9	Fluid	COPD	+	24	Sputum	RTI	+
10	Pus	NF	+	25	Pus	TA	-
11	Pus	DFU	+	26	Pus	DFU	-
12	Pus	CSOM	+	27	Pus	DFU	-
13	Urine	UTI	+	28	Sputum	RTI	+
14	Sputum	RTI	+	29	Blood	Pneumonia	-
15	Sputum	RTI	+	30	Pus	DFU	-

[Table/Fig-5]: Distribution of *exoT* genes of 30 *Pseudomonas aeruginosa* clinical Isolates in respect to sites of Infections.
CSOM: Chronic suppurative otitis media; NHTU: Non healing tropic ulcer; UTI: Urinary tract infection; NF: Necrotizing fascitis; COPD: Chronic obstructive pulmonary disease; DFU: Diabetes foot ulcer; RTI: Respiratory tract infection; TA: Traumatic amputation; CAUTI: Catheter associated UTI

Out of 30 strains of *P.aeruginosa* 11/30 (61.11%) isolates from pus detected *exoT* gene followed by urine 4/5 (80%), sputum 4/4 (100%), body fluid 1/1 (100%) and blood 0/2 (0%) [Table/Fig-6].

Sr.No.	Source	*exoT* (%)
1	Pus	11(61.11)
2	Urine	4 (80)
3	Sputum	4 (100)
4	Blood	0 (0)
5	Body fluids	1 (100)
6	Total	20 (66.67)

[Table/Fig-6]: Showing distribution of *exoT* genes *Pseudomonas aeruginosa* Clinical Isolates (Pus n=18, Urine n=5, Sputum n=4, Blood n=2, Fluid n=1) in different samples, Total n=30).

DISCUSSION

P.aeruginosa is one of the major and well identified nosocomial pathogen. It has capability to survive and multiply with minimal nutrients. It can cause severe infection in hospitalised patients. *P.aeruginosa* is one of the most common co-infecting pathogen and exotoxin T is virulence factor that make *P.aeruginosa* more virulent for host cells. This descriptive research study was undertaken to detect *exoT* gene encoding exotoxin T in *P.aeruginosa* clinical isolates. T3SS is a basic and important weapon of *P.aeruginosa* and several other Gram negative

organisms for survival and causation of disease. The T3SS is a needle like sharp tiny machine that carry and deliver effector proteins (exotoxins) directly into targeted cells of the host to start disease. These delivered exotoxin precipitate and continue progress of infection by changing normal functions of target cells, such as constant movement of network of protein filaments and microtubules in the cytoplasm, reactions of cells to inflammatory stimuli, signalling pathways and secretory trafficking [18]. T3SS complex cellular nano machine is a key weapon of several pathogenic Gram negative bacteria which works in a systematic planned mode of action and can alter the target cell in number in irregular manner. T3SS has gradually developed because of the pressure of the survival within infected cells.

Virulence factors injected by T3SS into host cells play important role for *P.aeruginosa* to be more virulent [19,20]. The gene *exoT*, modify the actin cytoskeleton, inhibit migration and multiplication of cell. Exotoxin T prevents adhesion, phagocytosis, excessive multiplication and stop epithelial barrier that help *P.aeruginosa* to cause spread type of infections [21]. Gene *exoT* is an important virulence gene encoding exoenzyme T. Therefore, detection of *exoT* gene is important while determining pathogenicity of *P.aeruginosa* in different type of infections.

In this research study, authors aimed to determine the prevalence of *exoT* virulent gene in 30 strains of *P.aeruginosa* isolated from various clinical samples in a Tertiary Care Hospital. PCR and gel electrophoresis technique was used for the detection of *exoT* gene in *P.aeruginosa* under study. In this study, the prevalence of *exoT* gene was 66.67%. Out of 30 strains of *P.aeruginosa* clinical isolates from the different clinical conditions, 20 (66.67%) detected *exoT* gene in all spreading type of infections caused by *P.aeruginosa. P.aeruginosa* isolates from pus (61.11%), sputum (100%), urine (80%) and bodyfluids (100%) samples showed presence *exoT* gene. Out of 30, 10 (33.33%) strains were found to be negative for *exoT* gene.

In other similar study in southern India, the prevalence of *exoT* was recorded as 84% [13]. Many researches all over the world studied the prevalence of *exoT* genes as an epidemiological marker in pathogenic *P.aeruginosa* causing different type of infections. The prevalence of *exoT* genes has been found to be variable in *P. aeruginosa* isolates obtained from different infections in the world. Prevalence of *exoT* gene recorded in Iran was 36.27% [22] and in Egypt and Romania, prevalence of *exoT* in *P.aeruginosa* clinical isolates were recorded as 100% [12,23].

Role of *exoT* gene is crucial in the causation of spreading type infections. T3SS virulence factors are responsible for seriousness of the infections with raised death rate [24]. The proven role of *exoT* virulence genes in the pathogenicity of *P.aeruginosa* would help in understanding the prognosis of *Pseudomonas* infections and designing an effective vaccine against the pseudomonas infections to prevent them. This may help in epidemiological study, deciding the treatment course for the infections caused by *P.aeruginosa*. These findings may help in identifying virulent gene targets for immune intervention which could regulate the severity of the host response and its effect on impairment caused by *P.aeruginosa*.

The identification of virulent markers of pathogens for identification of acute and chronic infections at early stage remains a critical area and still need large research. Such type of research studies and findings facilitate the prevention of infections caused by bacteria and can be very useful to control the *Pseudomonas* infections.

Limitation(s)

All the *P.aeruginosa* strains under study were obtained from In Patient Department (IPD) only. Therefore, prevalence of *exoT* gene in *P.aeruginosa* could not be studied in Out Patient Department (OPD) patient. Larger sample size of both IPD and OPD patients would have provided better status of prevalence of *exoT* virulent gene marker as well as difference and significance.

CONCLUSION(S)

Gene *exoT* encoding ExotoxinT plays a very crucial role in the causation of disease. The proven role of *exoT* virulence genes in the pathogenicity of *P.aeruginosa* would help in understanding the prognosis of *Pseudomonas* infections and designing an effective vaccine against the *Pseudomonas* infections to prevent them. This may help in epidemiological study, deciding the treatment course for the infections caused by *P.aeruginosa*. In future trends in diagnostic microbiology, focus should be on development of rapid tests required for detection of virulence factors which are important epidemiological markers apart from identification and antimicrobial susceptibility tests.

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Original Article

Microbiology Section

Prevalence of *exoT* Gene in *Pseudomonas aeruginosa* Isolated from Various Clinical Samples: A Cross-sectional Study

JAGANNATH DNYANOBA ANDHALE[1], M ANJANEYA SWAMY[2], RN MISRA[3]

ABSTRACT

Introduction: *Pseudomonas aeruginosa (P.aeruginosa)* is one of the most frequently co-infecting bacteria reported. Development of drug resistance, biofilm formation, cell associated factors make the *P.aeruginosa* more virulent. Type III secretion system controls expression of genes. *P.aeruginosa* chromosome harbours *exoT, exoS, exoU*, and *exoY* virulent genes. Gene *exoT* plays an important role in causation of infection. The identification of virulent markers of pathogens for identification of acute and chronic infections at early stage remains a critical area and still need large research.

Aim: To study the prevalence of *exoT* gene encoding exotoxin T in *P.aeruginosa* from clinical samples.

Materials and Methods: A descriptive cross-sectional research was conducted during January 2015 to March 2016 at the Department of Microbiology in Dr. D.Y. Patil Medical College, Pimpri, Pune, Maharashtra, India. Various clinical samples were processed using standard laboratory methods. The statistical analysis was done by using Chi-square test. Strains of *P.aeruginosa* isolated from various clinical samples were identified using standard laboratory methods, and *exoT* gene was detected by Polymerase Chain Reaction (PCR) and gel electrophoresis technique.

Results: Out of 30 strains of *P. aeruginosa*, 20 (66.67%) were isolated from male and 10 (33.33%) from female patients. Most of them belonged to the age group 41-60 years (46.67%). The *exoT* gene occurred in 20/30 (66.67%) isolates of *P.aeruginosa*, while 10/30 (33.33 %) showed negative amplification results. Out of 20 *exoT* genes in *P.aeruginosa*, 17/20 (85%) were detected from male and 3/10 (15%) from female patients.

Conclusion: Gene *exoT* of *P. aeruginosa* plays the crucial role in causation of disease. It is concluded that *exoT* gene can be a notable virulent element expressed by 66.67% of *P.aeruginosa* clinical isolates. The proven role of *exoT* virulence gene in the pathogenicity of *P.aeruginosa* would help in understanding the prognosis of *Pseudomonas* infection and designing an effective treatment and vaccine against the *Pseudomonas* infections to prevent them.

Keywords: Exotoxin T, Gram negative bacteria, Polymerase chain reaction

INTRODUCTION

Pseudomonas aeruginosa (*P.aeruginosa*) is an actively motile, biofilm forming Gram negative human opportunistic pathogen. It exhibits multidrug resistance and is widely connected with hospital acquired infections [1]. They are resistant to multiple antibiotics due to acquired or inherent determinants. It can cause acute and chronic infections [2]. *P.aeruginosa* causes serious infections such as endocarditis, pneumonia, septicaemia, wound infections, cystitis [3], blood stream infections, urinary tract infection and surgical site infections [4]. Biofilm formation, development of drug resistance, various secreted toxins, proteases, pyocyanin, exotoxins and different cell associated factors make *P.aeruginosa* more virulent [5]. *P.aeruginosa* has the ability to colonise the respiratory tract and is one of the members of normal flora of nasopharynx [6]. *P.aeruginosa* infections are more frequently observed in cystic fibrosis and in weakened immune patients. In a recent study, researcher documented *P.aeruginosa* as a common co-infecting pathogen in patients [7].

P.aeruginosa continues to exist in different environmental states because of different virulence factors and metabolic properties [8]. Toxins are released by passive transport from the cells secreted by one of the three secretion systems namely, Type I Secretion System (T1SS), Type II Secretion System (T2SS) and Type III Secretion System (T3SS). Type III secretary system plays a key role in determining virulence [9]. The Gram negative bacteria have a complex T3SS which is an essential machinery of *P.aeruginosa* to inject exotoxin T (*exoT*), exotoxin S (*exoS*) and exotoxin U (*exoU*) virulence factors directly into host cells [10] and can evoke different responses from the host suitable for spreading of infection [11]. Exotoxin produced during release and escape of pathogen mainly attacks host kinases and is responsible for adhesion, phagocytosis, with spreading type of infection from lung to the liver in experimental animal [9,12].

Very few researchers in India have focussed on *exoT* gene encoding exotoxin T, virulence factor of T3SS of *P.aeruginosa*. In previous similar study in India, the researcher documented 84% prevalence of *exoT* gene in *P.aeruginosa* strains obtained from various clinical samples [13]. Keeping these facts in mind, this study was designed to study the prevalence of *exoT* gene in *P.aeruginosa* obtained from different clinical samples in a tertiary care hospital.

MATERIALS AND METHODS

Present descriptive cross-sectional research was conducted during January 2015 to March 2016 at the Department of Microbiology in Dr DY Patil Medical College, Hospital and Research Centre, Pimpri, Pune, Maharashtra, India. Different clinical samples (pus, urine, sputum, blood and body fluids) were received from various wards irrespective of age and gender for routine culture and sensitivity tests. The isolates were processed and confirmed *P.aeruginosa* strains were screened for detection of *exoT* gene by PCR and gel electrophoresis techniques. The study was done after approval from Institutional Ethical Committee of Dr DY Patil Medical College, Hospital and Research Centre, Pimpri, Pune, Maharashtra, India.

Inclusion criteria: Samples showing *P.aeruginosa* as single causative agent of infection were included in this study. Total 30 strains were included in this research study.

Exclusion criteria: Samples showing mixed growth were excluded from this study.

Isolation and identification of *P.aeruginosa*: All clinical samples were inoculated onto MacConkey agar, Nutrient agar and Blood agar plates. Inoculated plates were incubated at 37ºC for 24 hours. After obtaining the growth, *P.aeruginosa* was identified by studying colony characteristics, production of pyocyanin pigments, grape like odour, growth at 42ºC, motility test, Gram staining, and positive oxidase, citrate, and catalase tests [14].

Extraction of DNA: For the detection of *exoT* gene, chromosomal DNA from the 30 clinical strains of *P.aeruginosa* clinical isolates was extracted and DNA purification was carried out using a commercial available DNA extraction kit (Ganeaid-Presto™ Mini gDNA bacteria Kit) as indicated by manufacturer's instructions.

Polymerase Chain Reaction (PCR): The sequences of the primers used in PCR for detection of *exoT* gene and its molecular weight are shown in [Table/Fig-1] [15,16].

Gene	Primer sequence	Amplicon size	Length (bp)
exoT	Forward 5'-AATCGCCGTCCAACTGCATGCG-3'	22	152
	Reverse 5'-TGTTCGCCGAGGTACTGCTC-3'	20	

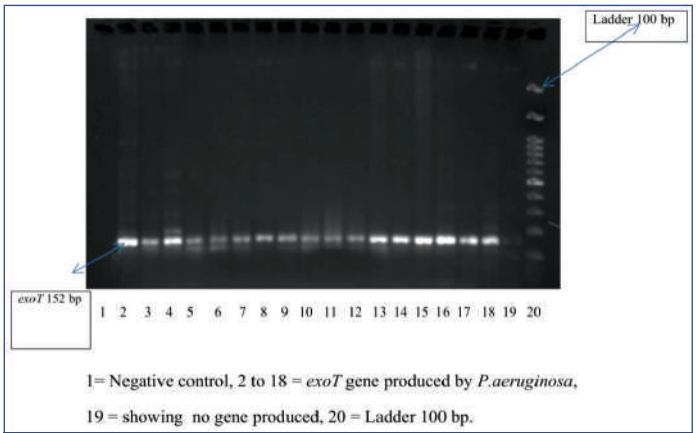
[Table/Fig-1]: The Primer sequence used for the detection of exoT genes.

For all PCRs, the DNA extracted from *P.aeruginosa* under study was used as templates. PCRs were carried out in 25 µL mixture containing 12.5 µL mastermix (Geneaid-Presto™Mini gDNA bacteria Kit), 1.5 µL forward primers, 1.5 µL reverse primers, 2.0 µL DNA template and 7.5 µL distilled water [Table/Fig-2].

Gene	Initial De-naturation	No.of Cycles	Denaturation in Each Cycle	Anneal-ing	Primer Extention	Final Extention
exoT	95ºC, 2 min	36	95ºC, 30 sec	58ºC,30 sec	72ºC, 30 sec	72ºC,5 min

[Table/Fig-2]: Polymerase Chain Reaction (PCR) conditions.

Gel electrophoresis: Electrophoresis was done using PCR products of *P.aeruginosa*.To prepare agarose gel, 2% agarose with ethidium bromide was used, as it shows clear resolution for small fragments. The quantity of agarose used for a gel preparation was around 250 mL. Images of PCR products were detected using transillumator by UV illumination is shown [Table/Fig-3]. PCR products were estimated by comparing with the 100bp DNA molecular size markers [17].



[Table/Fig-3]: Showing gel electrophoresis and amplification products of virulence gene (*exoT*) of *Pseudomonas aeruginosa* clinical isolates.

STATISTICAL ANALYSIS

The statistical analysis was done by using Chi-square test on line by graphpad prism 9.2.0.332. The calculated p-value was 0.0093 which is significant.

RESULTS

Out of 30 strains of *P.aeruginosa*, 20 (66.67%) were isolated from male and 10 (33.33%) from female patients. Most of the subjects belonged to 41-60 years of age group (46.67%). Out of 20 *exoT* genes in *P.aeruginosa*, 17/20 (85%) were detected from male and 3/10 (15%) from female patients [Table/Fig-4].

Age group (years)	Male	Female
0-20	00	00
21-40	02	01
41-60	12	02
61-80	03	00
Total	17	03

[Table/Fig-4]: Age and gender wise distribution of prevalence of *exoT* gene in *P.aeruginosa* (N=20).
Chi square 6.769, df-1, p-value=0.0093, p-value is statistically significant

The prevalence of *exoT* gene was 66.67%. Out of 30 strains of *P.aeruginosa* clinical isolates, 20 (66.67%) showed amplification of *exoT* gene and 10 (33.33%) strains showed negative amplification [Table/Fig-5].

S.N	Sample	Case	*exoT*	S.N	Sample	Case	*exoT*
1	Pus	Maxilla	+	16	Urine	UTI	+
2	Pus	CSOM	+	17	Pus	CSOM	+
3	Pus	NHTU	+	18	Pus	CSOM	-
4	Pus	Hydrocele	+	19	Urine	UTI	-
5	Urine	CUTI	+	20	Blood	Fever	-
6	Urine	UTI	+	21	Pus	Leg abscesses	+
7	Pus	Leg cellulitis	+	22	Pus	NF	-
8	Pus	DFU	+	23	Pus	NF	-
9	Fluid	COPD	+	24	Sputum	RTI	+
10	Pus	NF	+	25	Pus	TA	-
11	Pus	DFU	+	26	Pus	DFU	-
12	Pus	CSOM	+	27	Pus	DFU	-
13	Urine	UTI	+	28	Sputum	RTI	+
14	Sputum	RTI	+	29	Blood	Pneumonia	-
15	Sputum	RTI	+	30	Pus	DFU	-

[Table/Fig-5]: Distribution of *exoT* genes of 30 *Pseudomonas aeruginosa* clinical Isolates in respect to sites of Infections.
CSOM: Chronic suppurative otitis media; NHTU: Non healing tropic ulcer; UTI: Urinary tract infection; NF: Necrotizing fascitis; COPD: Chronic obstructive pulmonary disease; DFU: Diabetes foot ulcer; RTI: Respiratory tract infection; TA: Traumatic amputation; CAUTI: Catheter associated UTI

Out of 30 strains of *P.aeruginosa* 11/30 (61.11%) isolates from pus detected *exoT* gene followed by urine 4/5 (80%), sputum 4/4 (100%), body fluid 1/1 (100%) and blood 0/2 (0%) [Table/Fig-6].

Sr.No.	Source	*exoT* (%)
1	Pus	11(61.11)
2	Urine	4 (80)
3	Sputum	4 (100)
4	Blood	0 (0)
5	Body fluids	1 (100)
6	Total	20 (66.67)

[Table/Fig-6]: Showing distribution of *exoT* genes *Pseudomonas aeruginosa* Clinical Isolates (Pus n=18, Urine n=5, Sputum n=4, Blood n=2, Fluid n=1) in different samples, Total n=30).

DISCUSSION

P.aeruginosa is one of the major and well identified nosocomial pathogen. It has capability to survive and multiply with minimal nutrients. It can cause severe infection in hospitalised patients. *P.aeruginosa* is one of the most common co-infecting pathogen and exotoxin T is virulence factor that make *P.aeruginosa* more virulent for host cells. This descriptive research study was undertaken to detect *exoT* gene encoding exotoxin T in *P.aeruginosa* clinical isolates. T3SS is a basic and important weapon of *P.aeruginosa* and several other Gram negative

organisms for survival and causation of disease. The T3SS is a needle like sharp tiny machine that carry and deliver effector proteins (exotoxins) directly into targeted cells of the host to start disease. These delivered exotoxin precipitate and continue progress of infection by changing normal functions of target cells, such as constant movement of network of protein filaments and microtubules in the cytoplasm, reactions of cells to inflammatory stimuli, signalling pathways and secretory trafficking [18]. T3SS complex cellular nano machine is a key weapon of several pathogenic Gram negative bacteria which works in a systematic planned mode of action and can alter the target cell in number in irregular manner. T3SS has gradually developed because of the pressure of the survival within infected cells.

Virulence factors injected by T3SS into host cells play important role for *P.aeruginosa* to be more virulent [19,20]. The gene *exoT*, modify the actin cytoskeleton, inhibit migration and multiplication of cell. Exotoxin T prevents adhesion, phagocytosis, excessive multiplication and stop epithelial barrier that help *P.aeruginosa* to cause spread type of infections [21]. Gene *exoT* is an important virulence gene encoding exoenzyme T. Therefore, detection of *exoT* gene is important while determining pathogenicity of *P.aeruginosa* in different type of infections.

In this research study, authors aimed to determine the prevalence of *exoT* virulent gene in 30 strains of *P.aeruginosa* isolated from various clinical samples in a Tertiary Care Hospital. PCR and gel electrophoresis technique was used for the detection of *exoT* gene in *P.aeruginosa* under study. In this study, the prevalence of *exoT* gene was 66.67%. Out of 30 strains of *P.aeruginosa* clinical isolates from the different clinical conditions, 20 (66.67%) detected *exoT* gene in all spreading type of infections caused by *P.aeruginosa. P.aeruginosa* isolates from pus (61.11%), sputum (100%), urine (80%) and bodyfluids (100%) samples showed presence *exoT* gene. Out of 30, 10 (33.33%) strains were found to be negative for *exoT* gene.

In other similar study in southern India, the prevalence of *exoT* was recorded as 84% [13]. Many researches all over the world studied the prevalence of *exoT* genes as an epidemiological marker in pathogenic *P.aeruginosa* causing different type of infections. The prevalence of *exoT* genes has been found to be variable in *P. aeruginosa* isolates obtained from different infections in the world. Prevalence of *exoT* gene recorded in Iran was 36.27% [22] and in Egypt and Romania, prevalence of *exoT* in *P.aeruginosa* clinical isolates were recorded as 100% [12,23].

Role of *exoT* gene is crucial in the causation of spreading type infections. T3SS virulence factors are responsible for seriousness of the infections with raised death rate [24]. The proven role of *exoT* virulence genes in the pathogenicity of *P.aeruginosa* would help in understanding the prognosis of *Pseudomonas* infections and designing an effective vaccine against the pseudomonas infections to prevent them. This may help in epidemiological study, deciding the treatment course for the infections caused by *P.aeruginosa*. These findings may help in identifying virulent gene targets for immune intervention which could regulate the severity of the host response and its effect on impairment caused by *P.aeruginosa*.

The identification of virulent markers of pathogens for identification of acute and chronic infections at early stage remains a critical area and still need large research. Such type of research studies and findings facilitate the prevention of infections caused by bacteria and can be very useful to control the *Pseudomonas* infections.

Limitation(s)

All the *P.aeruginosa* strains under study were obtained from In Patient Department (IPD) only. Therefore, prevalence of *exoT* gene in *P.aeruginosa* could not be studied in Out Patient Department (OPD) patient. Larger sample size of both IPD and OPD patients would have provided better status of prevalence of *exoT* virulent gene marker as well as difference and significance.

CONCLUSION(S)

Gene *exoT* encoding ExotoxinT plays a very crucial role in the causation of disease. The proven role of *exoT* virulence genes in the pathogenicity of *P.aeruginosa* would help in understanding the prognosis of *Pseudomonas* infections and designing an effective vaccine against the *Pseudomonas* infections to prevent them. This may help in epidemiological study, deciding the treatment course for the infections caused by *P.aeruginosa*. In future trends in diagnostic microbiology, focus should be on development of rapid tests required for detection of virulence factors which are important epidemiological markers apart from identification and antimicrobial susceptibility tests.

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BURDEN OF ANEMIA AMONG PREGNANT WOMEN IN CORRELATION WITH BIRTH INTERVAL

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ABSTRACT

Background: Anemia reported during pregnancy is a burdensome public health problem all around the world, problem is vast among developing¬ countries. Women during pregnancy are more prone for developing anemia not only because of increased iron demand and its poor bioavailability along with hemodilution physiological increase in plasma volume (physiological increase in plasma volume) which acts synergistically. **Material & Methods:** In the present prospective observational study 400 Pregnant women were enrolled from outdoor, antenatal clinic and from ward by simple random sampling. Clearance from Institutional Ethics Committee was taken before start of study. Written informed consent was taken from each study participant. **Results:** In the present study out of total primigravida 118 (54.6%) had no anemia, 72 (33.3%) females had mild anemia, 26 (12%) females had moderate anemia and there were no cases of severe anemia in this group. Among the group of birth interval of less than two years, there were no cases of no anemia, 42 (45.6%) of pregnant women had mild anemia, 38 (41.4%) of pregnant women had moderate anemia and 12 (13%) of pregnant women had severe anemia. Among the group of birth interval of more than two years, there were no cases of no anemia, 32 (34.8%) of pregnant women had mild anemia, 58 (63.1%) of pregnant women had moderate anemia and 2 (2.2%) of pregnant women had severe anemia. These differences in burden of anemia was statistically highly significant (p value < 0.001). **Conclusions:** The magnitude and burden of anemia is very high and the population living among rural areas were at high risk of developing anemia. We found statistically significant correlation of anemia with birth interval and reported that the burden of severe anemia was higher among pregnant women who had birth interval of less than two years.

Key words: Anemia, Pregnancy, Birth interval.

INTRODUCTION

The word "Anemia" is a Greek word which means an- 'not', haima- 'blood', refers to 'no blood'. Anemia itself is not a disease but a precursor and predictive sign of the presence of disease. Anemia reported during pregnancy is a burdensome public health problem all around the world, problem is vast among developing¬ countries. Women during pregnancy are more prone for developing anemia not only because of increased iron demand and its poor bioavailability along with hemodilution physiological increase in plasma volume (physiological increase in plasma volume) which acts synergistically (1).

Anemia is among the strongest associated factor which decide the fate and outcome of pregnancy. Since anemia is act as silent epidemic, it is as harmful and compelling as infectious diseases epidemics. It was reported that anemia contributes for more than 20% of maternal deaths worldwide (2). Among these maternal deaths more than 50% of the maternal deaths occur among South Asian countries. India contributes for 80% of maternal death occurred among South Asian countries (3). There are several risk factors associated with morbidity and mortality among pregnant women such as postpartum hemorrhage, abortion, , low birth weight baby, still birth, high perinatal mortality, undercurrent infection, infant mortality and maternal mortality.(4)

Regarding this context of combating anaemia during pregnancy, with far reaching benefits in terms of safe motherhood and healthier future generations, an attempt has been made to know the magnitude of anaemia among urban and rural pregnant women along with to study the relationship between anaemia and contributory factor of birth interval to meet the challenge of protecting maternal and neonatal health.

Material & Methods

The present prospective study was conducted at department of obstetrics and gynaecology of Geetanjali Medical college and hospital, Udaipur. The study duration was of one year from June 2015 to July 2016. A sample size of 400 was calculated at 95% confidence interval at 10% acceptable margin of error by epi info software version 7.2. Pregnant women were enrolled from outdoor, antenatal clinic and from ward by simple random sampling. Clearance from Institutional Ethics Committee was taken before start of study. Written informed consent was taken from each study participant.

The data were collected by predesigned, multiple response type of questionnaire from each pregnant woman (above 18 years of age and beyond 12 weeks of amenorrhea) after taking the written consent. The questionnaire was address on the topics of anaemia and our study variables birth intervals and geographical living areas. Data analysis was carried out using SPSS v22. All tests were done at alpha (level significance) of 5%; means a significant association present if p value was less than 0.05.

RESULT

In the present study, we enrolled 400 pregnant women who were classified in two major groups according to the residential area. Women who had been pregnant first time and were enrolled for the study designated in a group of birth interval zero. We classified other two groups as birth interval less than two years and birth interval of more than two years between two consecutive pregnancies. There were 216 females in the group of birth interval zero, 92 females in the birth interval of less than two years and 92 females in the group of birth interval of more than two years. Among primigravida 118 (54.6%) had no anaemia, 72 (33.3%) females had mild anemia, 26 (12%) females had moderate anemia and there were no cases of severe anemia in this group. Among the group of birth interval of less than two years, there were no cases of no anemia, 42 (45.6%) of pregnant women had mild anemia, 38 (41.4%) of pregnant women had moderate anemia and 12 (13%) of pregnant women had severe anemia. Among the group of birth interval of more than two years, there were no cases of no anemia, 32 (34.8%) of pregnant women had mild anemia, 58 (63.1%) of pregnant women had moderate anemia and 2 (2.2%) of pregnant women had severe anemia. These differences in burden of anemia were statistically highly significant (p value < 0.001). [Table 1]

Table 1: Relationship between birth interval and severity of anaemia

Birth interval (years)	Severity				
	No anaemia	Mild anaemia	Moderate anaemia	Severe anaemia	Total
None	118 (54.6%)	72 (33.3%)	26 (12%)	0 (0%)	216 (100%)
Less than 2	0 (0%)	42 (45.6%)	38 (41.4%)	12 (13%)	92 (100%)
More than 2	0 (0%)	32 (34.8%)	58 (63.1%)	2 (2.2%)	92 (100%)
Total	118 (29.5%)	146 (36.5%)	122 (30.5%)	14 (3.5%)	400 (100%)
	$\chi^2 = 97.434$	df= 6	P< 0.001		

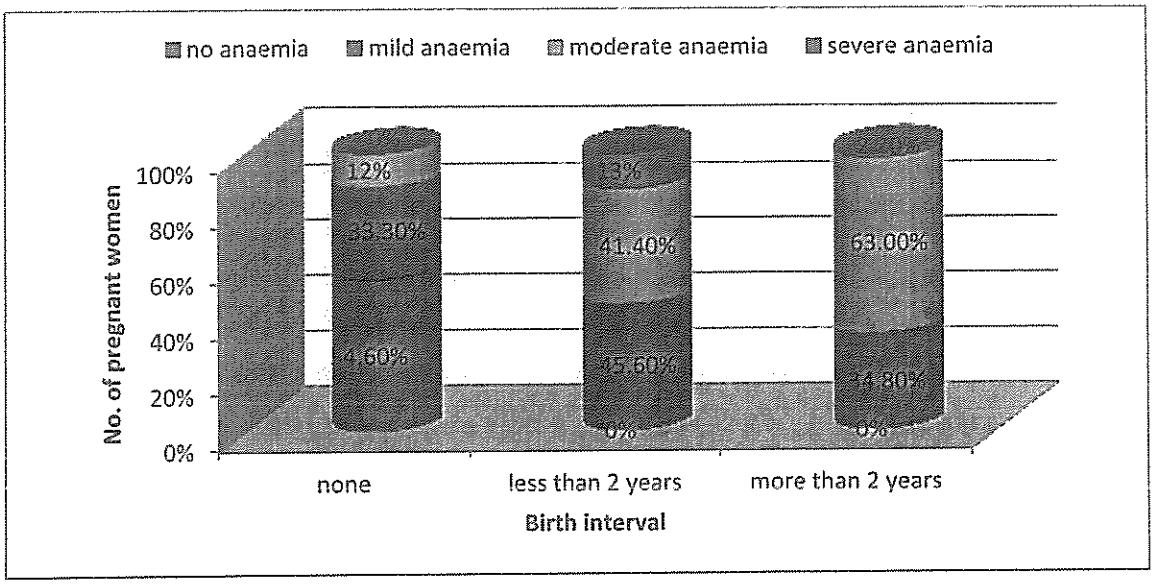
In the present study, among primigravida 118 (54.6%) who had no anaemia 74 were from urban area and 44 from rural area. Among 72 (33.3%) primigravida who had mild anemia 38 were from urban area and 34 from rural area and 26 (12%) primigravida who had moderate anemia 12 were from urban area and 14 from rural area. In the group of birth interval of less than two years, out of 42 (45.6%) of pregnant women who had mild anemia 22 were from urban area and 20 from rural area. Out of 38 (41.4%) of pregnant women who had moderate anemia 10 were from urban area and 28 from rural area. Out of 12 (13%) of pregnant women who had severe anemia were from rural areas. In the group of birth interval of more than two years, out of 32 (34.8%) of pregnant women had mild anemia 10 were from urban area and 22 from rural area. Out of 58 (63.1%) of pregnant women had moderate anemia 32 were from urban area and 26 from rural area. Out of 2 (2.2%) of pregnant women who had severe anemia both were from urban areas. This difference in burden of anemia was statistically highly significant (p value < 0.001). [Table2]

Table 2: Relationship between birth interval and severity of anaemia among urban and rural pregnant women

Birth interval (years)	Severity								
	No anaemia		Mild anaemia		Moderate anaemia		Severe anaemia		Total
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural	
None	74	44	38	34	12	14	0	0	216
<2	0	0	22	20	10	28	0	12	92
>2	0	0	10	22	32	26	2	0	92
Total	74	44	70	76	54	68	2	12	400

Urban ($\chi^2 = 41.750$, $p < 0.001$); Rural ($\chi^2 = 49.458$, $p < 0.001$)

Fig 1: Relationship between birth interval and severity of anemia



In the present study, among primigravida 118 (54.6%) who had no anaemia 74 were from urban area and 44 from rural area. Among 72 (33.3%) primigravida who had mild anemia 38 were from urban area and 34 from rural area and 26 (12%) primigravida who had moderate anemia 12 were from urban area and 14 from rural area. In the group of birth interval of less than two years, out of 42 (45.6%) of pregnant women who had mild anemia 22 were from urban area and 20 from rural area. Out of 38 (41.4%) of pregnant women who had moderate anemia 10 were from urban area and 28 from rural area. Out of 12 (13%) of pregnant women who had severe anemia were from rural areas. In the group of birth interval of more than two years, out of 32 (34.8%) of pregnant women had mild anemia 10 were from urban area and 22 from rural area. Out of 58 (63.1%) of pregnant women had moderate anemia 32 were from urban area and 26 from rural area. Out of 2 (2.2%) of pregnant women who had severe anemia both were from urban areas. This difference in burden of anemia was statistically highly significant (p value < 0.001). [Table2]

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<2	0	0	22	20	10	28	0	12	92
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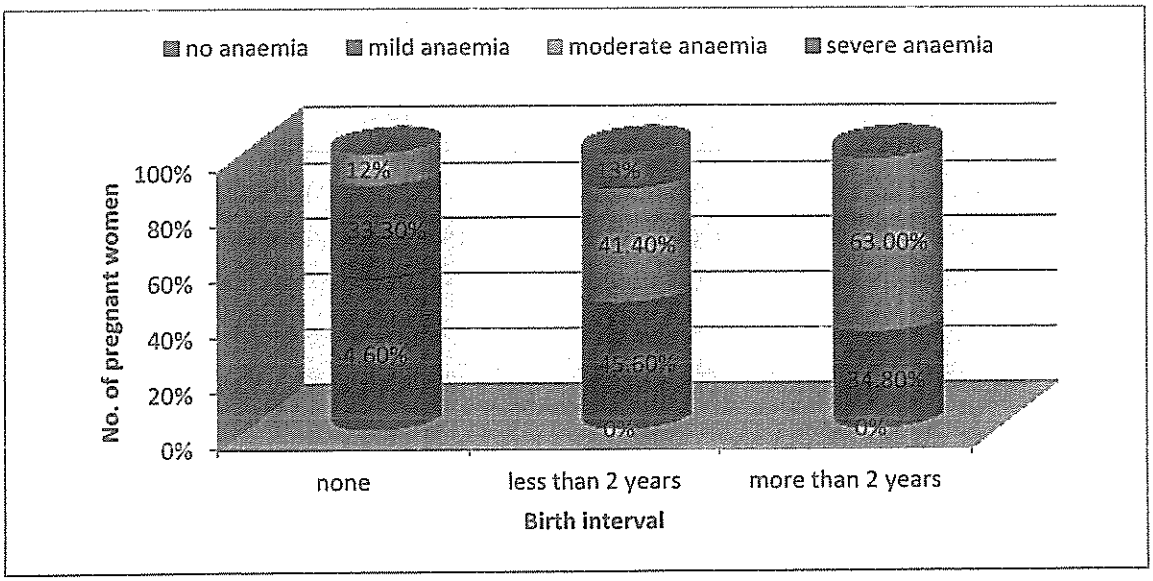
Urban ($\chi^2 = 41.750$, $p < 0.001$); Rural ($\chi^2 = 49.458$, $p < 0.001$)

Fig 1: Relationship between birth interval and severity of anemia



DISCUSSION

The present prospective study was conducted at the field practicing areas under department of obstetrics and gynaecology of our tertiary care hospital. The aim of present study was assessing the magnitude and burden of anaemia along in the correlation to birth intervals among two consecutive pregnancies. In the present study we enrolled 400 pregnant women from different urban and rural areas and further subdivided them into four subgroups of no anemia, mild anemia, moderate anemia and severe anemia.

In the present study the age of enrolled pregnant women was ranged from 19 to 38 years. The mean age of the enrolled pregnant women was 23.88 ± 3.66 years. There were no pregnant women in the present study who aged less than 19 years of age. In the present study the overall burden of anaemia was found to be 69.5% which was comparatively more among rural areas (76%) in comparison to the urban areas (63%) and difference in the burden of anaemia was statically significant ($p < 0.05$). The odds of anaemia were 1.4 times higher among rural areas than urban pregnant mothers. The results of present study were comparable and nearly similar to the results of surveys of India conducted by National Family Health Survey (NFHS-3) and another survey conducted by District Level Household Survey (DLHS-3). (5)(6) The results of present study were comparable and nearly similar to the study conducted by Toral M. Goswami et al among pregnant women in 2014 on anaemia status during pregnancy and effects of anemia on perinatal outcome.(7)

In the present study, there were 216 females in the group of birth interval zero, 92 females in the birth interval of less than two years and 92 females in the group of birth interval of more than two years. Among primigravida 118 (54.6%) had no anaemia, 72 (33.3%) females had mild anemia, 26 (12%) females had moderate anemia and there were no cases of severe anemia in this group. Among the group of birth interval of less than two years, there were no cases of no anemia, 42 (45.6%) of pregnant women had mild anemia, 38 (41.4%) of pregnant women had moderate anemia and 12 (13%) of pregnant women had severe anemia. Among the group of birth interval of more than two years, there were no cases of no anemia, 32 (34.8%) of pregnant women had mild anemia, 58 (63.1%) of pregnant women had moderate anemia and 2 (2.2%) of pregnant women had severe anemia. This difference in burden of anemia was statistically highly significant (p value < 0.001). A study by Abbasi RM et al showed found similar results with anemia and birth interval. (8)

In the present study, among primigravida 118 (54.6%) who had no anaemia 74 were from urban area and 44 from rural area. Among 72 (33.3%) primigravida who had mild anemia 38 were from urban area and 34 from rural area and 26 (12%) primigravida who had moderate anemia 12 were from urban area and 14 from rural area. In the group of birth interval of less than two years, out of 42 (45.6%) of pregnant women who had mild anemia 22 were from urban area and 20 from rural area. Out of 38 (41.4%) of pregnant women who had moderate anemia 10 were from urban area and 28 from rural area. Out of 12 (13%) of pregnant women who had severe anemia were from rural areas. In the group of birth interval of more than two years, out of 32 (34.8%) of pregnant women had mild anemia 10 were from urban area and 22 from rural area. Out of 58 (63.1%) of pregnant women had moderate anemia 32 were from urban area and 26 from rural area. Out of 2 (2.2%) of pregnant women who had severe anemia both were from urban areas. This difference in burden of anemia was statistically highly significant (p value < 0.001). Similar results were reported in a study by Vijay Kumar et al on s anaemia in pregnant women and found significant association of anaemia ($p < 0.05$) was found with birth interval. (9)

CONCLUSION

We concluded from the present study that the magnitude and burden of anemia is very high and the population living among rural areas were at high risk of developing anemia. We found statistically significant correlation of anemia with birth interval and reported that the burden of severe anemia was higher among pregnant women who had birth interval of less than two years.

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Original Research Article

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BURDEN OF ANEMIA AMONG PREGNANT WOMEN IN CORRELATION WITH ABORTION STATUS

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ABSTRACT

Background: Anemia itself is not a disease but a precursor and predictive sign of the presence of disease. Anemia reported during pregnancy is a burdensome public health problem all around the world; problem is vast among developing countries. Women during pregnancy are more prone for developing anemia not only because of increased iron demand and its poor bioavailability along with hemodilution. **Material & Methods:** In the present prospective observational study 400 Pregnant women were enrolled from outdoor, antenatal clinic and from ward by simple random sampling. Clearance from Institutional Ethics Committee was taken before start of study. Written informed consent was taken from each study participant. **Results:** Among pregnant women with nil past abortions 108 (29.7%) had no anaemia, 140 (38.5%) females had mild anemia, 106 (29.1%) females had moderate anemia and 10 (2.7%) had severe anemia in this group. Among pregnant women with 1 abortions 10 (35.7%) had no anaemia, 6 (21.4%) females had mild anemia, 12 (42.9%) females had moderate anemia and there was no cases of severe anemia in this group. Among the group of pregnant women with 2 abortions, 4 (66.7%) of pregnant women had moderate anemia and 2 (33.3%) of pregnant women had severe anemia. Among the group of pregnant women with >2 abortions, 2 (100%) of pregnant women had severe anemia. (p value < 0.001) **Conclusions:** The magnitude and burden of anemia is very high and the population living among urban and rural areas both was at higher risk of developing anemia. We found statistically significant correlation of anemia with increasing number of abortions.

Key words: Anemia, Pregnancy, Abortion status.

INTRODUCTION

Anemia is among the strongest associated factor which decide the fate and outcome of pregnancy. Since anemia is act as silent epidemic, it is as harmful and compelling as infectious diseases epidemics. It was reported that anemia contributes for more than 20% of maternal deaths worldwide **(1)**. The word "Anemia" is a Greek word which means an- 'not', haima- 'blood', refers to 'no blood'. Anemia itself is not a disease but a precursor and predictive sign of the presence of disease.

Anemia reported during pregnancy is a burdensome public health problem all around the world; problem is vast among developing countries. Women during pregnancy are more prone for developing anemia not only because of increased iron demand and its poor bioavailability along with hemodilution physiological increase in plasma volume (physiological increase in plasma volume) which acts synergistically **(2)**. Among these maternal deaths more than 50% of the maternal deaths occur among South Asian countries. India

contributes for 80% of maternal death occurred among South Asian countries (3).

There are several risk factors associated with morbidity and mortality among pregnant women such as postpartum hemorrhage, abortion, , low birth weight baby, still birth, high perinatal mortality, undercurrent infection, infant mortality and maternal mortality (4). Regarding this context of combating anaemia during pregnancy, with far reaching benefits in terms of safe motherhood and healthier future generations, an attempt has been made to know the magnitude of anaemia among urban and rural pregnant women along with to study the relationship between anaemia and contributory factor of abortion status to meet the challenge of protecting maternal and neonatal health.

MATERIAL & METHODS

The present prospective study was conducted at department of obstetrics and gynaecology of Geetanjali Medical College and hospital, Udaipur. The study duration was of one year from June 2015 to July 2016. A sample size of 400 was calculated at 95% confidence interval at 10% acceptable margin of error by epi info software version 7.2. Pregnant women were enrolled from outdoor, antenatal clinic and from ward by simple random sampling. Clearance from Institutional Ethics Committee was taken before start of study. Written informed consent was taken from each study participant.

The data were collected by predesigned, multiple response type of questionnaire from each pregnant woman (above 18 years of age and beyond 12 weeks of amenorrhea) after taking the written consent. The questionnaire was address on the topics of anaemia and our study variables abortions status and geographical living areas. Data analysis was carried out using SPSS v22. All tests were done at alpha (level significance) of 5%; means a significant association present if p value was less than 0.05.

RESULT

In the present study we enrolled 400 pregnant women who were classified in two major groups according to the residential area. Women who never had abortions were enrolled in a group of abortion status zero. We classified other three groups further as abortion status one, two and more than two. There were 364 females in the group of abortion status zero, 28 females in the abortion status one, 6 females in the abortion status two and 2 females in the group abortion status of more than two. Among pregnant women with nil past abortions 108 (29.7%) had no anaemia, 140 (38.5%) females had mild anemia, 106 (29.1%) females had moderate anemia and 10 (2.7%) had severe anemia in this group. Among pregnant women with one past abortions 10 (35.7%) had no anaemia, 6 (21.4%) females had mild anemia, 12 (42.9%) females had moderate anemia and there was no cases of severe anemia in this group.

Among the group of pregnant women with two past abortions, there were no cases of no anemia and mild anemia, 4 (66.7%) of pregnant women had moderate anemia and 2 (33.3%) of pregnant women had severe anemia. Among the group of pregnant women with more than two past abortions, there were no cases of no anemia, mild anemia and moderate anemia and 2 (100%) of pregnant women had severe anemia. These differences in burden of anemia was statistically highly significant (p value < 0.001). [Table 1]

Table 1: Relationship between abortions and severity of anaemia

Abortions	Severity				
	No anaemia	Mild anaemia	Moderate anaemia	Severe anaemia	Total
Nil	108 (29.7%)	140 (38.5%)	106 (29.1%)	10 (2.7%)	364 (100%)
1	10 (35.7%)	6 (21.4%)	12 (42.9%)	0 (0%)	28 (100%)
2	0 (0%)	0 (0%)	4 (66.7%)	2 (33.3%)	6 (100%)
More than 2	0(0%)	0 (0%)	0(0%)	2 (100%)	2 (100%)
Total	118 (29.5%)	146 (36.5%)	122 (30.5%)	14 (3.5%)	400 (100%)
$\chi^2 = 41.314$	df= 9	P< 0.001			

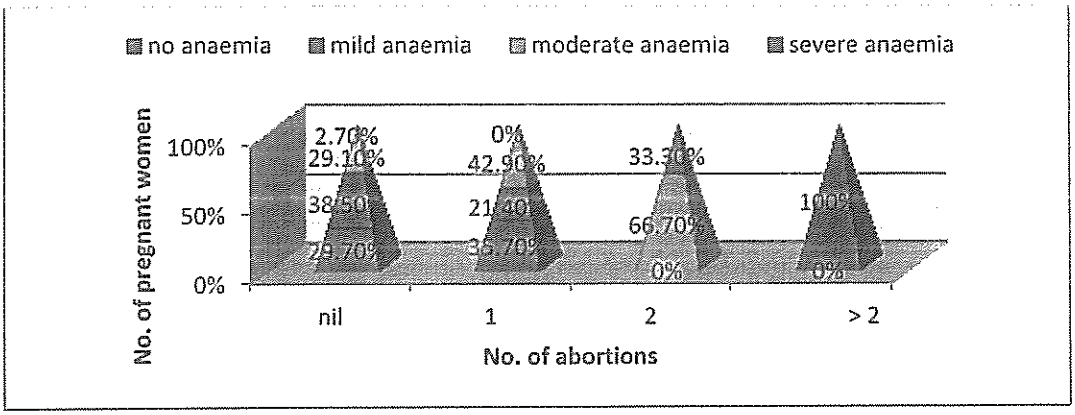
In the present study Among pregnant women with nil past abortions 108 (29.7%) had no anaemia 68 were from urban area and 40 from rural area. Out of 140 (38.5%) females had mild anemia 66 were from urban area and 74 from rural area. Out of 106 (29.1%) females had moderate anemia 44 were from urban area and 62 from rural area and out 10 (2.7%) who had severe anemia in this group all belong to rural areas. Among pregnant women with one past abortions 10 (35.7%) had no anaemia 6 were from urban area and 4 from rural area. Out of 6 (21.4%) females who had mild anemia 4 were from urban area and 2 from rural area. Out of 12 (42.9%) females who had moderate anemia 6 were from urban area and 6 from rural area. Among the group of pregnant women with two past abortions, all 4 (66.7%) of pregnant women who had moderate anemia were from urban areas and 2 (33.3%) pregnant women who had severe anemia were from rural areas. Among the group of pregnant women with more than two past abortions, both the 2 pregnant women who had severe anemia were belong to urban areas. These differences in burden of anemia was statistically significant (p value < 0.05). [Table 2]

Table 2: Relationship between abortions and severity of anaemia among urban and rural pregnant women

Abortion	Severity								
	No anaemia		Mild anaemia		Moderate anaemia		Severe anaemia		Total
	Urban	Rural	Urban	Rural	Urban	Rural	Urban	Rural	
Nil	68	40	66	74	44	62	0	10	364
1	6	4	4	2	6	6	0	0	28
2	0	0	0	0	4	0	0	2	6
>2	0	0	0	0	0	0	2	0	2
Total	74	44	70	76	54	68	2	12	400

Urban ($\chi^2 = 106.249$, $p < 0.001$); Rural ($\chi^2 = 17.708$, $p = 0.007$)

Fig. 1: Relationship between no. of abortions and severity of anaemia



DISCUSSION

The present prospective study was conducted at the field practicing areas under department of obstetrics and gynecology of our tertiary care hospital. The aim of present study was assessing the magnitude and burden of anaemia along in the correlation to birth intervals among two consecutive pregnancies. In the present study we enrolled 400 pregnant women from different urban and rural areas and further subdivided them into four subgroups of no anemia, mild anemia, moderate anemia and severe anemia. In the present study the age of enrolled pregnant women was ranged from 19 to 38 years. The mean age of the enrolled pregnant women was 23.88 ± 3.66 years. There were no pregnant women in the present study who aged less than 19 years of age.

In the present study the overall burden of anaemia was found to be 69.5% which was comparatively more among rural areas (76%) in comparison to the urban areas (63%) and difference in the burden of anaemia was statically significant (p <0.05). The odds of anaemia were 1.4 times higher among rural areas than urban pregnant mothers. The results of present study were comparable and nearly similar to the results of surveys of India conducted by National Family Health Survey (NFHS-3) and another survey conducted by District Level Household Survey (DLHS-3).(5)(6) The results of present study were comparable and nearly similar to the study conducted by Toral M. Goswami et al among pregnant women in 2014 on anaemia status during pregnancy and effects of anemia on perinatal outcome.(7)

In the present study, there were 364 females in the group of abortion status zero, 28 females in the abortion status one, 6 females in the abortion status two and 2 females in the group abortion status of more than two. Among pregnant women with nil past abortions 108 (29.7%) had no anaemia, 140 (38.5%) females had mild anemia, 106 (29.1%) females had moderate anemia and 10 (2.7%) had severe anemia in this group. Among pregnant women with one past abortion 10 (35.7%) had no anaemia, 6 (21.4%) females had mild anemia, 12 (42.9%) females had moderate anemia and there was no cases of severe anemia in this group.

Among the group of pregnant women with two past abortions, there were no cases of no anemia and mild anemia, 4 (66.7%) of pregnant women had moderate anemia and 2 (33.3%) of pregnant women had severe anemia. Among the group of pregnant women with more than two past abortions, there were no cases of no anemia, mild anemia and moderate anemia and 2 (100%) of pregnant women had severe anemia. These differences in burden of anemia were statistically highly significant (p value < 0.001). Similar results were reported in a study done by Gautam VP et al among rural areas of Delhi and found similar correlation.(8)

In the present study Among pregnant women with nil past abortions 108 (29.7%) had no anaemia 68 were from urban area and 40 from rural area. Out of 140 (38.5%) females had mild anemia 66 were from urban area and 74 from rural area. Out of 106 (29.1%) females had moderate anemia 44 were from urban area and 62 from rural area and out 10 (2.7%) who had severe anemia in this group all belong to rural areas. Among pregnant women with one past abortions 10 (35.7%) had no anaemia 6 were from urban area and 4 from rural area. Out of 6 (21.4%) females who had mild anemia 4 were from urban area and 2 from rural area. Out of 12 (42.9%) females who had moderate anemia 6 were from urban area and 6 from rural area. Among the group of pregnant women with two past abortions, all 4 (66.7%) of pregnant women who had moderate anemia were from urban areas and 2 (33.3%) pregnant women who had severe anemia were from rural areas. Among the group of pregnant women with more than two past abortions, both the 2 pregnant women who had severe anemia were belong to urban areas. These differences in burden of anemia was statistically significant (p value < 0.05). Similar results were reported in a study conducted by RG Viveki et al on Anaemia and Its Epidemiological Determinants among Pregnant Women and found significant association of anaemia and its severity with two or more abortions. (9)

CONCLUSION

We concluded from the present study that the magnitude and burden of anemia is very high and the population living among urban and rural areas both were at higher risk of developing anemia. We found statistically significant correlation of anemia with increasing number of abortions and reported that the burden of severe anemia was higher among pregnant women who had more than two abortions.

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Original Research Article

EFFECT OF TRADITIONAL APPROACH ON JAUNDICE IN PREGNANCY, ITS RISK FACTOR & NEONATAL JAUNDICE

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Abstract

Hyperbilirubinemia is a common disease that occurs especially in the first week of birth and is one of the most common causes of hospitalisation of the term and preterm infants in neonatal hospitals. It usually occurs on the second day of birth and is not usually harmful, and a self-limiting condition, where disease usually improves without treatment after reaching the normal amount of bilirubin but very high levels of bilirubin may lead to kernicterus as permanent brain damage. Several types of Bilirubinemia have been reported in neonates including physiological jaundice, pathological jaundice, jaundice due to breastfeeding or breast milk and hemolytic jaundice including three subtypes due to Rh factor incompatibility. Mothball use, a possible trigger for hemolysis in newborns with G6PD deficiency, was reported by 43 mothers (4%). Families commonly avoided exposure of their newborns to direct sunlight (88%) and kept their newborns in dark rooms during the first 7 days (77%). The old Chinese literature also had very detailed and accurate description of the clinical features of kernicterus. Herbal medicine has been used to treat NNJ for a long time, and is still practiced in some parts of China up to the recent decades. The infants were, however, at the same time treated with a variety of other herbs or herbal combinations, as well as western medicine including steroids, plasma, phototherapy, phenobarbitone, and exchange transfusion.

Keywords: Neonatal Jaundice, Pregnancy, Risk Factors, Traditional Approach, Bilirubin, Kernicterus

Introduction

Neonatal jaundice is a common event that occurs especially in the first week of birth [1] [2] [3] and is one of the most common causes of hospitalisation of the term and preterm neonates in neonatal wards [1]. Based on the present evidence, 80% of premature infants have clinical symptoms, including yellowish skin and sclera, caused by serum bilirubin levels [4] [5]. Hyperbilirubinemia is a common disease that occurs especially in the first week of birth [1] [2] [3] and is one of the most common causes of hospitalisation of the term and preterm infants in neonatal hospitals [1]. It usually occurs on the second day of birth and is not usually harmful, and a self-limiting condition, where disease usually improves without treatment after reaching the normal amount of bilirubin [6] [7], but very high levels of bilirubin may lead to kernicterus as permanent brain damage. Nevertheless, diagnosis of newborn jaundice and its management will play an important role in the health of newborns [8]. If jaundice lasts more than 14 days, it is called to be prolonged neonatal jaundice [6].

An imbalance between bilirubin production and conjugation is the main mechanism of jaundice, which leads to an increase in bilirubin levels. This imbalance often occurs due to the immature liver and the rapid breakdown of red blood cells, which may be involved with several factors [9] [10] [11] [12]. The indirect bilirubin value in the physiologic jaundice of the term neonates does not exceed 12 mg/dL on the third day, and, this maximum increase reaches 15 mg/dL in preterm infants on the fifth day [13].

In physiologic jaundice, the maximum indirect bilirubin of infants who fed breast milk may be higher than those fed with *skimmed milk* (15-17 mg/dL versus 12 mg/dL); this higher level is probably due to the lower consumption of fluid by infants who are breastfeeding [14].

Types of Hyperbilirubinemia

Several types of Bilirubinemia have been reported in neonates including physiological jaundice, pathological jaundice, jaundice due to breastfeeding or breast milk and hemolytic jaundice including three subtypes due to Rh factor incompatibility, ABO blood group incompatibility and Jaundice associated with Glucose-6-phosphate dehydro-genase (G6PD) deficiency [15].

Physiological Jaundice

It is the most abundant type of newborn hyperbi-lirubinemia, having no serious consequences [16]. Neurodevelopmental abnormalities including as athetosis, loss of hearing, and in rare cases intel-lectual deficits, may be related to high toxic level of bilirubin [17]. Jaundice attributable to physio-logical immaturity which usually appears between 24-72 h of age and between 4th and -5th days can be considered as its peak in term neonates and in preterm at 7th day, it disappears by 10-14 days of life [18]. Unconjugated bilirubin is the predomi-nant form and usually its serum level is less than 15 mg/dl [19]. Based on the recent recommenda-tions of the AAP, bilirubin levels up to 17-18 mg/dl may be accepted as normal in term of healthy newborns [20].

Pathological Jaundice

Bilirubin levels with a deviation from the normal range and requiring intervention would be de-scribed as pathological jaundice [16].

Breast Feeding and Breast Milk Jaundice

Exclusively infants with breastfeeding have a dif-ferent physiological pattern for jaundice com-pared with artificially feed babies [15]. Jaundice in breast fed babies usually appears between 24-72 h of age, peaks by 5-15 days of life and disappears by the third week of life. Higher bilirubin levels have been reported in these infants [21].

Hemolytic Jaundice

The most common causes of hemolytic jaundice include (a) Rh hemolytic disease, (b) ABO incom-patibility and (c) Glucose-6-phosphate dehydro-genase (G-6-PD) deficiency and minor blood group incompatibility.

(A) Rh Factor Hemolytic Disease

Rhesus hemolytic disease of the newborns (RHDN) results from maternal red-cell alloimmunization [22].

(b) ABO Incompatibility

The incidence of the incompatibility of the ABO blood groups of the mother and fetus, when the mother has the blood group O and the newborn has the A or B blood group, is 15-20% of all pregnancies [23].

(c) Jaundice Associated With G6PD Defi-ciency

Deficiency, hereditary spherocytosis, and minor group incompatibilities should be managed simi-lar to ABO incompatibility. G6PD, most com-mon enzymopathy, is the deficiency of an en-zyme in RBCs [24].

Clinical Examination of Jaundice

Originally described by Kramer [25], dermal staining of bilirubin may be used as a clinical guide to the level of jaundice. Dermal staining in newborns progresses in a cephalocaudal direction [26].

Measurement of Bilirubin Levels

Bilirubin level can be checked through biochemi-cal method, Bilimeter or trans cutaneous bilirubinometer [26].

Biochemical

The gold standard method for bilirubin estima-tion is the total and conjugated bilirubin assess-ment based on the van den Bergh reaction [27].

Bilimeter

Spectrophotometry is the base of Bilimeter and it assesses total bilirubin in the serum. Because of the predominant un-conjugated form of bilirubin, this method has been found a useful method in neonates.

Transcutaneous Bilirubinometer

This method is noninvasive and is based on the principle of multi wavelength spectral reflectance from the bilirubin staining in the skin [27].

Instructions and Precautionary Measure for Parents during Physiological Jaundice

The benign nature of jaundice should be explained and demonstrated to the parents. The mother should be encouraged to breast-feed her baby frequently and exclusively, at least eight to twelve times per day for initial several days, with no top feeds or glucose water whatsoever [25]. Mother should be told to bring the baby to the hospital if the color on the legs looks as yellow as the face. Any newborn discharged before 48 h of life should be evaluated again in the next 48 h for

breastfeeding sufficiency and development of jaundice [25].

Care Practices, Risk Factors, and Beliefs

The majority of women initially breast- and formula fed their infants while waiting for their breast milk to come in. After the first week, however, the vast majority exclusively breast-fed. Exclusive formula feeding was rare. Mothball use, a possible trigger for hemolysis in newborns with G6PD deficiency, was reported by 43 mothers (4%). Families commonly avoided exposure of their newborns to direct sunlight (88%) and kept their newborns in dark rooms during the first 7 days (77%). When asked about the effects of sunlight on newborns, 33% thought sunlight was harmful of whom 171 thought it damaged the skin and/or eyes, 142 believed newborns were "too young/weak" and "would get sick" if exposed, and 2 thought it caused congestion. On the assessment of maternal knowledge of jaundice and found that less than half had ever heard of newborn jaundice, and only 27% thought that jaundice could potentially be harmful. Only 11% received teaching on jaundice after birth.

On the inquiry about the home use of traditional, herbal, or over-the-counter treatments, as these might delay care-seeking behavior and newborn follow-up care. One-hundred sixty-four mothers reported using traditional, herbal, or over-the-counter treatments for newborn problems during the first week. Thirty used herbal remedies to treat jaundice. Although cost was the most commonly reported potential barrier to care (17%), the majority reported none. Routine well-baby follow-up care before 14 days was rare (2.5%); 6% of mothers sought newborn care for medical concerns during the first 2 weeks after birth.

Table 1: Average Incidence of Risk Factors for Neonatal Jaundice

Mean of Incidence	Incidence Range	Incidence of Risk Factor
Hypertension (11.85%)	Hypertension (4.7–19%)	Hypertension (4.7%), hypertension (19%)
Preeclampsia (14.3%)	Preeclampsia (14.3%)	Preeclampsia (14.3%)
Vaginal bleeding (3.3%)	Vaginal bleeding (3.3%)	Vaginal bleeding (3.3%)
Diabetes (6.14%)	Diabetes (2.78–9.5%)	Diabetes (2.78%), diabetes (9.5%)
Premature rupture of membranes (2.7%)	Premature rupture of membranes (2.7%)	Premature rupture of membranes (2.7%)
Natural vaginal delivery (45.85%)	Natural vaginal delivery (16.7–75%)	Natural vaginal delivery (58.1%), NVD (75%), NVD (58.2%), NVD (73.5%), NVD (16.7%), NVD (48.48%), NVD (58%)
Maternal infections (3.45 %)	Maternal infections (3.45 %)	Maternal infections (3.45 %)
Preterm delivery (33.3%)	Preterm delivery (32–35%)	Preterm delivery (32.9%), gestational age under 32 weeks (35%), gestational age 35 weeks and higher (32%)
Use of herbal medicines based on maternal cultural beliefs (69.4%)	Use of herbal medicines based on maternal cultural beliefs (69.4%)	Use of herbal medicines based on maternal cultural beliefs (69.4%)
Reduction in breastfeeding rate (21.21%)	Reduction in breastfeeding rate (21.21%)	Breastfeeding (91%)

Pregnancy Problems

One of the maternal problems that affects neonatal jaundice incidence, is premature delivery and also premature birth. In a study, 30% of cases of neonatal jaundice were due to prematurity. Uridine diphosphoglucuronide acid-glucuronyl transferase (UDPGT) enzyme maturity is related to gestational age: the activity of this enzyme is one third among infants with 32 weeks of gestational age compared to term neonates, and as a result, the possibility of jaundice and its complications is increased in premature infants. On the other hand, delay in milk production and weakness of infant sucking lead to decreased caloric intake, dehydration and increase in enterohepatic circulation of bilirubin, thus resulting in increased concentration of bilirubin [28, 29].

PROM was also a maternal risk factor. In previous studies, the history of PROM in pregnancy was observed in 1.7%–4.8% of infants with jaundice. In a study, prolonged rupture of membrane was one of the maternal predisposing factors relevant to neonatal jaundice. In 40% of premature cases, there is a history of PROM. Thus, prematurity may be the main cause of jaundice in newborns with PROM [30].

Another risk factor for neonatal jaundice is ABO incompatibility, the result of mother's O blood group and nenonate's A or B blood group. ABO incompatibility, G6PD enzyme deficiency, prematurity, cephalohematoma, and RH incompatibility were the most prevalent risk factors for early neonatal jaundice. Also, there was a significant correlation between ABO incompatibility and jaundice prevalence.

Herbal Treatment of Neonatal Jaundice (NNJ)

Jaundice was described in Chinese literature as early as 3000 years ago. In the first Chinese medical book, Nei Ching, which was written in 1000 BC, jaundice

was described as ''yellow skin, yellow sclera, yellow urine.'' NNJ was first described in the book ''On the Origins and Symptoms of Diseases'' written in 610 AD, in which NNJ was alleged to be caused by the ''heat'' produced by the mother's viscera. ''Heat'' is a common Chinese medical term used to describe all kinds of physiological and pathological dysfunctions of the body. NNJ in the Chinese medical concept is a condition that originates from intrauterine life. NNJ was referred to as ''tai huang,'' meaning fetal jaundice. Another term ''tai dan'' referred to more severe jaundice, which might be the equivalent of pathological jaundice in modern terms. NNJ had been attributed to both ''internal'' and ''external'' causes. Internal causes that have been implicated included ''heat and moisture'' acquired from the womb or breast milk. External causes that have been described included toxins and demons, which most likely referred to infective agents. The Chinese medical practitioners also recognized ''weakness'' and ''lack of protection'' of the newborns. Biliary obstruction, referred to as ''stasis of blood flow,'' as well as inherited conditions had also been mentioned as causes of NNJ. The old Chinese literature also had very detailed and accurate description of the clinical features of kernicterus. Herbal medicine has been used to treat NNJ for a long time, and is still practiced in some parts of China up to the recent decades. The infants were, however, at the same time treated with a variety of other herbs or herbal combinations, as well as western medicine including steroids, plasma, phototherapy, phenobarbitone, and exchange transfusion. In the Chinese medical literature, the pharmacological properties of these herbs had been described. Many of these herbs have a bacteriostatic effect on a number of bacteria. Some have been shown to have an immunosuppressive effect on the anti - A, anti - B, and anti –D antibodies. A choleretic action of increasing bile excretion by rendering bile juice more dilute has been observed in some. Gancao contains ingredients with adrenocorticosteroid action. A number of case series have been published showing that herbal treatment using ''Yin chin'' and other herbs resulted in more speedy subsidence of jaundice than those who were treated with western medicines. However, little is known about the nature of these western medicines or the methodology used in these studies. In the English literature, there is a report on a study investigating the effect of Yin chin, Gardenia, Da huang, and Huang qin on bilirubin metabolism in rats. The finding showed that treatment with these herbs resulted in induction of UDP glucuronide transferase and C- glutathione transferase. The effects, however, were only small compared to the enzyme induction property of phenobarbitone. It can be concluded that although herbal treatment of NNJ has been practiced for a long time in China, its effectiveness remains doubtful and no convincing evidence, either pharmacological or epidemiological, has demonstrated its usefulness. The evaluation of the role of herbal treatment in NNJ requires properly conducted randomized clinical trials.

Conclusion

Evaluation of risk factors for neonatal hyperbilirubinemia is important because high risk factors play an important role in neonatal jaundice in a Hospital. Large-scale studies are also needed for further and also by the control group. Since the promotion of neonatal health as a vulnerable group in the health care services has a special place, so the evaluation of neonatal jaundice in all levels of health services should be considered as a fundamental policy. Medical scientists should search for new treatments and preventive measures having no side effects and capable of recovering babies more speedily. Partners should screen their ABO blood groups as well as Rh fac-tor before marriage. Consanguineous marriages should be avoided. In conclusion, reviewing studies addressing maternal risk factors for neonatal jaundice has shown that maternal risk factors play an important role in the incidence of neonatal jaundice. These risk factors included maternal age, hypertension, diabetes, cesarean section, birth order, PROM, preterm delivery, LBW, frequency of breastfeeding and neonatal weight loss. Therefore, regular and effective care seems to be necessary during pregnancy including training about the harmful effects of some herbal medicines, proper nutrition for the mother and normal delivery, and moreover, following-up the baby in case of complications such as PROM, GDM, high blood pressure and preeclampsia during pregnancy in order to prevent premature birth and neonatal sepsis, which are important causes of hyperbilirubinemia.

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Original Research Article

A STUDY ON ATTITUDE, BEHAVIOR AND UMBILICAL CORD CLAMPING ON NEONATAL JAUNDICE IN PREGNANCY: TREATMENT APPROACHES AFTER PARTURITION

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Abstract

The aim of the present study was to investigate cord clamping practice and treatment approaches for term vaginal births in Indian hospital, where the majority of births have an Obstetrician as the lead. A stopwatch was used to time the cord clamping interval at 55 term vaginal births in a tertiary hospital. The stopwatch was pressed once at the time of the birth and once when the first clamp was applied to the umbilical cord. Mode of birth, maternal position for birth and whether midwives and or doctors and neonatal health practitioners were involved in the birth was documented alongside the cord clamping timing. Cord clamping timing ranged from a minimum of 14 seconds to a maximum of 34 minutes. The median umbilical cord clamping time for all births in the study was 3.5 minutes. The median cord clamping time was likely to be longer when the woman had a spontaneous vaginal birth rather than an instrumental birth; when she birthed in a side-lying or upright position rather than a seated position; when a midwife facilitated the birth rather than a doctor and when there was no neonatal team present at the birth. The median cord clamping time of 3.5 minutes is aligned with current local, national and international guidelines. Midwives are likely to facilitate longer cord clamping times as they are more likely than doctors to attend spontaneous uncomplicated births which do not warrant immediate separation of mother and baby for preventative or resuscitative measures.

Keywords: Resuscitative measures, Cord clamping, Spontaneous vaginal birth, Behavior and Umbilical Cord Clamping, Neonatal Jaundice

Introduction:

Since its introduction as one of the first ever interventions in childbirth, umbilical cord clamping has been the topic of ongoing historical debate, physiological speculation and a multitude of experimental studies. As with many childbirth interventions, cord clamping does not stand alone but is instinctively linked with other interventions such as active management of the third stage of labour and newborn resuscitation. With the rapidly growing evidence around the harms of immediate cord clamping, in particular a reduction in blood volume leading to low iron stores for infants at three to six months of age (McDonald *et al.*, 2013).

When a cord is left attached to the placenta after birth, a significant proportion of the blood will flow from the placenta to the newborn contributing to between one-third and one-quarter of total potential blood volume at birth (Farrar *et al.*, 2011; Yao *et al.*, 1969; Begley *et al.*, 2019).

Methods

After performing an extensive literature review it became evident that, despite a dramatic change in guidelines for health practitioners around when to clamp the cord, little evidence existed on whether this guidelines was being implemented into practice in the current maternity system. In response to this gap in knowledge, the Timing of Cord Clamping (TOCC) study was devised to measure actual timings and some of the influences on current practice.

The TOCC study is a descriptive observational study of cord clamping practice at term vaginal births in a tertiary hospital.

Quantitative research methodology was chosen because the aim was to quantify practice, i.e. to accurately measure the time interval between birth and cord clamping. A question that lends itself to numerical measurement is best resolved from a positivist paradigm, in an objective and observable way, using quantitative methodology (Dyson & Norrie, 2013). A relatively large data set can be analysed when a quantitative methodology is used. When these data are examined using statistical techniques, a summary of trends and underlying patterns in clinical practice can be produced. Although the TOCC study answered important questions around the actual timing of cord clamping it did not provide us with an in-depth insight on how the individuals involved perceived or interpreted the situation. Further research from a qualitative perspective

would be a useful follow up to the TOCC study to allow us to describe personal experiences of the women and the health practitioners at the time of birth.

The research involved an observational study of cord clamping practice. In an observational study, information is collected first hand by a researcher based on how people are seen to behave or interact in certain situations (Rees, 2011). The investigator has no control over study variables and merely observes outcomes. This has less risk involved than an interventional study, in which changing an aspect of clinical practice may have a detrimental impact on healthcare (National Ethics Advisory Committee, 2012). Overt participant observation has the advantage over questionnaires and interviews as it is more likely to record accurate data, by avoiding the significant discrepancies that may exist between self-reported estimations and objective measurement (Hutton *et al.*, 2013). People are not always able to accurately describe or articulate their own actions. Unlike surveys, observation does not rely on memory, and therefore data is likely to be more accurate (Rees, 2011).

The data obtained from this observational study was examined using descriptive statistics to identify any relationships between umbilical cord clamping timing and the circumstances of each birth. The term "descriptive", when used in relation to statistics, indicates that data will be described and summarised rather than using inferential statistics which are more able to be generalised to the wider population (Dyson & Norrie, 2013).

One of the aims of the TOCC study was to compare Indian birth data collected from July 2019 to June 2020 to data collected ten years earlier in an Indian study where births were observed (Hutton *et al.*, 2013). In both studies, the context was a large tertiary hospital where births are conducted by both doctors and midwives. Of particular interest is the change in cord clamping practice over the ten years between studies. In addition, a comparison is made between two different maternity systems: a system where the majority of women (94.2%) choose a midwife as their lead maternity career and a other system where the majority women (93%) have an obstetrician or family physician as their lead maternity carer (Guliani, 2015).

Study Protocol

This study was informed by an observational study of cord clamping practice in a tertiary hospital (Hutton *et al.*, 2013). The TOCC study observed term vaginal births, both spontaneous and instrumental, in order to provide a data set comparable to the Hutton *et al.* study.

Health practitioners working in a birthing suite in Indian tertiary hospital were asked to use a stopwatch to time the interval between the birth of a baby and the time when the first clamp was applied to the cord. No extra research person was at the birth in the TOCC study: the stopwatch duty was allocated to a member of staff who would otherwise have been present in the birthing room. This differed from the Hutton *et al.* study, which used researchers as additional attendees at the birth. Where the research role is allocated to a midwife who attends to assist the LMC at a birth, they are in an ideal role to at act as overt participant observer as they are familiar with the environment and thus have the insider's perspective. Another crucial advantage of using the hospital midwives as participant observers is that it negates the need for a separate researcher to be in the room (in addition to the existing birth attendants) which may have a negative influence on the birth 'territory' (Hastie & Fahy, 2009).

It is conceivable that this observational study would add stress to women at time of their birth, an outcome that the investigator was keen to avoid. However, as the study was observing the health practitioners and not directly the woman, it was anticipated that this stress would be minimized. Health practitioners participants in the TOCC study were advised that, if there was an emergency procedure at the time of birth, TOCC study requirements would cease if they were likely to have an impact on normal management of the birth. The aim was to mitigate any risks by informing the assisting midwife that the stopwatch was never to take precedence over any usual care. It is recognized that many other factors could have been included in this study that may have an influence on cord clamping timing. As described in the Locality section below, the initial data collection table was more extensive but the table was restricted to make it more manageable for the health practitioners recording data for the study. Rees (2011) suggests that the number of activities recorded as part of observational studies needs to be limited so that observers are not overwhelmed when events unfold quickly, as they do during a birth.

All participants, both pregnant women and maternity healthcare professionals were provided with information on the study. Information leaflets and consent forms were designed as part of the ethics application. Copies of this supporting documentation is included in Appendices two and three. In order to compare findings to a previous observational study of cord clamping (Hutton *et al.*, 2013). Sample size of 100 term vaginal births at the chosen tertiary hospital.

Exclusion & Inclusion Criteria

Women who birthed breech babies, multiple babies, who birthed prior to 37 weeks and/or who birthed outside of the tertiary unit were excluded from this study as these situations affect the decision-making around cord clamping. Women who birthed vaginally assisted by ventouse (suction) and/or forceps were included in the study but not births that progressed to caesarean section. Variations in cord clamping timing do exist at caesarean section and indeed, at the time of the study the local guideline recommended an interval of 2 minutes for operative birth (CDHB, 2018). However, caesarean births were excluded from the TOCC study to further attempt to provide an accurate comparison to a previous cord clamping observational study (Hutton *et al.*, 2013). It is

likely that results may have been quite different if the sample had included caesarean and preterm births or had the study been conducted in a primary midwifery- led setting.

After obtaining consent, and prior to delivery, the forth coming newborn was randomly assigned to either delayed cord clamping (DCC) or immediate cord clamping (ICC) group. In the DCC group the umbilical cord was clamped after 30 seconds or when it stops pulsating. The exact time was recorded by use of a stopwatch, with complete expulsion of the infant as starting point. In the ICC group clamping was done within 10 seconds after delivery. A sample of cord blood was collected from the placental side after clamping and ligating the fetal side for Hemoglobin and Hematocrit estimations. Before discharging home (usually at 36-48hrs of life) the babies was assessed for clinical signs of polycythemia, hyperviscocity or hyperbilirubinemia.

Data Collection and Analysis

The initial aim was for hospital midwives to be trained as participant observers, and to collect specific data at births attended as a 'second midwife'. However, due to the acknowledgement that very little training is needed to use a stopwatch, during data collection the most appropriate member of staff present at the birth did the timings. This was often the hospital midwife, but may also have been the LMC or a delegated student (midwifery or medical). The stopwatch was pressed once at the time that the entire baby was born and then again when the first clamp was applied to the cord.

Results

The TOCC study ran from July 2019 to June 2020. Recruitment for the TOCC was slower than anticipated despite efforts to promote the study to LMCs and directly to pregnant women. At the beginning, after five months of recruitment, 30 births had been recorded in the study notebook and therefore recruitment was extended for a further 4 months in order to allow more time for the full quota of 100 births. The first birth to have data recorded was on the August 2019 and the last birth was recorded on April 2020. Data on 56 term vaginal births were collected. There were no twin births in the TOCC study data.

Of the 36 health practitioners who consented to have information collected from births that they facilitated, 31 were midwives and eight were doctors. Most of the health practitioners had one birth timed as part of the TOCC study. One midwife had 22 births timed, another midwife had nine births timed, two midwives each had two births timed. The information in the TOCC notebooks was collected by LMC midwives or hospital midwives, including for births where a doctor was facilitating.

Consent forms were collected for the 56 women who had their births recorded as part of the TOCC study. It is not known how many women consented to the study and then were not included in data collection as these consent forms were not collected.

Exclusion

One birth was excluded from the data analysis. The words "36 weeker" were documented in the comments box. This was outside the TOCC study criteria of 37 or more weeks gestation. With this birth excluded, the final number of births included for analysis was 55. The data were presented in table 1.

Table 1: Exclusions Criteria (Cord clamping times of all study participants)

Particular	n
Births where consent obtained and data collected	56
Exclusions (36 week gestation)	1
Births for analysis	55

The median umbilical cord clamping time for all births in the TOCC study was 3.5 minutes. For the purpose of analysis, times have been converted from stopwatch display of minutes:seconds:centiseconds to minutes to two decimal places.
The range of umbilical cord clamping times in the TOCC data set was from 0.23 minutes to 34 minutes. The inter quartile range (IQR) describes the middle 50% of these times. The 25^{th} centile for the TOCC data is 2.18 minutes and the 75^{th} centile is 5.68 minutes. Therefore, the IQR is 2.18 -5.68. The IQR can also be represented as a calculated range, i.e. 5.68 - 2.18 = 3.5 minutes. The data were presented in table 2.

Table 2: Cord clamping time for all study participants

Particular	Cord clamping time (minutes)
Range	0.23 - 34.00
Median (IQR*)	3.50 (2.18 - 5.68)

Frequency distribution of cord clamping times

Four babies had their cords clamped less than one minute after their birth and seven babies had their cords clamped over ten minutes after their birth. The majority of babies (64%) had their cords clamped between one and five minutes. The data were presented in table 3.

Table 3: Frequency distribution of cord clamping times

Cord clamping time (minutes)	n (%)
Less than 1	4 (7%)
1-2.99	16 (29%)
3-4.99	19 (35%)
5-9.99	9 (16%)
More than 10	7 (13%)

Where the interval between baby's birth and placental birth was longer than 10 minutes, birth health practitioners were asked to record >10 in the study notebook. The reason for not requesting a precise figure was because, in planning for the study, it was anticipated that data collection would usually be done by a hospital-employed midwife and that she or he was unlikely to be able to stay beyond ten minutes to stop the time on the stopwatch due to other birthing suite demands. In reality, it was often the Lead Maternity Carer midwife who used the stopwatch and who was then present beyond the birth of the placenta. When results were analyzed, seven births had a cord clamping time of more than ten minutes. Of these seven births, four midwives chose to document the precise time and three midwives chose to document the time as ">10". As the majority of this data was known, I chose to add actual times to the data set. In the four cases where precise times were recorded, the cord clamping time ranged from 11.85 minutes to 34 minutes.

Where the cord was clamped before the full birth of the baby's body, e.g. when the cord was wrapped tightly around the baby's neck, healthcare health practitioners were asked to document this as 0 minutes. No births in the TOCC study were recorded as 0 minutes.

Mode of birth and cord clamping times Of the 55 births in the TOCC study, 45 (81.8%) were spontaneous not in water, one (1.8%) birth was spontaneous in water and nine (16.4%) births were instrumental. Mode of birth is represented in Figure 2. Due to the low number of water births, the results for spontaneous births both in and out of water have been combined.

The median cord clamping time for a spontaneous birth (3.71 minutes) was longer than for an instrumental birth (2.08 minutes). The IQR for a spontaneous birth (2.67 - 6.23) was wider than for an instrumental birth (0.55 - 2.30), indicating that there was more variation in the cord clamping practice at spontaneous births. The maximum time that a cord was left intact at an instrumental birth was 4.15 minutes, whereas for a spontaneous birth the maximum time was 34 minutes. This data is included in table 4.

Table 4: Cord clamping times according to mode of birth

Mode of birth	n (%)	Range	Median (IQR)
Spontaneous (in or out of water)	46 (83.6%)	0.33 - 34.00	3.71
Instrumental (ventouse or forceps)	9 (16.4%)	0.23 - 4.15	2.08

Spontaneous births were most likely (29/46: 63%) to be followed by a cord clamping time of between 1 and 5 minutes. Instrumental births were most likely (7/9 :78%) to be followed by a cord clamping time of between 0 and 3 minutes. None of the births in the instrumental group had a cord clamping time of over 5 minutes whereas 35% of the births in the spontaneous group had a cord clamping time of over 5 minutes.

Table 5: Frequency distribution of cord clamping times according to mode of birth

Cord clamping time category (minutes)	Spontaneous n	Instrumental n
Less than 1	1	3
1-2.99	12	4
3-4.99	17	2
5-9.99	9	0
More than 10	7	0
Total	46	9

There was significant difference in mean hematocrit at 24 hr in Immediate group and Delayed group. There was significant difference in mean bilirubin at 24 hr in Immediate group and Delayed group. There was some reduction in hemoglobin (cord blood) (g/ dl) and hematocrit (cord blood)(%) from birth to 24 hr and increase in Bilirubin (cord blood) (mg/dl) from birth to 24 hr in both the groups. Clinical jaundice was found in baby in both the group at birth. The data were presented in table 5 & 6.

Table 6: Comparison of investigation at birth and at 24 hr in ICC Group and DCC Group

	ICC					DCC				
Investigations	at birth		at 24 hr			at birth		at 24 hr		
	Mean	S.D	Mean	S.D	mean	Mean	S.D	Mean	S.D	mean
hemoglobin (cord blood)	17.28	0.86	17.13	0.77	0.17	18.68	0.74	18.44	0.78	0.25
hematocrit (cord blood)(%)	52.42	5.5	51.52	2.35	0.86	56.82	2.23	55.02	5.44	1.6
Bilirubin (cord blood)	1.26	0.3	5.44	1.73	4.17	1.34	0.53	6.53	1.88	5.16

Table 7 and 9 demonstrated knowledge of study population towards immediate care of newborn and Knowledge regarding practices of study population respectively.

Table 7: knowledge of study population towards immediate care of newborn

Items	Frequency of Correct	Percent
The immediate care of newborn start during birth.	43	42.8%
The immediate care of newborn included five steps.	64	68.6%
About the identification band there Is three identification bands.	8	7.5%
Type of identification band (infant foot prints and code number).	22	21.7%
The identification band should include (the mother full name, hospital admission, sex of the infant, date and time of delivery).	22	21.7%
Total percentage		32.3%

Table 8: Knowledge regarding practices of study population

Items	Frequency of Correct	Percent
During the delivery of the head we wipe the face and eye, suction of the mouth and nares if needed.	9	52%
Suctioning the mouth before the nares.	89	71.5%
Use sterile bulb syringe when suction the mouth and nares	22	12.8%
Dry the newborn by use two sterile towels.	92	95.6%
Placed the newborn immediately after delivery on the mother's abdomen.	85	78.7%
The identification band putting immediately before cutting the cord	33	26%
During cutting and clamping the cord put the infant in the mother's abdomen.	85	67.6%
To cut and tie the cord we use sterile (gauze, scissors and artery forceps).	35	36.7%
Cutting the cord immediately after cessation of cord pulsation (2-3min after birth).	7	3 5.5%
Use separate sterile scissor during cutting the cord.	80	83.3%
Total percentage		**55.7%**

TREATMENT OF NEONATAL JAUNDICE AFTER PARTURITION

1. All women should be encouraged to breastfeed 8 to 12 times a day
2. Supplementation is recommended only for dehydrated newborns and where weight loss from birth is >10%. Expressed breast milk is the preferred supplementation.
3. Routine supplementation with intravenous fluids, honey or dextrose water for newborns with jaundice is not recommended
4. No interruption of breastfeeding should be done for any jaundice.

- Phototherapy can be delivered by light - emitting diode (LED) or fibreoptic or fluorescent lamps or tubes or bulbs.
- Do not use sunlight as treatment for hyperbilirubinaemia. Exposing the baby to sunlight does not help in treatment of jaundice and is associated with risk of sunburn and therefore should be avoided.

5. Exchange transfusion should be done by central or peripheral route aiming replacement of double the baby's blood volume and by skilled personnel in a well-equipped centre.

6. Immediate EBT is recommended if infant shows signs of ABE or if TSB is ≥25 mg/dL above the recommended age and risk specific cut off TSB
7. For Rhesus is immunization, the best choice would be O (Rh) negative packed cells suspended in AB plasma. (Rh) negative whole blood or cross-matched baby's blood group (Rh negative) may also be used.
8. For ABO is immunization, O group (Rh compatible) packed cells suspended in AB plasma or O group whole blood (Rh compatible with baby) should be used.
9. In other situations baby's blood group should be used. All blood must be cross matched against maternal plasma.

Discussion

Cord clamping was one of the earliest interventions to be introduced to birthing practice. Immediate clamping became widely adopted in the 1960's as part of active management of the third stage of labour, introduced to reduce adverse outcomes from postpartum haemorrhage. However, the review of the literature in chapter two demonstrated multiple benefits for infants who have deferred cord clamping without an increase in maternal haemorrhage rates.

In the TOCC study, able to accurately record the interval between birth and cord clamping at 55 term vaginal births in a tertiary hospital. The median was 3.5 minutes and the IQR was 2.18 - 5.68 minutes, while the shortest cord clamping time was 0.23 minutes and the longest was 34 minutes. These results are indicative of a move towards longer cord clamping times in practice. Newborns in the TOCC study were more likely to receive a prolonged period of cord clamping if their mother birthed in an upright or side-lying position rather than seated position, when the birth was spontaneous rather than assisted by forceps or ventouse, where the birth was facilitated by a midwife rather than a doctor and where there was no neonatal team in attendance.

The median cord clamping time in this study was 3.5 minutes which demonstrates a move away from immediate cord clamping. However, the optimal time for cord clamping is unknown. Blood continues to flow through the cord after the birth accounting for approximately one-quarter to one-third of potential total blood volume in term babies (Farrar *et al.*, 2011; Yao *et al.*, 1968). Most studies define immediate cord clamping as within the first 15 seconds of birth, with delayed/deferred cord clamping ranging from one to five minutes post birth (if a time value was used) or sometimes defined as the cord being clamped after pulsations ceased and/or after placental birth (Hutton & Hassan, 2007; McDonald *et al.*, 2013).

It is still not clear whether the optimal time for cord clamping should be an actual time point, such as one minute or five minutes, or whether it should be related to other factors such as neonatal breathing efforts. Physiological studies on humans and animals demonstrate that placental transfusion is dependent on a number of factors and therefore a "time value" for optimal cord clamping is individual for each newborn. There is a move to use terminology such as "Wait for White", to recommend waiting until the cord is flaccid and empty of blood (Burleigh, 2016), "Aerate-Breathe-Clamp" or "Physiological-Based Cord Clamping" to recommend individualised practice according to the newborn response to extra-uterine transition (Knol *et al.*, 2019).

In the TOCC study, the position associated with the longest interval between birth and cord clamping (median 6.37; IQR 4.15 - 9.48) was side-lying, adopted by women at 7/55 (13%) births. In the author's experience, births in the side-lying positions are often followed by an initial period of the newborn lying alongside the woman, on a flat surface and in skin-to-skin contact. This flat surface allows the birth to position the baby with an effective open airway and thus to encourage newborn spontaneous breathing with an intact cord without having to disturb maternal or infant position. In contrast, with seated/recumbent positions the newborn will lie on the mother's abdomen which is less likely to be an effective flat surface to assist airway opening and is more likely to be interrupted if the woman has to move.

Conclusion

The main finding of this study was a median cord clamping time of 3.5 minutes for the 55 term vaginal births observed at a tertiary hospital where the majority of births have an Obstetrician as the leads.

The TOCC study aimed to accurately record birth to cord-clamping interval at 100 term vaginal births and to investigate factors which may influence practice such as mode of birth, maternal position for birth and health practitioners involvement. In the final analysis, despite a three-month extension in the recruitment period, the total number of births accurately recorded was 55. While a larger study may provide more generalisable results, there would likely still be considerable challenges to recruitment unless significant resourcing was available. The consistency of findings in this small study does provide confidence that there has been a shift to longer cord clamping times.

Clamping and cutting of the umbilical cord at birth is the oldest and most prevalent intervention in humans. Various studies have advocated the practice of DCC which was found to be true in our study as well. Moreover there were no significant associated adverse effects. It is a safe, simple and low cost delivery procedure that should be incorporated in integrated programs.

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Original Research Article

Prevalence of Thyroid Disorders in Pregnancy

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ABSTRACT

Objective: The present study was carried out to find out the prevalence of various thyroid disorders among pregnant women in their first trimester in the southern area of Rajasthan.
Material & Methods: The study was conducted during the period of 1year from July 2017 to July 2018. 200 pregnant women attending antenatal clinic for their routine antenatal visit in first trimester were included in the study. Routine blood and urine investigations along with serum TSH, FT3 and FT4 were done in all the study participants.
Results: Age of the patient's ranged from 19 to 38 with the mean age of 25.66±3.90 years. Mean gestational age of study population was 8.12±1.63 weeks. The mean TSH, FT3 and FT4 values were 1.499, 2.386 and 1.410 respectively. Thyroid disorders were found in 14%patients out of 200 study participants. 86% patients were euthyroid among the study participants. 7% patients were found to be having subclinical hypothyroidism. 4% were having overt hypothyroidism and 3% were having subclinical hyperthyroidism.
Conclusion: The study revealed high prevalence of thyroid disorders (14%) among pregnant women in their first trimester specially hypothyroidism (11%). Routine antenatal thyroid screening should be performed in all pregnant women.

Keywords: Hypothyroidism, antenatal, hyperthyroidism, eclampsia

INTRODUCTION

Normal thyroid hormone levels are necessary in maintaining pregnancy and in development of fetus. Thyroid dysfunctions are more common in female than in male. Maternal thyroid functions changes during pregnancy and leads to thyroid disorders in absence of adaptation to these changes. Thyroid disorders during pregnancy can result in substantial adverse fetomaternal outcomes. Furthermore, thyroid dysfunction can be readily diagnosed with simple and reliable blood tests and easily corrected with economical and easily available treatments. [1]

Worldwide, thyroid disorders are common in women of child-bearing age. [2] During pregnancy, demands on the hypothalamic-pituitary-thyroid axis increases which commonly leads to borderline thyroid abnormalities. Both hyper and hypo-thyroidism types of thyroid disorders can occur during pregnancy and correction of these disorders dramatically reduces the risk of adverse fetomaternal outcomes like foetal loss, preterm birth, pre-eclampsia and eclampsia and maternal morbidity. [3, 4]

According to the western literature, the prevalence of hypothyroidism in pregnancy is around 2.5%. The prevalence of gestational diabetes is around 0.1–0.4% and that of thyroid autoimmunity (TAI) is around 5-10%. [5]

There are very few data from India about the prevalence of thyroid dysfunction in pregnancy especially in the southern Rajasthan. With this background, the present study aims to find the prevalence of thyroid disorders including hyperthyroidism, hypothyroidism and Subclinical Hypo and hyper- thyroidism during pregnancy in southern part of Rajasthan.

MATERIALS AND METHODS

The present study was a prospective study carried out in the department of Gynaecology and Obstetrics, Ananta institute of medical sciences, Rajsamand during the period of 1 year from July 2017 to July 2018.

200 patients attending OPD in their first trimester for routine antenatal check up were randomly selected and included in the study.

Inclusion criteria:

1. ≤ 12 week gestation
2. Singleton pregnancy
3. Primi/ multigravidae

Exclusion criteria:

1. Patients who were not willing to give consent.

Procedure:

Detailed history of all the patients was taken regarding symptoms of thyroid disorders, past medical and obstetric history, family history and personal history. Complete general and systemic examination was done in all the patients. Per abdominal and per vaginal examination were also done and findings were recorded.

Routine blood and urine investigations along with serum TSH, FT3 and FT4 were done in all the study participants. Pregnancy ≤12 week was confirmed by clinical examination, pregnancy test and ultrasonography. The reference ranges of the test values used in this study were as per the Guidelines of American Thyroid Association (ATA) for the diagnosis and management of thyroid disease during pregnancy and postpartum. As per regulation 14.2 of ATA Guidelines, if trimester specific ranges for TSH are not available in the laboratory, the following normal reference ranges are recommended: 1st trimester - 0.1 to 2.5 m IU/L, 2nd trimester - 0.2 to 3.0 m IU/L and 3rd trimester - 0.3 to 3.0 m IU/L. Normal free T4 level is 0.7 to1.8 ng/ml and free T3 level is 1.7 to 4.2 pg/ml.

Ethical consideration: Permission was taken from institutional ethical committee and written consent was taken from all the study participants.

RESULTS

200 pregnant women in their first trimester were included in present study. Age of the patients ranged from 19 to 38 with the mean age of 25.66±3.90 years. Mean gestational age of study population was 8.12±1.63 weeks.

The mean TSH, FT3 and FT4 values were 1.499, 2.386 and 1.410 respectively. (Table 1)

Table.1 Baseline parameters of the study participants

S.No.	Parameters	Value (Mean ±SD)
1	Age	25.66±3.90 years
2	Gestational Age	8.12±1.63 weeks
3	TSH	1.499±0.324 IU/L
4	FT3	2.386±0.537 ng/ml
5	FT4	1.410±0.461 pg/ml

Thyroid disorders were found in 28 cases (14%) out of 200 study participants. Table 2 illustrates variety of thyroid disorders in the study population. 86% patients were euthyroid among the study participants. 7% patients were found to be having subclinical hypothyroidism. 4% were having overt hypothyroidism and 3% were having subclinical hyperthyroidism.

Table 2. Percentage of thyroid disorders in study participants

S.No.	Type	Number	Percentage
1	Euthyroid	172	86
2	Overt Hypothyroidism	8	4
3	Subclinical hyperthyroidism	6	3
4	Subclinical hypothyroidism	14	7
5	Overt Hyperthyroidism	0	0
6	Total	200	100

DISCUSSION

The present prospective study was conducted in a tertiary healthcare centre of southern Rajasthan. 200 pregnant women

with ≤12 weeks of gestation, who met the inclusion criteria, were included in the study.

The prevalence of thyroid disorders was 14% in present study. Many studies done in the past had similar results. Taghavi et al found 14.6% prevalence of thyroid disorders in their study. [6] Ajmani et al found 13.25% cases of thyroid disorders in their study. [7] Similarly, Weiwei Wang et al (10.2%), Sahu et al (12.7%) and Dhanwal DK et al (14.3%) had comparable results in their studies. [8-10]

The prevalence of thyroid disorder was very less (5%) in a study conducted by Thanuja PM et al [11], while the prevalence was very high (26.5%) in a study by Rajput et al [12], hence the results of these studies were in contrary with present study.

The prevalence of subclinical hypothyroidism in present study was 7%. In a study done by Sangeeta Palhwa et al, the prevalence of subclinical hypothyroidism was 6%. [13] Similarly, in a study by Sahu MT et al, the prevalence was 6.47% which is also comparable to our study. [9]

All women who have been diagnosed subclinical hypothyroidism during pregnancy should be tested for antithyroid antibodies because it can be associated with other autoimmune disorders like type I diabetes and can have adverse fetomaternal outcome. [14,15] ATA updated its guidelines in 2017 for the management of thyroid disorders in pregnancy. They suggested that Thyroxine should be started if antithyroid antibodies are present and initial level of TSH is 2.5- 4 mIU/L. If initial TSH level is > 4mIU/L, then Thyroxine should be started irrespective of the status of antithyroid antibodies. Usually the Thyroxine is started in the dose of 50 microgram per day to treat subclinical hypothyroidism and thyroid function tests are repeated after 4 weeks of starting treatment. [16, 17]

The prevalence of overt hypothyroidism in present study was 2%, which was consistent with the results obtained by Saraladevi et al with the prevalence of 2.8% [18] and partly consistent with the results obtained by Sahu MT et al, in which the prevalence was 4.58%. [9]

In present study, prevalence of subclinical hyperthyroidism and overt hyperthyroidism were 3% and 0% respectively. The prevalence of subclinical and overt hyperthyroidism was 0.5 and 0.4% respectively in the study done by Stagnaro Green A. [17] Similarly in the study done by Saraladevi et al the prevalance were 1.8% and 0.6% respectively. [18]

Our study had few limitations that fetomaternal outcomes were not included in the study. The sample size was also small. Hence, further researches with large sample size are advisable.

CONCLUSION

The study revealed high prevalence of thyroid disorders (14%) among pregnant women in their first trimester specially hypothyroidism (11%). Hyperthyroid disorders are rare in pregnant women. Due to immense impact of thyroid disorders on the fetomaternal outcome, we advocate the routine antenatal thyroid screening.

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Special Article

Postpartum Thyroiditis

SUDHA SHARMA*, D C SHARMA**

POSTPARTUM thyroiditis (PPT) is a syndrome of thyroid dysfunction that follows parturition within a year. In a typical case, transient thyrotoxicosis with low radioactive iodine uptake (RAIU) occurs within a few months after delivery and is followed by a period of hypothyroidism of several months duration with eventual return to euthyroid state. Spontaneous recovery occurs in most patients, but recurrence is experienced by many patients after 2-4 years[1].

PREVALENCE:

The prevalence of postpartum thyroiditis reported from different parts of world varies from 5.5-21%[2-4]. In a recent study a prevalence of 13% has been reported from India[5]. The variability in prevalence could be due to differences in the distribution of environmental or genetic risk factors.

CLINICAL FEATURES:

The spectrum of clinical presentation varies from a characteristic course of three sequential phases, the thyrotoxic phase, hypothyroid phase and recovery phase, to thyrotoxicosis alone or hypothyroidism alone[3]. Transient thyrotoxicosis generally occurs 1-3 months after parturition and lasts for 1-2 months. About one half of these patients return to euthyroid phase and remain so at least for some time. In the remaining half a hypothyroid phase that varies in duration from about 2-9 months develops 3-6 months after delivery. Almost all patients return to euthyroid state.

In majority of the patients symptoms are often mild and non-specific with fatigue being a prominent feature of both the thyrotoxic and hypothyroid phase. Examination reveals that thyroid gland is enlarged in only 50% of cases and is not associated with pain and tenderness. Enlargement is usually mild and not accompanied by nodularity[3].

Women with long-standing goitre and/or serum antithyroid antibodies during pregnancy or after delivery are more likely to develop PPT[2]. Lymphocytic infiltration is the most prominent pathological feature[6]. In addition to these changes certain other changes in the lymphocytes suggest that PPT is an auto-immune disease[6]. PPT has also been reported in patients with other autoimmune thyroid diseases like Hashimoto's thyroiditis and Graves' disease. There is strong association with the HLA-DR3 and HLA-DR5 haplotypes[6], which are also associated with atrophic and goitrous varieties respectively, of the Hashimoto's thyroiditis. The postpartum occurrence of the disorder is probably due to rebound of immune activity after its suppression during pregnancy[7].

Transient thyrotoxic phase is a result of sudden, uncontrolled release of preformed hormone because of loss of tissue integrity. Such forms of thyrotoxicosis due to thyroiditis is referred to as 'destruction induced' or 'thyrolytic hyperthyroidism'[8]. It is postulated that the iodine status of thyroid at the time of immunological injury may modify the clinical expression of the disorder[10]. Thus in iodine deficiency areas it is possible that an insufficient amount of thyroid iodine and thyroxine are leaked out during the destructive phase to produce thyrotoxicosis in these patients. Consistent with this view one study from India reported the finding of hypothyroidism as the sole manifestation of PPT[5].

RECURRENCE:

As the vague symptoms are generally present in most

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Dear sir/Madam

11-09-2019

MSN: NO: IJCAR-9839/2019

AUTHORS NAME: Sudha Sharma and Dinesh Chandra Sharma

ARTICLE TITLE: PREVALENCE AND DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS (GDM) AND FETOMATERNAL OUTCOME IN WOMEN WITH GDM

Dear sir/Madam

Thank you for your cooperation. At the same time, we gladly inform you that your paper entitled. PREVALENCE AND DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS (GDM) AND FETOMATERNAL OUTCOME IN WOMEN WITH GDM. with the registration number. IJCAR-9839/2019, for which you are the correspondence author, was accepted for publication in **International Journal of Current Advanced Research.** As a result, your article/paper will be published in the following issues of the journal, Volume: 8; Issue: 9 pp. XXX-XXX, September, 2019

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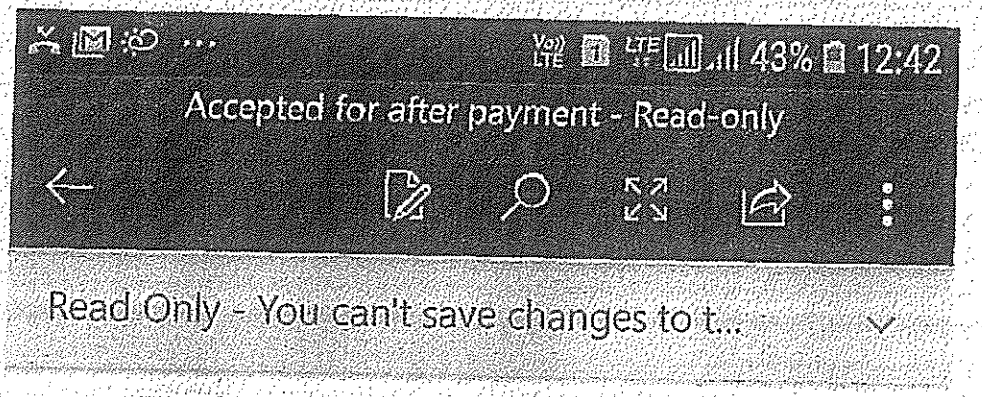

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Research Article

PREVALENCE AND DIAGNOSIS OF GESTATIONAL DIABETES MELLITUS (GDM) AND FETOMATERNAL OUTCOME IN WOMEN WITH GDM

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ABSTRACT

Objective: the study was conducted to diagnose the gestational diabetes mellitus (GDM) in early pregnancy using glucose challenge test (GCT) and glucose tolerance test (GTT) and to find out the prevalence of GDM in southern part of Rajasthan and fetomaternal outcome in those GDM patients.

Material and Methods: It was a prospective study carried out in the department of Gynaecology and Obstetrics of a tertiary healthcare centre during the period of 2 years from January 2017 to January 2019. 700 random pregnant women with 18-28 week of gestation were subjected to 50 gram GCT. Women with abnormal GCT were then subjected to 75 gram 2 hour GTT test. Patients were followed up till delivery and perinatal and maternal status were recorded.

Results: The age of the study participants ranges from 18 to 36 years with the mean age of 24±3 years while the mean age of GDM diagnosed women was 28.3±2 years. Out of 700 pregnant women included in the study, 67 women were found to have abnormal GCT and 27 women (3.8%) out of these 67 were found to have abnormal OGTT and were diagnosed with GDM. Most of the GDM patients were having plasma glucose level between 166-175mg/dl (33.33%) followed by 155—165mg/dl (29.62%). There was no fetal loss, no congenital abnormalities; no birth asphyxia in any of the newborns of GDM diagnosed women. 4 out of 27 newborns had macrosomia (weight >4kgs) and 3 newborns had IUGR (weight < 2.5kgs). Mean birth weight was 2.67 kgs.

Conclusion: prevalence of GDM in present study was 3.8%. Routine screening of pregnant women before 28 week of gestation with GCT and GTT should be performed because it is an easy, economical and patient friendly test. Prompt diagnosis and early management can improve maternal and perinatal outcome.

INTRODUCTION

Gestational Diabetes Mellitus (GDM) is defined as any degree of glucose intolerance with the onset of pregnancy or first recognized during pregnancy. [1] Women with history of GDM are at an increased risk of adverse fetomaternal outcome and also at increased risk of future diabetes, predominantly type II including their children. [2] Therefore it is important to diagnose the GDM as early as possible to prevent adverse fetomaternal outcome and complications.

There are many controversies regarding methods of screening and diagnosis of GDM and their cost-effectiveness. Precise level of glucose intolerance which characterizes GDM has also been controversial over past few decades. In 1964, O'Sullivan and Mahan performed study on 752 pregnant women and suggested the use of glucose values in diagnosis of GDM after 3 hour 100 gram oral glucose tolerance test (OGTT).[3]

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This diagnostic criteria was further modified by National Diabetes Data Group Criteria (NDDG) in 1979 by adjusting diagnostic thresholds upward.[4] This NDDG thresholds were adopted and recommended by American Diabetes Association (ADA) as diagnostic cut-off points for GDM until 1999.[5]

In 2000, ADA revised the recommendation for GDM diagnostic criteria and proposed adoption of Coustan and Carpenter Criteria (CCC) thresholds instead of NDDG thresholds.[6]

The International Association of Diabetes and Pregnancy Study Groups (IADPSG) in 2010 decided to use mean values of fasting, 1 hour and 2 hour blood glucose of all pregnant females as reference and chose to use odds ratio of 1.75 to define the diagnostic cut-offs for GDM, which led to the development of the widely used and accepted IADPSG criteria. [7]

Still there are some controversies regarding screening of pregnant women for GDM. The ADA recommends selective screening for GDM in pregnant women who are at high risk,

while other guidelines, including those of American College of Obstetrics and Gynecologists (ACOG), support screening of all pregnant women for GDM.[8, 9] The present study used the IADPSG criteria (2010) for diagnosing GDM in which fasting OGTT was performed with 75 gram glucose and if fasting plasma glucose (FPG) is ≥126 mg/dl, overt diabetes is diagnosed and if FPG is < 126 mg/dl, then GDM is diagnosed if any one of the values exceeds the threshold shown below:

	Fasting	1 hour	2 hour
Plasma Glucose (mg/dl)	≥92	≥180	≥153

The variation in prevalence of GDM worldwide depends on various screening and diagnostic methods used as well as on age and ethnicity of the pregnant women of the particular region.[10-16] The OGTT is usually performed between the 24th and 28th week of gestation; however, in women with associated risk factors like previous gestational diabetes or family history of diabetes, OGTT should be performed earliest soon after diagnosis of pregnancy.[16] Early screening can avoid serious complications in women with GDM.[17]

The present study is aimed to find out the prevalence and diagnosis of GDM in southern part of Rajasthan with the use of GCT and OGTT and fetomaternal outcome in the patients of GDM .

MATERIAL AND METHODS

The present study was a prospective study carried out in the department of Gynaecology and Obstetrics, Ananta institute of medical sciences, Rajsamand during the period of 2 years from January 2017 to January 2019.

700 pregnant women with gestation of 18-28 week were randomly recruited from the antenatal clinic of our institute. All the 700 women were given 50 gram glucose load for glucose challenge test (GCT) without regard to the time of last meal and the venous blood samples were collected after 1 hour for estimating plasma glucose. GCT was marked abnormal if 1 hour plasma glucose was > 140 mg/dl (7.77 mmol/L).

All the women with abnormal results were then subjected to 2 hour 75 gram oral glucose tolerance test (OGTT) for confirmation. In OGTT, initial blood sample was taken after overnight fasting and the patient was then asked to drink solution of 75 gram glucose in 200 ml water. If fasting plasma glucose (FPG) was ≥126 mg/dl, overt diabetes was diagnosed and if FPG was < 126 mg/dl, then GDM was diagnosed if any one of the values exceeds the threshold as shown below:

	Fasting	1 hour	2 hour
Plasma Glucose (mg/dl)	≥92	≥180	≥153

Patients were followed up till delivery and maternal and perinatal status was recorded.

RESULTS

The age of the study participants ranges from 18 to 36 years with the mean age of 24±3 years.

Out of 700 pregnant women included in the study, 67 women were found to have abnormal GCT and these 67 women were then subjected to 2 hour, 75 gram OGTT. 27 women (3.8%) out of 67 were found to have abnormal OGTT and were diagnosed with GDM. The mean age of the GDM diagnosed women was 28.3±2 years.

Most of the GDM patients were having 2 hour plasma glucose level between 166-175mg/dl (33.33%) followed by 155—165mg/dl (29.62%). (Table 1)

Table 1 Range of plasma sugar level in GDM patients

Plasma sugar level (mg/dl)	Number of patients	Percentage
155-165	8	29.62
166-175	9	33.33
176-185	7	25.92
>185	3	11.11
Total	27	100%

There was no fetal loss, no congenital abnormalities; no birth asphyxia in any of the newborns of GDM diagnosed women. 4 out of 27 newborns had macrosomia (weight >4kgs) and 3 newborns had IUGR (weight < 2.5kgs). Mean birth weight was 2.67 kgs.

DISCUSSION

The worldwide prevalence of gestational diabetes ranges from 1-14%. [18, 19]

In India, prevalence rates reported to be between 4.6% and 14% in urban areas, and 1.7% and 13.2% in rural areas. [20]
In present study, the overall prevalence of GDM was 3.8%. The figure was comparable to the studies done in the past by Indian workers like Maheshwari *et al* and Kumar *et al* with the prevalence of GDM 4.9% and 5.5% respectively. [21, 22]

The mean age of all study participants in present study was 24±3 years while the mean age of GDM diagnosed women was 28.3±2 years. Similar results were obtained in the study by Ismail NA *et al* who reported the mean age of 27.9 years in GDM patients. [23] Hence increasing age of patient was significantly associated with GDM.

High perinatal mortality rate in uncontrolled GDM patients has been reported by O'Sullivan JB *et al* in 1973. [24] Similarly, Fareed P *et al* showed 9% perinatal mortality in GDM patients compared to 1% in control group. [25] The results were in contrary to the results of present study. In present study, there was no perinatal mortality and no congenital malformation was there. Mean birth weight of the newborns was 2.67 kgs. This could be made possible because of early screening for GDM and management of the patients.

4 out of 27 newborns (14.81%) had macrosomia (weight >4kgs) and 3 newborns (11.11%) had IUGR (weight < 2.5kgs). This observation was comparable to past studies done by Fareed P *et al*, Wahi P *et al* and Bener AB *et al* where macrosomia was found 17%, 16.2% and 10.3% respectively. [25, 26, 27]

CONCLUSION

The study concluded that the prevalence of GDM is 3.8% in southern area of Rajasthan. Increasing age of pregnancy is significantly associated with GDM. We advocate the routine screening of pregnant women before 28 week of gestation with 50 gram GCT because it is an easy, economical and patient friendly test as patient need not to come fasting for this test. Patients who have abnormal value in GCT should be subjected to GTT for confirmation of GDM. Prompt diagnosis and early management can improve maternal and perinatal outcome.

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Special Article

Postpartum Thyroiditis

JIMA (Special Article

SUDHA SHARMA*, D C SHARMA**

POSTPARTUM thyroiditis (PPT) is a syndrome of thyroid dysfunction that follows parturition, within a year. In a typical case transient thyrotoxicosis with low radioactive iodine uptake (RAIU) occurs within a few months after delivery and is followed by a period of hypothyroidism of several months duration with eventual return to euthyroid state. Spontaneous recovery occurs in most patients, but recurrence is experienced by many patients after 2-4 years[1].

PREVALENCE :

The prevalence of postpartum thyroiditis reported from different parts of world varies from 5.5-21%[2-4]. In a recent study a prevalence of 13% has been reported from India[5]. The variability in prevalence could be due to differences in the distribution of environmental or genetic risk factors.

CLINICAL FEATURES :

The spectrum of clinical presentation varies from a characteristic course of three sequential phases, the thyrotoxic phase, hypothyroid phase and recovery phase, to thyrotoxicosis alone or hypothyroidism alone[6]. Transient thyrotoxicosis generally occurs 1-3 months after parturition and lasts for 1-2 months. About one half of these patients return to euthyroid phase and remain so at least for some time. In the remaining half a hypothyroid phase that varies in duration from about 2-9 months develops 3-6 months after delivery. Almost all patients return to euthyroid state.

In majority of the patients symptoms are often mild and non-specific with fatigue being a prominent feature of both the thyrotoxic and hypothyroid phase. Examination reveals that thyroid gland is enlarged in only 50% of cases and is not associated with pain and tenderness. Enlargement is usually mild and not accompanied by nodularity[7].

Women with long-standing goitre and/or serum antithyroid antibodies during pregnancy or after delivery are more likely to develop PPT[6]. Lymphocytic infiltration is the most prominent pathological feature[6]. In addition to these changes certain other changes in the lymphocytes suggest that PPT is an auto-immune disease[6]. PPT has also been reported in patients with other autoimmune thyroid diseases like Hashimoto's thyroiditis and Graves' disease. There is strong association with the HLA-DR3 and HLA-DR5 haplotypes[8], which are also associated with atrophic and goitrous varieties respectively, of the Hashimoto's thyroiditis. The postpartum occurrence of the disorder is probably due to rebound of immune activity after its suppression during pregnancy[9].

Transient thyrotoxic phase is a result of sudden, uncontrolled release of preformed hormone because of loss of tissue integrity. Such forms of thyrotoxicosis due to thyroiditis is referred to as "destruction induced" or "thyrolytic hyperthyroidism"[6]. It is postulated that the iodine status of thyroid at the time of immunological injury may modify the clinical expression of the disorder[10]. Thus in iodine deficiency areas it is possible that an insufficient amount of thyroid iodine and thyroxine are leaked out during the destructive phase to produce thyrotoxicosis in these patients. Consistent with this view one study from India reported the finding of hypothyroidism as the sole manifestation of PPT[5].

RECURRENCE :

As the vague symptoms are generally present in most

(Continued on page 172)

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A STUDY OF MATERNAL MORTALITY IN A RURAL MEDICAL COLLEGE, HOSPITAL

SUDHA SHARMA

SUMMARY

This study analysis maternal mortality, its causes & preventable factors during a period of 5 years from 1989-1993. There were 1751 births & 29 maternal deaths during this period making maternal mortality rate of 16.5/1000 births. Direct causes were responsible for 72.2% deaths. Haemorrhage was responsible for 27.5% deaths, sepsis for 20.6% and toxemia for 17.2% deaths. Indirect causes were present in 27.4% of deaths in the form of anemia 10.3%, malaria 10.3%, viral encephalitis and hepatitis 3.4% each. In 90-95% of maternal deaths preventable factors were present. This could have been done by proper ante and intra natal care, by correction of anemia and by providing effective blood transfusion services.

MATERNAL AND METHODS

The present study is a retrospective analysis of maternal deaths over a period of five year carried out in department of obstetric and Gynaecology of Pramukhswami Medical College, Karamsad, Gujarat. This institute is a rural medical college, mainly caters to illiterate, rural and low socioeconomic community. The aim was to find out various factors responsible for the maternal deaths and preventive measures if any.

The study was done from 1989-1993. During this period there were total 29 maternal deaths. Individual case papers of these patients were thoroughly scrutinised for full details about parity, antenatal booking, age of the patient, admission death interval and causes of deaths.

Dept. of Obst. & Gyn. P.S. Medical College, Karamsad, Gujarat.

Accepted for Publication on 21.07.1994.

OBSERVATIONS

In 5 years duration from 1989-1993 there were 1751 births and 29 maternal deaths giving the incidence of 16.5/1000 births.

All the patients except one were admitted as emergency cases. They all belonged to low socio economic group.

Table I shows agewise distribution of maternal deaths.

Table II shows distribution of patients on the basis of parity.

Table III shows the interval between admission and death.

Table IV shows causes of deaths.

Major cause of death was haemorrhage. As such direct causes were responsible for 72.2% deaths. Of the various causes of haemorrhage 37.5% were because of ante partum haemorrhage, 25% were due to postpartum haemorrhage. Ectopic pregnancy, inversion of uterus and disseminated intravascular coagulation contributed 12.5% each. Sepsis accounted for 20.6% of maternal deaths. 50% of it were due to pregnancy with septicemia, 33.3% were due to puerperal sepsis and

Table I

Age in years	No. of deaths	Percentage
Less than 20	3	10.6
20-30	20	66.9
> 30	6	20.6

Table II

Parity	No. of patients	Percentage
Primigravida	9	31.0
Multigravida	15	51.7
Grandmultipara	5	17.2

Table III

Admission to death interval	No. of patients	Percentage
< 24 hours	22	75.8
within a week	7	24.1

Table IV

Direct causes	No. of patients	Percentage	Indirect causes	No. of patients	Percentage
Haemorrhage	8	27.5	Anemia	3	10.3
Sepsis	6	20.6	Malaria	3	10.3
Toxemia	5	17.2	Viral encephalitis	1	3.4
Thromboembolism	2	6.9	Hepatitis	1	3.4
Total	21	72.2		8	27.4

Accepted

16.6% died because of septic abortion.

Toxemia attributed to 17.2% deaths. Out of these 4 cases had eclampsia and one had fulminant toxemia. 6.9% of deaths were accounted by thromboembolism.

In indirect causes anemia and malaria were responsible for 20.3%, one patient had viral encephalitis and another had hepatitis making 27.4% for indirect causes.

DISCUSSION

The present study showed a very high maternal mortality rate of 16.5/1000 births. Maternal mortality has been reported by various authors varying from 1.04/1000 births (Warawalla et al, 1989) to as high as 16.5 per 1000 births. This high incidence of maternal mortality could be due to multiple factors. As this institute is draining mainly poor and rural community, so unawareness about the antenatal care was the most important factor, as evident by the fact that none of the patients except one has received antenatal care. Though facilities for antenatal and intranatal care are present, most of the expectant mothers in rural community do not take advantage of these due to ignorance, carelessness, illiteracy, social and religious taboos.

Haemorrhage remained the commonest (27.5%) cause of death. Association of moderate to severe anemia contributed to increase in the risk from haemorrhage. Anemia was present in 84.5% of patients and it was the sole cause of death in 3 patients (10.3%). In other studies haemorrhage was responsible for deaths in 35.2% (Devi & Singh, 1987), 22.8% (Beebi,1987) and 35.6% Varawalla et al, 1989). In many cases non availability of blood at critical time was the cause of death.

Although the use of $MgSO_4$ has dramatically reduced deaths due to eclampsia, due to late referrals by the local village practitioners and ignorance on the part of relatives, most of the patients were received in a moribund condition. None of the patient had prior antenatal check up. These deaths could have been prevented by proper antenatal care and early hospitalization.

Sepsis claimed 27.5% of deaths in this study as compared to 7% (Devi & Singh, 1987), 12% (Beebi, 1987) & 3.3% (Varawalla et al, 1989) deaths reported in different studies.

CONCLUSIONS

It can be assumed that most of the maternal deaths could have been prevented but had occured as a result of negligence on the part of the patients, their relatives and local practitioners. For prevention specially in India, there is an urgent need for proper implications of existing health programmes in rural areas. For improvement of the female health status it is necessary to give them health education, knowledge of hygiene and importance of antenatal care and complications of pregnancy. Many deaths can be prevented by early and proper antenatal care, avoidance of unwanted and repeated births, training of traditional birth attendants and refresher courses for village medical practitioners and timely available facilities for blood transfusion.

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Deaths due to anemia and sepsis along with hemorrhage, DIC, anesthesia difficulties/complications, and nonavailability of ICU bed are considered potentially preventable causes and accounted for 25.38% (33/130) of all deaths.

Conclusion

The classical triad of causes of maternal mortality in our study remained sepsis, eclampsia, and hemorrhage, in the same order. According to the WHO report (2005) "make every mother and child count" hemorrhage is the leading cause of death. Sepsis and hemorrhage deaths are considered one of the potentially preventable causes of MDs.

The present study highlights the importance of early antenatal registration of all pregnancies and regular follow-up of cases by trained staff. Poor nutritional status, lack of antenatal care, unawareness of warning signs of pregnancy, unsupervised dai-handled deliveries, social bias toward blood donation, and late referrals are the major contributory factors leading to poor maternal prognosis.

The lessons learnt through review of records of MDs have helped us to identify the high-risk group, solely for the purpose of improving service-delivery system by ascertaining the cause of death, reason(s) for inability to provide appropriate care at appropriate time, and finding the key interventions at service-delivery level to prevent similar deaths. There should be active management of high-risk group by frequent ANC visits, direct consultant supervision, liberal use of CTG, color Doppler study, biochemical markers, fluid and component transfusions, aggressive management of infection, and closer monitoring of women in labor. Vigorous mass campaign for community-based maternal education program should be the top priority of all maternal and child health programs.

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MATERNAL AND NEONATAL ANEMIA AND IRON STATUS IN URBAN, RURAL AND TRIBAL POPULATION OF UDAIPUR

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Introduction

Anemia, especially due to iron deficiency, is a major public health problem throughout the world, because of high morbidity rate, its effect on work performance and immune function of the afflicted person, and on growth and mental development of the children, and high mortality during pregnancy and childhood[1]. Anemia is also widespread in India[4] and its prevalance is reported to be higher in females than in males and more in infants and children than in adults[2]. Therefore, it was considered pertinent to know how far the anemia and iron deficiency in newborn was as a consequence of maternal anemia and iron deficiency. Such studies have been done in the past but the results were conflicting. Some workers found that maternal iron deficiency did affect neonatal iron status[3-7]. While there were others who did not concur[8-12]. The present study was, therefore, aimed to re-examine the maternal-foetal relationship with respect to severity of anemia of the mother using all the red cell indices as well as iron status parameters.

Materials and Methods

The subjects of this study were parturient women admitted to the labor room of Zannana Hospital, Udaipur for delivery during July 1989 to September 1990. Only those cases were included who were free from infection and inflammation and had normal spontaneous delivery without any complications. These were selected solely on the basis of their hemoglobin level and were grouped into four : Group I ; non-anemic, Hb> 10 g/dl ; Group II, mild anemia - Hb 8.1 to 10 g/dl ; group III, moderate anemia - Hb. 6.1 to 8g/dl ; and Group IV, severe anemia - Hb < 6g/dl. The number of cases in each of the four groups was twenty.

Blood sample of mother was taken at the time of delivery, while cord blood was collected for the blood of newborn. The details are given in the earlier publication[3]. Hemoglobin (Hb), total red blood cell count (TRBC), packed cell volume (PCV), mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), and mean corpuscular hemoglobin concentration (MCHC) were determined as described in another paper[13]. The estimation of serum iron (SI), total iron binding capacity (TIBC) and transferrin saturation or percent saturation (PS) was done as reported in our recent report. Unpaired student's 't' test was applied to statistically evaluate the difference of values between the two groups and correlation coefficient (r) was calculated to establish the correlation between two parameters[14].

Results and Discussion

The maternal hematologic and iron values in the four groups is given in Table I. It can be seen that, except TIBC, there was progressive fall in all the values as the severity of anemia increased. On statistical evaluation of data the values in each group were found to be significantly different. An examination of red cell indices indicated the presence of microcytic hypochromic anemia in most of the mothers suggesting iron deficiency as the cause of anemia which conclusion is supported by SI, PS and TIBC values. As PS is also an indicator of storage iron the alarmingly low values indicate iron deficiency as a serious public health problem in some of the pregnant mothers of this region[15].

The hematologic values of the newborns were also significantly lower in anemic groups when compared to nonanemic group, except TIBC, which was increased (Table I). A progressive decline in these values was noted with the severity of anemia of mother. When the observed red cell indices were compared with normal values quoted in a standard Textbook of Pediatrics[16] many newborns were found to have values lower than lowest value of the normal range. This is especially evident in case of MCHC, MCH or TRBC than Hb. The red cell indices suggested that many babies had normocytic hypochromic anemia even at the time of birth. Serum iron of many was below normal range of neonates[16]. All these observations point to existence of iron deficiency and iron deficient erythropoiesis in the newborns. This means that iron deficiency in the mother not only affects her own iron status but also her newborn baby, albeit to a lesser extent. This is despite the fact that foetal tissues get priority over maternal requirements. The failure of those workers who reported contrary to it was partly due to use of only a single criteria (e.g. Hb), selection of cases of less severe form of anemia and faulty comparison of neonatal values with the adult values.

A significantly lower value of transferrin saturation in newborns of anemic mothers mean they are endowed with significantly lower iron stores at time of birth. So many of them may develop anemia in infancy or childhood, if not already present. A confirmation of this possibility has been published[5]. In this study, indirect confirmation of the observation that maternal iron deficiency anemia and iron status did affect foetal iron status, was provided by correlation between maternal and foetal Hb, SI and PS values. A significant correlation was found between maternal SI and neonatal SI ($r = 0.407$; $P < 0.001$) and Hb ($r = 0.362$; $P < 0.001$), maternal PS and neonatal SI ($r = 0.504$; $P < 0.001$) and Hb ($r = 0.569$; $P < 0.001$) and maternal Hb and neonatal Hb ($r = 0.468$; $P < 0.001$) indicating that neonatal Hb and SI values are dependent upon maternal SI values on which also depends maternal Hb value and that storage iron of mother (as reflected by maternal PS) also affects newborn's hemoglobin and serum iron.

Such low hematologic and iron values may seem unusual in the West, but in India these are not uncommon. The reasons are numerous but are different for different population groups. The subjects of this study actually belonged to urban, rural or tribal population and area. It was seen that hemoglobin and iron status of urban women, and the worst was in case of tribal women (Table II). It may be because urban women generally had awareness about hygiene and antenatal care, were having small families, better educational background, better socioeconomic status and hence better nutrition, than their counterparts in rural and tribal area. The main cause of iron deficiency and consequent anemia in them was poor bioavailability of non-heme iron from cereal based predominantly vegetarian diet. This aspect has been discussed in detail in another paper currently under publication[17]. Rural women had moderate anemia and lower iron status because of additional factors like repeated pregnancies and parasitic infections. Frequent attacks of

TABLE I

Hematological and Iron Values in Mothers and Newborns of Different Groups

Group		Hb (g/dl)	TRBC (10^6/mm^3)	PCV (%)	MCV (fl)	MCH (pg)	MCHC (g/dl)	SI (μg/dl)	TIBC (μg/dl)	PS (%)
Group-I Non-anemic (Hb>10.0 g/dl)	Mother	10.7 ± 0.4	3.72 ± 0.2	34.0 ± 1.6	88.7 ± 5.2	28.4 ± 1.1	31.3 ± 1.4	88.8 ± 12.2	317.3 ± 16.2	28.2 ± 5.2
	Newborn	16.0 ± 0.9	5.00 ± 0.4	53.5 ± 3.3	108.7 ± 4.0	33.8 ± 1.5	31.0 ± 0.9	121.7 ± 20.1	227.8 ± 16.2	54.0 ± 10.7
Group-II Mild anemia (Hb>8.1–10 g/dl)	Mother	8.7 ± 0.3	3.19 ± 0.2	28.5 ± 1.5	82.3 ± 3.3	27.4 ± 1.2	30.6 ± 0.9	49.4 ± 6.7	389.8 ± 30.0	16.2 ± 3.4
	Newborn	15.2 ± 0.6	4.64 ± 0.3	49.5 ± 2.3	106.6 ± 4.5	32.9 ± 2.0	30.8 ± 1.5	110.9 ± 11.5	240.1 ± 13.6	46.8 ± 11.9
Group-III Moderate anemia (Hb>6.1–8 g/dl)	Mother	7.4 ± 0.5	2.70 ± 0.2	24.5 ± 1.4	80.3 ± 4.5	25.0 ± 2.2	29.0 ± 2.1	41.4 ± 8.0	435.8 ± 31.6	9.6 ± 2.6
	Newborn	15.0 ± 0.6	4.50 ± 0.3	48.8 ± 2.7	105.1 ± 2.9	32.3 ± 1.4	29.8 ± 1.0	109.9 ± 12.4	242.3 ± 13.3	43.2 ± 7.8
Group-IV Severe anemia (Hb<6.0 g/dl)	Mother	5.2 ± 0.7	2.20 ± 0.2	18.5 ± 2.7	76.2 ± 6.7	22.8 ± 2.2	27.3 ± 1.3	30.9 ± 5.7	457.6 ± 22.8	6.8 ± 1.6
	Newborn	14.8 ± 0.8	4.46 ± 0.2	47.6 ± 3.2	104.9 ± 3.5	32.0 ± 1.1	29.2 ± 1.0	105.9 ± 12.1	249.6 ± 13.7	42.6 ± 7.4

No. of cases in each group was 20
All values are mean ± SD

TABLE II

Iron Status of Urban, Rural and Tribal Women and their Newborns and of Booked and Unbooked Cases

Group		Hb (g/dl)	SI (μg/dl)	TIBC (μg/dl)	PS (%)	Hb (g/dl)	SI (μg/dl)	TIBC (μg/dl)	PS (%)
Urban	26	10.6 ± 0.6	85.6 ± 15.6	317.8 ± 22.2	27.9 ± 5.5	16.0 ± 0.9	122.6 ± 19.9	225.9 ± 12.4	53.9 ± 10.2
Rural	46	7.9 ± 1.0	46.4 ± 16.4	410.2 ± 29.8	13.9 ± 6.2	15.1 ± 0.8	108.2 ± 18.0	243.1 ± 14.3	45.2 ± 9.9
Tribal	8	4.9 ± 0.8	28.7 ± 5.7	468.0 ± 22.9	6.1 ± 1.6	14.9 ± 1.1	103.7 ± 13.4	244.4 ± 15.3	42.3 ± 8.5
Booked	39	9.2 ± 1.6	68.8 ± 23.7	359.2 ± 26.1	19.8 ± 9.0	15.6 ± 0.9	118.0 ± 19.8	233.6 ± 15.6	51.4 ± 10.6
Unbooked	41	6.7 ± 1.5	37.8 ± 9.9	436.9 ± 37.7	8.9 ± 3.2	14.8 ± 0.7	103.4 ± 4.8	246.1 ± 13.9	41.8 ± 7.9

All values are mean ± SD

malaria may also have contributed to anemia. The main cause of severe anemia and iron deficiency in the tribal women is appalling poverty (income - less than Rs.200/- per capita per month), undernutrition, diet inadequate in calories (less than 1000 calories/day) as well as protien and other hematopoietic nutrients, unhygienic conditions, frequent attacks of diarrhoea and malaria, parasitic infestations, and of course, repeated pregnancies with short spacing and prolonged lactation period.

As all the women were prescribed calcium and iron-folic acid tablets in antenatal clinic it was considerd desirable to see the impact of antenatal checkup and advise on iron status and blood picture. There was a highly significant difference ($P < 0.001$) between all the parameters of booked and unbooked cases confirming better iron status of the mothers who had attended the antenatal clinic as well as their newborn babies (Table II). As this study specifically selected cases of anemia, the women who had benefitted most from antenatal services were excluded. However, it must be admitted that the iron status of some of the women, who had attended the antenatal clinic, as well as their newborns, was far from satisfactory (Table II). The poor iron status of these women is intriguing. It is believed that the reasons are dietary in origin. The intake of iron in the cereal based predominantly vegetarian diet is twice the intake of iron by people of western countries consuming predominantly meat group of foodstuffs[17,18].

Thus their diet was actually not deficient in iron, hence iron supplementation did not improve iron status. Perhaps what was lacking was ascorbic acid (a potent promoter of iron absorption) and protein because consumption of citrus fruits was negligible[19] and vegetarian food is poor in quality of protein[19]. Hence, it may be more sensible to prescribe during antenatal period a nutrient which is actually deficient, i.e. ascorbic acid or protein, rather than one which is quite adequate or to recommend animal food items like, meat, liver, fish and poultry to improve iron status and correct the anemia.

Summary and Conclusion

The hematologic and iron status parameters were determined in the parturient women with varying degree of severity of anemia and their new borns. It was found that the urban, rural and tribal women exhibited anemia and iron deficiency in increasing order of severity and that the maternal iron deficiency and anemia affected red cell indices and iron status of the neonate. In general, women who had received antenatal services, as well as their newborns, had better hematologic and iron status, yet it was far from satisfactory in some of them, presumably due to consumption of cereal based predominantly vegetarian diet, rich in iron, but poor in ascorbic acid and protein. It is, therefore, suggested that supplementation of ascorbic acid during antenatal period may be more beneficial than giving iron tablets/tonic.

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Original Research Article

Knowledge and practices pertaining to menstruation among the school going adolescent girls of UHTC / RHTC area of Government Medical College, Kota, Rajasthan

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ABSTRACT

Background: To achieve the goal of Millennium Development Goal 2 (universal education), 3 (gender equality and women empowerment) and, 5 (improving maternal health), it is important that there is effective menstrual hygiene and knowledge among adolescent girls since it has direct and indirect effects both to achieve the MDG and to promote the reproductive health. A study was carried out among the school going adolescents in UHTC (Urban Health Training centre) and RHTC (Rural Health Training centre) area of Department of Community Medicine, Government Medical College, Kota, Rajasthan with the following aims and objectives, Status of knowledge of school going adolescent girls about menstruation and their practice during menstruation. The objective of the study was to assess the knowledge and practices regarding menstruation among school going adolescents.

Methods: It was a school based descriptive cross sectional study conducted from November 2016 to March 2017. The school was selected randomly in RHTC and UHTC area of GMC, Kota. A pretested and structured questionnaire was used. Data was entered, processed and analyzed using SPSS version 20.

Results: In this study there were 300 girl students (150 each from RHTC and UHTC area schools), of which 55.33% had menarche at the age of 13 years, 66.00% of girls were aware about menstruation before the menarche whereas 91.67% of girls heard about the sanitary napkins, most of the girls (81.00%) had got the knowledge about menses from their mother, 62.67% of girls heard about the menstrual hygiene and for practices observed, 65.67% girls were using sterilized sanitary napkins and 42.00% of girls burn the waste material.

Conclusions: Traditional beliefs regarding menstruation still persist and menstrual hygiene among the adolescents was found to be unsatisfactory. It highlights the need of targeted interventions to raise awareness and provision of family health education package to all girls. Menstrual hygiene is an issue that needs to be addressed at all levels.

Keywords: Knowledge, Menstrual hygiene, Millennium development goal, Intervention

INTRODUCTION

Adolescents are a large and growing segment of the world's population where more than half of the world's population is below the age of twenty five defined as a period of life between 10–19 years.[1] According to UNICEF report (The State of World's Children 2011), it is estimated that there are 1.2 billion adolescents aged 10-19 years in the world, forming 18% of world population and about 88% of them live in developing countries. In India, adolescent accounts for 20% of countries population. It is a highly dynamic period characterized by

Table 3: Distribution of study subjects according to knowledge and area (n=300).*

Response Questionnaire	UHTC (n=150) No (%)	RHTC (n=150) No. (%)	Total (n=300) No. (%)
Awareness about menstruation before menarche	109 (73.67)	89 (59.33)	198 (66.00)
Heard about Sanitary Napkins	143 (95.33)	132 (88.00)	275 (91.67)
Knew about Free supply of Sanitary napkins	109 (72.67)	116 (77.33)	225 (75.00)
Heard about Menstrual Hygiene	109 (72.67)	79 (52.67)	188 (62.67)
Heard about RTI / STI	74 (49.33)	56 (37.33)	130 (43.33)
Source of information before menarche*			
Mother	127 (84.67)	116 (77.33)	243 (81.00)
Sister	29 (19.33)	16 (10.67)	45 (15.00)
Friends	40 (26.67)	68 (45.33)	108 (36.00)
Mass Media	48 (32.00)	48 (72.67)	157 (52.33)

*Multiple responses, total not additive.

Table 4: Distribution of study subjects according to practice and area

Response Questionnaire	UHTC (n=150) No. (%)	RHTC (n=150) No. (%)	Total (n=300) No. (%)
Use of Absorbant			
Sterilized Sanitary Napkins	116 (77.33)	81 (54.00)	197 (65.67)
Old Cloth	34 (22.67)	69 (46.00)	103 (34.33)
Outdoor Sports activity during menstrual period	29 (19.33)	15 (10.00)	44 (14.67)
Abdominal pain during menstruation	133 (88.67)	86 (57.33)	219 (73.00)
Irregular Menstruation	71 (47.33)	48 (32.00)	119 (39.67)
Use of toilets for the change of pads	144 (96.00)	102 (68.00)	246 (82.00)
Sharing of menstrual problems with mother / elderly relative	127 (84.67)	103 (68.67)	230 (76.67)
Sharing of menstrual problems with friends	23 (15.33)	47 (31.33)	70 (23.33)
Restriction of Kitchen activity	48 (32.00)	114 (76.00)	162 (54.00)
Disposal of used napkins / cloth			
Open area disposal	29 (19.33)	67 (44.67)	96 (32.00)
Burn	52 (34.67)	74 (49.33)	126 (42.00)
In municipal dustbins	69 (46.00)	9 (06.00)	78 (26.00)
Washing of hands after use			
With Water	39 (26.00)	60 (40.00)	91 (30.33)
With Soap	111 (74.00)	90 (60.00)	201 (67.00)

*Multiple responses, total not additive

The average age of menarche came out to be 12.99 ± with more than half of the participants (55.33%) having menarche at the age of 13 years followed by (25.67%) for 14 years and the least 0.33% at the age of 9 years. Difference in age of menarche between rural and urban area was insignificant ($p<0.01$) (Table 2).

When we saw for the knowledge of girls regarding the menstruation, we found that 66.00% of girls were aware about menstruation before the menarche, 91.67% of girls had heard about the sanitary napkins. Most of the girls (81.00%) had got the knowledge about menses from their mother, 52.33% of girls got the knowledge from mass media. On the other hand 62.67% of girls had information about menstrual hygiene and 43.33% of girls were aware about RTI / STI (Table 3).

When we saw for practices among adolescent girls, there were 65.67% girls were using sterilized sanitary napkins while rest of the study subjects were using cloths, 73.00% girls had the complaint of pain during menstruation and 39.67% had irregular menstruation while 54.00% of girls had restriction for kitchen activity due to social customs in their home. When we enquired about the disposal practices of sanitary napkins / pads, 42.00% of girls burn the waste material followed by 28.67% for open area disposal, on the other side 46.00% of urban girls and only 06.00% of rural girls use municipal dustbins (Table 4).

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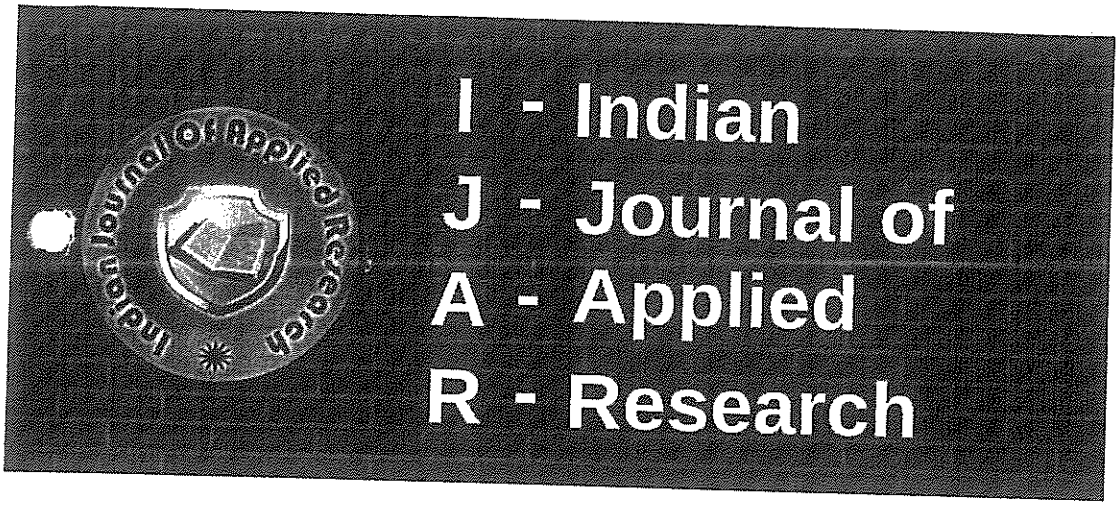

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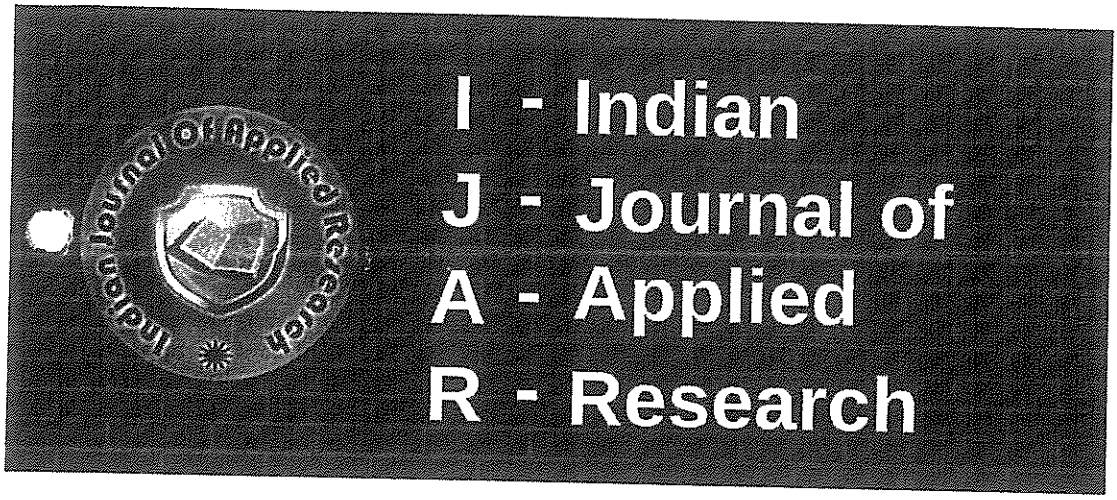

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STUDY OF CLINICAL PRESENTATION, RISK FACTORS AND RESULTS OF SURGERY IN PELVIC ORGAN PROLAPSE IN TRIBAL POPULATION OF SOUTH RAJASTHAN

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ABSTRACT Pelvic organ prolapse in rural and tribal population is major health disability in perimenopausal and post menopausal women(1).The disorder accounts for 20% of women waiting for major gynaecological surgery.(2) The Prevalence of pelvic floor dysfunction was reported to be 21% with 19.02% of the women experiencing urinary incontinence (3) Present study has been conducted on 1267 patients who have undergone vaginal hysterectomy with pelvic floor repair at PIMS UMARDA UDAIPUR in the last three years. Age, parity, low socioeconomic status, anemia, repeated vaginal deliveries, squatting all day chronic cough and manual labor and strenuous farming have been major causes. Vaginal hysterectomy with pelvic floor repair treats 90% of the disability.Aim of present study is to study causes suggest preventive aeps and to evaluate the results of surgery

KEYWORDS : Urinary incontinence, Pelvic floor dysfunction. Pelvic organ prolapsed, utero vaginal prolapse, cystocele, rectocele, enterocele, pelvic floor repair, vaginal hysterectomy

INTRODUCTION

Pelvic Floor Dysfunction including pelvic organ prolapse is one of the largest unaddressed issues in women's health care today (4). It is common and undermines the quality of life (5). Patients with pelvic floor dysfunction usually present with symptoms of incontinence which can be either urinary or anal, pelvic organ prolapse or dysfunctional bowel. It is rarely life threatening, but the symptoms can be embarrassing and, if left untreated, it can lead to social isolation, sexual inhibition, restricted employment and leisure opportunities and potential loss of independence. The women consider pelvic floor dysfunction as a normal part of the aging process and not as a disease/disorder and this is one of the reasons for not seeking medical treatment. The other reasons for non-consultation are fear of hospital visits, investigations and surgeries, lack of money/time, shyness to report issues related to reproductive system, lack of female doctors in the rural setup and dependency on their husband for treatment in terms of permission, escort and finance (6)

Uterine-prolapse is the herniation of the uterus into or beyond the vagina as a result of failure of the ligamentous and fascial supports. It often coexists with prolapse of the vaginal walls, involving the bladder or rectum(9) The Oxford Family Planning Association study reveals Level 1: The cardinal-uterosacral ligament complex provides apical attachment of the uterus and vaginal vault to the bony sacrum. Uterine prolapse occurs when the cardinal-uterosacral ligament complex breaks or is attenuated. Level 2: The arcus tendineous fascia pelvis and the fascia overlying the levator ani muscles provide support to the middle part of the vagina. Level 3: The urogenital diaphragm and the perineal body provide support to the lower part of the vagina.(7) the risk factors include Older age, Race, Family history, Increased body mass index, Higher parity, Vaginal delivery Constipation Intrapartum variables (macrosomia, long second stage of labour, episiotomy, epidural analgesia) Increased abdominal pressure and Menopause. Although vaginal delivery is clearly associated, specific obstetric risk factors remain controversial. Macrosomia, prolonged second stage of labour, episiotomy, anal sphincter injury, epidural analgesia, and the use of forceps and oxytocin have all been proposed as risk factors but have not been proved (8). Conservative treatment includes Pelvic floor muscle training and vaginal pessary. Definitive surgery is vaginal hysterectomy with pelvic floor repair (9)

MATERIALAND METHODS

Present study has been undertaken to determine the predisposing factors in development of pelvic organ prolapse and to suggest preventive measures. Further it is aimed at analysising the results of surgery. Study has been carried out at PACIFIC INSTITUTE OF MEDICAL SCIENCES UMARDA UDAIPUR RAJASTHAN. Maximum patients are tribals of south rajasthan and are very poor and malnourished. these women are married at early age have repeated pregnancies and vaginal deliveries by untrained dias putting lots of pressure no episiotomy .They usually squat all day and for toilets. They suffer from chronic cough due to smoke in kitchen OR bidi smoking and high prevevalance of tuberculosis. They can easily hide prolapsed in loose clothings. Period of study has been 2014 to 2017. Maternal age, parity, education, socio-economic status, type of delivery was in recorded. Pre-existing maternal disease, chronic cough anemia, was recorded. Maternal weight obstetric complications, tobacco use were recorded. Symptoms are recorded. Sensation of a bulge or protrusion seeing or feeling a bulge Pressure AND Heaviness Urinary symptoms include Incontinence, frequency, or urgency. There is Weak or prolonged urinary stream and Feeling of incomplete emptying. Manual reduction of prolapse is needed to start or complete voiding ("digitation") Change of position needed to start or complete voiding. Bowel symptoms include, Incontinence of flatus, or liquid or solid stool Feeling of incomplete emptying, Straining during defecation and Digital evacuation needed to complete defecation. Splinting (pushing on or around the vagina or perineum) needed to start or complete defecation ("digitation") Sexual symptoms include Dyspareunia (painful or difficult intercourse) Lack of sensation. Examination includes local, per speculum and per vaginal examination to degree of prolapsed. Any bleeding or discharge per vagina were recorded. General examination includes weight, anemia and blood pressure. Laboratory studies, hemoglobin, leukocyte count, blood sugar, urea, keratinize; liver enzymes, urine albumin and sugar were recorded. Imaging studies, x-ray chest and ultrasonography were recorded. A pelvic examination should be done (using a Sim's single bladed speculum) to define the extent of the prolapse and establish the compartments of the vagina affected (anterior, posterior, or apical). The patient should be at rest and straining during a Valsalva manoeuvre. The oestrogen status of the tissues (signs of vaginal atrophy) and the size and mobility of the uterus and adnexae should be assessed. Stage 0: No prolapsed Stage I: The most distal portion of the prolapse is >1 cm above the level of the hymen Stage II: The most distal portion of the prolapse is ≤1 cm proximal or distal to the hymen Stage III: The most distal portion of the prolapse is >1 cm below the hymen but protrudes no further than 2 cm less than the total length of the vagina Stage IV: Complete eversion of the vagina They were followed post operatively with regard to symptom relief and anatomical correction was analysed after eight weeks and at 6 months

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Original Research Article

Life Saving Obstetric Hysterectomy in Tertiary Care Hospital, Risk Factors and Indications

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Abstract

Maternal mortality ratio in India is 199per 100000 births, MMR in Rajasthan is 208 per 100000 live births and MMR in Udaipur is 284 per 100000 live births (2016) [1]. Leading causes include post partum hemorrhage (30%), sepsis, unsafe abortions, rupture of uterus and obstructed labor [2]. Emergency hysterectomy in obstetrics is rarely indicated and is always debatable but if performed timely and wisely can be life saving [3]. In the present study 24 cases (92.30%) belonged to age group of 26-35 years. 22cases (84.61%) belonged to Para 3 and 4. 14 cases (53.84%) required emergency obstetric hysterectomy to control atonic post partum hemorrhage . 6 cases (23.07%) were due to rupture of uterus , 4 case (15.38%) was due to sepsis 1 case due to cervical ectopic pregnancy. 20(76.92%) were unbooked cases with no antenatal care. There was no maternal mortality. Aim of the present study is to help reducing maternal morbidity and mortality and to suggest ways of improving maternal outcome.

Keywords: Obstetric hysterectomy, Emergency hysterectomy, Rupture uterus, Trauma to uterus, Septic abortion, Post partum hemorrhage.

Emergency hysterectomy has been considered as life saving procedure in obstetric hemorrhage since last 200 years [4]. With advent of potent drugs like prostaglandins, oxytocin, ergotamine, hemocoagulase (botroclot), tranexemic acid, blood transfusion and antibiotics, the requirement of obstetric hysterectomy has been brought down considerably [5]. Conservative approach like internal iliac artery ligation, hemostatic sutures on uterus, embolisation of uterine artery, is quite effective when ever available. Inspite of all this progress emergency hysterectomy still remains the life saving procedure and for better results it should be timed well and not done as last resort [6]. Post-partum hemorrhage remains an important cause of significant maternal morbidity and mortality throughout the world [7]. Uterine rupture is associated with clinically significant uterine bleeding, fetal distress, expulsion or protrusion of the fetus, placenta or both into the abdominal cavity, and the need for prompt cesarean delivery and uterine repair or hysterectomy [8]. The risk factors for rupture include previous cesarean sections, multiparity, malpresentation and obstructed labor, uterine anomalies and use of prostaglandins for however, the most commonly associated risk factor. The most consistent early indicator of uterine rupture is the onset of a prolonged, persistent, and profound fetal bradicardia. The signs and symptoms of uterine rupture are typically nonspecific, which makes diagnosis difficult. Delay in definitive therapy causes significant fetal morbidity. For the best outcome, vaginal birth after previous cesarean section needs to be looked after in an appropriately staffed and equipped unit for an immediate cesarean delivery and advanced neonatal support [9].

This is a prospective observational study done in a Tertiary Care Center, hospital of PIMS (PACIFIC INSTITUTE OF MEDICAL SCIENCES, VILLAGE UMARDA, UDAIPUR, RAJASTHAN from 2014 to 2019. Women who underwent emergency peripartum hysterectomy after cesarean delivery or following vaginal birth due to severe post-partum hemorrhage and who did not respond to conservative treatment were included in the study. Primary outcomes included indications, risk factors, maternal morbidity, and mortality. Age, parity, socioeconomic status, education

Complains and details of illness, obstetric history, medical and surgical history was noted. General examination included presence of anemia, blood pressure and edema. Systemic examination included cardiac and lung condition. Uterine height, presentation, position, contraction were noted. History of bleeding per vagina was recorded. Ultrasonic examination results were recorded. Blood HB, SUGAR, UREA, CREATININE, BLOOD COUNTS, BT, CT, PT, HIV, HBSAG VDRL, URINE SUGAR and ALBUMIN, BLOOD GROUPING results recorded. INDICATIONS, RISK FACTORS AND OUTCOME of emergency obstetric hysterectomy were recorded.

Table-1: Age distribution of cases of emergency obstetric hysterectomy

S.No	Age In Years	No Of Patients	Percentage
1	Less than 20	0	0
2	20-25	0	0
3	26-30	10	38.46
4	31-35	14	53.84
5	More than 36	2	7.70
		26	100

Table-2: Parity distribution of cases of emergency obstetric hysterectomy

S. No.	Parity	Number	Percentage
1	0	0	0
2	1	0	0
3	2	0	0
4	3	14	53.84
5	4	8	30.76
6	5	4	15.40
		26	100

Table-3: Risk factors of emergency hysterectomy

S. No	Risk Factors	No	Prcentage
1	Pregnancy induced hypertension	20	76.92
2	Anemia	18	69.23
3	Ante partum hemorrhage, accidental and placenta previa	4	15.38
4	Post caesarean pregnancy	6	23.07
6	Twins	1	7.70
7	Induction of labor	4	15.38
8	Un Booked cases with no antenatal visits	20	76.92

Table-4: Indications of emergency obstetric hysterectomy

S.No	Indications	Number	Percentage
1	Atonic post partum hemorrhage		
	Normal vaginal delivery	2	7.70
	Caesarean delivery	4	15.40
2	Rupture uterus		
	Post caesarean preg		
	Misuse of oxytocic	4	15.40
	spontaneous	2	7.70
	Unscarred uterus		
	spontaneous	2	7.70
	Misuse of oxytocic	2	7.70
3	Placenta praevia	2	7.70
4	placenta acreta	2	7.70
5	Septic abortion	4	15.40
6	Cervical ectopic pregnancy bleeding	2	7.70
		26	100

24 cases (92.30%) belonged to age group of 26-35 years 22 cases (84.61%) belonged to Para 3 and 4. 20(76.92%) had pregnancy induced hypertension,18(69.23% had anemia, 4(15.38%) and ante partum hemorrhage, 6(23.07) were post caesarean pregnancies.1(3.84%) were twins and 4(15.38%) induced patients 14 cases (53.84%) required emergency obstetric hysterectomy to control uterine bleeding. 10 cases (38.46%) were rupture of uterus due to misuse of oxytocics and 2case (7.70%) were due to sepsis.

Fig-1: Accidental hemorrhage with couvelaire uterus

Fig-2: Placenta acreta with post partum hemorrhage

The incidence of peripartum hysterectomy is 4.1 cases per 10,000 births. Maternal mortality is 0.6% [10]. Previous cesarean delivery, maternal age over 35 years, parity of three or greater, previous manual placental removal, previous myomectomy and twin pregnancy were all risk factors for peripartum hysterectomy. The risk associated with previous cesarean delivery was higher with increasing number first cesarean delivery in the current pregnancy were also at increased risk. Earlier studies [11] revealed incidence of 0.04 %. Prior cesarean delivery was present in 88 % of the patients; a majority of the patients were grand multiparous, Para $\geq$ 6 (65 %). The incidence of hysterectomy after cesarean delivery was much higher than after vaginal delivery (0.3 vs. 0.01 %). Common indications included placenta accreta (65 %), uterine atony (27 %), and uterine rupture (8 %)

Post-operatively, 25 patients (38 %) developed DIC, 32 (48.5 %) had febrile illnesses, and 22 (33 %) experienced injury to the urinary tract. The maternal mortality in other study was 4.5 % [12]. In another study [13] there were 18 cases of emergency hysterectomy (14 caesarean hysterectomy and four postpartum hysterectomy, after vaginal delivery), giving a rate of 0.36/1,000 deliveries. Overall, the most common indication for hysterectomy was placenta accreta (28%) and uterine atony (28%). Although there was no maternal death, intra- and postoperative complications were prevalent including cardiac arrest, disseminated intravascular coagulopathy, pulmonary edema, septicemia, and bladder injury [14]. Placenta accreta is becoming a leading cause of emergency postpartum hysterectomy [15]. Although hysterectomy is a life saving operation, it is associated with high maternal morbidity.

In the present study we did not have any maternal mortality. 20 (76.92%) were antenatal unbooked .24 cases (92.30%) belonged to age group of 26-35 years. 22cases (84.61%) belonged to Para 3 and 4. 14 cases (53.84%) required emergency obstetric hysterectomy to control uterine bleeding. cases (23.07%) were due to misuse of oxytocics and 1 case (7.70%) was due to sepsis. it has been observed in the present study that atonic post partum hemorrhage requires to be controlled in time. Multiparity big baby placenta praevia placenta acreta delayed and obstructed labor malnourished anemic compromised patient are the contributory factors. Uterine bleeding after MTP due to trauma to uterus are other factors. One interesting case of cervical ectopic pregnancy also required hysterectomy to control bleeding. Prevention lies in proper control of post caesarean normal delivery trials and mis use of oxytocics. A prompt and early decision to perform emergency hysterectomy can save life.

With the advent of prostaglandins, potent oxytocics, potent clotting factors, blood and blood products, newer antibiotics and newer conservative interventions requirement of emergency hysterectomy has markedly reduced, but this still remains life saving tool. Decision should not be delayed and will definitely reduce maternal mortality and morbidity. Regular ante natal care is the basic tools in identifying risk factors and prompt treatment.

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Original Article

Assessment of Hormonal and Reproductive Factors Associated with Low Back Pain in Reproductive Female in A Tertiary Care Teaching Hospital

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ABSTRACT

Background: *Low back pain related disability and work absence accounts for high economical costs in modern society. A prevalence of 28-80% has been found with increase of prevalence with age and female preponderance.*

Methods: *The present study was conducted on 150 non pregnant women complaining of low back pain attending Department of Obstetrics and Gynaecology, Pacific Institute of Medical Sciences during the period of one year. A brief questionnaire was used to screen, among the respondents, the occurrence of low back pain in the past year.*

Results: *Low back pain was associated with high BMI, high waist circumference, more number of children, irregular and prolonged duration of menstruation, young maternal age at first birth and with history of abortion.*

Conclusion: *The present study conclude that Hormonal and reproductive factors are associated with low back pain.*

Keywords: *Hormonal factors, Reproductive factors, Reproductive female*

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INTRODUCTION

Low back pain is defined as pain and discomfort, localized below the costal margin and above the inferior gluteal folds, with or without referred leg pain. Chronic low back pain is defined as low back pain persisting for at least 12 weeks, unless specified otherwise. A simplified and practical classification, which has gained international acceptance, is to divide low back pain into three categories-the so called "diagnostic triage"[1] : 1. Specific spinal pathology 2. Nerve root pain pain/radicular pain 3. Non-specific low back pain Low back pain is common disorder, affecting around one-third of UK adult population each year. About 20% of people of low back pain (that is 1 in 15 of population) will consult their GP about it. The presence of low back pain during pregnancy is widely reported.[2-5] One systematic review identified 56 population prevalence studies of low back pain (Walker 2000). Thirty studies were of acceptable quality. Point prevalence of low back pain ranged from 12-33%. The two reviews on low back pain in school children and adolescents reported a prevalence approaching that reported for adults.[6,7] Low back pain fluctuates over time with frequent recurrences and exacerbations.[8] The first review reported that, after a first episode of low back pain, the proportion of patient who still experienced pain after 12 months was on average 62% (range 42-75%), the percentage who experienced relapses of pain was 60% (range 44-78%) and the percentage who had relapses of work absence was 33% (range 26-37%).[9] Factors which are associated with low back pain are young age at menarche, irregular or prolonged menstruation, past pregnancy, young maternal age at first birth, and duration of oral contraceptive use, hysterectomy and use of estrogens during

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menopause.[10] Other factors associated with low back pain are previous miscarriage, presence of endometriosis, clinically suspected pelvic inflammatory disease, caesarean section scar, pelvic adhesions, sexual abuse, anxiety, and depression. Back pain is a commonly described symptom of the premenstrual syndrome.[11] Therefore this study was conducted to assess the hormonal and reproductive factors associated with low back pain in reproductive female.

METHODS

The present study was conducted on 550 non pregnant women complaining of low back pain attending Department of Obstetrics and Gynaecology, Pacific Institute of Medical Sciences during the period of one year. The subjects were randomly allocated and found 150 patients suffering from low back pain.

Inclusion criterion

1. Women attending outpatient department of obstetrics and Gynecology in UISEMH.
2. All females of age 20-45 yrs. of any religion and socioeconomic status.

Exclusion criterion

1. Women who have attained physiological menopause.
2. Subjects who were not able to communicate because of dialect or hearing problems.

Study protocol

A brief questionnaire was used to screen, among the respondents, the occurrence of low back pain in the past year. The questions included occurrence of low back pain, demographic factors and reproductive health history. Low back pain was identified among subjects who have back pain lasting for more than a day in an area between the lower coastal margin and the gluteal folds with or without radiation into leg to below the knees during the past one year. The anthropometric measurements included measures of body height (cm) and weight (kg) using standard measurement equipment's. Waist and hip circumference (cm) were assessed using a measuring tape while the subject was standing. Other factors evaluated were occupation, education and smoking. Sociodemographic profile, menstrual and obstetric history were noted and also the use of oral contraceptives.

RESULTS

Out of 550 subjects, 150 were patients of low back pain. Majority of patients, 58.8% were in age range of 45-50 years and only 10.5% in 25-30 years of age group. Out of 150, 55.6% belongs to socioeconomic Class 1 and 2. Only 35 patients had education of university and above. 28% (42/150) were Labourers and rest 72% had some other occupation. 58.66% (88/150) had weight below median (60 kg) and only 41.34% had weight above median.

Patients with BMI (>25kg/m^2) were 52.5% and 47.5% had BMI below 25 kg/m^2. 111 out of 150 had waist circumference of <80 cm and 92 (61.33%) had more than 80 cm. Their waist-hip ratio is <0.8 in 82 patients (54.66%).

Majority of patients had more than two parity (62.6%). Patients with vaginal and caesarean delivery were 62 (41.33%) and 88 (58.66%) respectively. 84 patients out of 150 had irregular menstruation. Majority of them (67.4%) had duration of flow of more than 8 days. 98 patients had premenstrual syndrome. 65.5% patients had undergone sterilization and 42.66% (64/150) were using oral contraceptives. 95 patients had history of abortion and 34.5% patients had pelvic organ prolapse.

DISCUSSION

The study showed that hormonal and reproductive factors like irregular or prolonged menstrual cycle were associated with low back pain. Estrogen related factors like past pregnancy, young maternal age at first birth, oral contraceptive use were specifically associated with low back pain. Young age at menarche was also associated with low back pain. One theory is that increased estrogen results in increased laxity of joints and ligaments. This increased laxity then leads to LBP. Like results from other studies, association was found between the number of children and low back pain.[12,13] A previous population-based survey found a linear association between the number of live births and chronic low back pain. Results from our study suggest that there is association between the parity and low back pain. In a population-based survey among women younger age at first pregnancy was also associated with a high prevalence of ever having low back pain.[13] Our study shows association between younger age at first pregnancy and low back pain. In 1995, Brynhildsen et al reported that many health professionals believe that there is an association between oral contraceptive uses with low back pain, despite the lack of scientific evidence.[14] Unlike this study our study showed no association between oral contraceptive use and LBP. We found menarche at young age (<11 YEARS) to be not associated with LBP. Although LBP is positively correlated with menstruation in women and back pain is a common symptom of the premenstrual syndrome, there are only few studies describing the association between the menstrual pattern and musculoskeletal disorders.[12,15]

CONCLUSION

Hormonal and reproductive factors like an irregular or prolonged menstrual cycle are associated with low back pain, suggesting that these factors are associated with musculoskeletal pain in general. Factors related to increased estrogen levels like past pregnancy, young maternal age at first birth, duration of oral contraceptive use may specifically increase the risk of low back pain. More research is needed to examine these associations and unravel biologic explanations.

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Assessment of Hormonal and Reproductive Factors Associated with Low Back Pain in Reproductive Female in A Tertiary Care Teaching Hospital

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Dear Dr. Vikas Gupta

Following the review of your manuscript with above mentioned Manuscript ID, submitted on 03.01.2021, Editorial Board is pleased to inform you that your manuscript is accepted for publication as Original Research Article under the section of Obstetrics & Gynaecology in the forthcoming issue of International Archives of BioMedical and Clinical Research. Your article has been sent for further processing and editing.

We thank you for submitting your valuable work to International Archives of BioMedical and Clinical Research and hope in future you would keep on sending high quality manuscripts to our journal.

With Best Regards,

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Section [redacted] Article

Recurrence Rate in Primary Pterygium Managed by Surgical Excision of Pterygium with Application of Mitomycin-C over Bare Sclera and Free Conjunctival Autografting

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ABSTRACT

Background: *To study recurrence rate in 50 cases of primary pterygium managed by surgical excision of pterygium along with application of mitomycin-C 0.02% over bare sclera for 2 minutes and ipsilateral free conjunctival autografting.* ***Methods:*** *This prospective observational study was carried out on 50 patients of primary pterygium operated between 15.03.2016—10.08.2016. Pterygium excision was done, 0.02% mitomycin-C was applied over bare sclera for 2 minutes and ipsilateral free conjunctival autografting was done using sutures. Patients were followed up for a mean period of 13.27 months for recurrence.* ***Results:*** *55 eyes of 50 patients were operated by above technique by a single surgeon1. Three (3) patients were lost in follow up. In an average follow-up time of 13.27 months, recurrence was found in only 1 case (1.92%). No serious side effects were observed in this study.* ***Conclusions:*** *Primary Pterygium managed by excision of pterygium followed by intraoperative mitomycin-C application and conjunctival autografting is an easy, reproducible and cost effective method which helps in reducing recurrence with minimal complications.*

Key words: *Pterygium, mitomycin-C, conjunctival autografting, recurrence rate.*

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INTRODUCTION

Pterygium is a condition in which subconjunctival tissue proliferates as a vascularized granulation tissue to invade and destroy superficial layers of cornea as a triangular encroachment usually from nasal side. It has an apex (head), neck and body and contains abnormal, elastotic fibrous tissue. It may present as atrophic, flat & slow growing having less chances of recurrence or it may present as rapidly progressing fleshy growth with high recurrence rates after excision.

Ordinarily it is asymptomatic. Symptoms may arise due to repeated inflammation, infection and cosmetic disfigurement. It may diminish vision due to induced astigmatism and encroachment into pupillary area. It may cause diplopia, interfere with contact lens wear and very rarely it may undergo neoplastic changes. Etiology is not clearly understood. Presence of numerous fibroblasts and elastodysplasia implicate actinic damage leading to abnormal tissue formation.

Prophylactic treatment such as avoiding long exposure to sunlight, dry & dusty environment and using UV protected glasses may help. Medical therapy is usually symptomatic in the form of decongestant, NSAID & Lubricant eye drops. Surgery is the definitive treatment.

Excision of Pterygium by bare sclera technique alone has unacceptably high recurrence rates so different modalities of

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treatment have been tried along with it. Closure Techniques have been tried using grafts (free conjunctival, Limbal-conjunctival, mucosal and amniotic membrane) with or without help of serum, glue or sutures. Antimetabolites such as Thio-tepa, Mitomycin-C & Daunorubicin and anti-VEGF drugs like bevacizumab & ranicizumab have also been tried. Keratoplasty may be used in special cases.

METHODS

The present study was conducted on 50 (fifty) patients with primary pterygium attending the eye-OPD of Ananta hospital from 25.05.2016—10.08.2016. They were managed by surgical excision of pterygium with intraoperative mitomycin-C 0.02% application for 2 minutes and free conjunctival autografting from same eye. All operations were performed by single surgeon so that surgeon's factor did not influence the outcome. Selection criteria were patients who had primary pterygium and were willing to undergo the surgery after understanding the nature of the treatment, its potential complications and prognosis.

Exclusion criteria were recurrent pterygium, associated ocular diseases and patients who did not turn-up in follow up. A written consent was taken from all the patients before the procedure. All pterygia were divided into 4 Grades as suggested by Youngson RM in 1972. Lab tests done were FBS, Hb, BT, CT, HIV, HBsAg and HCV

Surgical Technique

All patients were operated under peribulbar block. Pterygium head was shaved off the cornea trying for a minimal & smooth keratectomy and was excised midway between limbus and canthus. Freshly prepared Mitomycin 0.02% was applied over bare sclera for 2 minutes after which thorough irrigation was done using normal saline. Slightly larger sized superotemporal conjunctival flap was dissected as thin as possible without button holing. After excision, the graft was correctly oriented over bare sclera and sutured with interrupted 8-0 silk sutures. Post-operative Lubricant eye drops & Moxifloxacin eye drops QID was used. After 2 days moxifloxacin was switched over to Tobramycin-Dexamethasone eye drops QID. Patient was reviewed weekly for a month, fortnightly for 2 months and monthly thereafter for at least 6 months. Recurrence was defined as fibrovascular tissue crossing over limbus on to clear cornea in the area of previous pterygium excision.

RESULTS

Seventy patients (71) patients of pterygium attended eye OPD from 25.05.2016—10.08.2016.

As per selection criteria 50 patients (34 male and 16 female) of primary pterygia were selected and 21 were excluded. Five patients were operated for bilateral pterygia and; so, a total of 55 pterygia were operated. Three (3) patients were lost in follow-up leaving behind 52 cases of pterygia for the study. Maximum no. of patients (37.87%) was in 31-40 yrs age group.

Presenting complaints were Irritation, watering & redness in 45 (90%), discomfort & itching in 36 (72%) and cosmetic disfigurement in 5 (10%) patients.

Pterygia were graded as suggested by Youngson[1] R.M. (1972) into four Groups I—IV

And subdivided into 'a' for small sized pterygium and 'b' for large fleshy pterygium.

Most patients were in III b group 21 (40.4%) with majority falling in II and III grades 45 (86.5%)

Mean duration of disease was 8.25 years (Range 2—20 yrs). Follow up time varied from 7—15 months (Mean 13.27 months)

Pterygium was nasal in all cases and bilateral in 12 cases. In patients having bilateral pterygia 5 patients opted for surgery in both eyes and 7 patients opted for surgery in only one eye having advanced pterygium. Ocular movements were normal and IOP was within normal range (10—20 mm of Hg) in all cases. Post-op subjective complaints were mild ocular pain in 34(68%), redness & discomfort in 33(66%) and foreign body sensation, epiphora & itching in 21(42%). Treatment was conservative and symptoms resolved in coming days.

Objective signs in early Post-op were haemorrhage/hematoma beneath the graft in 8(15.4%), serous exudates beneath the graft in 8(15.4%), cut through one/two sutures in graft in 3(5.7%), encroachment of graft over cornea in 2(3.8%) and Superficial punctuate epitheliopathy of cornea in 2(3.8%). All were managed conservatively and they resolved in coming days. Superotemporal donor bed of conjunctiva healed uneventfully.

A late Post-op complication was graft retraction in 2(3.8%) cases which healed normally within 3—4 weeks. Recurrence was found in only 1(1.92%) case after 45 days of surgery in a 21-year-old patient who had bilateral fleshy pteryiga (Grade IV 'b') pre-operatively.

Anterior segment, ocular movements & IOP showed no significant changes when compared to pre-op findings.

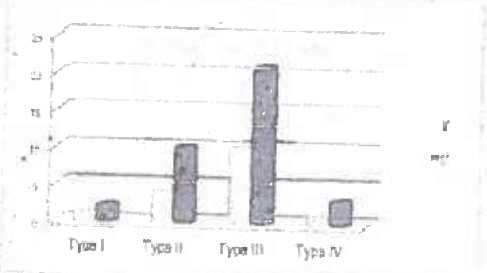

Figure 1. GRADING OF 52 PTERYGIA.

Grading of 52 Pterygia			
TYPE	PTERYGIUM INVADING	'a'	'b'
I	<1.5 mm cornea	1	2
II	< half the radius of cornea	4	10
III	>half the radius of cornea	10	21
IV	almost center of cornea	1	3

DISCUSSION

One of the most important aim in management of pterygium is to prevent its recurrence after removal. Different modalities of treatment have been tried to prevent recurrence with varying success. We tried to combine two well documented modalities of treatment for management of pterygium.

In our study 55 primary pterygia (in 50 patients) were operated by surgical excision of pterygium, intra-operative application of 0.02% mitomycin-C over bare sclera for 2 minutes and ipsilateral free conjunctival autografting. Out of these 55 cases, 3 were lost in follow-up leaving 52 cases for the study. All the operations were performed by single surgeon[11], so that the surgeon's factor did not influence the surgical outcome in terms of complications and recurrence. Maximum number of pterygia was in II and III grades 45 (86.5%).

Duration of disease in our study varied from 2—20 yrs (mean 8.25 yrs). Follow-up time varied from 7—15 months (mean 13.27 months).

Post-operative complaints were mild and were successfully managed conservatively.

Post-operative complications were trivial and got resolved by conservative treatment.

Recurrence was found in 1 case (1.92%) in our study after 45 days of surgery in a 21 yr old person who had bilaterally large fleshy pterygia (grade IV 'b') preoperatively.

Hirst LW (1994)[12] found that 50% recurrences occur within 120 days of surgery and 97% by 12 months. Recurrence could be contributed to the fact that the disease activity is more in young age groups and the fleshiness of pterygium which is a significant risk factor in recurrence as was found by Tan et al[13] in 1999.

When only mitomycin-C was used, Recurrence rates observed was 4% by Frucht Pery[14] (1994), 25% by Levartovsky[15] (1998) and 7.9% by Cheng[16] HC (2001).

When only Conjuctival autografting was performed, Recurrence rate observed by Kenyon[17] (1985) was 5.3%, Riordan [18] Eva P (1993) was 7.64% and Ti se[9] et al (2000) was 20.8%.

Wong[10] VA & Law FC(1999) found 18% recurrence in conjunctival autograft cases and 9% recurrence in patients treated with mitomycin-C + conjunctival autograft.

Serious complications reported by Rubinfeld[111] (1992) such as corneal ulceration, scleral thinning, cataract formation, uveitis, secondary galucoma and plaque formation were not found in our study.

The combined use of these two modalities (mitomycin-C & conjunctival autografting) has not been studied extensively in the management of pterygium. We used mitomycin-C in low dose and for short duration, as recommended in previous studies, to minimize complications.

In our study combined use of these two modalities has been found to be synergistic to each other; thereby increasing the success rate and decreasing the complications.

CONCLUSION

In the present study 52 primary pterygia were managed by surgical excision of pterygium, application of 0.02% mitomycin-C over bare sclera for 2 minutes followed by ipsilateral free conjunctival autografting. In an average follow-up time of 13.27 months the recurrence was found in only 1 case (1.92%); which is much lower as compared to bare sclera technique alone or when combined with either mitomycin-C or with conjunctival autografting. Complications encountered in present study trivial in nature & were easily managed. No serious side effects were observed in this study. In the view of low recurrence rate with minimal and mild complications this cost-effective modality of pterygium management seems to be a very good choice as a first line of treatment for primary pterygium.

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ROLE OF INTRANASAL CORTICOSTEROID IN ALLERGIC RHINOCONJUNCTIVITIS

ENT

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ABSTRACT

Objective: To assess the relationship between allergic rhinitis and allergic conjunctivitis and to assess the role of Intranasal corticosteroid in the management of Allergic rhinoconjunctivitis.

Material and methods: The study was done in Ananta Institute of medical Sciences, Rajsamand, Rajasthan from February 2016 to October 2017. A total of 100 patients with the diagnosis of allergic rhinitis or allergic conjunctivitis attended ENT or Ophthalmology outpatient department were included in our study. Type I allergy was tested by a specific IgE antibody test in the blood. iTNSS (instantaneous total nasal symptom score), iTOSS (instantaneous total ocular symptom score), rTNSS(reflective total nasal symptom score) and rTOSS (reflective total ocular symptom score) were noted before as well as after 1 week treatment with intranasal steroid spray Fluticasone Furoate(FF).

Results: A total of 100 patients were included in our study out of which 47 were male and 53 were female. Age of the patients ranges from 20 to 60 years with the mean age of 34.8 years.

79% cases included in present study were having symptoms of rhinoconjunctivitis, 13% cases were having only rhinitis symptoms and rest 8% were having only conjunctivitis symptoms.

The mean pre treatment iTNSS and iTOSS scores were 4.45±2.70 and 2.35±1.45 respectively, similarly, the mean post treatment iNSS and iTOSS were 2.36±1.74 and 1.16±1.43 respectively.

Conclusion: eye symptoms frequently occur in allergic rhinitis and the mechanism behind this can be explained by a neural mechanism i.e. nasal-ocular reflex. Intranasal steroid like Fluticasone Furoate with high topical potency and low potential for systemic effects is a good candidate for rhinitis treatment as well to manage ocular symptoms.

KEYWORDS

Allergic rhinoconjunctivitis, intranasal steroid, Fluticasone Furoate

Introduction:

Rhinitis is defined as an inflammation of nasal mucosa and is characterized by itching of eyes/ears/nose/palate, sneezing, nasal congestion, clear rhinorrhoea, post nasal drip, facial pain, morning cough, headache, red watery eyes and/ or sleep disturbances.

When symptoms of rhinitis are triggered by an allergen, the resulting condition is referred to as allergic rhinitis. Allergic rhinitis may be seasonal, perennial, or may occur sporadically after specific exposures.

Eye symptoms frequently occur in patients with allergic rhinitis and are among the most bothersome symptoms so it is better to use term allergic rhinoconjunctivitis (AR) instead of using allergic rhinitis or allergic conjunctivitis separately for such symptoms.

In addition to the typical nasal and eye symptoms, AR leads to a significant impairment of the quality of life of its sufferers when measured by both generic and specific quality of life instruments [1, 2]. Also associated with the disease are fatigue and daytime sleepiness,(1,3) reduced work productivity,(4–6) impaired cognitive functioning,(7, 8) reduced learning abilities,(9) and impaired sleep (10).

The pathophysiological mechanisms of the eye symptoms in allergic rhinoconjunctivitis include a direct effect on the eye by deposited allergen and indirect effects related to the deposition of allergen in the nasal mucosa. One of these proposed mechanisms is the existence of a nasal-ocular reflex whereby the nasal allergic reaction leads to an afferent reflex response, the efferent limb of which results in eye symptoms. Among the treatments available for allergic rhinitis, intranasal steroids are most efficacious for nasal symptoms and have also shown sizeable efficacy related to eye symptoms. It is helpful for diagnosing the allergic conjunctivitis and rhinitis to have a clearer understanding of the relationship between the two diseases. So the objective of the present study is to assess the relationship between allergic rhinitis and allergic conjunctivitis and to assess the role of intranasal corticosteroid in the management of Allergic rhinoconjunctivitis.

Material and Method:

The study was done in our tertiary care hospital from February 2016 to October 2017. A total of 100 patients with the diagnosis of allergic rhinitis or allergic conjunctivitis attended ENT or Ophthalmology outpatient department were included in our study.

All the patients were thoroughly examined, clinical history was taken and routine laboratory investigations were performed to rule out any co morbid disorders.

Allergic conjunctivitis was diagnosed as if the patient had characteristic symptoms and signs based on criteria set out by Buckley in 1998(11), and allergic rhinitis was diagnosed according to the criteria set out by allergic rhinitis impact on asthma (ARIA) in 2001(12).

Type I allergy was tested by a specific IgE antibody test in the blood. Eosinophils were detected in superficial conjunctival scrapings of the superior tarsal conjunctiva, and mucosal surface scrapings of middle meatus was taken in some severe cases (with permission of patient for the examination).

iTNSS (instantaneous total nasal symptom score), iTOSS (instantaneous total ocular symptom score), rTNSS(reflective total nasal symptom score) and rTOSS (reflective total ocular symptom score) were noted of all the patients. Fluticasone Furoate nasal spray was then advised to all the patients to administer two puffs twice a day. Post treatment scores were then calculated after one week of treatment with intranasal steroid.

Pre treatment and post treatment scores were compared to know about the efficacy of intranasal steroids in the treatment of allergic rhinoconjunctivitis.

Results:

A total of 100 patients were included in our study out of which 47 were male and 53 were female.

Age of the patients ranges from 20 to 60 years with the mean age of 34.8 years.

79% cases included in present study were having symptoms of

patients included, 100 patients were having only rhinitis symptoms and 96 were having only conjunctivitis symptoms.

The mean pre treatment rTNSS and rTOSS scores were 4.45±2.70 and 2.48±1.56 respectively. Similarly the mean post treatment rNSS and rTOSS were 2.36±1.74 and 1.26±1.43 respectively (Table. 1). The results showed significant reduction in nasal and ocular symptom after 1 week of treatment with intranasal steroid (p value < 0.05).

Table.1 The mean pre-treatment and post-treatment total nasal symptom score and total ocular symptom score.

Scores	Pre-treatment score	Post-treatment score
rTNSS	4.25±2.45	2.45±1.80
rTOSS*	2.48±1.56	1.26±1.30
iTNSS	4.45±2.70	2.36±1.74
iTOSS	2.35±1.45	1.16±1.43

Boldface type indicates significance at a value of $p < 0.05$.
rTNSS : reflective total nasal symptom score; iTNSS: instantaneous total nasal symptom score;
rTOSS: reflective total ocular symptom score; iTOSS: instantaneous total ocular symptom score.

Discussion:

Allergic rhinoconjunctivitis is often used interchangeably with allergic rhinitis because ocular symptoms are usually present in allergic rhinitis. Studies have found a high incidence of watery/itchy eyes in allergic rhinoconjunctivitis (61–81%) (13, 14). Similarly in present study, 79% patients were having eye symptoms in allergic rhinoconjunctivitis.

There have been so many evidences and studies that support intra nasal steroids as a single-modality treatment for both nasal and ocular symptoms of allergic rhinoconjunctivitis (15, 16).

Consistent with previous studies, present study also indicated significant reduction in nasal and ocular symptoms after using fluticasone furoate nasal spray for 1 week.

The present study suggested that the beneficial effect of intra nasal steroids in reducing eye symptoms in allergic rhinoconjunctivitis is in support of existence of a nasal-ocular reflex.

However, several other mechanisms of this beneficial action have been proposed. By inhibiting local nasal inflammation i.e., production of cytokines and infiltration of inflammatory cells—intranasal steroids may have indirect systemic effects that reduce inflammation in other tissues, including the eyes (17).

Another possible explanation is that intranasal steroids may reduce inflammation of the nasolacrimal duct, thereby improving nasolacrimal drainage and reducing conjunctival exposure to allergens and inflammatory mediators (18). This hypothesis is undermined by the finding that nasolacrimal duct blockage does not increase the response to ocular antigen challenge, and by the Jones test, which shows continued patency of the nasolacrimal duct during allergic reactions in the nose (19).

It has also been suggested that intranasal steroids may travel through the nasolacrimal duct and thereby have direct anti- inflammatory effects on the conjunctiva. The lack of steroid related ocular side effects, such as glaucoma and cataract, indicates that movement through the nasolacrimal duct is not a viable mechanism for the ocular effects of intranasal steroids.

Although corticosteroids have potent systemic anti-inflammatory effects, systemic absorption of these agents after topical administration is below the level that would be expected to produce systemic effects, especially after the drug has been diluted by the blood before it can be delivered to the eye. The systemic bioavailability of fluticasone furoate after intranasal administration is less than 0.5%. Therefore, it is unlikely that intranasal steroids act systemically to relieve ocular symptoms, especially those caused within minutes of antigen challenge (18, 20).

Although our study investigated the effect of one of the available intranasal steroids, Fluticasone Furoate Nasal Spray, it is likely that the observed beneficial effect on eye symptoms in patients with allergic rhinoconjunctivitis extends to other agents also within this class.

This is evidenced by several clinical studies using other intranasal steroids that demonstrate similar beneficial effects on eye symptoms (21,22).

Conclusion:

Eye symptoms (itching, watery eyes, and redness) are an important part of the overall burden of allergic rhinoconjunctivitis and are associated with significant bother to allergy sufferers. These effects probably occur by several mechanisms, the most obvious of which, is the direct deposition of allergen in the conjunctiva and the generation of an ocular inflammatory response. Another mechanism that might contribute to the genesis of ocular symptoms in allergic individuals is a neural reflex generated in the nose upon exposure to allergen that results in an amplification of the allergic response to the other nostril and also to both eyes i.e. naso-nasal and nasal-ocular reflex. This mechanism might explain the efficacy of intranasally administered steroids in controlling ocular symptoms.

Fluticasone Furoate nasal spray is a new topical corticosteroid, with enhanced-affinity and a unique side-actuated delivery device, which is effective in improving nasal symptoms of AR. Significant improvement in ocular symptoms and in quality of life was also demonstrated. Its low oral bioavailability and high plasma protein binding minimize systemic adverse effects. A potentially prolonged nasal retention time may further enhance the efficacy of FF, which may allow for a once-daily dosing regimen in adults, adolescents, and children.

FF with high topical potency and low potential for systemic effects is a good candidate for rhinitis treatment. As expected for all new drugs, long-term safety and efficacy studies are required, which can establish the potential modification in allergic rhinoconjunctivitis management.

Conflict of interest:

No conflicts of interest exist for these authors. No relevant financial relationship exists between the authors and procedures or products used in this manuscript.

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Research Article

Allergic

Comparative analysis of efficacy and safety of Bilastine 20 mg and Levocetirizine 5 mg in the treatment of Allergic Rhinoconjunctivitis

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Objective: The present study was conducted to assess the efficacy and safety of bilastine 20 mg and compare the results with that of levocetirizine 5 mg in the treatment of allergic rhinoconjunctivitis. **Material and Methods:** It was a prospective study conducted in the Department of Ophthalmology and Department of Otorhinolaryngology at a tertiary institute of southern Rajasthan, India during the period of 6 months from September 2019 to February 2020. 100 patients of chronic allergic rhinoconjunctivitis were included in the study, of which 50 were treated with Bilastine 20 mg, and the rest 50 patients were treated with levocetirizine 5 mg. The primary assessment was done by calculating the total symptom score (TSS) before and after the 7th and 14th post-treatment day. **Results:** The age of the patients ranges from 10 years to 65 years with a mean age of 32±5.2 years. The primary efficacy parameter for assessment was a reduction in total symptom score (TSS). Both bilastine 20 mg and levocetirizine 5 mg significantly reduced the TSS on the 7th and 14th post-treatment days (p-value< 0.001). There was no significant difference between TSS of bilastine and levocetirizine after 7 days (p-value= 0.41) and after 14 days treatment (p-value= 0.68). Adverse events were reported by 10% of patients in the bilastine group and by 38% of patients in the levocetirizine group. **Conclusion:** Bilastine is a selective H1 antihistamine with good efficacy and excellent safety profile and it is highly recommended to use it as a first-line treatment for allergic rhinoconjunctivitis.

Keywords: Allergic rhinoconjunctivitis, Anticholinergic, Antihistamines, Total symptom score, Urticaria

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Introduction

Allergic rhinoconjunctivitis is a common problem worldwide and its incidences are increasing day by day [1]. Data suggest that approximately 10-40% of the global population is affected by allergic rhinoconjunctivitis [2-5]. Allergic diseases impose a negative impact on a patient's physical, social, and psychological functioning with an adverse effect on a person's work capacity and quality of life.

H1 antihistamines are used as first-line treatment to treat allergic rhinoconjunctivitis for a long time [6-8]. First-generation H1 antihistamines have many side effects including anticholinergic effects, sedation, and interaction with alcohol and other drugs. Second-generation H1 antihistamines are free of anticholinergic effects, cause no sedation, and do not interact with alcohol or other drugs and thus, are used as first-line treatment for allergic diseases.

Bilastine is a newer generation, selective H1 antihistamine of the piperidine family. It was first approved by the European society of physicians in 2010 for symptomatic treatment in allergic rhinoconjunctivitis (seasonal or perennial) and now it is available worldwide [9].

Bilastine displays only limited penetration across the blood-brain barrier so does not cause sedation or somnolence and does not alter the cognitive performance of the patient, also does not potentiate the effects of alcohol. It does not exhibit any anticholinergic or cardiotoxic effect. So bilastine is comparatively safe and well-tolerated H1-antihistamine for the treatment of allergic rhinoconjunctivitis.

The present study has been performed to compare the efficacy and safety of bilastine 20 mg with levocetirizine 5 mg for the treatment of allergic rhinoconjunctivitis.

Material and Methods

It was a prospective study conducted in the Department of Ophthalmology and Department of Otorhinolaryngology at Ananta Institute of Medical Sciences, Rajsamand during the period of 6 months from September 2019 to February 2020.

Study design: Prospective, randomized, double-blind study.

Study population: 100 patients Who attended ENT or Ophthalmology outdoor with the clinical diagnosis of allergic rhinitis or allergic conjunctivitis during the study period, were included in the study. Out of 100 patients, 50 were treated with Bilastine 20 mg, and the rest 50 patients were treated with levocetirizine 5 mg. Both the medicines were advised to take once a day orally for 2 weeks.

Inclusion criteria:

All the patients who attended ENT or ophthalmology outdoor with the clinical diagnosis of allergic rhinitis or allergic conjunctivitis during the study period were included in the study.

Exclusion criteria:

01. Non-allergic rhinitis
02. History of intake of any type of anti-allergic medication for the past 2 weeks
03. Patients are unable to complete the questionnaire or not willing to take part in the study.

Assessment:

Primary outcome: All the study participants were advised to record their total symptom score (TSS) daily for 2 weeks (14 days). TSS was calculated daily as the sum of four nasal symptoms (sneezing, itching, rhinorrhea, and congestion) and three non-nasal symptoms (ocular symptoms- tearing, itching, and redness) symptom score (NSS and NNSS respectively).

Secondary outcome: All the patients in both groups were asked to report any adverse events suffered during and after the treatment.

Statistical analysis

Data analysis was performed using Statistical Package for Social Sciences (SPSS) software, version 19.0. Data of both the groups were compared and analyzed by Chi-square test or Student's t-test.

Results

100 patients with a clinical diagnosis of allergic rhinoconjunctivitis were included in the study and were randomized to double-blind treatment with bilastine 20mg and levocetirizine 5mg once daily for 2 weeks.

The age of the patients ranges from 10 years to 65 years with the mean age of 32±5.2 years.

The primary efficacy parameter for assessment was a reduction in total symptom score (TSS). Both bilastine 20 mg and levocetirizine 5 mg significantly reduced the TSS on the 7th and 14th post-treatment days (p-value< 0.001). There was no significant difference between TSS of bilastine and levocetirizine after 7 days (p-value= 0.41) and after 14 days treatment (p-value= 0.68). this shows that the symptom-relieving effect of both bilastine and levocetirizine are comparable (Table 1).

Table-1. Effect of treatment on total symptom score (TSS) in bilastine and levocetirizine groups.

Total symptom score	Bilastine group (mean±SD)	Levocetirizine group (mean±SD)	P-value
Pre-treatment score	7.47±2.10	7.41±2.06	0.88
Post-treatment score (on 7th day)	3.66±1.80 (0.0001*)	3.97±1.99 (0.0001*)	0.41
Post-treatment score (on 14th day)	2.79±1.05 (0.0001**)	2.88±1.14 (0.0001**)	0.68

*P-value between pre-treatment and 7th post-treatment day score.

**P-value between pre-treatment and 14th post-treatment day score.

Adverse events were reported by 10% of patients in the bilastine group and by 38% of patients in the levocetirizine group. The most common adverse event was somnolence followed by fatigue and dry mouth. All the adverse events were mild in severity (Table 2).

Table-2. Adverse events reported during 2 weeks of treatment with bilastine and levocetirizine.

Adverse events	Bilastine group (n=50)	Levocetirizine group (n=50)
Headache	1	2
Somnolence	1	11
Fatigue	3	3
Dry mouth	0	3
Total	5 (10%)	19 (38%)

Discussion

Allergic rhinoconjunctivitis affects people of all ages and harms a person's work efficiency and quality of life [10-17]. Second generation oral H1 antihistamines such as Bilastine, are prescribed as a first-line medication to treat allergic rhinoconjunctivitis [7,8,18,19].

Bilastine is a potent and highly selective oral H1-antihistamine that meets all the criteria of ARIA guidelines for medications to treat allergic rhinitis. The present study was specifically designed to assess the efficacy and safety profile of bilastine for the treatment of chronic allergic rhinosinusitis and to compare these with that of levocetirizine.

In the present study, both bilastine 20 mg and levocetirizine 5 mg significantly reduced the TSS on the 7th and 14th post-treatment days (p-value< 0.001). Pre-treatment TSS in the bilastine group was 7.47±2.10 which was reduced to 3.66±1.80 on the 7th post-treatment day and further reduced to 2.79±1.05 on the 14th post-treatment day. Similarly, pre-treatment TSS in the levocetirizine group was 7.41±2.06 which was reduced to 3.97±1.99 on the 7th post-treatment day and further reduced to 2.88±1.14 on the 14th post-treatment day. There was no significant difference between TSS of bilastine and levocetirizine after 7 days (p-value= 0.41) and after 14 days treatment (p-value= 0.68). Adverse events were reported by 10% of patients in the bilastine group and by 38% of patients in the levocetirizine group. The most common adverse event was somnolence followed by fatigue and dry mouth. All the adverse events were mild in severity (Table 2).

Our findings of the efficacy of bilastine are following the preliminary findings of Kuna P et al who performed a similar study with 683 patients in 2009. They compared the effect of bilastine with cetirizine and placebo. The mean TSS on the 14th day was reduced in the bilastine and cetirizine group to a similar and significantly greater extent, compared with the placebo group (p-value<0.001). Also when the comparison is done for adverse events, significantly fewer patients in the bilastine group experience somnolence (p value<0.001) and fatigue (p-value = 0.02) than patients in the cetirizine group [20].

Another study was performed in the past by Bachert C et al with a comparison of bilastine 20 mg, Desloratadine 5 mg, and placebo. A total of 721 patients of rhinoconjunctivitis were included in the study. TSS was significantly reduced in the bilastine group with the placebo group (p value< 0.001). The safety profile of bilastine and desloratadine was comparable to placebo [21].

Similar studies were carried out by Davila et al. and Bartra et al in 2011 and the results were following the present study.

They analyzed the data about the effect of bilastine upon nasal obstruction and ocular symptoms in 2-4 weeks duration clinical trial. Davila found a significant reduction in nasal obstruction symptom score after two weeks of treatment of bilastine 20 mg or cetirizine 10 mg or desloratadine 5 mg when compared to placebo. (p-value < 0.001). similarly, Bartra et al. found bilastine more effective in relieving ocular symptoms than placebo and as effective as other active comparators [22,23].

Zuberbier T et al. performed a placebo-controlled comparative study of the safety and efficacy of bilastine 20 mg and levocetirizine 5 mg for the treatment of chronic urticaria. They found the efficacy of bilastine 20 mg was comparable to levocetirizine 5 mg in the treatment of chronic urticaria. The differences in overall adverse events were not significant among the treatment groups [24].

In summary, the present study confirms and support the literature that bilastine 20 mg is a novel, safe, and effective treatment option for patients with chronic allergic rhinosinusitis

Limitations

01. Small sample size

02. The study was conducted over a short period

Conclusion

Bilastine is a new generation, non-sedating H1 antihistamine of the piperidine family. The present study was a comparative analysis of efficacy and safety between bilastine 20 mg and levocetirizine 5 mg for the treatment of chronic allergic rhinoconjunctivitis. The study suggests that a therapeutic dose of 20 mg bilastine meets current EAACI/ARIA criteria for medications used in the treatment of allergic rhinoconjunctivitis. Bilastine has similar efficacy to another second-generation H1 antihistamine with a more favorable safety profile so it can be used as a first-line treatment of allergic rhinoconjunctivitis.

What does the existing study add to the existing knowledge?

Many antihistamines are used as first-line treatment for allergic rhinoconjunctivitis but older generation antihistamines have some safety issues so newer medications are used nowadays.

Bilastine is a newer generation non-sedative H1 antihistamine with comparable efficacy and a better safety profile.

The present study adds various benefits of bilastine over other antihistamines and supports the fact that bilastine can be used as a first-line treatment for allergic rhinoconjunctivitis.

Author Contribution

Dr. Devendra Sharma: Study concept and design, revision and proof.

Dr. Hemendra Bamaniya: Data Analysis, statistics, and final drafting

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To,

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LETTER OF ACCEPTANCE

Dear Sir/madam,

Thank you very much for submitting your following Paper:

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Authors Name: Dr. Devendra Sharma, Dr. Hemendra Bamaniya
Corresponding Author: Dr. Hemendra Bamaniya, Associate Professor, Department of Otorhinolaryngology, Ananta Institute of Medical Sciences, Rajsamand, Rajasthan

We are pleased to inform you that your paper has been accepted for publication in OAS VOL.6 NO. 3 SEPT-DEC 2020 issue. This letter will serve as my formal acceptance of your paper to the 'Ophthalmology and Allied Sciences (OAS)'.

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Original Research Article

To Compare efficacy of carboxymethyl cellulose .5% eye drops versus use of 0.5% carboxymethylcellulose eye drop with combination of 0.1% tacrolimus ointment twice daily for treatment of severe dry eyes

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Abstract

Background: Dry eye disease is a common disorder provoking changes in tear film and ocular surface. Untreated dry eye could cause ocular infections, corneal ulcer and blindness. Only a few drugs are authorized so far for the treatment of severe dry eye disease and the possibilities of evolution in this sector are immense.**Objectives:** Compare efficacy of carboxy methyl cellulose .5% eye drops versus use of 0.5% carboxy methylcellulose eye drop with combination of 0.1% tacrolimus ointment twice daily for treatment of severe dry eyes.**Material and Methods:** 40 patient presenting with severe dry eye were selected randomly. They were divided into 2 groups. Group I received CMC.5% eye drops four times a day and group II received of 0.1%tacrolimus ointment two times daily and .5% CMC eye drops 4times a day. All patients were evaluated on day 0, 2 weeks, 1 month, 3 month and 6 month for relief in ocular symptoms and diagnostic dry eye tests.**Results:** The mean age in group I was 40.72 ± 6.85 years and in group II was 39.2 ± 5.28 years. Ocular discomfort, dryness and tearing were seen in all the cases. Comparison of different parameters after six months of treatment between group I and II showed that the comparision of net score in two groups is statistically significant($p < 0.05$). **Conclusion:** There was statistically significant difference between the outcome of two groups.Group 2 patients who used combination of of 0.1%tacrolimus ointment two times daily along with CMC 0.5% eye drops 4 times a day were better relieved as compared to patients in group 1 who used 0.5% CMC eye drops four times daily for treatment of severe dry eyes

Keywords: Carboxymethylcellulose, Tacrolimus, Dry eye

Introduction

Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface[1]. Dry eye is one of the most common causes of ocular morbidity in patients presenting to an ophthalmology outpatient department. Approximately one out of seven individuals aged 65–84 years report symptoms of dry eye often or all of the time[2].Management of dry eye depends on the cause and severity of the condition.Various strategies have been described for medical management of dry eye; these include, the topical use of lubricants (artificial tear substitutes), topical corticosteroids and anti-inflammatory therapies, cyclosporine ophthalmic emulsion, tacrolimus ointment and the systemic use of antioxidants (e.g., omega-3 fatty acids)[1,2].Artificial tears are aqueous solutions containing polymers that determine their viscosity, retention time, and adhesion to the ocular surface. Various polymers currently in use include cellulose derivatives (e.g., hydroxypropyl methylcellulose [HPMC], carboxymethylcellulose [CMC]), polyvinyl derivatives (e.g.,polyvinyl alcohol), chondroitin sulfate, and sodium hyaluronate. In mild-to-moderate cases, they are the mainstay of treatment. Artificial tears act by replenishing the deficient aqueous layer of the tear film and diluting the inflammatory cytokines[2,3]. A novel treatment therapy for severe dry eye cases with potent anti-inflammatory effects as well as sufficient safety is needed. Tacrolimus(FK 506) is a macrolactam derivative with immuno modulatory and anti-inflammatory activity[4]. Produced by the fungus *Streptomyces tsukubaensis*, it suppresses T cell activation and IL-2 production by binding to an immunophilin and inhibiting the enzymatic activity of calcineurin[4,5]. Extensive testing has shown systemic absorption of tacrolimus to be below quantifiable levels with no evidence of cancer risk or significant local side effects and only occasional reports of transient burning or pruritus at the application site[6].Topical tacrolimus ointment is commercially available in two strenghts 0.03% and 0.1%[7].Topical tacrolimus 0.03% skin ointment has been used effectively for inflammatory conditions of the anterior segment[8-11]. The good safety profile of 0.1% tacrolimus ophthalmic suspension based on the low blood concentration of tacrolimus, coupled with demonstrated better efficacy, make it an important tool for treating severe dry eye cases. Therefore we chose 0.1% tacrolimus ointment in this study.Side effects noted in use of tacrolimus ointment are burning sensation, activation of herpes simplex dendritic keratitis and development of molluscum contagiosum[12,13].There is lack of studies regarding this topic in this area so we did this study to see efficacy of 0.1% tacrolimus ointment in treatment of severe dry eye cases.

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Material and Methods

A comparative prospective study was carried out at Saraswathi Institute Of Medical Sciences Anwarpur(Hapur).Patients were enrolled from February 2019 to September 2019. 20 patients i.e 40 eyes were included in each group presenting with severe dry eye in eye OPD.Patients were randomly divided in two groups Inclusion criteria: 1. Patients with severe dry eye willing to participate in the study and followup

Exclusion criteria

Patients with trachoma 2.Patients with infectious diseases of eye 3.Patients with hypersensitivity to tacrolimus 4. Patients who had less than 6 months follow up 5.Systemic administration of immuno supressants within 2 weeks prior to study.6.pregnant or lactating females7.patients with any cardiac,renal or hepatic disease or diabetes.This study was conducted in compliance with the Declaration of Helsinki.Study was approved by ethical committee of the institute. A valid written consent was taken from patients after explaining study to them. Detailed history was taken. Appropriate laboratory work up was done. Group 1 where patients used carboxy methyl cellulose .5% eye drops four times a day for treatment of severe dry eye. Group 2 in which patients used 0.5% carboxy methyl cellulose eye drops four times daily along with .1% tacrolimus ophthalmic ointment twice daily in treatment of severe dry eyes. All patients were evaluated on day 0, 2 weeks, 1 month, 3 month and 6 month for relief in ocular symptoms and diagnostic dry eye test were done. Diagnostic dry eye test included SCH—Schirmer's test, TBUT—tear breakup time, FLU—fluorescein stain,Rose Bengal staining and marginal tear strip test.Each ocular symptoms(ocular discomfort,foreign body sensation,itching,dryness, photophobia, lacrimation) and dry eye test were scored from 0 to 3 depending on severity and combined score of all symptoms and test was calculated on each follow up visit for each eye individually of each patient in both groups. Net score was calculated as difference between total score (of all symptoms and test) on day 0 and total score at 6 month follow up. Net score actually gives improvement score after use of drug for 6 months in both groups. Net score is then compared in both groups to find the comparative efficacy of drugs in both groups.Net score in both groups was compaired using unpaired t test.

Results

Table 1: Distribution of cases as per age and sex

Parameters	Group I	Group II
Total cases	20	20
Age (Mean±SD)	40.72 ± 6.85	39.2 ± 5.28
Gender (M:F)	11:9	10:10

The mean age in group I was 40.72 ± 6.85 years and in group II was 39.2 ± 5.28 years.Two groups were comparable with regards to age and sex in distribution of patients

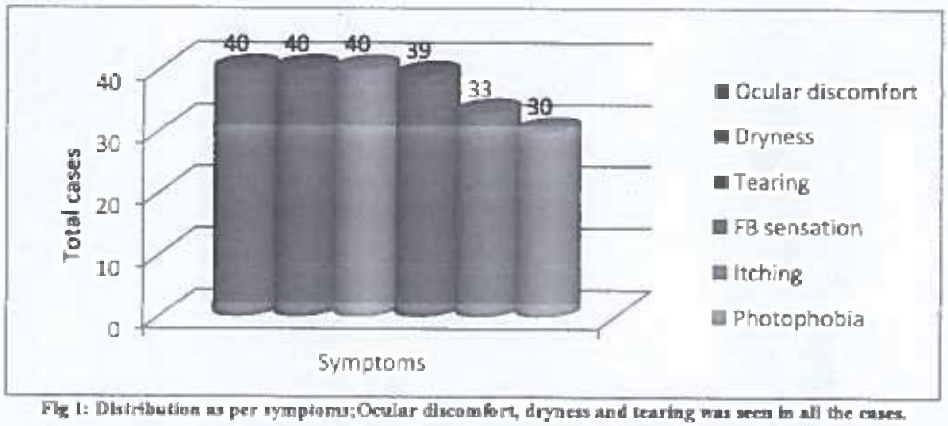

Fig 1: Distribution as per symptoms;Ocular discomfort, dryness and tearing was seen in all the cases.

Table 2: Parameters in both the groups on day 0

Parameters	Group I Mean score	Group II Mean score
Marginal tear strip test	1.75	1.55
SCH	1.72	2.0
TUBT	1.67	1.7
FLU	1.67	1.65
Rose Bengal staining	1.72	1.92
Ocular discomfort	2.20	2.02
Foreign body sensation	2.0	1.87
dryness	2.25	2.02
Itching	1.40	1.80
Photophobia	1.35	1.62
Tearing	1.87	1.65

SCH—Schirmer's test, TBUT—tear breakup time, FLU—fluorescein stain

Table 3: Different parameters in group I and group II after 6months

Parameters	Group I Mean score	Group II Mean score
Marginal tear strip test	0.72	0.15
SCH	0.55	0.30
TUBT	0.25	0.27
FLU	0.40	0.05
Rose Bengal staining	0.42	0.25
Ocular discomfort	0.65	0.32
Foreign body sensation	0.65	0.37
dryness	0.72	0.42
Itching	0.20	0.07
Photophobia	0.35	0.15
Tearing	0.85	0.40

Table 4: Comparision of score parameters between group 1 and group 2 of each ocular symptom and dry eye test between day 0 and 6 month

Parameters	Group 1 (Mean Change Score)	Group 2(Mean Change Score)
Marginal tear strip test	1.03	1.40
Schirmer test	1.17	1.70
TBUT	1.42	1.43
FLU	1.27	1.60
Rose Bengal staining	1.30	1.67
Ocular discomfort	1.55	1.70
Foreign body sensation	1.35	1.50
Dryness	1.53	1.60
Itching	1.20	1.10
Photophobia	1.00	1.45
Tearing	1.02	1.25

Net score-difference between total score of each ocular symptom and dry eye test between day zero and 6 month.
Mean net score in group 1=13.75
Mean net score in group 2=16.45
Net score in group 2 is more than group 1
The difference in net score of 40 eyes from each group was found to be statistically significant $p<0.05$(unpaired t-test)

Discussion

Dry eye is a common complaint among middle-aged and older adults and its prevalence increases progressively with age[14-16]. Studies from India reported that the prevalence varies between 18.4% and 53 % [17-19]. This was a comparative study conducted on 40 severe dry eye cases presenting to eye OPD. The mean age in group I was 40.72 ± 6.85years and group II was 39 ± 5.28 years respectively. Similar study was concluded by Moawad P et al[20] In the present study the male to female ratio was 1:1 with 21 (52.5%) males and 19 (47.5%) females. Majority of patients reported dramatic symptomatic relief during treatment period.Patients showed improvement in terms of decrease in score values at different follow ups.All patients had relief in foreign body sensation,discomfort,tearing,photophobia,dryness and itching.At the end of study i.e.at 6 months,eyes having score 03 for different symptoms were 0 in both groups,those with moderate score 02 for different symptoms were more in group 1 as compared to group 2 and greater percentage of eyes from group2 had score 0 for different ocular symptoms. In the present study ocular discomfort, dryness, tearing was seen in all cases. While in a study by Kamalakshy J et al[21] most frequent ocular surface symptom in confirmed cases of dry eye was itching. In another study by Lee AJ et al conducted in Indonesia burning sensation was the most common symptom [14]. In this study use of topical tacrolimus0.1% ointment and CMC 0.5% in group II showed significant improvement in all the parameters specially TBUT and SCH which was in accordance to other studies like Moawad P et al[20] and MoscoviciBK et al[22] and Aoki S et al[23].This is explained by the fact that the ocular surface, lacrimal glands and the neuronal feedback loop that make up a single functional unit for the maintenance of ocular surface homeostasis leading to improvement of the ocular surface.Moscoviki et al[22] showed significant decrease in sandy or gritty feeling, dryness, itching and blurred vision in patients treated with tacrolimus.03%.A study by Marco E S et al[23]showed improvement in signs and symptoms of dry eye diseases in patients treated with tacrolimus 03% .In our study results show better relief in all ocular symptoms in group 2.Therefore our study is in accordance with study of Moscoviki et al[22] and Marco E S et al[23].

Tacrolimus has immunomodulatory role so it effectively improves tear secretion in immune origin dry eye patients.Mean net score in group 2 was more than group 1 indicating more improvement in group 2.Difference in net score in both groups was found to be statistically significant. A recent publication by Ashena Z et al[25] also mentions the immunomodulatory role of 0.3% tacrolimus in treatment severe dry eye cases.In our study, only two patients from group 2 showed burning sensation after use of tacrolimus ointment but burning sensation subsided gradually and no patient discontinued the drug use which was consistent with study by Rustin et al[6].

Conclusion

Present study concludes that there is statistically significant difference in response(in terms of improvement in tear film profile tests and ocular symptoms) in patients treated with combination of tacrolimus 0.1% ointment and CMC 0.5% drops as compared to patients treated with .5% CMC eye drops only. It also strengthens the fact that topical tacrolimus0.1% twice daily plus CMC 0.5% has no adverse effect.

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Prevalence and Causes of Visual Impairment in an Area of Western Uttar Pradesh

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ABSTRACT

Introduction: It has been recently estimated by the World Health Organization (WHO) that there are 285 million visually impaired people worldwide, among whom 39 million are blind.

Aims and Objectives: To study Prevalence and causes of visual impairment in an area of western Uttar Pradesh.

Methodology: This was cross-sectional study in the 3217Patients attending eye OPD in Saraswathi Institute of ophthalmology Hapur from Jan2018 to October 2018. Patients above 30 years of age were enrolled for study.2234 patients fit the inclusion criteria.2016 participated in study. Detailed ocular examination was done. visual impairment was defined as visual acuity less than 6/18 in better eye. The details of patients and all routine investigations were carried out. The causes of visual impairment were found out. Data entered to excel sheet and analyzed by Excel software for windows 10.

Result: In our study we have seen that the majority of the patients were in the age group of 60-70 (39.14%), followed by 50-60 in 28.42%, 40-50 were 12.40%, >70 were 11.66%, 30-40 were 8.38%. The majority of the patients were Male i.e. 55.85% and Female were 44.15% Out of 2016 patients 665 i.e. 33% were having visual impairment. The most common cases were Cataract - 39%; Uncorrected refractive errors- 21%; Retinal diseases like diabetic retinopathy and age related macular degeneration- 13%; Trauma- 9%; Glaucoma- 8%; Iridocyclitis- 6%; Corneal opacity -4%.

Conclusion: It can be concluded from our study that majority of the patients were in the age group of 60-70, the majority of the patients were Male. The prevalence of VI was 33% and most common causes were Cataract, Uncorrected, refractive errors, Retinal diseases, Trauma, Glaucoma, Iridocyclitis, Corneal opacity.

Keywords: *Visual Impairment (VI), Cataract, Refractive errors, Retinal diseases, Corneal opacity, Glaucoma*

Introduction

It has been recently estimated by the World Health Organization (WHO) that there are 285 million visually impaired people worldwide, among whom 39 million are blind.[1] In India, 62 million people are estimated to be visually impaired, 8 million of them being blind.[1] Visual impairment is currently defined as presenting visual acuity of less than or equal to 6/18 in the better eye, whereas blindness is defined as presenting visual acuity of less than or equal to 3/60 in the better eye.[2] Disability is an umbrella term for impairments, activity limitations, and participation restrictions.[2] The registration of blindness or visual impairment entails a certification of the disabled individuals based on which social services are coordinated. It also provides contemporary data regarding the incidence and causes of visual impairment for analysis and to set up priorities for their prevention. Registration of blindness is voluntary in India and the certificate is issued by a duly constituted medical board of experts, which includes an

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ophthalmologist. All individuals with visual disability of 40% or higher are entitled to various concessions and job benefits according to guidelines issued by the Ministry of Social Justice and Empowerment of the Government of India.[3] According to the 58th round data from the National Sample Survey Organization (NSSO) in India, blindness and visual impairment were found to account for 10.88% and 15.27%, respectively, of all categories of disabilities.[4] So we have found out causes of visual impairment in an area of western Uttar Pradesh.

Methodology

This was cross-sectional study in the 3217 patients attending Eye OPD in Saraswathi Institute of ophthalmology Hapur from Jan2018 to October 2018. Patients above 30 years of age were enrolled for study.2234 patients fit the inclusion criteria.2016 participated in study. Detailed ocular examination was done. Visual impairment was defined as visual acuity less than 6/18 in better eye. The details of the patients and all routine investigations were carried out. The causes of visual impairment were found out. Data entered to excel sheet and analyzed by Excel software for windows 10.

Result

3217 Patients attended Eye OPD in Saraswathi Institute of ophthalmology Hapur from Jan2018to October 2018. Patients above 30 years of age were enrolled for study.2234 patients fit the inclusion criteria.2016 participated in study.

Table 1: Distribution of the patients as per the age

Age	No.	Percentage (%)
30-40	169	8.38
40-50	250	12.40
50-60	573	28.42
60-70	789	39.14
>70	235	11.66
Total	2016	100.00

The majority of the patients were in the age group of 60-70 (39.14%), followed by

50-60 in 28.42%, 40-50 were 12.40%, >70 were 11.66%, 30-40 were 8.38%.

Table 2: Distribution of the patients as per the sex

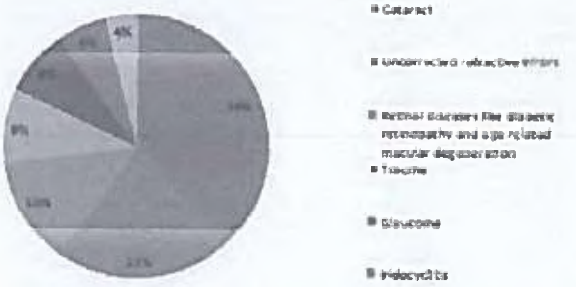
Sex	No.	Percentage (%)
Male	1126	55.85
Female	890	44.15
Total	2016	100.00

The majority of the patients were Male i.e. 55.85% and Female were 44.15%

Table 3: Distribution of the patients as per the Visual impairment

Visual impairment	No.	Percentage (%)
Cataract	259	39%
Uncorrected refractive errors	140	21%
Retinal diseases like diabetic retinopathy and age related macular degeneration	86	13%
Trauma	60	9%
Glaucoma	53	8%
Iridocyclitis	40	6%
Corneal opacity	27	4%
Total	665	100%

Out of 2016 patients 665 i.e. 33% were having visual impairment. Most common causes were Cataract - 39%; Uncorrected refractive errors- 21%; Retinal diseases like diabetic retinopathy and age related macular degeneration- 13%; Trauma- 9%; Glaucoma- 8%; Iridocyclitis- 6%, Corneal opacity -4%.



Graph 1: Distribution of as per the patients as per the Visual impairment

Discussion

Eye diseases, vision loss and resulting disability remain major public health concerns.[5] It has been

estimated that globally 253million people are visually impaired out of which 36million are blind and 217million have moderate to severe visual impairment (VI). [6] Though there has been a decline noted in prevalence of blindness over recent times, blindness has actually increased in absolute terms owing to increase in numbers of older people with rise in life expectancy.[6] Much of this global burden is distributed unevenly and some regions have higher burden compared with others. The south Asia (that includes India) region contributes maximum to global blindness and moderate or severe visual impairment burden. It is estimated that south Asia has 12million blind people and 61million people with moderate or severe Visual Impairment[6] The age standardised prevalence of moderate or severe Visual Impairment in South Asia is three times higher than high-income regions.[6] Much of the load of blindness (80%) has been attributed to avoidable causes that can be either prevented or corrected easily.[5] The maximum Visual Impairment is seen in older adult population that is after 50years of age.86% of those blind and 80% of those with moderate or severe Visual Impairment are older than 50years[6]. The global eye health action plan 2014–2019, endorsed by the 66th World Health Assembly, charted out broad eye health programmatic components. A vital target was set to achieve reduction in prevalence of avoidable Visual Impairment by one-quarter until 2019 against baseline values in year 2010. One of the key objectives included under this plan was to undertake epidemiological surveys on Visual Impairment at regular intervals nationally and subnationally, so as to generate evidence about magnitude and causes of Visual Impairment.[7] According to recent global estimates, India records one of the highest prevalence of Visual Impairment. The age-standardized prevalence of blindness and moderate or severe VI in India is 4% and 17%, respectively, among adults aged 50 and more.[6] The last nationwide blindness assessment undertaken in India was published way back in 2008.[8]

In our study we have seen that the majority of the patients were in the age group of 60-70 i.e 39.14%, followed by 50-60 (28.42%), 40-50 (12.40%), >70(11.66%), 30-40 (8.38%). Majority of the patients were Male i.e. 55.85% and Female were 44.15%. Out of 2016 patients 665 i.e. 33% were having visual impairment. The most common cases were Cataract - 39%; Uncorrected refractive errors- 21%; Retinal diseases like diabetic retinopathy and age related macular degeneration- 13%; Trauma- 9%; Glaucoma- 8%; Iridocyclitis- 6%; Corneal opacity -4%.

Sumit Malhotra et [13] al found Visual Impairment to be 24.5% (95% CI 21.1 to 26.3) in their study. This is almost similar to recent population-level estimates from southern states of India. The reported prevalence of Visual Impairment in adults aged >50 years in a newly formed southern state of Telengana was 23.5% (95% CI 22.1 to 25.0).[12] The Andhra Pradesh Rapid Assessment of Visual Impairment study that included both rural and urban clusters estimated prevalence of Visual Impairment as 23.1% (95% CI 21.8 to 24.5).[13] They also found 87% of VIisual Impairment was contributed by two causes—uncorrected refractive errors (50%) followed by cataract (37%). The most common causes for blindness (57%) and severe Visual Impairment (70%) was cataract. This is consistent with other studies[9 10 11] where 80%–90% of Visual Impairment is attributed to these two causes. Globally, majority of Visual Impairment is contributed by uncorrected refractive errors followed by cataract. Cataract and uncorrected refractive errors combined contributed to 55% of blindness and 77% of vision impairment in adults aged 50 years and older in 2015.[12] Also, globally in 2015, the leading causes of moderate or severe Visual Impairment in those aged 50 years and older were uncorrected refractive errors (52%) followed by cataract (25%).

Conclusion

It can be concluded from our study that majority of the patients were in the age group of 60-70yrs of age and majority of the patients were Male. The prevalence of Visual Impairment was 33% and most common causes were Cataract, Uncorrected, refractive errors, Retinal diseases, Trauma, Glaucoma, Iridocyclitis, Corneal opacity

Conflict of Interest: Nil

Source of Funding: The study was carried out at Saraswathi Institute Of Medical Sciences,Hapur and no extra financial support was required

Ethical Clearance: Ethics committee approval was obtained before study

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Comparative Study of CMC 0.5% Eye Drops versus Combination of .05% Cyclosporin Ophthalmic Emulsion and 0.5% CMC Eye Drops in Dry Eye Disorders

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Abstract

Background: Dry eye disease is a common disorder provoking changes in tear film and ocular surface. Untreated dry eye could cause ocular infections, corneal ulcer and blindness. Only a few drugs are authorized so far for the treatment of dry eye disease and the possibilities of evolution in this sector are immense. **Objectives:** Compare efficacy of carboxy methyl cellulose .5% eye drops with combination of 0.5% carboxy methyl cellulose eye drops and .05% cyclosporin ophthalmic emulsion for treatment of dry eyes. **Material and Method:** 40 patient presenting with dry were selected randomly. They were divided into 2 groups. Group I received CMC.5% eye drops four times a day and group II received .05% Cyclosporin ophthalmic emulsion two times daily and .5% CMC eye drops 4times a day. All patients were evaluated on day 0, 2 weeks, 1 month, 3 month and 6 month for relief in ocular symptoms and diagnostic dry eye tests. **Results:** The mean age in group I was 39.72 ± 6.85 years and in group II was 40.2 ± 5.28 years. Ocular discomfort, dryness and tearing were seen in all the cases. Comparison of different parameters after six months of treatment between group I and II showed that the comparision of net score in two groups is statistically significant($p < 0.05$). **Conclusions:** There was statistically significant difference between the outcome of two groups.Group 2 patients who used combination of cyclosporin0.05% ophthalmic emulsion two times daily along with CMC 0.5% eye drops 4 times a day were better relieved as compared to patients in group 1 who used 0.5% CMC eye drops four times daily for treatment of dry eyes.

Keywords: *Carboxymethylcellulose, Cyclosporine, Dry eye*

Introduction

"Dry eye is a multifactorial disease of the tears and ocular surface that results in symptoms of discomfort, visual disturbance, and tear film instability with potential damage to the ocular surface. It is accompanied by increased osmolarity of the tear film and inflammation of the ocular surface.[1] Dry eye is one of the most common causes of ocular morbidity in patients presenting to an ophthalmology outpatient department. Approximately one out of seven individuals aged 65–84 years report symptoms of dry eye often or all of the time.[2]Management of dry eye depends on the cause and severity of the condition.Various strategies have been described for medical management of dry eye, these include, the topical use of lubricants (artificial tear substitutes), topical corticosteroids and anti-inflammatory therapies, cyclosporine ophthalmic emulsion, and the systemic use of antioxidants (e.g., omega-3 fatty acids).[1,2]

Artificial tears are aqueous solutions containing polymers that determine their viscosity, retention time, and adhesion to the ocular surface. Various polymers currently in use include cellulose derivatives (e.g., hydroxypropyl methylcellulose [HPMC], "carboxymethylcellulose [CMC]), polyvinyl derivatives (e.g., polyvinyl alcohol), chondroitin sulfate, and sodium hyaluronate. In mild-to-moderate cases, they

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are the mainstay of treatment. Artificial tears act by replenishing the deficient aqueous layer of the tear film and diluting the inflammatory cytokines.[2,3] cyclosporine 0.05% emulsion has been approved by the US FDA for its treatment. Given the role of inflammation in dry eye, it makes sense that anti-inflammatory agents have been evaluated in its treatment.[4]

These is lack of studies regarding this topic in this area so we did this study to see efficacy of these two treatment over each other

Material and Method

A comparative prospective study was carried out at Saraswathi Institute Of Medical Sciences Anwarpur(Hapur). Patients were enrolled from February 2018 to July 2018. 20 patients i.e 40 eyes were included in each group presenting with dry eye in eye OPD.Patients were randomly divided in two groups. Detailed history was taken. Appropriate laboratory work up was done. Group 1 where patients used carboxy methyl cellulose .5% eye drops for treatment of dry eye. Group 2 in which patients used 0.5% carboxy methyl cellulose eye drops along with .05% cyclosporin ophthalmic emulsion for treatment of dry eyes. All patients were evaluated on day 0, 2 weeks, 1 month, 3 month and 6 month for relief in ocular symptoms and diagnostic dry eye test were done. Diagnostic dry eye test included SCH—Schirmer's test, TBUT—tear breakup time, FLU—fluorescein stain,Rose Bengal staining and marginal tear strip test. Each ocular symptom(ocular discomfort,foreign body sensation,itching,dryness,photophobia,lacrimation) and dry eye test were scored from 0 to 3 depending on severity and combined score of all symptoms and test was calculated on each follow up visit for each eye individually of each patient in both groups. Net score was calculated as difference between total score (of all symptoms and test) on day 0 and total score at 6 month follow up. Net score actually gives improvement score after use of drug for 6 months in both groups. Net score is then compared in both groups to find the comparative efficacy of drugs in both groups.Net score in both groups was compaired using unpaired t test This study was approved by institutional ethics committee

Results

Table 1: Distribution of cases as per age

Parameters	Group I	Group II
Total cases	20	20
Age (Mean±SD)	39.72 ± 6.85	40.2 ± 5.28
Gender (M:F)	11:9	10:10

The mean age in group I was 39.72 ± 6.85 years and in group II was 40.2 ± 5.28 years.

Diagram 1: Distribution as per symptoms.

Ocular discomfort, dryness and tearing was seen in all the cases.

Table 2: Parameters in both the groups on day 0

Parameters	Group I Mean score	Group II Mean score
Marginal tear strip test	1.65	1.55
SCH	1.72	2.0
TUBT	1.67	1.7
FLU	1.67	1.65
Rose Bengal staining	1.72	1.92
Ocular discomfort	2.20	2.02
Foreign body sensation	2.0	1.87
dryness	2.25	2.02
Itching	1.40	0.80
Photophobia	1.35	1.22
Tearing	1.97	1.65

SCH—Schirmer's test, TBUT—tear breakup time, FLU—fluorescein stain

Table 3: Different parameters in group I and group II after 6months

Parameters	Group I Mean score	Group II Mean score
Marginal tear strip test	0.62	0.15
SCH	0.55	0.30
TUBT	0.25	0.27
FLU	0.40	0.05
Rose Bengal staining	0.42	0.25
Ocular discomfort	0.65	0.32
Foreign body sensation	0.65	0.37
dryness	0.72	0.42
Itching	0.20	0.07
Photophobia	0.35	0.12
Tearing	0.95	0.40

Table 4. Comparision of score parameters between group 1 and group 2 of each ocular symptom and dry eye test between day 0 and 6 month

Parameters	Group 1 (mean change score)	Group 2(mean change score)
Marginal tear strip test	1.03	1.40
Schirmer test	1.17	1.70
TBUT	1.42	1.43
FLU	1.27	1.60
Rose Bengal staining	1.30	1.67
Ocular discmfort	1.55	1.70
Foreign body sensation	1.35	1.50
Dryness	1.53	1.60
Itching	1.20	0.73
Photophobia	1.00	1.10
Tearing	1.02	1.25

Net score-difference between total score of each ocular symptom and dry eye test between day zero and 6 month

Mean net score in group 1=13.75

Mean net score in group 2=15.7

Net score in group 2 is more than group 1

The difference in net score of 40 eyes from each group was found to be statistically significant $p<0.05$(unpaired t-test)

Discussion

Dry eye is a common complaint among middle-aged and older adults and its prevalence increases progressively with age[9-11] Studies from India reported that the prevalence varies between 18.4% and 63.%[14,15,16]

This was a comparative study conducted on 40 dry eye cases presenting to eye OPD. The mean age in group I was 36.72 ± 6.85years and group II was 38 ± 5.28 years respectively. Similar study was concluded by Shah S et al.[10] In the present study the male to female ratio was 1:1 with 21 (52.5%) males and 19 (47.5%) females. This was in accordance with Shah S et al.[10] where the ratio was 1:1. On the contrary Female dominance was reported by Behera S et al. [11]

In the present study middle age formed 60% of the study grup patients. Similar higher middle age population was seen with Shah S et al[10], Kamalakshy J et al[12] and Titiyal JS et al[13] study.

Majority of patients reported dramatic symptomatic relief during treatment period.Patients showed improvement in terms of decrease in score values at different follow ups.All patients had relief in foreign body sensation,discomfort,tearing,photophobia,dryness and itching.At the end of study i.e.at 6 months,eyes having score 03 for different symptoms were 0 in both groups,those with moderate score02 for different symptoms were more in group 1 as compared to group2 and greater percentage of eyes from group2 had score 0 for different ocular symptoms

In the present study ocular discomfort, dryness, tearing was seen in all cases. While in Kamalakshy J et al[12] most frequent ocular surface symptom in confirmed cases of dry eye was itching. In another study by Lee AJ et al[14] conducted in Indonesia burning sensation was the most common symptom.

In this study use of topical cyclosporine 0.05% and CMC 0.5% in group II showed significant improvement in all the parameters specially TBUT which was in accordance to other studies like Shah S et al[16], Byun YJ et al[17], Sall K et al.[18]This is explained by the fact that the ocular surface, lacrimal glands and the neuronal feedback loop that make up a single functional unit for the maintenance of ocular surface homeostasis leading to improvement of the ocular surface Sall K et al.[19]

Sall K et al[19] showed significant decrease in sandy or gritty feeling, dryness, itching and blurred vision in patients treated with cyclosporine .05%.A study by Cross WD et al[22]showed improvement in signs and symptoms of dry eye diseases in patients treated with cyclosporine 2% Study by Sodhi et al [23] showed statistically significant improvement in only lacrimation and photophobia in patients treated with cyclosporine 2%while none of the ocular complaints showed significant improvement in patients treated with artificial tear eye drops .In our study results show better relief in all ocular symptoms in group 2.Therefore our study is in accordance with study of Sall K et al [19] Cross WD et al[22] but not in accordance with study of Sodhi et al [23].Difference could be because of the fact that all patients enrolled in study by Sodhi et al were of non immune origin and cyclosporine has immunomodulatory role.

Mean net score in group 2 was more than group 1 indicating more improvement in group 2.Difference in net score in both groups was found to be statistically significant.A recent study by Sal KN et al on American patients has also shown improvement in ocular symptoms and tear film tests value with combination of cyclosporine and artificial tear eye drops[24]

In our study, none of the patients showed any drug related adverse effects which was consistent Shah S et al[16], Kinoshita S et al[20] and Small DS et al.[21]

Conclusion

Present study concludes that there is statistically significant difference in response(in terms of improvement in tear film profile tests and ocular symptoms) in patients treated with combination of cyclosporine 0.05% and CMC 0.5% drops as compared to patients treated with .5% CMC eye drops only.. It also strengthens the fact that topical cyclosporine A 0.05% twice daily plus CMC 0.5% has no adverse effect .

Conflict of Interest-NIL

Source of Funding-The study was carried out at Saraswathi Institute Of Medical Sciences,Hapur and no extra financial support was required

Ethical Clearance-Ethics committee approval was obtained before study

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Original Research Article

Comparison between bepotastinebesilate 1.5% eye drop versus olopatadine hydrochloride 0.2% eye drop in cases of allergic conjunctivitis

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Abstract

Background: Allergic conjunctivitis is an increasingly prevalent allergic reaction having clinical gravity similar to asthma and allergic rhinitis. **Aims and Objectives:** To study Comparison between bepotastinebesilate 1.5% eye drop versus olopatadine hydrochloride 0.2% eye drop in cases of allergic conjunctivitis. **Methodology:** forty consecutive patients presenting from March 2018 to July 2018 in Eye OPD at Saraswathi institute of medical sciences Hapur, with symptoms of ocular itching associated with allergic conjunctivitis a were enrolled in this study. Here, Group A (1st drug B and 2nd drug O) (n=20), Group B(1st drug O and 2nd drug B) (n=20), where Bepotastinebesilate 1.5% eye drop, OD Olopatadine hydrochloride 0.2% eye drop. 1stvisit done after 1st day of starting the drug, 2nd visit (day 16) after use of first medication, 3rd Visit (day 39) after use of second medication. The itching symptoms and all Ocular allergy symptoms were graded on 5 points scale. The statistical analysis done by unpaired t-test and calculated by SPSS 19 version software. **Result:** the majority of the patient were in the age group of 40-50 i.e. 60% followed by 30-40-17.5%, 20-30 were 12.5%, 50-60 were 10%. The mean age was (Mean ±SD) 41.68 ± 8.51. The majority of the patients were females 65% and males were 35%. At first visit the symptoms itching were comparable with each other as Ocular itching grading on 5 point scale was 4.2 ± 0.52 and 4.35 ± 0.49 in group A and B respectively (t=0.94 df=38,p>0.05) ; on2nd visit (day 16)after use of first medication the relief score in ocular itching was significantly higher in Group A i.e. 3.9± 0.79 versus 2.85 ± 0.67 in group B (t=4.9 df=38,P<0.0001), 3rd Visit (day 39)after use of second medication the score was significantly higher in Group B i.e. 3.7±0.47 as compared to 2.65 ±0.81in group A (t=5.0 df=38, P<0.0001). At 2nd visit (day 16) after use of first medication the relief score in all ocular allergy symptoms was significantly higher in Group A i.e. 3.55± 0.69 as compared to2.65± 0.75 in group B (t=5.23, df=38, p<0.0001) , at 3rd Visit (day 39)after use of second medication the score was significantly higher in Group B i.e. 3.2±0.70 as compared to 2.3±0.73in group A (t=4.92 , df=38,p<0.0001). **Conclusion:** at the baseline both the drugs were comparable with each other, at second visit the score was variable but at the end the response with respect to score and patients preference the bepotastinebesilate 1.5% was found superior to olopatadine hydrochloride 0.2% with respect to treatment of allergic conjunctivitis.

Key Word: bepotastinebesilate 1.5% ,olopatadinehydrochloride 0.2% , allergic conjunctivitis

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INTRODUCTION

Allergic conjunctivitis is an increasingly prevalent allergic reaction having clinical gravity similar to asthma and allergic rhinitis. Currently around, 40% of global population is suffering from allergic conjunctivitis (Azari and Barney, 2013)[1]. Exposure to particulate matter less than 2.5 µm can lead to allergic reactions. Studies have reflected impact of high PM2.5 levels on increasing prevalence of allergic conjunctivitis among countries like Japan (Mimura et al, 2014)[2]. Among the case countries, 40% of the population in Japan is suffering from conjunctivitis and the prevalence is increasing rapidly

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(Rosario andBielory, 2011)[3]. This is due to change in lifestyle and environmental factors. Further, in case of Africa, the prevalence was found to be 32% and was found most prevalent among children aged between 1-16 years (38.4%) (Malu, 2014)[4]. On the other hand in USA and Australia it was found to be 20%. Similarly in case of UK it was found to be 17.5% (Perkin, Bader, Rudnicka, Strachan, and Owen, 2015)[5]. In comparison the prevalence in India is on higher side with 25.5% population affected by this allergy (Puri, Ashat, Singh Sarpal, Kaur, and Kumar, 2013). High level of allergy in India is because of high pollution levels in the country. Critical review of the situation reflects that the prevalence is common among children studying in government schools due to poor hygiene. Further, in India, consequence of allergic conjunctivitis is blindness (prevalent among 1.84%) and corneal blindness (prevalent among 8.6%) (Dandona and Dandona, 2001, adii, C. (2016))6,7. So with such a significant health problem of allergic conjunctivitis in India, we have studied whether bepotastinebesilate 1.5% eye drop or olopatadine hydrochloride 0.2% eye drop in cases of allergic conjunctivitis is superior in the management of Allergic conjunctivitis as perceived by the patients

METHODOLOGY

forty consecutive patients presenting from March 2018 to July 2018 in Eye OPD at Saraswathi institute of medical sciences Hapur, with symptoms of ocular itching associated with allergic conjunctivitis were enrolled in this study. Patients with age more than 18 years, had a diagnosis of allergic conjunctivitis with no concurrent unrelated ocular diseases, had no plans to undergo ocular surgery during the study period were included into the study while patients who had a known hypersensitivity to either agent, history of alcohol or drug abuse, positive history of an ocular herpetic infection, an active ocular infection, or any significant illness , Patients who were actively taking steroids or antihistamines within 7 days prior to enrollment, pregnant, planning to become pregnant, or nursing/lactating were excluded. The enrolled patients were assigned sequentially according to a computer-generated randomization list to receive bepotastinebesilate 1.5% or olopatadine hydrochloride 0.2% in a 1:1 ratio. Patients instilled either bepotastinebesilate 1.5% twice daily (at approximately 8 am and 5 pm) or olopatadine hydrochloride 0.2% once daily (at approximately 8 am) for 16 days. Following a 7-day washout period during which only preservative-free artificial tears were used twice daily, patients were crossed-over to the other treatment for 16days. Each treatment was provided in the packaging originally approved by the Food and Drug Administration, but the single investigator was masked as to which treatment the patient was currently using. Patients were instructed to use gentle eye lid closure for at least two minutes after dosing and to repeat instillation of a single drop if there was uncertainty as to whether successful instillation of the treatment had occurred In addition, patients wearing contact lenses were encouraged to use glasses during the study period. Patients completed an office questionnaire at visit 1 (baseline, day 0), visit 2 (day 16), and visit 3 (day39). During visit 1, prior to dispensing the treatment, patients were asked to rate the following items on a five-point scale: ocular itching associated with allergies; and satisfaction with over-the-counter allergy medication. During visit 2, a different survey questionnaire was administered. Prior to dispensing the second medication, the patients were asked to rate the following items on a five-point scale: ocular itching prior to dosing in the morning; how well the eye drop relieved ocular itching during the day,and the comfort of the drop. The patients were assessed for adverse events. Following the questionnaire, the patients received preservative-free artificial tear drops and were instructed to use the drops twice daily for one week prior to starting the second treatment. On day 23, patients were informed to discontinue using the artificial tear drops and to start using the new treatment for 16days. During visits 2 and 3, the patients were assessed for adverse events. In addition, a final summary questionnaire was given at visit 3. The patients were asked to choose which eye drop provided better all-day relief of ocular itching and was more comfortable. Lastly, the patients were asked to choose which medication they would like to have as a prescription to continue treating their allergic conjunctivitis. During the study period the treatment relieved their ocular itch (graded on a 1–5 scale, with 5 being completely relieved) and how well the treatment relieved all of their ocular allergy symptoms (graded on a 1–5 scale, with 5 being completely relieved). Ocular allergy symptoms included ocular itch, epiphora, conjunctival chemosis, hyperemia, and eye lid edema. Here Group A (1^{st} drug B and 2^{nd} drug O) (n=20), Group B(1^{st} drug O and 2^{nd} drug B) (n=20), where B→Bepotastinebesilate 1.5% eye drop, O→ Olopatadine hydrochloride 0.2% eye drop . 1^{st}visit done (0 day) of starting the drug, 2^{nd} visit (day 16) after use of first medication, 3^{rd} Visit (day 39)after use of second medication. The itching symptoms and all Ocular allergy symptoms was graded on 5 point scale. The statistical analysis done by unpaired t-test and calculated by SPSS 19 version software.

RESULT

Table 1: Distribution of the patients as per the age

Age	No.	Percentage (%)
20-30	5	12.5
30-40	7	17.5
40-50	24	60
50-60	4	10
Total	40	100
Mean ±SD		41.68 ± 8.51

The majority of the patient were in the age group of 40-50 i.e. 60% followed by 30-40-17.5%,20-30 were12.5%, 50-60 were 10%. The mean age was (Mean ±SD) 41.68 ± 8.5

Table 2: Distribution of the patients as per the sex

Sex	No.	Percentage (%)
Male	14	35
Female	26	65
Total	40	100

The majority of the patients were females 65% and males were 35%.

Table 3: Distribution of the patients with respect to symptoms itching on subsequent visits

Ocular itching grading on 5 point scale	Group A (1st drug B and 2nd drug O) (n=20)	Group B(1st drug O and 2nd drug B) (n=20)	p-value
1st visit	4.2 ± 0.52	4.35 ± 0.49	t=0.94 df=38 p>0.05
2nd visit (day 16)after use of first medication	3.9± 0.79	2.85 ± 0.67	t=4.9 df=38 P<0.0001
3rd Visit (day 39)after use of second medication	2.65 ±0.81	3.7±0.47	t=5.0 df=38 P<0.0001

At first visit the symptoms of itching were comparable with each other as Ocular itching grading on 5 point scale was 4.2 ± 0.52 and 4.35 ± 0.49 in group A and B respectively (t=0.94 df=38,p>0.05) ; on2nd visit (day 16)after use of first medication the relief score in ocular itching was significantly higher in Group Ai. e. 3.9± 0.79 versus 2.85 ± 0.67 in group B (t=4.9 df=38, P<0.0001), 3rd Visit (day 39) after use of second medication the relief score in ocular itching was significantly higher in Group B i.e. 3.7±0.47 as compared to 2.65 ±0.81 in group A (t=5.0 df=38, P<0.0001)

Table 4: Distribution of the patients with respect to all ocular allergy symptoms on subsequent visits

All Ocular allergy symptoms (grading on 5 point scale)	Group A (1st drug B and 2nd drug O) (n=20)	Group B(1st drug O and 2nd drug B) (n=20)	p-value
2nd visit (day 16)after use of first medication	3.55± 0.69	2.65± 0.75	t=5.23 , df=38 P<0.0001
3rd Visit (day 39)after use of second medication	2.3±0.73	3.2±0.70	t=4.92 , df=38 p<0.0001

At 2nd visit (day 16) after use of first medication the relief score in all ocular allergy symptoms was significantly higher in Group A i.e. 3.55± 0.69 vs 2.65± 0.75in group B (t=5.23, df=38, p<0.0001), at 3rd Visit (day 39)after use of second medication the relief score in all ocular allergy symptoms was significantly higher in Group B i.e. 3.2±0.70 as compared to 2.3±0.73 in group A (t=4.92 , df=38, p<0.0001).

DISCUSSION

Bepotastine is an H1-antihistamine and an inhibitor of histamine release from mast cells.[9] It is a piperidine derivative, similar to fexofenadine, ebastine, and loratidine.[10] Multiple anti-inflammatory effects have been demonstrated, possibly as downstream mediators of the antihistamine activity. For example, in vitro studies suggest that bepotastine specifically suppresses proinflammatory cytokine production by keratinocytes, including inhibition of CD54 expression.[11] Recent work on guinea pigs showed that bepotastine, along with several other H1-antihistamines, reduces vascular hyper-permeability in both antigen-induced and histamine-induced hyperpermeability models.[12] This work also showed that bepotastine inhibits in vitro eosinophil chemotaxis induced by leukotriene B4, and pretreatment with bepotastine limits conjunctival eosinophil infiltration after topical antigen challenge.[12] The pharmacokinetic properties of bepotastine as an ophthalmic solution are described in Phase I trial data from Japan, and these will be described as reported in the FDA Office of Clinical Pharmacology review of the Japanese data. In a repeated instillation study was performed four-times-a day dosing in both eyes

for 7 days in 12 healthy adult male subjects, half of whom instilled bepotastinebesilate 1.0% and half instilled the 1.5% formulation. Venous blood samples were measured by high-performance liquid chromatography and demonstrated a bepotastine plasma concentration peak 1–2 hours postinstillation. The mean maximum concentration (Cmax) for the 1.5% group was 7.3 ±1.9 ng/mL, which was much lower than the Cmax seen in the Phase I single oral dose trial, even at the lowest tested oral dose (Cmax was 22.4 ± 2.1 ng/mL for the 2.5 mg oral dose). At the clinically relevant, approved Japanese oral dose of 10 mg, the Cmax was 101.3 ± 3.5 ng/mL, which is over 13 times higher than the Cmax seen in the repeated ophthalmic dosing trial. Thus, although there is systemic absorption of the ophthalmic drop, the plasma concentrations are quite low, minimizing the likelihood of systemic adverse effects. Furthermore, plasma concentrations at 24 hours postinstallation were below the quantifiable limit of 2 ng/mL in 11 of 12 subjects. In the oral single-dose study, 75%–90% of the administered dose was secreted in the urine as unchanged drug by 24 hours after administration within the 2.5–40 mg dose range. An additional Phase I study addressed the metabolism of bepotastine by liver microsomes, showing that there was minimal metabolism by CYP3A4, CYP2C9, and CYP2C19, again as reported by the FDA Office of Clinical Pharmacology review of the Japanese data9. Within the relevant concentration range, it was concluded that bepotastine would likely have no effects on concomitantly metabolized drugs involving these enzymes. Finally, a protein-binding Phase I study was performed, demonstrating 55.4% mean plasma protein binding of the drug 1–2 hours after a 10 mg oral dose.[8] This binding level was independent of plasma drug concentration. In our study we have found the majority of the patient were in the age group of 40-50 i.e. 60% followed by 30-40-17.5%, 20-30 were 12.5%, 50-60 were 10%. The mean age was (Mean ±SD) 41.68 ± 8.51. The majority of the patients were females 65% and males were 35%. At first visit the symptoms of itching were comparable with each other as Ocular itching grading on 5 point scale was 4.2 ± 0.52 and 4.35 ± 0.49 in group A and B respectively (t=0.94 df=38,p>0.05) ; on2nd visit (day 16)after use of first medication the relief score in ocular itching was significantly higher in Group A i.e. 3.9± 0.79 versus 2.85 ± 0.67in group B (t=4.9 df=38,P<0.0001), 3rd Visit (day 39)after use of second medication the relief score in ocular itching was significantly higher in Group B i.e. 3.7±0.47 as compared to 2.65 ±0.81 in group A (t=5.0 df=38, P<0.0001). At 2nd visit (day 16)after use of first medication the relief score in all ocular allergy symptoms was significantly higher in Group A i.e. 3.55± 0.69 as compared to 2.65± 0.75 in group B (t=5.23 , df=38,p<0.0001) , at 3rd Visit (day 39)after use of second medication the relief score in all ocular allergy symptoms was significantly higher in Group B i.e. 3.2±0.70 as compared to 2.3±0.73 in group A (t=4.92, df=38,p<0.0001). Craig F McCabe[13] found at study end, 63.3% and 66.7% of patients preferred bepotastinebesilate 1.5% for all-day relief of ocular itching and all-day relief of itchy/runny nose, respectively. At study end, there was no significant difference in the number of patients preferring one treatment over the other for comfort. Overall, 66.7% of patients stated that they would prefer to treat their allergic conjunctivitis with bepotastinebesilate 1.5% over olopatadine hydrochloride 0.2%. Conclusion: Based on their evaluation of therapeutic performance, patients preferred bepotastinebesilate 1.5% over olopatadine hydrochloride 0.2% by two-to-one for the treatment of allergic conjunctivitis.

CONCLUSION

at the baseline both the drugs were comparable with each other , at second visit the score was variable but at the end the response with respect to score and patients preference ,the bepotastinebesilate 1.5% was found superior to olopatadine hydrochloride 0.2% with respect to treatment of allergic conjunctivitis.

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OBSTACLES ENCOUNTERED DURING TREATMENT OF CLUBFOOT BY PONSETI METHOD IN WESTERN RAJASTHAN

Community Medicine

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ABSTRACT

INRTODUCTION: Idiopathic clubfoot affects approximately 50,000 children each year and is one of the leading causes of disability in India. Ponseti's technique of casting, tenotomy and bracing is an acceptable method worldwide in its management.

MATERIAL AND METHOD: The Ponseti technique is very slowly picking up in our country, inspite of its ease of usage and compatible results. In this retrospective study of 215 patients enrolled from march 2013 to June 2016. We will be discussing the ponseti's technique in brief, various set-up's where the technique is being adopted and the obstacles faced by parents at each level.

RESULTS: In our study total 37 (17.2%) parents' encountered obstacles. The most frequent obstacles to the Ponseti method in our study are lack of awareness for clubfoot treatment (43.2%), patient transportation and distance to treatment centres (24.3%),poor socioeconomic status (13.5%), complications during serial casting (13.5%),and (5%) other obstacles.

CONCLUSION: Inspite of Ponseti casting technique becoming a common method to treat clubfoot worldwide, In India there are several physician & patients related factors influencing the outcome. There is lack of awareness programs in media (TV/newspaper), schools and colleges and in public meetings. In our country there is no national health programme for clubfoot deformity, so diagnosis of clubfoot deformity is frequently missed at delivery points like sub centers, PHC, CHC and District hospitals. Poor transportation in remote, hard desert area producing hurdle for weekly serial casting and regular follow up.

KEYWORDS

Club Foot, Ponseti's Technique, Indian Population.

INTRODUCTION

Clubfoot or Congenital Talipes Equino Varus (CTEV) is a common complex congenital deformity of the foot. It is a three-dimensional deformity having four components: Equinus, Varus, Adductus and Cavus[1,2]. Many cases are associated with neuromuscular diseases, chromosomal abnormalities, Mendelian and non Mendelian syndromes and in rare cases with extrinsic causes. The incidence differs in different races[3]. Idiopathic clubfoot affects 1-2children per thousand live birth and is one of the leading causes of disability worldwide. Ponseti's technique of casting, tenotomy and bracing is an acceptable method worldwide in its management[4,5]. However, in this study, only the cases with idiopathic congenital clubfoot deformity are included, occurring in otherwise normal infants.

Ponseti's Technique:

The technique is done in the followingstep[6,7,8].

1. Classifying the child's deformity based on aetiopathology and treatment stage on first presentation.
2. Grading the deformity by Dimeglio's/Pirani's classification system.
3. Patient's family counselling and setting up of club foot clinics.
4. Application of casts in a weekly manner by first putting the foot in supination and then gradually abducting in sequential casts till the navicular covers the talar head completely clinically manifested as 70° of abduction, avoiding eversion or forced dorsiflexion in weeklycasts".
5. Tenotomy, if it is found that tendoachilles is tight ,as without tenotomy we cannot achieve 10° of dorsiflexion.
6. Bracing schedule to be followed till the age of 3 years and follow-up subsequently. Ponseti's technique is presently established only for congenital idiopathic club feet and trials are undergoing for syndromic, neglected and complicated club feet.

The Ponseti method has change the management of idiopathic club foot deformity from a typically surgical approach[12] to a primarily non operative Approach[9,10].

Establishment's or setup's where Ponseti's technique is being practised in India:- Government or Institutional setups; Non Government institutional setups; Private nursing homes and clinics.

AIMS &OBJECTIVES

1. To find out the obstacles during treatment of ctev by Ponseti.
2. Enligten the solutions for obstacles to achieve 100% acceptability for treatment.

RESULTS

Out of the 215patients treated 139 patients (65%) were from a rural background and 76 patients (35%)belonged to urban areas.

Table;1-Distribution of patients according to Area.

Area/Background	No Of Patients	Percentage (%)
Rural	139	65
Urban	76	35
Total	215	

The patients were classified as per Pirani scoring system. In our study 37 (17.2%)patients encountered obstacles in the treatment of ctev. The most frequent obstacles to the Ponseti method in India in our study was lack of awareness of treatment of ctev in the country 16 (43.3%) these patients missed follow-up and serial casting weekly, which led to improper follow up after Correction and incompatibly issues with brace application.

patient transportation and distance to treatment centres 9(24.3%), in our study patients came from rural desert area 60 patients from about 50 km.12 patients from about 100 kms.37 patients from 150 kms,22 patients from 250 kms,8 patients from 300 kms ,Patient transportation and distance to tpeatment centres which led to patient's not returning back till full correction.

Poor socioeconomic status 5 patients (13.5%), these parents cannot afford expenditure of treatment. and complications during serial casting.

5 patients (13.5%) which led to patient's families discontinued the treatment in between or led to complications like skin blisters, incorrect application of plaster Casts. 90% of the parents had attended weekly clinics with 67% indicating that they did not know about clubfoot and its treatment.

Table;2- Obstacles Encountered During Treatment Of Clubfoot by Ponseti method In Western Rajasthan

S.No.	Obstacles Encountered During Treatment Of Clubfoot In Western Rajasthan	No.of patients	Percentage (%)
1.	lack of awareness of treatment of ctev	16	43.3
2.	Patient transportation and distance to treatment centres	9	24.3
3.	Poor socioeconomic status	5	13.5

4.	Complication like skin blisters, incorrect application	5	13.5
5.	Other complication	2	5.4
Total		37	

Factors Influencing the Successful Management at Various Level of Healthcare:-

Patient related- Other forms of club foot management like- parents may seek non ponseti management methods, traditional medicines and other methods. These are ineffective and delay make ponseti treatment more difficult. This problem can be managed with education of family and there health care provider. There is public belief in some culture that clubfoot is caused by evil spirits , due to sins or misdeed of family or parents . The child with disability is a source of shame and is hidden by family .They do not have the benefits of an examination of newborn by trained healthcare workers . They don't have awareness of the diagnosis and the need for early treatment including misinformation that ponseti method is ineffective . These obstacles can be overcome by establishing clubfoot clinic and make ponseti management facility for every clubfoot affected feet . Engage parents to clubfoot clinic and discuss management and follow up to parents ,caregivers, and convey the message of free treatment in the society. Involve local government, panchayat, municipal corporation, schools, meetings, PHC ,CHC ,religious places, NGO to assist the very poor by facilitating transport and spread awareness about complete cure of CTEV patient.

Health institutional- Most of the government setups do not treat children with club foot deformity in a major manner. This is because clubfoot has not received importance at govt level in the centre or state , in spite of being the major presentation .This is the sad reality even under the department of Health and Family Welfare at PHC, CHC and even district hospitals where doctors and nursing staff are not aware about CTEV treatment by ponseti. There is neither any training facility to empower skills in CTEV treatment nor any national health programs for CTEV disbilty . In rajasthan where 75% rural and 60 % area is desert and less institutional delivery, awareness programs are very necessary at each level from beneficiary to health system. There is less number of orthopedic surgeon in the state and orthopaedic surgeons in these setups are busy in population control programs/Trauma or private practice rather than taking care of club foot children. Even most of the medical colleges in the govt setup do not stick to exclusive use of Ponseti's technique inspite of having speciality clinics. Ponseti's technique is used only if a thesis is given to a post-graduate or if a particular consultant is trained in this technique . "Cure" along with govt. has taken initiative in managing these patient's , specially in some states where comprehensive care in the form of training, counselling, models and materials, follow-up record sheets& braces are provided by them . But such scheme is yet limited to largecities and medical colleges.

The patient related barrier are simple to understand. Most of the Govt. set ups including Govt. Medical Colleges cater to the poor people. Poverty, illetracy and distances are the major barrier in managing a club foot child by parents. Parents prefer a one time surgery may be with inferior results rather than travelling long distances every week to get the plaster changed. Also routinely there is no provision to admit children for day-care Ponseti's technique. The need for prolongel bracing is the second barrier in the method. Insuring economic/free supply of bilateral foot dorsiflexion - Abduction brace is almost impossible.

Speciality clinics:- Most of the poor parents discontinue treatment due to lack of awareness. long term brace does not suit the parents & compliance becomes an important issue. Most of the medical colleges, even if they run a speciality clinic of club foot have their day and time fixed and so patient's with club foot won't get round the clock attention, apart from any emergency treatment if complication arises. Ponseti's clinics overcomes these problems to some extent as the parents see the outcome of others who are not following instruction, leading to recurrence of symptoms.

Non govt funded institutes:- They also treat club foot in the ideal way i.e. Ponseti's technique but the cost of treatment becomes tremendous as the consultation fee/plastering fee/plaster material cost/Anaesthetist cost/OT cost for tenotomy and post op. ward even in a day care setting are very high. They also require trained assistants to hold the foot in corrected position or apply the cast. Tenotomy even if it is a minor surgery require the complete pre-operative/intra operative and postoperative protocol in these institutes.

So, parents think that instead of having so many plaster'sand then surgery, why not go for a single one timed surgery which willnot only save money but time as well.

Summary of obstacles in the practice of Ponseti's technique

1. Parents from affluent societies insist to give anaesthesiato that child is not irritable and do not cry during manipulationor cast application. This eventually leads to more complications,edema and poor results.
2. Orthopaedic surgeons are still not very familiar to new terminology, classification systems and Ponseti's technique.
3. The technique does not work if speciality clinic is not initated. Patient counselling is a must.
4. Institutes which do not have full time Orthopaedic Surgeonassist one time correction rather than repeated visits of patint and orthopaedic surgeons.
5. Tenotomy is projected as a major surgery at times.
6. Avoiding tenotomy or bracing is a major cause of recurrence.
7. Poor results are also seen if a wrong selection of case is done & neglected, Complicated or syndromic clubfoot are counselledand treated like idiopathic club foot.
8. Social stigma of CTEV.

Recommendations for overcoming obstacles:-

1. Making the government aware of Ponseti's protocol and taking its help in establishing club foot clinics, where children withclub foot will be treated only by trained and appointed orthopedic surgeons.
2. Provision of post correction basic braces free of cost, whenthe brace is returned after use and reapplied to another child till 3 yrs of age.
3. Provision of well equipped operation theatre with anaesthetino that tenotomy may be done properly with antisepsis and without pain and children with neurological, syndromic and complicted clubfoot be also treated with surgical care. Provision of a post operative ward and shelter for these children and their families.
4. Free transport of these children to and from to the pre identified clinics as to insure attendance and full treatment.
5. Making a national health programs for CTEV patients.
6. Making a training schedule for CTEV treatment and counselling to orthopaedic doctors and assistants.
7. Engage more and more public to CTEV treatment awareness programs via media TV/newspaper, posters in hospital premis, schools ,colleges, awareness programs in community meeting ,and religious places.
8. Involve more NGO for awareness, counselling of CTEV parents.
9. Make a provision to give expenditure to CTEV patients.
10. Make a future policy for CTEV affected children.
11. Arrange a clubfoot clinic in remote desert area.

DISCUSSION

In spite of Ponseti casting technique becoming a common method to treat clubfoot worldwide, in developing countries like India, there are several physician & patients factors influencing the outcome. Skill management in improving Physician and Patient's family factors should be integrated in practise to prevent neglect in treatment .A Programme about proper application of Ponseti technique for doctors and patient's family education can help .

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A COMPARATIVE PROSPECTIVE STUDY OF THE RESULTS OF CLOSED REDUCTION AND PERCUTANEOUS KIRSCHNER WIRE FIXATION UNDER IMAGE INTENSIFIER CONTROL OF DISPLACED SUPRACONDYLAR FRACTURE OF HUMERUS IN CHILDREN

Orthopaedics

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ABSTRACT

INTRODUCTION:- This study was conducted to assess the results of closed reduction and percutaneous kirschner wire fixation under image intensifier control of displaced supracondylar fracture of humerus in Children.

METHOD:- In this prospective study 40 cases with supracondylar humerus fracture treated with closed reduction(25 cases) or fixation with Kirschner wires under image intensifier(15cases) and evaluated clinically and radiologically. The assessment of anatomical and functional outcome was made according to Mitchell and Adams criteria.

RESULT:- In our study 40 cases were studied. The age of patient ranged from 6 to 10 years. Male to female ratio was 4:1.Maximum cases were extension type(95%). The assessment of anatomical and functional outcome was made according to Mitchell and Adams criteria. 5 cases (20%) in closed reduction and 9 cases (60%) in fixation with K wire were rated as excellent, 10 cases (40%) rated as good, 10 cases (40%) was rated as poor in closed reduction and 4 case(26.6%) was rated as good and 2 cases (13.4%)was rated as poor in fixation with k wire.

CONCLUSION:- We concluded that Closed reduction and plaster of paris splinting should be reserved for minimally displaced fractures. Further attempts at closed reduction should be made, as repeated manipulations increasers' incidence of myositis ossifications and residual stiffness.In all other cases, closed reduction and fixation with Kirschner wires under image intensifier control should be attempted

KEYWORDS

Supracondylar of humerus, Kirschner wire, Modified Garland classification, closed reduction.

INTRODUCTION

Supracondylar fractures of humerus constitute 60% of the fractures around elbow in children, thus being the commonest fracture around the elbow in children. The management of displaced supracondylar fractures is controversial, there are no set guidelines as to which reduction is acceptable and which is not. Surgeon treats the fracture according to his personal preference or according to the method prevalent in his Centre.

Two types of the supracondylar fractures of humerus are encountered in children

1. The Extension type : which is more common
2. The flexion type : which is less common

Fall onto the outstretched hand with the elbow in full extension leading to supracondylar fracture of humerus. Laxity of ligaments which allow hyperextension of elbow to occur. Henrikson[1] (1966) had shown that children with supracondylar fractures of humerus are more likely to have hyperextension of normal elbow and also children with hyperextension are more susceptible to repeated supracondylar fractures. The rarer type is the flexion type of fracture. It is caused by the direct fall on the flexed elbow and its distal fragment is displaced anteriorly. Although the extensive literature on this fracture describes several methods of treatment, both conservative and operative , it would appear that none is suitable for all fractures, not has any method gained universal acceptance. Therefore, this fractures has been rightly nick named as the misunderstood fracture by Gartland[2] (1949).

Gartland proposed a useful classification for supracondylar fractures:
Type I : Undisplaced fracture,
Type II : Displaced with intact posterior cortex.
Type III : Displaced with no cortical contact.

Modified Garland classification of supracondylar fracture
Type I : Undisplaced;
Type II : Hinged posteriorly
Type III : Displaced;
Type IV : Displaces into extension and flexion.

Whatever maybe the controversy in treatment, but the ultimate aim is the management of these fractures even today as what Sirs[3] suggested in 1939 are to prevent volkman's ischaemic contracture and malunion, restore function to elbow, achieve satisfactory reduction, thus attaining cosmetically acceptable results.

The impulse for this clinical study of supracondylar fractures of humerus cam chiefly from the fact that almost every day one or more patients with this fracture visited the emergency Plaster Room of this hospital. As compared to the Western countries, articles on this subject by Indian authors are much less. Thus, the field for the study on supracondylar fractures of humerus remains still wide open in the Indian patients.

AIMS and Objectives

1. To study the results of managing displaced supracondylar fractures of humerus of children by using conservative closed reduction methods and percutaneous Kirschner wire fixation under Image Intensifier.
2. If possible to formulate guidelines to select the better method of treatment of displaced supracondylar fractures of humerus in children.
3. To assess the elbow functions after fracture has healed.

Material and methods

Forty cases have been studied; all patients with displaced supracondylar fractures of humerus were admitted in the orthopedic emergency and subjected to detailed clinical and radiological examination according the case Performa.

These patients were subjected to closed manipulation and immobilization by plaster of paris slab, under general anesthesia as early as possible. All the closed reduction was carried out by the method described by Charnley[4] (1961), which is briefly described below.

The patients are anesthetized; the radial pulse is palpated before starting the manipulation. The elbow is gently extended and a strong longitudinal traction exerted by gripping the patients wrist and distal forearm. The distal forearm moves into line by straight longitudinal traction and any lateral displacement is automatically corrected by tension of surrounding soft parts. It lateral displacement has not been overcome; some lateral pressure while the elbow is extended completes the reduction. Now the surgeon grips the lower end of distal humerus in his passive or fixing hand maintaining traction in the long axis of the forearm, the thumb of the passive fixing hand pushes the olecranon forwards as the elbow is flexed. The fingers of the passive had pulls the proximal fragment backwards. The elbow should be hyper flexed (to 120 degree) or to a position where the radial pulse is normal. Now an above elbow plaster of paris slab is applied and the limb is elevated and a close watch is kept on the digital circulation and radial pulse. The patients elbow is immobilized for 3 weeks after which mobilization of the joint started.

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The patients unsatisfactory reductions will be reduced under general anaesthesia. Traction is applied to the forearm in supination, and the shorting and lateral or medial displacements are corrected. Once adequate reduction have been achieved, as confirmed with the image intensifier, then under all aseptic precautions two kirschner wires 1.4 to 1.8 millimeters in diameter are introduced, one through the lateral epicondyle and one through the medial epicondyle. These two kirschner wires are directly obliquely and proximally unit they pass through the opposite side of the cortex. In order to secure sufficient fixation of the fracture, it is imperative that the two wires must pass through the proximal fragment or shaft. The final position of the wires is checked under the image intensifier and if found satisfactory, the protruding parts of the wires are cut off below the skin surface and a plaster splint is applied from the shoulder to the knuckles, with elbow at right angle and the forearm in neutral of pronation supination.

Check x-rays are taken and the limb examined for any postoperative neurological deficit. After three weeks, the plaster slab is removed and elbow mobilization started. The Krischner wires are removed after four weeks under local anaesthesia.

Results obtained were graded according to Mitchell and Adams criteria[2] (1961) and presented. Mitchell and Adams criteria (1961) as given below.

Excellent : Change in carrying angle of less than 5 degree loss of range of motion of less than 10 degree No. symptoms'

Good : Change in carrying angle of 5-15 degree. Loss of range of motion of 10-20 degree. No symptoms.

Poor : Change of carrying angle or reduction of motion above these limits. Any notable symptoms.

RESULTS

Table : 1 Demographic characteristic of patients in both groups

Factors	Closed reduction and plaster of paris slab	Closed reduction internal fixation with Kirchner wire	P value
Mean Age (in years)	7.92±2.99	8.40±2.44	0.602
Sex (male/female)	20/05	12/03	0.992
Anatomical classification	01/25	01/15	0.707
Hospital stay	2.36±1.18	2.20±1.01	0.664

Table : 2 Comparison of the two modalities of treatment

Types	Closed reduction and plaster of paris slab	Closed reduction internal fixation with Kirchner wire	P value
Excellent	05	09	0.01
Good	10	04	0.502
Poor	10	02	0.152
Total	25	15	

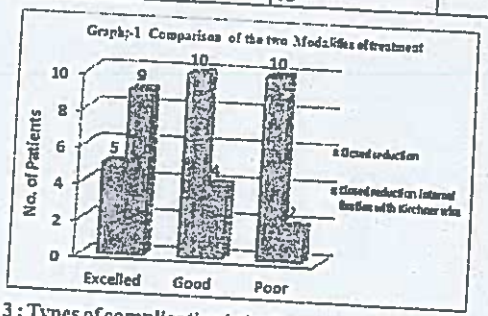

Table 3 : Types of complication in both groups

Types of complication	Closed reduction and plaster of paris slab	Closed reduction internal fixation with Kirchner wire	P value
Vascular	02	00	0.519
Neurological	00	01	0.375
Loss of motion	00	01	0.375
Myositis ossificans	00	00	00
Superficial infection	00	02	0.134
Cubitus varus	08	01	0.11
Cubitus valgus	00	00	00
Hyper extension of elbow	01	00	0.432

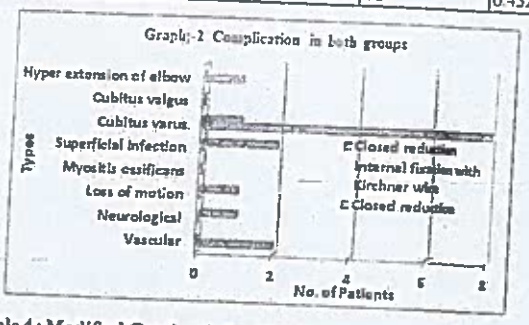

Table 4 : Modified Gartland classification

Type	No. of Cases	Percentage
II	10	25
III	18	25
IV (Extension)	10	25
Flexion	02	05

DISCUSSION

Supracondylar fractures of humerus as the "misunderstood fracture" because in present problems in management in the form of vascular complications, cosmetically unacceptable deformities and stiff elbows to say the least. Unfortunately no uniform mode of treatment is available which is suited to all grades of fractures, in order to achieve consistently acceptable and a normal functioning elbow.

The maximum incidence of supracondylar fracture in present study was seen in 6-10 years of age group and the average was 7.27 years.

Males out number females in all age groups. The ratio being 4:1 in favour of males. This is a consistent feature in series reported by Holmberg[4] (1945), Maylahn and Fahey[5] (1958) and Henrikson[2] (1966), the fracture being twice more comm on in males than females.

The left side was injured in 27 cases (67.5%) and right side in 13 cases (32.5%) respectively. This agree with the findings of Holmberg[4] (1945), Maylahn and Fahey[5] (1958) and Edman and Lohr[3] (1963).

Flexion type of Supracondylar fracture of humerus is less common than the extension type. In the present study only 2 cases (5%) of flexion type were seen. Incidence in Western literature ranges from 2.5% to 10%.

The Majority of cases were of the closed type (36 cases) in the present series. Four cases of open fracture were seen with all having a punctured wound in the cubital fossa. All four of the fractures healed without any consequences.

Twenty nine cases came to the hospital more than 12 hours after the injury. The parents ignored the child's cry probably due to ignorance till the elbow became swollen and severely painful.

In all patients an initial attempt at closed reduction under general anesthesia was carried out. Subsequently, 25 cases were definitively continued on conservative treatment with plaster of paris splinting and 15 cases by close reduction and Kirschner wires fixation under image intensifier control.

Grading the end results according to Mitchell and Adams' Criteria (1961), we classified the results into two groups (1) Satisfactory [Excellent +Good] and (2) Unsatisfactory [Poor]. We got 40% poor results with closed reduction and plaster of paris splinting and 60% were satisfactory.

Close reduction and fixation with K wires under Image Intensifier gave maximum percentage of excellent results (60%). Closed reduction gave 20% excellent results. Closed reduction and fixation under image intensifier has following main advantages.

1. It makes accurate reduction possible

2. Hospital stay is shortened

The average time taken for gaining elbow motion was more with close reduction and internal fixation with K wire under image intensifier cases. Time taken is more because soft tissues around the elbow are subjected to surgical trauma.

The overall incidence of nerve involvement was 3.92% in the present series, with one case of redial nerve and one of medial nerve involvement. Ulnar nerve involvement was not encountered. Both these cases were treated an expectant lines and both recovered completely within 9 weeks.

The overall incidence of cubitus varus in the present study was 22.5% which compares favorably with the average incidence of 30% given by **Siris[3] (1939), Brewster and Karp[9] (1940), Sandegard[10] (1943), Aikten[11] (1943) and Madsen[12] (1955).** No case of cubitus valgus was seen in the present series.

CONCLUSION

Closed reduction and plaster of paris splinting should be reserved for minimally displaced fractures. Further attempts at closed reduction should be made, as repeated manipulations increasers' incidence of myositis ossifications and residual stiffness.

In all other cases, closed reduction and fixation with Kirschner wires under image intensifier control should be attempted. If it is done as a last resort after repeated manipulation the percentage of poor results increases. Thus, closed reduction and Kirschner wire fixation under image intensifier is advisable for displaced supracondylar fractures of humerus. It should be performed as early as possible (not later than five days) and should not be done when patient has undergone repeated manipulations because of the high incidence of myositis ossifications and stuffiness of elbow postoperatively.

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ORIGINAL RESEARCH PAPER

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OBSTACLES ENCOUNTERED DURING TREATMENT OF CLUBFOOT BY PONSETI METHOD IN WESTERN RAJASTHAN

Community Medicine

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ABSTRACT

INRTODUCTION: Idiopathic clubfoot affects approximately 50,000 children each year and is one of the leading causes of disability in India. Ponseti's technique of casting, tenotomy and bracing is an acceptable method worldwide in its management.

MATERIAL AND METHOD: The Ponseti technique is very slowly picking up in our country, inspite of its ease of usage and compatible results. In this retrospective study of 215 patients enrolled from march 2013 to June 2016. We will be discussing the ponseti's technique in brief, various set-up's where the technique is being adopted and the obstacles faced by parents at each level.

RESULTS: In our study total 37 (17.2%) parents' encountered obstacles. The most frequent obstacles to the Ponseti method in our study are lack of awareness for clubfoot treatment (43.2%), patient transportation and distance to treatment centres (24.3%).poor socioeconomic status (13.5%), complications during serial casting (13.5%),and (5%) other obstacles.

CONCLUSION: Inspite of Ponseti casting technique becoming a common method to treat clubfoot worldwide. In India there are several physician & patients related factors influencing the outcome. There is lack of awareness programs in media (TV/newspaper). schools and colleges and in public meetings. In our country there is no national health programme for clubfoot deformity, so diagnosis of clubfoot deformity is frequently missed at delivery points like sub centers, PHC, CHC and District hospitals. Poor transportation in remote, hard desert area producing hurdle for weekly serial casting and regular follow up.

KEYWORDS

Club Foot, Ponseti's Technique, Indian Population.

INTRODUCTION

Clubfoot or Congenital Talipes Equino Varus (CTEV) is a common complex congenital deformity of the foot. It is a three-dimensional deformity having four components: Equinus, Varus, Adductus and Cavus[1,2]. Many cases are associated with neuromuscular diseases, chromosomal abnormalities, Mendelian and non Mendelian syndromes and in rare cases with extrinsic causes. The incidence differs in different races[3]. Idiopathic clubfoot affects 1-2children per thousand live birth and is one of the leading causes of disability worldwide. Ponseti's technique of casting, tenotomy and bracing is an acceptable method worldwide in its management[4,5]. However, in this study, only the cases with idiopathic congenital clubfoot deformity are included, occurring in otherwise normal infants.

Ponseti's Technique:

The technique is done in the followingstep[6-9].

1. Classifying the child's deformity based on aetiopathology and treatment stage on first presentation.
2. Grading the deformity by Dimeglio's/Pirani's classification system.
3. Patient's family counselling and setting up of club foot clinics.
4. Application of casts in a weekly manner by first putting the foot in supination and then gradually abducting in sequential casts till the navicular covers the talar head completely clinically manifested as 70° of abduction, avoiding eversion or forced dorsiflexion in weeklycasts[11].
5. Tenotomy, if it is found that tendoachilles is tight ,as without tenotomy we cannot achieve 10° of dorsiflexion.
6. Bracing schedule to be followed till the age of 3 years and follow-up subsequently. Ponseti's technique is presently established only for congenital idiopathic club feet and trials are undergoing for syndromic, neglected and complicated club feet.

The Ponseti method has change the management of idiopathic club foot deformity from a typically surgical approach[12] to a primarily non operative Approach[13,14].

Establishment's or setup's where Ponseti's technique is being practised in India:- Government or Institutional setups; Non Government institutional setups; Private nursing homes and clinics.

AIMS &OBJECTIVES

1. To find out the obstacles during treatment of ctev by Ponseti.
2. Enligten the solutions for obstacles to achieve 100% acceptability for treatment.

RESULTS

Out of the 215patients treated 139 patients (65%) were from a rural background and 76 patients (35%)belonged to urban areas.

Table;1-Distribution of patients according to Area.

Area/Background	No Of Patients	Percentage (%)
Rural	139	65
Urban	76	35
Total	215	

The patients were classified as per Pirani scoring system. In our study 37 (17.2%)patients encountered obstacles in the treatment of ctev. The most frequent obstacles to the Ponseti method in India in our study was lack of awareness of treatment of ctev in the country 16 (43.3%) these patients missed follow-up and serial casting weekly, which led to improper follow up after Correction and incompatibly issues with brace application.

patient transportation and distance to treatment centres 9(24.3%). in our study patients came from rural desert area 60 patients from about 50 km,12 patients from about 100 kms,37 patients from 150 kms,22 patients from 250 kms,8 patients from 300 kms ,Patient transportation and distance to treatment centres which led to patient's not returning back till full correction.

Poor socioeconomic status 5 patients (13.5%), these parents cannot afford expenditure of treatment. and complications during serial casting.

5 patients (13.5%) which led to patient's families discontinued the treatment in between or led to complications like skin blisters, incorrect application of plaster Casts. 90% of the parents had attended weekly clinics with 67% indicating that they did not know about clubfoot and its treatment.

Table;2- Obstacles Encountered During Treatment Of Clubfoot by Ponseti method In Western Rajasthan

S.No.	Obstacles Encountered During Treatment Of Clubfoot In Western Rajasthan	No of patients	Percentage (%)
1.	lack of awareness of treatment of ctev	16	43.3
2.	Patient transportation and distance to treatment centres	9	24.3
3.	Poor socioeconomic status	5	13.5

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4.	Complication like skin blisters, incorrect application	5	13.5
5.	Other complication	2	5.4
Total		37	

Factors Influencing the Successful Management at Various Level of Healthcare:-

Patient related- Other forms of club foot management like- parents may seek non ponseti management methods, traditional medicines and other methods. These are ineffective and delay make ponseti treatment more difficult. This problem can be managed with education of family and there health care provider. There is public belief in some culture that clubfoot is caused by evil spirits , due to sins or misdeed of family or parents . The child with disability is a source of shame and is hidden by family .They do not have the benefits of an examination of newborn by trained healthcare workers . They don't have awareness of the diagnosis and the need for early treatment including misinformation that ponseti method is ineffective . These obstacles can be overcome by establishing clubfoot clinic and make ponseti management facility for every clubfoot affected feet . Engage parents to clubfoot clinic and discuss management and follow up to parents ,caregivers, and convey the message of free treatment in the society. Involve local government, panchayat, municipal corporation, schools, meetings, PHC ,CHC ,religious places, NGO to assist the very poor by facilitating transport and spread awareness about complete cure of CTEV patient.

Health institutional- Most of the government setups do not treat children with club foot deformity in a major manner. This is because clubfoot has not received importance at govt level in the centre or state , in spite of being the major presentation .This is the sad reality even under the department of Health and Family Welfare at PHC, CHC and even district hospitals where doctors and nursing staff are not aware about CTEV treatment by ponseti. There is neither any training facility to empower skills in CTEV treatment nor any national health programs for CTEV disbilty . In rajasthan where 75% rural and 60 % area is desert and less institutional delivery, awareness programs are very necessary at each level from beneficiary to health system . There is less number of orthopedic surgeon in the state and orthopaedic surgeons in these setups are busy in population control programs/Trauma or private practice rather than taking care of club foot children. Even most of the medical colleges in the govt setup do not stick to exclusive use of Ponseti's technique inspite of having speciality clinics. Ponseti's technique is used only if a thesis is given to a post-graduate or if a particular consultant is trained in this technique . "Cure" along with govt. has taken initiative in managing these patient's , specially in some states where comprehensive care in the form of training, counselling, models and materials, follow-up record sheets& braces are provided by them . But such scheme is yet limited to large cities and medical colleges.

The patient related barrier are simple to understand. Most of the Govt. set ups including Govt. Medical Colleges cater to the poor people. Poverty, illetracy and distances are the major barrier in managing a club foot child by parents. Parents prefer a one time surgery may be with inferior results rather than travelling long distances everyweek to get the plaster changed. Also routinely there is no provision to admit children for day-care Ponseti's technique. The need for prolonged bracing is the second barrier in the method. Insuring economic/free supply of bilateral foot dorsiflexion - Abduction brace is almost impossible.

Speciality clinics:- Most of the poor parents discontinue treatment due to lack of awareness. long term brace does not suit the parents & compliance becomes an important issue. Most of the medical colleges, even if they run a speciality clinic of club foot have their day and time fixed and so patient's with club foot won't get round the clock attention, apart from any emergency treatment if complication arises. Ponseti's clinics overcomes these problems to some extent as the parents see the outcome of others who are not following instruction, leading to recurrence of symptoms.

Non govt funded institutes:- They also treat club foot in the ideal way i.e. Ponseti's technique but the cost of treatment becomes tremendous as the consultation fee/plastering fee/plaster material cost/Anaesthetist cost/OT cost for tenotomy and post op. ward even in a day care setting are very high. They also require trained assistants to hold the foot in corrected position or apply the cast. Tenotomy even if it is a minor surgery require the complete pre-operative/Intra operative and postoperative protocol in these institutes.

So, parents think that instead of having so many plaster and then surgery, why not go for a single one timed surgery which will not only save money but time as well.

Summary of obstacles in the practice of Ponseti's technique

1. Parents from affluent societies insist to give anaesthesia so that child is not irritable and do not cry during manipulation or cast application. This eventually leads to more complications oedema and poor results.
2. Orthopaedic surgeons are still not very familiar to new terminology, classification systems and Ponseti's technique.
3. The technique does not work if speciality clinic is not affiliated. Patient counselling is a must.
4. Institutes which do not have full time Orthopaedic Surgeon insist one time correction rather than repeated visits of patient and orthopaedic surgeons.
5. Tenotomy is projected as a major surgery at times.
6. Avoiding tenotomy or bracing is a major cause of recurrence.
7. Poor results are also seen if a wrong selection of case is done & neglected, Complicated or syndromic clubfoot are counselled and treated like idiopathic club foot.
8. Social stigma of CTEV.

Recommendations for overcoming obstacles:-

1. Making the government aware of Ponseti's protocol and taking its help in establishing club foot clinics, where children with club foot will be treated only by trained and appointed orthopedic surgeons .
2. Provision of post correction basic braces free of cost, when the brace is returned after use and reapplied to another child till 3 years of age.
3. Provision of well equipped operation theatre with anaesthetist so that tenotomy may be done properly with antisepsis and without pain and children with neurological, syndromic and complicated clubfoot be also treated with surgical care. Provision of a post operative ward and shelter for these children and their families.
4. Free transport of these children to and from to the pre identified clinics as to insure attendance and full treatment.
5. Making a national health programs for CTEV patients.
6. Making a training schedule for CTEV treatment and counseling to orthopaedic doctors and assistants.
7. Engage more and more public to CTEV treatment awareness programs via media TV/newspaper, posters in hospital premise, schools ,colleges, awareness programs in community meetings ,and religious places.
8. Involve more NGO for awareness, counselling of CTEV parents.
9. Make a provision to give expenditure to CTEV patients.
10. Make a future policy for CTEV affected children.
11. Arrange a clubfoot clinic in remote desert area.

DISCUSSION

In spite of Ponseti casting technique becoming a common method to treat clubfoot worldwide, in developing countries like India, there are several physician & patients factors influencing the outcome. Skill management in improving Physician and Patient's family factors should be integrated in practise to prevent neglect in treatment .A Programme about proper application of Ponseti technique for doctors and patient's family education can help .

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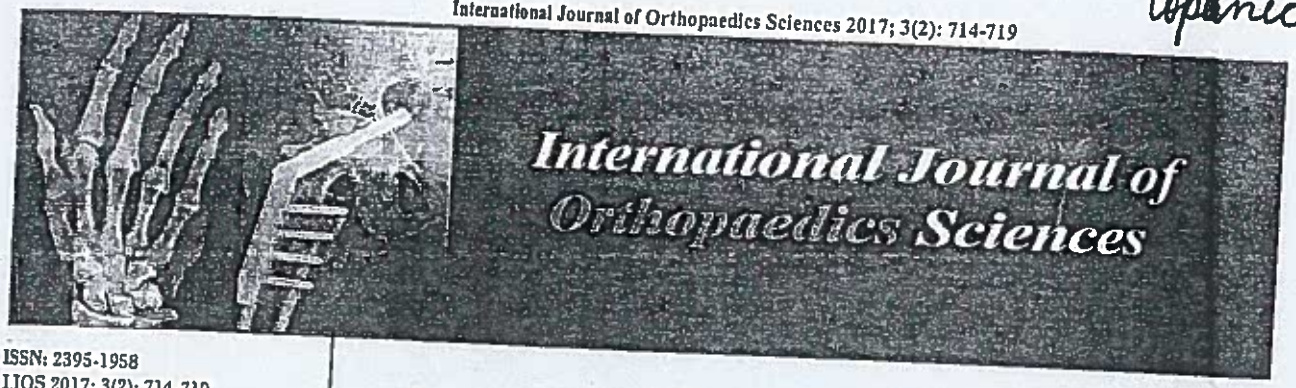

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Segmental tibial fractures treated with unreamed interlocking nail – A prospective study

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Abstract
Introduction: Fractures of tibia are common and major skeletal injuries. Treatment of such fractures in adults is a challenge to orthopaedic surgeons due to its poor soft tissue coverage and poor blood supply. The aim towards treatment for the segmental fracture tibia is union maintaining normal length, normal alignment without rotational deformity, normal joint movements and reduced hospital stay.
Method: In our department since 2012 to 2014, 51 segmental tibia fractures were treated with unreamed interlocking intramedullary nailing technique with one proximal and one distal locking screws. Postoperatively, early mobilization exercises and weight-bearing were begun. The functional results were assessed by measuring union period and knee range of movements at 6 months.
Results: Fracture healing was obtained in 49(96%) cases within the expected time period. 2(3.2%) patients had non union between proximal and middle segment. 46 (90%) were anatomic (valgus/varus<5^0). 5(9.8%) patients had malunion with valgus more than 5^0. Average range of movement observed at 4 months was 125^0 (70^0-140^0). Superficial infections were noted in 2 patients with compound fracture effectively treated with antibiotics.
Discussion and Conclusion: We conclude that unreamed interlocking nail fixation in segmental tibial fractures seems to be less time consuming, preserves blood supply, relatively simple and good method of treatment with good functional outcome and patient satisfaction provided proper selection of fractures done.

Keywords: Segmental tibial fractures, interlocking nail, poor blood supply, major skeletal injuries

Introduction

Fractures of tibia are common and major skeletal injuries mostly associated with high velocity trauma and often accompanied by substantial damage of the surrounding soft tissue. Treatment of such fractures in adults is a challenge to orthopaedic surgeons due to its poor soft tissue coverage and poor blood supply. The aim towards treatment for the segmental fracture tibia is union maintaining normal length, normal alignment without rotational deformity, normal joint movements and reduced hospital stay. The present study has been taken to review the result of segmental fractures of tibia treated with unreamed intramedullary interlocking nailing.

Material and Methods

This study was conducted between June 2012 to May 2014in the Department of Orthopaedics, Dr. S.N. Medical College and Associated Group of Hospitals, Jodhpur, Rajasthan. 51 patients were admitted in the Department of Orthopaedics with either open (37) or close segmental tibia fractures (14) and treated with interlocking nail. All patients were subjected to a detailed history and clinical examination with particular emphasis on mode of injury, time of injury, interval between injury and hospital admission and nature of treatment taken prior to admission. Clinical examination was including general, systemic, neurovascular and local examination of injured part. Depending on nature of injury relevant radiological examination was done.

Anterior posterior and lateral radiograph were done to diagnose fracture type. Routine preoperative investigation was done.

Open fractures were immediately irrigated, washed and temporarily immobilized with posterior POP above knee slab. Patient was operated within 48 hours of hospital admission.

Inclusion Criteria

- All skeletally mature patients.
- Open segmental tibial fractures (grade I to grade II Gustilo Aderson type)
- Close segmental tibial fractures without soft tissue involvement.

Isometric quadriceps exercise and toes mobilization was started from second postoperative day. Regular weekly follow up was done to inspect wound condition and other complication for compound fractures and regular 2 week follow up for close fractures.

- Passive knee mobilization exercise was started when pain and swelling subside. Active range of motion (ROM) exercise was started after 3 days postoperatively in all patients. Serial radiographs were taken at 4 week interval. Partial weight bearing was started after 21 days, Non weight bearing walking with the help of a walker started after 3 to 5 days and full weight bearing was started after 6 to 8 weeks depending upon the radiological appearance. Patients were followed up periodically on an outpatient basis on 2nd, 4th, 6th, 10th, 14th, 18th week and 6th month. Clinical and radiological assessment will be done for pain, deformity, shortening, range of motion of knee, ankle, subtalar joints and radiological union. final outcome will be assessed using Johner and Wruh's criteria.

Johner and Wruh's criteria [5] for evaluation of final results.

Sl no.	Criteria	Excellent	Good	Fair	Poor
1.	Non-union, infection, Amputations	None	None	None	Yes
2.	Neurovascular disturbances	None	Minimal	Moderate	Severe
3.	Deformity				
	Varus/valgus	None	2-5	6-10	>10
	Anteversion/Recurvation	0-5	6-10	11-20	>20
	Rotation	0-5	6-10	11-20	>20
4.	Shortening	0-5mm	6-10mm	11-20mm	>20mm
5.	Mobility				
	Knee	Normal	>80	>75	<75
	Ankle	Normal	>75%	>50%	<50%
	Subtalar	>75%	>50%	<50%	--
6.	Pain	None	Occasional	Moderate	Severe
	Gait	Normal	Normal	Insignificant limp	Significant limp
7.	Strenuous activities	Possible	Limited	Severely limited	Impossible
8.	Radiological Union	Consolidated	Consolidated	Union	Not consolidated

Results

In our series maximum numbers of patients (78.42 %) were in age group 21 to 50 years, with age ranging from 18 to 76 years. The mean age of patients under study was 40.6 years. Male: female ratio of our series was 3.25:1, with males being involved almost three and a half times more than females. In our series, 38 cases were open segmental fractures of tibia and 8 cases were closed fractures with compromised soft tissue. Road traffic accident was the most common mode of injury in 44 cases (86.27 %), fall from height in 5 cases and assault in 2 cases. Right leg was involved in 32 cases, left knee in 19 cases. Most common associated injury was clavicle fractures in 10 cases. Other associated injuries seen were [Figure 1].The mean interval between injury and surgery was 1.5 (range, 1–2) days. Primary treatment elsewhere (n=6) was the most common cause of delay in surgery. Six patients required blood transfusion due to open injuries or simultaneous fractures of other bones. The mean hospital stay was 9.5 (range, 5–19) days. The mean interval between surgery and clinical union was 18.2 (range, 14–23) weeks. The mean follow-up period was 10 (range, 10-30) months.

Postoperative complications were observed as in [Figure 2].

Out of 51 cases, 48 had normal leg extension. 3 cases had extensor lag < 10^0 while no cases had > 10^0 extensor lag.

In our series out of 51 cases, 42 cases had either full or more than 140^0 range of motion, 8 had range of motion between 120^0 to 140^0, 1 case had range of motion between 90^0 to 120^0.All patients had range of motion more than 90^0 (acceptable).

No angulation was present in 45 cases. Angulation < than 10^0 was present in 5 cases, angulation in between 10^0 to 20^0 was present in 1 case.

According to johner and wruth's criteria results seen were as shown in [Table 1].

Discussion

The commonest cause of the fracture being high velocity road traffic accidents. In our series 86.27% of the fractures groups were due to high velocity road traffic accidents.

Most of the authors used reamed interlocking nails viz. Olerud and Karlstrom (1972), Puno ét ál (1986), Klemn and Borner (1986), Ekelandét ál (1993) and Renner et ál (1993)[9-11] used undreamed tibial nail while Court-Brown ét al (1990)[12-15] did a comparative study of reamed and unreamed nails. "Reaming resulted in the destruction of all vessels of the medullary canal, rigid nailing with reaming leads to a higher incidence of infection as dead bone produced due to reaming (debris/endosteal necrosis) acts as a good culture medium for bacteria (Bintcliffe *et al.* 1984) [16, 17]. while medullary nail without reaming caused minor damage to the blood supply. Court Brown CM *et al.* (1996) [12-15] made a prospective study in 50 cases and concluded that reamed is better than unreamed nailing in tibial closed fractures. Larsen *et al.* (2004) studied 45 patients and concluded that the average time to fracture healing was 16.7 weeks in reamed group and 25.7 weeks in the unreamed group. The difference was significant (P=0.004). Mohit Bhandari *et al.* (2008) [18] conducted a multicenter, blinded randomized trial of 1319 adults in whom a tibial shaft fracture was treated with either reamed or undreamed intramedullary nailing and demonstrated a possible benefit for reamed intramedullary nailing in patients with closed fractures. They found necrosis of the inner 50-70% of the cortex after reaming. In our study we used unreamed nail in 38 patients and reaming only in proximal segment (To make high and anterior entry which prevents anterior projection of small proximal fragment due to pull of

patellar tendon) in remaining 13 patients.

In our study 74.51% patients were having open injury, this is in agreement with the study shown by Woll and Duwelius [19] who have reported an incidence of 75% open fractures in this pattern of injury.

Many authors support and recommend fixation with intramedullary nailing [35] with advent of interlocking nail provide superior results [12, 13]

Similar to our study and observations Ekeland and Alho [20, 21] examined 43 patients with segmental tibial fractures out of which they reported one non union, one deep and one superficial infection and finally they concluded that the interlocking nail proved to be efficient mode of treatment for comminuted segmental and unstable tibial fractures.

In our series 2 patients (3.9%) had superficial wound infection of the proximal incision site. This responded to the usual oral antibiotics and daily dressings. One patient (1.96%) had deep infection. Regular dressing, oral antibiotics and guarded weight bearing was continued till the fracture united (18 weeks). two cases had superficial infection were Gustilo's grade II. The injury surgery interval in one of these cases was 7days and the other 2 were 4-5 days (because of associated head injury). This delay in the surgery was the probable cause of superficial infection in two cases and deep infection in one case. This indicates that early surgery with a proper antibiotics cover is a must when considering a case of compound tibial fracture for nailing.

We encountered 3 cases of delayed union in which, after waiting for about 16 weeks when abundant callus was not visible in the skiagram and the patient had persistent tenderness over the fracture site. Two of the cases had hypertrophic type of non-union. The reason in one of these cases was probably a deep infection due to improper hygiene and non -compliance of the patient to follow the weight bearing protocol and other instructions and also lack of regular antibiotic intake. This indicates the importance of regular follow up and patients compliance.

The distal fracture is the usual site for the non-union, proposed reason for this being the direct injury to the soft tissue overlying this fracture and natural tendency to slow union in fractures at this location [22].

Although other authors reported no significant difference in union rate at proximal and distal fracture sites. this is consistent with our results as in our study we got non- union in two patients at proximal fracture site.

Most common postoperative complication was anterior knee pain in 5 patients. Occasional Pain in knee was a common problem in 32 patients, 5 patients had constant pain after activity. However the pain did not disturb the activities of daily living in majority of patients.

In our series out of 51 cases 47 (92.15%) had acceptable Johner and wruth's criteria for functional results (sum of excellent and good results). Excellent in 36 (70.59%), good in 11 (21.57%), fair in 3 (5.87%) and poor in 1 (1.97) Ekeland and Alho [20, 21] reported results excellent in 29, good in 13 and fair in 2 and poor in one out of 45 cases.

Conclusion

From the observation of present study it is concluded that the high-energy trauma associated with this pattern of injury poses many challenges to the surgeon due to the precarious blood supply of the intermediate segment and the serious damage to the surrounding soft tissues. The risk of non-union, delayed union, infection and additional procedures is high as seen in this series of patients. The preferred method of initial fracture stabilisation is the use of unreamed interlocking intramedullary tibial nail with immediate soft tissue cover whenever possible, this procedure require less surgical time, hospital stay, is cost effective and have minimum complications with good functional outcome.

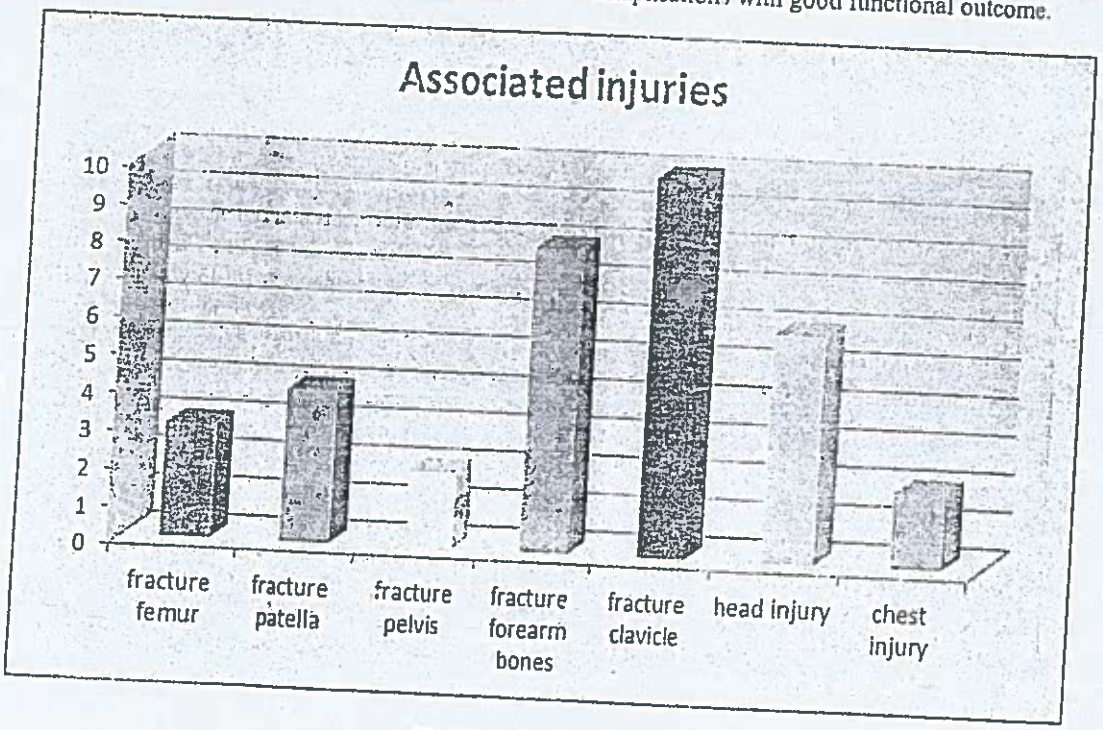


Fig 1: Associated injuries

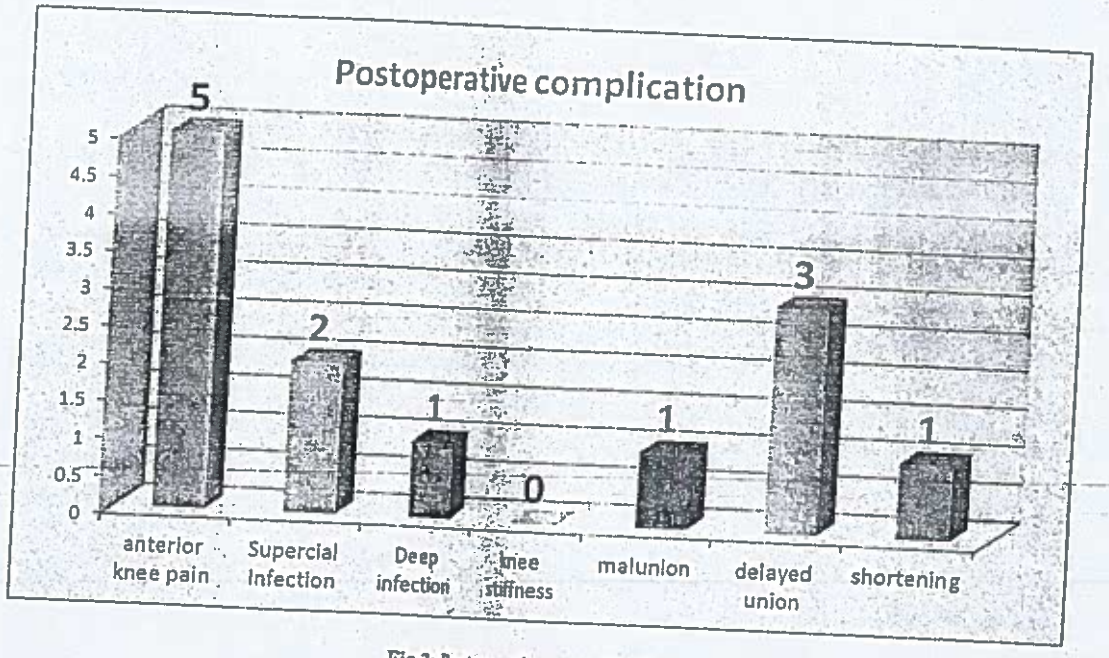
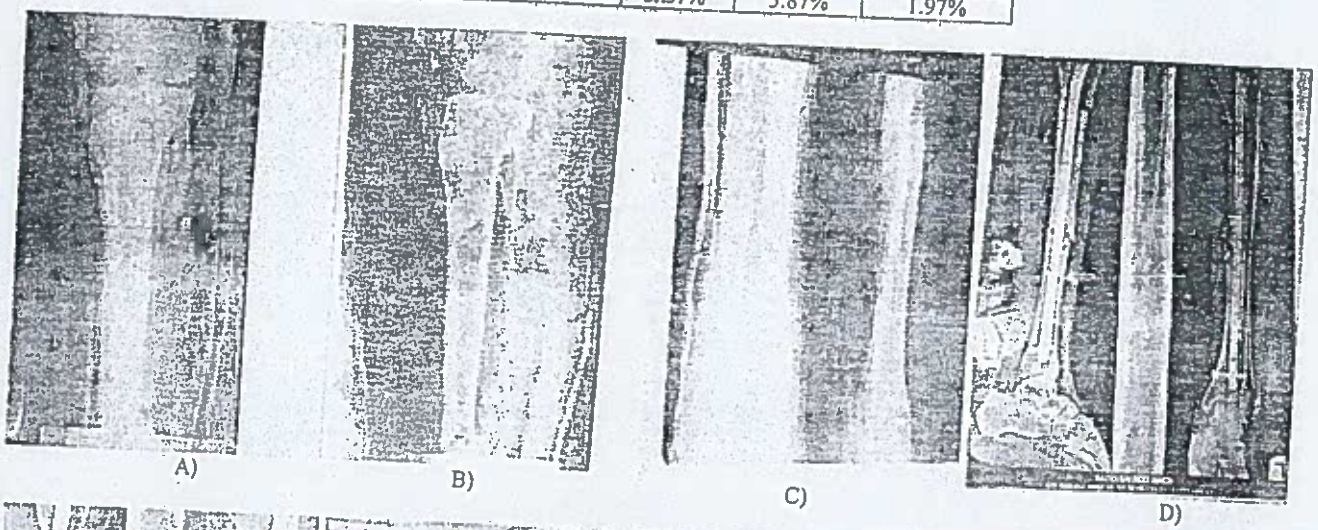
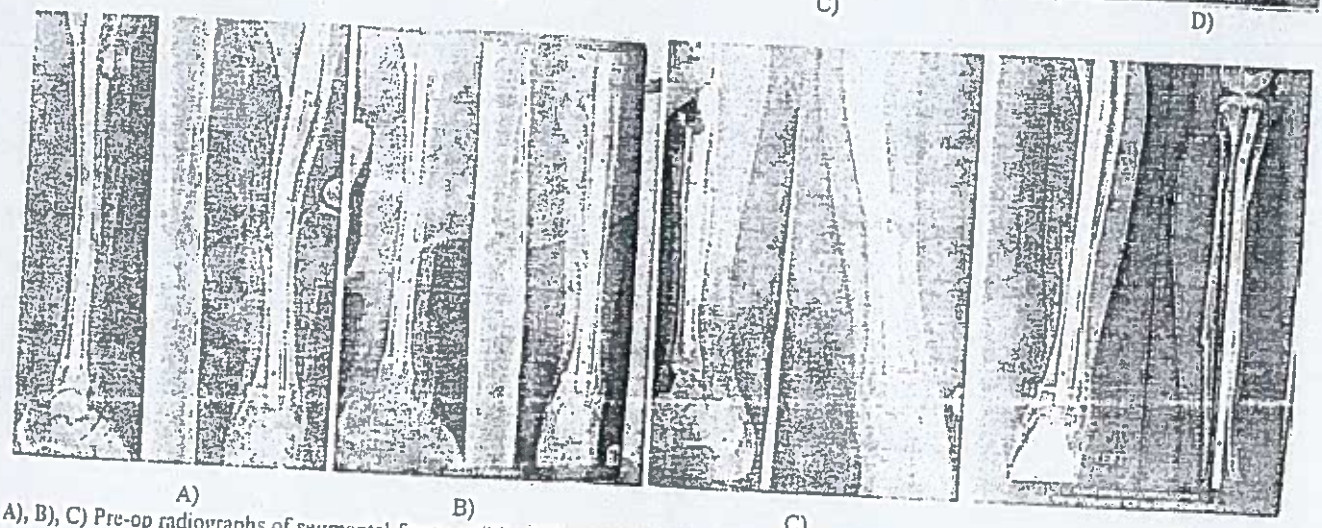


Fig 2: Post operative complication

Table 1: Johner and wruth's criteria[5] for final results

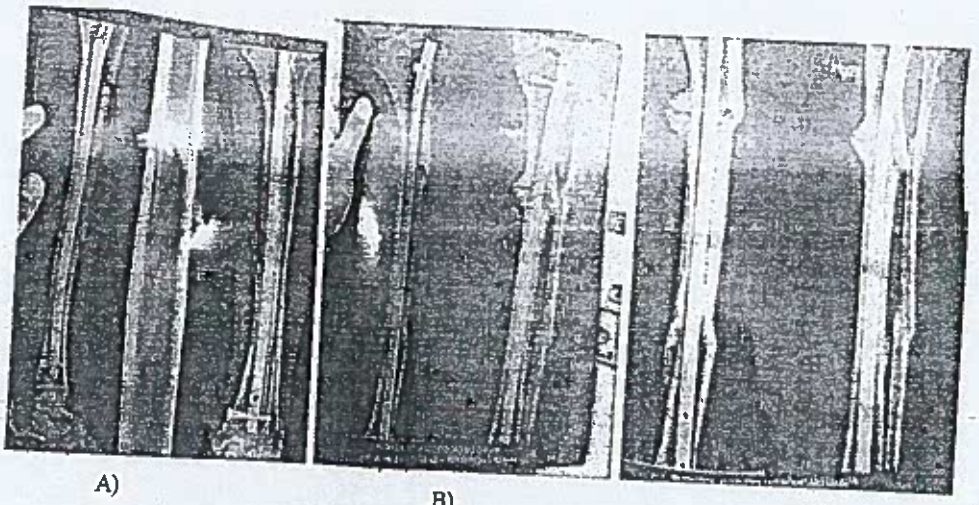
No. of cases	Acceptable results		Unacceptable results	
	Excellent	Good	Fair	Poor
51	36	11	3	1
100%	70.59%	21.57%	5.87%	1.97%





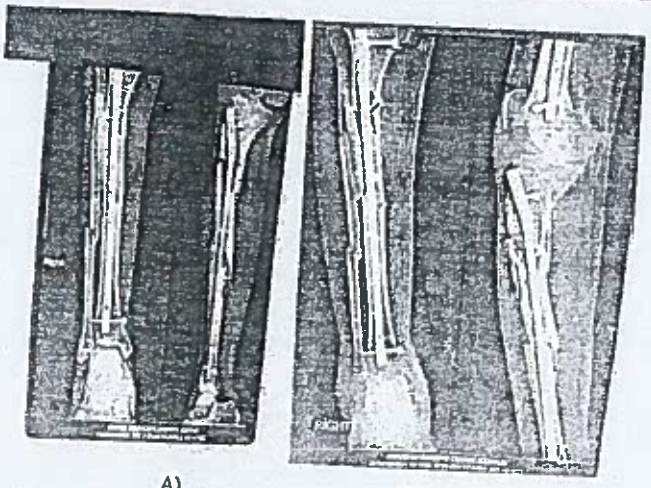
A), B), C) Pre-op radiographs of segmental fracture tibia. D) Immediate post-op radiograph E) One moth follow up F) Two month follow up. G) Three month follow up H) 6 month follow up with radiological union.

Case 1



A) B) C)

Case 1: Radiographs showing hypertrophic nonunion at proximal fracture site.



A) B)

Case 2: Radiographs showing infective nonunion at proximal fracture site.

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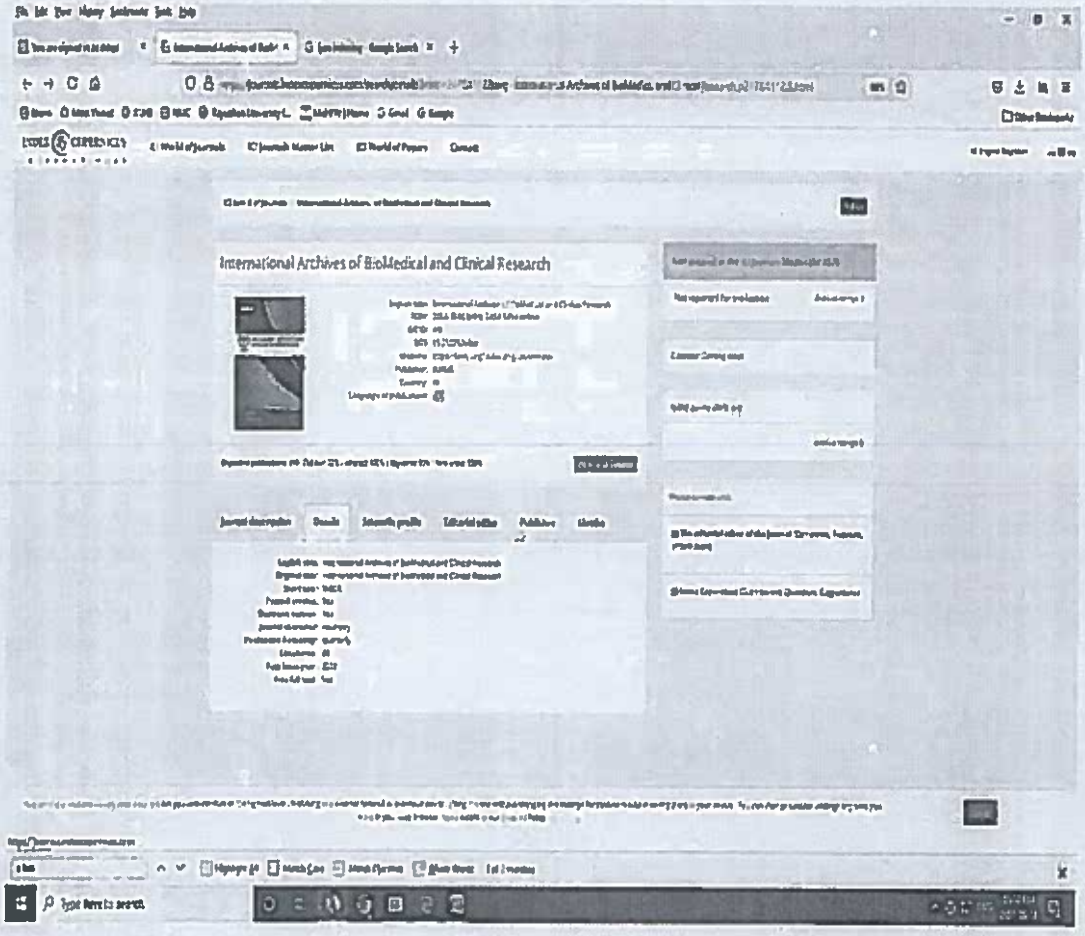
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Section

Article

A Hospital Based Study on Functional and Radiological Outcome of Volar Barton's Fracture treated with Volar T – Plate

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Dr. Mohan Lal Vishnoi,
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Background: *Fractures may occur due to low energy or high energy injuries. High energy injuries are more frequent cause of volar Barton's fracture.*
Methods: *90 total number of cases were included in this study who attended the OPD. This study was conducted in Department of Orthopedics.*
Results: *In our study we were included total 90 cases of 0-60 age group. Mode of injury we were seen Fall on outstretched hand in 63 cases and Road traffic accident in rest cases. This study revealed that subject & functional result which were excellent in 18 & 27, good in 48 & 45 cases, fair in 15 & 6 cases, poor in 9& 12 cases respectively.*
Conclusions: *This study disclosed that maintaining anatomical reduction is key stone for satisfactory outcome. Best functional results were achieved till 6 months of treatment.*

Keywords: *Barton's fracture, Orthopedics, anatomical reduction*

INTRODUCTION

It well known that Barton's fractures is named after the American surgeon John Rhea Barton, who first described it in 1838. It is a fracture of the distal end of the radius which involves the articular surface.[1] This fracture can be either an anterior marginal or posterior marginal fractura. These fractures may occur due to low energy or high energy injuries. High energy injuries are more frequent cause of volar Barton's fracture.[2-5] Volar Barton's fractures are different from other distal radius fractures. There is an associated radio carpal dislocation in Barton's fracture. In these type of fractures, conservative treatment is usually unsuccessful. Whereas, in other distal radius fractures, the functional outcome with conservative treatment is good. Complications like loss of reduction, malunion, nonunion, deformity, subluxation and instability are also associated with these types of fractures.[6-8] Several surgical treatment methods are reported in literature. Open reduction and internal fixation with a volar plate system have displayed good results. The main advantages of this system are reduction of articular surface and achieves immediate stability of joint leading to early mobilization of wrist and potential reduction of wrist and finger stiffness and reduction of early onset of wrist osteoarthritis.[9-11]

Fractures of the distal radius found the most common skeletal injuries. It is treated by Orthopaedic surgeons. These

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injuries are responsible for one sixth of all fractures assessed in emergency room. The fractures of distal end radius comprise nearly 10-12% of skeletal trauma. These fractures occur due to the fall on out-stretched hand or road traffic accidents. Malunion is the most common complication. It leads to deformity, decreased range of motion at wrist and hand, decreased grip strength due to arthritis.[12] Excellent surgical handling of bone and soft tissues with early post-operative mobilization, help the functional outcome.[13,14] Dislocation of the radiocarpal joint is generally present in intra-articular fractures involving the dorsal or volar rim of the radius. Barton described the fractures of the dorsal rim of radius, that is why it is referred as volar Barton's fracture.[15] This fracture is also categorized as Type 23 B3 in Muller AO classification. Several surgical techniques have been published in literature.[16,17] But the present treatment of choice is ORIF with volar plating. The stability attained with volar plate facilitates in maintenance of reduction and allows early mobilization.[18,19]

METHODS

Study population:- 90 total number of cases were included in this study who attended the OPD.

Study area:- This study was conducted in Department of Orthopedics.

Data collection:- Study included 30 cases of volar Barton fractures treated with buttress plate and screws. Only Fernandez type II (intraarticular fracture produced by shearing) was considered.

Data analysis:- Data were analyzed by using Microsoft excel.

RESULTS

In our study we were included total 90 cases of 0-60 age group. Among all 36 cases were belongs to 41-50 age group followed by 21-30 (27),31-40 (18), & 51-60 (9) age group. We observed that dominant side involvement in 72 cases while non-dominant side involvement was in 18 cases. Mode of injury we were seen Fall on outstretched hand in 63 cases and Road traffic accident in rest cases. This study revealed that subject & functional result which were excellent in 18 & 27, good in 48 & 45 cases, fair in 15 & 6 cases, poor in 9& 12 cases respectively.

Table 1: Age-wise distribution of patients

Age group	No. of cases
0-20	0
21-30	27
31-40	18
41-50	36
51-60	9
Total	90

Table 2: Distribution of cases according to involvement of side

Side involved	No. of cases
Dominant	72
Non-dominant	18

Table 3: Distribution of cases according to mode of injury

Mode of injury	No. of cases
Fall on outstretched hand	63
Road traffic accident	17
Total	90

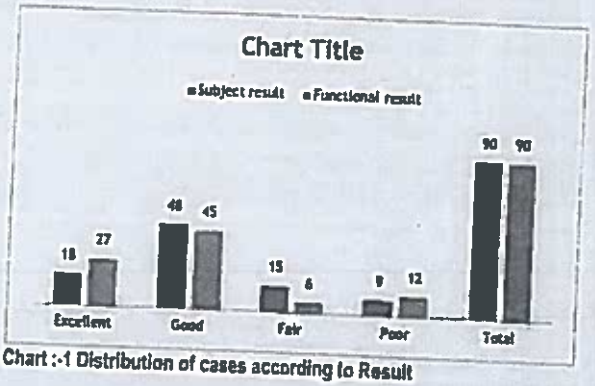

Chart :-1 Distribution of cases according to Result

DISCUSSION

In the present study 90 patients were included. They belonged to age group of 21 to 70 years with average age of 45 years. Results showed that distal end radius fractures occurred maximum in the age group of 41-50 years i.e. 40%. The main reason behind young population get these fractures more is increasing incidence of motor vehicle accidents which is most common mode of injury in this group. Our findings also revealed that males were predominant i.e. 90% whereas females were only 10%. This could be explained by the fact that males are more commonly involved in road traffic accidents. Similar results were found by King RE.[20]

It is also observed that 80% of patients were having right side involvement. The prevalence of right side was due to the fact that right hand was dominant in all cases. Other studies such as Donald et al. (1982), James (1991) also found the similar results.

In this study all fractures were reduced and fixed anatomically. The union rate was 100%. The fracture healing process is not hindered due to the cancellous bone character. So, the success rate is high. Only the 12 out of 90 patients showed restriction of range of movement due to slight finger contraction that were labeled as fair result. These findings are supported by the study of Kapoor and co-workers (2000). Postoperatively, median nerve function was not affected in any case in the present study. also found the similar findings. Thus, this study suggests that the release of the median nerve is not necessary in ORIF of volar Barton's fractures. Volar plate fixation of unstable distal fractures has been described recently in literature. Results of the present study are similar to the radiological evaluation and functional assessments presented in recent reports.

In the present study, patients were suffered from rupture of the flexor pollicis longus tendon. Drobetz and Kutscha-Lissberg reported that if fracture instability demands distal placement of hardware, close follow-up investigations and hardware removal should be considered at the first sign of flexor tendon irritation. This was also an important point for

Though, T-buttress plate is useful for achieving anatomical reduction, but care must be taken to avoid the complication of tendon rupture. The findings of this study showed that the scores of 27 patients were excellent, 45 patients good, and 12 patients fair.

CONCLUSION

This study analyzed 90 cases of volar Barton fracture operated by various surgeons. It can conclude that most common mode of injury was fall on outstretched hand. Anatomical and functional results were satisfactory in 80% cases fair in 13.3% cases and 6.6% cases had poor result. Complications were observed in 20% cases. Maintaining anatomical reduction is key stone for satisfactory outcome. Best functional results were achieved till 6 months of treatment.

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Section Article

A Hospital Based Prospective Study on Acute Scrotum: Evaluation, Diagnosis, Intervention and Management

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Background: Generally, testis is partly covered by tunica vaginalis derived from processus vaginalis in anterior part. If testis, epididymis and distal part of spermatic cord is covered by tunica-vaginalis, torsion of the testis may occur in this serosal space. The major differential diagnoses are acute epididymitis, strangulated hernia, hematocle, hydrocle, testis tumor and idiopathic scrotal edema
Methods: This prospective study was carried out among 100 male patients between the age group of 14 to 70 years. Around 100 cases were included in our study.
Results: We observed that swelling & pain seen in every cases while fever in 48 cases, burning micturition in 30 cases, abdominal pain in 16 cases & 12 cases of trauma. All the patients treated conservatively responded well with complete recovery.
Conclusions: Our study revealed that Conservative treatment in the form of rest, scrotal support, antibiotics and analgesics is effective in cases of epididymo orchitis and idiopathic scrotal edema.

Keywords: epididymo orchitis, Conservative treatment, tunica vaginalis

INTRODUCTION

The term acute scrotum can be defined as signs and symptoms associated with local inflammation of the scrotum that appear suddenly and generally are not associated with trauma. These signs and symptoms are scrotal pain, swelling, redness and heat.[1] In other words, acute scrotum is an acute painful swelling of the scrotum or its contents accompanied by local signs and general symptoms. In children, the most common causes of acute scrotum are testicular torsion, appendix testis torsion, epididymitis, orchitis and pyocele.[2]

Spermatic cord or torsion of testis is certainly the most serious condition. It affects the scrotum[2] that requires urgent diagnosis and treatment to save the testis and avoid testicular loss, fertility problems and medicolegal issues.[1]

Testicular loss commences past twelve hours of initiation of symptoms. Testicular loss will definitely happen beyond twenty-four hours of symptoms. That is why in the absence of ancillary studies surgeons immediately explore the acute scrotum.[1]

Torsion of testis contains almost 15-40% of all acute testicular pain. This condition depends on abnormal relation of testis to scrotal tissue coverage.

Testicular scan and color doppler ultrasound are the two most commonly used preoperative studies. Testicular scans reliably reveal whether the testes have vascular flow or not but are difficult to be obtained during the night. Doppler ultrasounds are operator dependent and when done by

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experienced physician, can reduce the number of emergency operations and hospitalization days.

Generally, testis is partly covered by tunica vaginalis derived from procesus vaginalis in anterior part. If testis, epididymis and distal part of spermatic cord is covered by tunica-vaginalis, torsion of the testis may occur in this serosal space.[2] The major differential diagnoses are acute epididymitis, strangulated hernia, hematocle, hydrocle, testis tumor and idiopathic scrotal edema.[3]

Clinical judgment by the surgeon is undoubtedly the most important factor in assessing testicular salvage. In case of doubt the next step is immediate surgical scrotal exploration. Exact diagnosis of testicular torsion mostly can be confirmed by prompt scrotal exploration. Prognosis is essential when detorsion of the affected testis is performed within first 6 hours.[4]

Even with all the investigations, mostly availab'e only in a few centers in India. Early scrotal exploration remains to be the main stay for diagnosis as well as a therapeutic modality.

METHODS

Study Population:- Total 100 cases were included in this study.

Study Area:-This study was conducted in Department of Surgery.

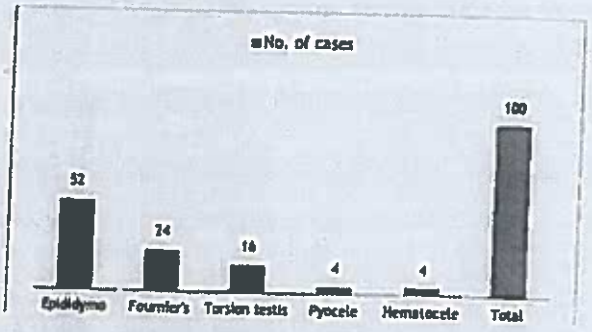
Data collection:- This prospective study among 100 male patients between the age group of 14 to 70 years who visited the surgical outpatient with a history of acute scrotal pain and/or swelling.

Data analysis:- Data were analysed by using Microsoft excel.

RESULTS

In our study we were included total 100 cases. Among all cases, 52 cases of epididymoorchitis followed by Fournier's Gangrene (24 cases), torsion testis (16 cases),4 cases of pyocele & hematocele were found. Out of 100 cases 44 cases of 31-40 age group ,22 cases of 21-30 cases, 12 cases of 41-50 cases,10 cases of 51-60 cases, 8 cases of 11-20 age group & 4 cases of 61-70 age group.

We observed that swelling & pain seen in every case while fever in 48 cases, burning micturition in 30 cases, abdominal pain in 16 cases & 12 cases of trauma. All the patients treated conservatively responded well with complete recovery. In surgically treated patients, post-operative recovery was uneventful in 18 cases with 6 cases developing wound infection as a complication. Average stay in the hospital was 6.27 days in patients with conservative management, 6.39 days in cases of torsion testis and 23.19 days in cases of Fournier's gangrene.



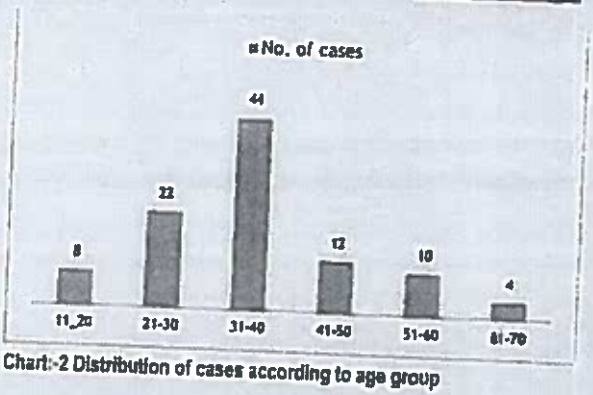


Chart:-2 Distribution of cases according to age group

Table 1: Distribution of cases according to symptoms

Symptoms	No. of cases
Swelling	100
Pain	100
Fever	48
Burning micturition	30
Trauma	12
Pain abdomen	16
Pus discharge from scrotum	10

Table 2: Distribution of cases according to management

Treatment	No. of cases
Conservative	52
Incision and drainage	4
Scrotal exploration and drainage	12
Debridement	12
Orchidopexy	10
Orchidectomy	6
Evacuation of hematocele	4

DISCUSSION

Acute scrotum is common among younger individuals with a maximum incidence. It is also common in people who are involved in strenuous work. Trauma and urinary symptoms have a significant effect on the disease. Scrotal swelling with pain is the most common presenting feature which may or may not be associated with fever and burning micturition.

Color Doppler ultrasound is useful tool for evaluating testicular perfusion. Gray scale ultrasound helps to assess the cystic or solid nature of scrotal mass. It often the signs of an inflamed epididymis and a necrotic testicle. In the settings of torsion, a normal homogenous echo pattern shows viable testis whereas a hypo echoic or non-homogenous testis is likely to be non-viable. Ultrasound of the scrotum is extremely sensitive in the diagnosis of acute scrotum with blood investigations and urine analysis being supportive.

Due to the anatomic location and mobility of the scrotum,

right testis is injured more often than the left one. The reason could be its greater propensity to be trapped against the pubis or inner thigh.[5] Testicular rupture is a tears in the tunica albuginea resulting in extrusion of the testicular contents. Speedy surgical intervention is crucial. Ruptured testis can be salvaged, if surgical repair is performed within 72 hours of testicular injury.[5] In the present study, mean time between surgery and the initial trauma was 35 hours. Sports injuries were the most common causes of significant testicular injury. All testes were salvaged, though two boys developed testicular atrophy during follow up. In the diagnosis of testis torsion, standard and Doppler ultrasound accomplishes specificity of 80%-100%.[6] Acute phase proteins can be helpful in the differentiation of acute epididymitis from other non-inflammatory causes of acute scrotum.[6] Even with mentioned diagnostic procedures, sometimes it is not possible to distinguish between TT or some other conditions that mimics clinical presentation of TT. Hence, a surgical intervention is actually a diagnostic procedure. It is always justified in any dilemma for the accuracy of diagnosis. Previously, it has been shown that there is a positive correlation between low air temperature and TT.[7-9]

In this study, TT also most commonly occurred in January. A number of boys underwent surgery in winter and summer, and the lowest number in autumn. The reason could be the relative contraction of cremasteric muscle in winter and increased physical activity in summer, mainly water sports.

CONCLUSION

It can be concluded that Conservative treatment in the form of rest, scrotal support, antibiotics and analgesics is effective in cases of epididymo orchitis and idiopathic scrotal edema. Emergency surgical exploration is beneficial in cases of torsion testis and Fournier's gangrene. Follow up of the patients is essential to find out the complications in form of sterility, development of fistulae and involvement of contralateral side at a later period.

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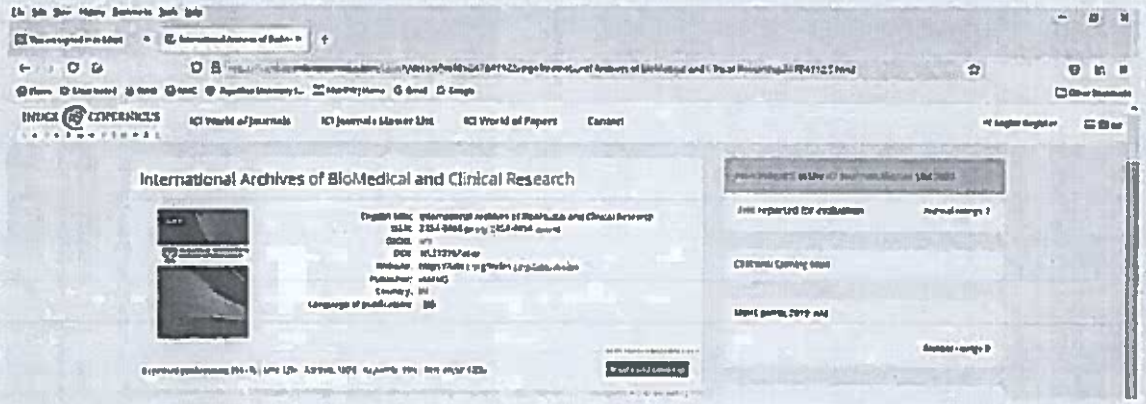

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Bacteriological Study of Post-Operative Wound Infections in ICU of Surgery in a Tertiary Care Teaching Hospital

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Original Article

Bacteriological Study of Post-Operative Wound Infections in IPD of Surgery in a Tertiary Care Teaching Hospital

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ABSTRACT

Background: *The postoperative wound infection varies from 1 to 9 percent, depending on the surgical procedure. Due to postoperative wound infection, the length of stay in hospital increases. It also increases the cost of the procedure and is associated with significant morbidity. Staphylococcus aureus is the causative agent in 15 to 30% of these infections, though the pathogen isolated differs according to the surgical site.*

Methods: *The population of study was 200. Among 200 cases 29 cases got bacterial infection. This study was conducted in Department of surgery and the patients were recruited on the basis of inclusion and exclusion criteria.*

Results: *In this study we were included total 200 cases. We found that 78 cases of clean wound followed by clean contaminated 54, contaminated 38 & 30dirty wound. Prevalence of infection was 14.5%.*

Conclusion: *Post-operative wound infections are a serious medical problem that has to be tackled due to its increased morbidity, mortality and medical care costs. An active surveillance program is recommended.*

Keywords: *Post –operative wound, Contaminated wound, Organism*

INTRODUCTION

It has been reported by World Health Organization (WHO) that hospital acquired infections to be one of the major infectious diseases having an enormous economic impact worldwide.[1] It is estimated that such infections affect around 2 million people annually resulting in 5% to 15% of them requiring hospitalization.[2]

The postoperative wound infection varies from 1 to 9 percent, depending on the surgical procedure. Due to postoperative wound infection, the length of stay in hospital increases. It also increase the cost of the procedure and is associated with significant morbidity.[3] Staphylococcus aureus is the causative agent in 15 to 20% of these infections, though the pathogen isolated differs according to the surgical site.[4] Risk factors which may responsible for acquiring an infection can be divided into host factors, surgical and environmental factors, and microbial characteristics. Host factors which may contribute to an increased risk of infection are age, prolonged pre-operative length of stay, and concurrent infection at another body site. Increased infection risk may cause an extended surgical procedure. The wound classification, the use of a razor for hair removal before surgery may also be dependent on the surgeon's technical skill.[5]

Even with advances in operative techniques and a better understanding of the pathogenesis of wound infection and wound healing, surgical site infections continue to be a major cause of morbidity and mortality for patients undergoing operative procedures. It is reported that incidence of wound sepsis in India is from 10%-33%. Though, the incidence of wound complications in the obstetric population fluctuates with rates ranging from 2.8% to 26.6%. 1-3 Surgical site infection (S.S.I.) is a valuable tool to demonstrate the magnitude of the problem.

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On the basis of the above discussion, the present study was undertaken for early recognition of the problem so that early intervention can be done for better management of postoperative would infections.

METHODS

Study Population:- The population of study was 200.Among 200 cases 29 cases got bacterial infection.

Study Area:- This study was conducted in Department of surgery.

Data collection:- The operative wound was inspected at frequent intervals for clinical evidence of infection. When infection was suspected, three swabs were taken by using sterile cotton swab sticks. One swab was placed in a sterile tube containing Stuart's transport medium for isolation of anaerobic organisms. The second swab was used for Gram staining and the third inoculated on plates of Nutrient agar, Blood agar and McConkey's agar respectively. Swabs in Stuart's medium were inoculated on blood agar plate containing Gentamicin and incubated in MacIntosh Fildes jar using palladized asbestos catalyst, for 48 hours by evacuation and replacement with 90% hydrogen and 10% carbon dioxide.

Data analysis:-Data were analysed by using Microsoft excel.

RESULTS

In this study we were included total 200 cases. We found that 78 cases of ,clean, wound followed by ,clean contaminated 54, contaminated 38 & 30dirty wound. We had done 43 Lower segment caesarean section,14 Hysterectomy,25 ENT surgeries, 25 Plastic Surgeries,25 Orthopedic surgeries, 16 Bowel surgeries, 12 Urological surgeries,4 Appendicectomy, 3 Cholecystectomy, 4 Hernia surgeries, 3 Hydrocele surgeries,19 Cataract surgeries &,7 other surgeries. Among 200 surgeries, we were found 29 infected cases which showed in table1. We also observed that predisposing factor which were anemia, malignancy, diabetes, chronic illness, immunodeficiency state. We found that 20.6% infected cases with P. aeruginosa followed by E. coli (17.2%), K. pneumonia (10.3%). Bacteroids spp. & Cons 6.8%, S. aureus, Citrobacter & Streptococci which were 3.4%.

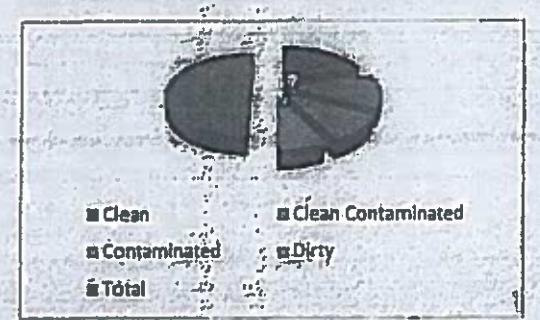

Chart:1 Distribution of cases according to contaminated wound

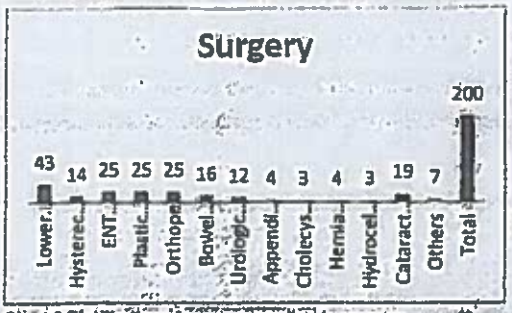

Chart:2 Distribution of cases according to surgery

Table -1 Distribution of cases according to infected cases

Surgery	Frequency	Infected cases
Lower segment caesarean section	43	3
Hysterectomy	14	2
ENT surgeries	25	3
Plastic Surgeries	25	3
Orthopedic surgeries	25	7
Bowel surgeries	16	5
Urological surgeries	12	2
Appendicectomy	4	1
Cholecystectomy	3	1
Hernia surgeries	4	1
Hydrocele surgeries	3	-
Cataract surgeries	19	-
Others	7	1
Total	200	29

Table:-2 Distribution of cases according to predisposing factor

Predisposing factor	Infected cases
Anemia	5
Malignancy	7
Diabetes	4
Chronic illness	3
Immunodeficiency state	1
Other	3
Total	23

DISCUSSION

Out of 200 patients, 29 got infected post operatively. The post-operative infection rate was 14.5% in the present study. Many workers have reported the percentage of post-operative wound infections in range of 10% to 76.9%.[7-11] In this study, the rate of post-operative wound infections could be attributed to the progressive trend towards operating the older patients and performing more complicated procedures on contaminated and dirty surgical

sites. Likewise presence of drain led to development of wound infections with increased frequency. Though drainage provides an outlet for collected serum and blood and prevents haematoma formation, reducing the chances of infection still presence of drain for a longer time may act as a pathway for pathogenic bacteria to enter the wound. Thus, it increases the risk of infection. Similarly, in emergency surgeries, the infection rate was high as compared to the elective ones. Similar observations have been found by other studies also.[12]

Table:-3 Distribution of cases according to isolates

Isolates	No. of organism	Percentage
Staphylococcus aureus	1	3.4
CONS	2	6.8
Pseudomonas aeruginosa	6	20.6
Escherichia coli	5	17.2
Klebsiella pneumonia	3	10.3
Proteus spp.	1	3.4
Citrobacter species	1	3.4
Beta haemolytic Streptococci	1	3.4
Bacteroides species	2	6.8
Total	29	100

Higher infection rates were reported in different kind of surgeries such as bowel surgeries (38.46%), orthopaedic surgeries (29%), urological surgeries (25%), cholecystectomy (21.05%) & appendectomy (18.18%).[13] The reason could be impaired host defenses in these patients and longer hospitalization. In this study, the bacterial isolates obtained indicate a polymicrobial flora. Similar findings were found by other researchers.[14]

Many infections are caused by Gram-negative bacilli. Though, the single most common bacterial isolate was Staphylococcus aureus. The bacterial isolates commonly found were Pseudomonas aeruginosa, E. coli and Klebsiella species, all known to be hospital pathogens. In the present study, isolation of anaerobic bacteria was very uncommon. The antibiotic sensitivity profile of isolates showed that a large number of multidrug resistant strains were common in the hospital environment. Hence, it may be stated that post-operative wound infections occur with more frequency. So, more strict steps are needed to reduce the incidence. Whenever the infection occurs, proper laboratory identification of the pathogen along with its sensitivity profile must be obtained to treat the patient with proper antibiotics. It is also important to watch whether it is causing cross infection or resulting in spread as a hospital infection.[15-17]

It was reported that operative time ≥ 240 minutes was related with increased overall complications.[18] In orthopedic surgeries, post-operatory infections present a significant risk and the use of antibiotics increases the population of pathogens exhibiting resistance against them. Silver nanoparticles seem to be a new therapeutic avenue for their safety. They can be implanted in bone cement for the prevention of infections.[17-19]

It can be concluded that post-operative wound infections are a serious medical problem. It has to be handled properly due to its increased morbidity, mortality and medical care costs. It is recommended that an active surveillance program should be undertaken.

CONCLUSION

Post-operative wound infections are a serious medical problem that has to be tackled due to its increased morbidity, mortality and medical care costs. An active surveillance program is recommended.

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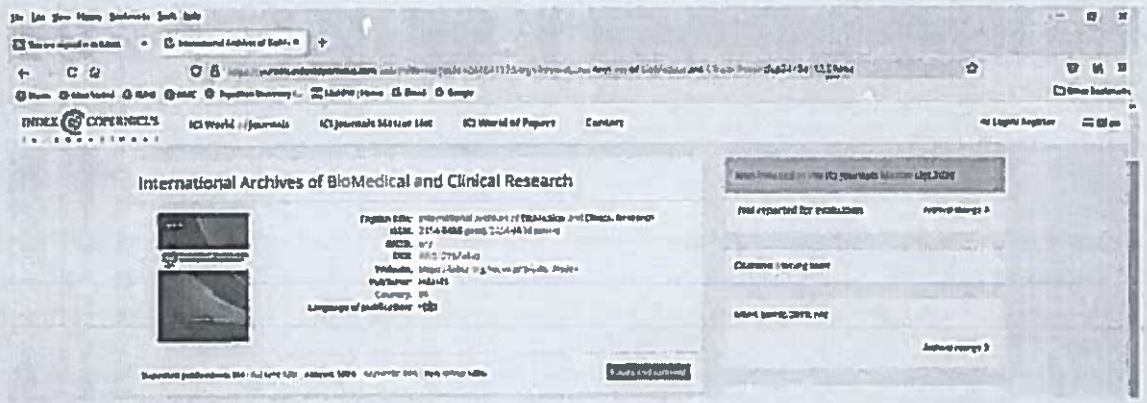

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A Transparent Study on Use of Teriparatide and Zoledronic Acid in Cases of Osteoporosis

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Section Orthopaedics

Original Article

A Prospective Study on Use of Teriparatide and Zoledronic Acid in Cases of Osteoporosis

Manish

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ABSTRACT

Background: Present prospective study is intended to compare role of Teriparatide and Zoledronic acid in osteoporosis as well as in pathological fracture due to osteoporosis so as to help elderly postmenopausal women to combat with osteoporosis & complications arising due to it.
Methods: This study is carried out in the department of orthopedics. Total of 100 women were included at the time of beginning but 20 women were lost in the follow up due to various reasons
Results: 51 patients of group 1 were given Zoledronic acid & 29 patients were given Teriparatide. Patients were evaluated up to 12 months at regular intervals. Serial DEXA scans were done, assessment & comparison were done accordingly.
Conclusions: Treatment of osteoporosis is multimodal with no definitive single molecule available. This study compared Zoledronic acid & Teriparatide. Although T-score has nearly the same value, but our study resulted in increased BMD score & fewer side effects by the use of Teriparatide, so it is concluded that patient with very low BMD requires treatment with Teriparatide.

Keywords: Teriparatide, Zoledronic Acid, Osteoporosis

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INTRODUCTION

Osteoporosis is a disease characterized by microarchitectural deterioration of bone leading to increase bone fragility and a subsequent increase in fracture risk. Osteoporosis is operationally defined by WHO as a bone mineral density 2.5 standard deviation or below the young adult mean (T-score <2.5).

BMD increases from birth with nearly 90% of bone mass acquired by age of 20. Peak bone mass is achieved by age of 30, thereafter it begins to decrease slowly.

Osteoporosis is due to many modifiable (drugs & lifestyle) & non modifiable (age related, post-menopausal) factors. Generally, patients with osteoporosis are asymptomatic unless any complication occurs like predominant fracture. Patient present with back pain & increase thoracic kyphosis, she or someone in the family may have noticed that her height has diminished. X-ray of the spine may show wedging or compression of one or more vertebral bodies and often the lateral view also shows the calcification of the aorta.

This is the typical picture, but sometimes the first clinical event is a low energy fracture of the distal radius, the hip or the ankle. Women who have had one low energy fracture have twice the normal risk of developing another.

Osteoporosis is currently being treated by different pharmacological groups available like Bisphosphonate, Teriparatide, Calcitonin, Denusumab etc.

The main focus in this study is to compare the role of Zoledronic acid (bisphosphonate) Vs Teriparatide (recombinant PTH) in osteoporosis as well as in pathological fractures due to osteoporosis.

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DEXA may show significantly reduced bone density in the vertebral bodies or femoral neck. It is highly accurate method that has become the standard for measurement of bone density. It measures usually lumbar spine & hip but in post-menopausal women most sensitive is spine.

Aims & Objectives –

Prime aim of this study is to compare the role of Zoledronic acid & Teriparatide for treatment of osteoporosis & pathological fractures due to osteoporosis for-

1- Long term results after 12 months.
2- Recovery of function after 6 months.
3- Evaluation of BMD.
4- Symptomatic & Functional outcome.

METHODS

This is a prospective study which includes patients of post-menopausal female treated in the Department of Orthopedics.

A total of 100 patients were included in our study group out of which 15 patients did not turn for follow up & 5 patients expired. So, 80 patients were included in our study. 51 patients were given Zoledronic acid & 29 were given Teriparatide.

All the cases which fulfilled our inclusion were included in the study which were randomly categorized in 2 category;

1- Those who were managed by Zoledronic acid (in a dose of 5 mg IV infusion at each sitting over a period of 15 minutes, two such doses at 6 months interval).
2- Those who were managed by Teriparatide (in a dose of 20 micrograms /day by subcutaneous injection for 12 months). The patients with BMD -4 were treated by Teriparatide.

The evaluation of role of both drugs was done by evaluating clinical profile & bone mineral density at different interval of 6 & 12 months.

Inclusion Criteria-

Postmenopausal women between 45 to 85 years of age with-

1 T-score of -2.5 or less at lumbar spine Or
2 T-score of-2.0 or less at femoral neck, total hip or lumbar spine with at least one documented osteoporotic vertebral fracture or a previously documented history of an osteoporotic clinical non vertebral fracture due to trivial trauma.

Exclusion Criteria-

1- Any prior use of strontium
2- Any past or active renal disease
3- Prior treatment with any IV or oral Bisphosphonates longer than 3 months consecutively. If bisphosphonates exposure is less than oe equal to 3 months, a washout period of 1 year to randomization is required.
4- Non osteoporotic forms of metabolic bone disease such as not limited to Paget's disease of bone, osteomalacia, osteogenesis imperfect or multiple myeloma.
5- Less than 3 evaluable lumbar vertebrae (L1 to L4) for DEXA measurement.
6- Treatment with osteoporotic therapies such as Raloxifene, calcitonin or hormone replacement therapy (HRT) within 3 months of randomization.
7- Allergy or previous exposure to Teriparatide.

At the time of admission or beginning of treatment detailed history taken on following points-

-Age, Menopausal status, Drug history, Treatment taken before reporting to hospital, Associated injuries, Any hereditary disease.

-General & systemic examination.

-Local Examination – that includes presenting complaints along with spine tenderness, height, weight & BMI.

-Routine blood investigations-that includes hemogram, RBS, serum urea & creatinine, Complete urine examination, S.osteocalcin, S. estradiol, LFT,S. vitamin D 3 level, S.PTH, S. calcium & Alk. Phosphatase, chest xray, ECG all leads.

-Radiological Examination- Xray (DL spine AP & lateral view, Pelvis-both hip).

BMD (Dexa scan).

If required than CT scan, MRI, Bone biopsy, USG.

Several noninvasive techniques are available for estimating skeletal mass or density, these includes dual energy Xray absorptiometry (DXA), single energy Xray absorptiometry (SXA), quantitative CT & ultrasound. DXA is highly accurate xray technique that has become standard for measuring bone density. Although it can be used for measurement in any skeletal site, clinical determination usually are made of the lumbar spine & hip. In our study DXA is the investigation of choice.

T-Score

T-score the no. of standard deviation above or below the mean for the healthy 30 yrs old of same sex and ethnicity as the patient.

T-score -1 or higher; Normal BMD.

T-score -1 to -2.5; osteopenia

T-score -2.52 or lower; osteoporosis.

All patients were given 1000 mg calcium daily and 800 IU vitamin D daily. All patients were given adequate diet of protein & patient with low BMI given extra dose of protein & encouraged foe weight bearing exercise.

Evaluation of outcome-

The patients were followed up for period of 12 months.

Improvement in clinical profile and BMD at initiation of therapy & each follow up was recorded in a proper case sheet, however the patients were advised to report immediately to the hospital in case they experience any adverse effects of both drugs.

RESULTS

The present study was conducted in the department of orthopaedics, Pacific medical college and hospital Udaipur Rajasthan from Dec 2017 to June 2019 in a consecutive series of patients who presented in the outpatient department with age of 45 to 85 years with osteoporosis who fulfilled inclusion criteria of the study.

This is a prospective cohort study and patients were randomly allocated into two treatment group (group 1 patients were managed by Zoledronic acid and group patients were managed by Teriparatide) according to the order one by one.

A total of 100 patients were included in the study out of which 15 patients did not turned for follow up for 6 months and 5 patients expired. So, 80 patients were included in the study group out of which 51 patients was given Zoledronic acid and 29 patients was given Teriparatide.

Table 1: Age distribution in Zoledronic acid group

AGE GROUP(in years)	No. of patients	Percentage
45-55	12	23.52%
55-65	17	33.33%
65-75	12	23.52%
75-85	10	19.60%
TOTAL	51	100

Table 2: Age distribution in Teriparatide group

AGE GROUP (in years)	No. of patients	Percentage
45 - 55	6	20.68%
55 -65	13	44.82%
65 -75	7	24.13%
75 -85	3	10.34%
TOTAL	29	100%

Table 3: Clinical profile

Variable	Zoledronic acid (no. of patients)	Teriparatide (no. of patients)
Decrease in bone pain	32	25
Increase physical activity	29	25

Table 4: Decreased risk of pathological fractures

Variable	Zoledronic Acid (n=14)		Teriparatide (n=10)	
Decreased risk of refracture (pathological fracture)	Vertebral	Non-Vertebral	Vertebral	Non-Vertebral
	5	2	6	2

Table 5: Side effects

Side effect	No. of cases(zoledronic acid)	No of cases(teriparatide)
No	29	24
Fever	8	1
Nausea	2	-
Malaise	2	-
Flu like symptoms including arthralgia	10	1
Skin side effects	-	2
Mild dizziness and leg cramps	-	1

Table 6: Mean bone mineral density in form of T – score at each follow up

Time interval	Zoledronic acid(no. of patients)		Teriparatide(no. of patients)	
0 (initial)	-	2.77	-	2.74
6 months	-	2.67	-	2.59
12 months	-	2.64	-	2.53

Table 7: Mean and standard deviation of T score

T-score	0 MONTH		6 months		12 months	
	Zoledronic acid	Teriparatide	Zoledronic acid	Teriparatide	Zoledronic acid	Teriparatide
Mean	-2.77	-2.67	-2.67	-2.59	-2.64	-2.53
SD	0.189	0.324	0.185	0.294	0.186	0.256
n	51	29	51	29	51	29

Table 8: Average increase in BMD

Time interval	Zoledronic acid group	Teriparatide group
6 months	3.61%	5.47%
12 months	4. 69%	7.58%

Bone mineral density:

Before treatment – Zoledronic acid – 2.77 and Teriparatide – 2.74

Mean T- score in both groups was near same value

At 6 months - Zoledronic acid – 2.67 and Teriparatide – 2.59

At 6 months p value >0.05. so, no significant difference in increase in mean T- score in Teriparatide group than Zoledronic acid.

At 12 months - Zoledronic acid – 2.64 and Teriparatide – 2.53

At 12 months p value <0.05 so significant difference in increase in mean T- score in Teriparatide group than Zoledronic acid.

Average percentage increase in BMD from initial to final in Teriparatide – 7.58%

And the statistical significance at initial p =0.65, at 6 months p = 0.14 and at 12 months p = 0.01, value are p< 0.005

Overall after complication of study p <0.01 which is <0.05 means significant increase in BMD in Teriparatide group.

DISCUSSION

Various studies have been conducted to evaluate the best treatment of osteoporosis however, no single treatment has been proven to be superior over other treatment.

In this study only postmenopausal women in the age group of 45-89 year included. Mean age of Zoledronic acid group is 62.3 year & in Teriparatide group it is 62.7 year with a mean age of 62.5 year. In Meenal Jain et al[1] mean age for Zoledronic acid group is 60.4 year & for Teriparatide group is 60.69 year.

In Cosman et al[2,3] study –mean age was 65.9 years.

In our study we have included postmenopausal women only which is consistent with previous studies too.

In this study bone pain decreased in 62.7% & 86.2 % in Zoledronic acid & Teriparatide group respectively.

In Zoledronic acid group 49% cases demonstrated increase in physical activity while in Teriparatide group had 86.2 % women increase in physical activity.

In our study, Zoledronic acid group had 62.5% decreased risk of vertebral fracture & 33.3 % decrease risk in non-vertebral fracture. In Teriparatide group this reduction in risk was 85.7% & 66.65 % respectively.

Black DM et al[4] –once yearly Zoledronic acid for treatment of post-menopausal osteoporosis reduces the risk of vertebral fractures by 77% & non vertebral fractures by 25 %.

Robert M Neer et al[5] effect of PTH on fracture & BMD- in post-menopausal female shows vertebral fracture reduction risk 90% & non vertebral fracture risk reduction 53 %.

Teriparatide group had fewer adverse effects as compared to Zoledronic acid group which mainly consist of fever, nausea, leg cramps, dizziness, flu like symptoms.

Cosman et al[2] – Rate of adverse effect within the first 3 days after infusion of Zoledronic acid is 58.45% and 27% with Teriparatide whereas those after 3 days were comparable across both groups.

In our study improvement in mean T-score was quite superior in Teriparatide group as compared to Zoledronic acid at the end of 12 months.

Average increase in BMD from initiation to cessation of treatment are 4.69 % and 7.58 % in Zoledronic acid & Teriparatide group respectively.

Meenal Jain et al[1]- percentage change in BMD Zoledronic acid was 4 to 6 % and it was 8 to 10 % in Teriparatide group.

CONCLUSION

The result of this study shows that average increase in BMD was significantly greater in Teriparatide group (7.5%) than Zoledronic acid (4.1%).

The slightly higher values in clinical profile improvement were observed in group treated by Teriparatide as compare to Zoledronic acid.

Risk of refracture reduction is greater in Teriparatide group than Zoledronic acid. Some adverse effects were observed after infusion of Zoledronic acid, they used to appear usually within 48 hours that mainly includes fever, malaise, arthralgia, restlessness, headache but none of the case showed any change in liver or renal functions.

The patients with hypercalcemia, hyperparathyroidism, multiple myeloma, Paget's disease & bone malignancies were not given Teriparatide as it is against the pharmaco-physiological action of Teriparatide.

This study concludes that both Zoledronic acid & Teriparatide are good options for treatment of postmenopausal osteoporosis with supplementation therapy of vitamin-D & calcium.

It is concluded that the patients with very low BMD profile require treatment with Teriparatide as they do not respond very well to Zoledronic acid.

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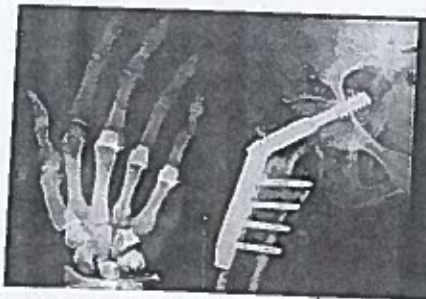

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Evaluation of functional outcome of cemented bipolar hemiarthroplasty for treatment of osteoporotic proximal femoral fractures in elderly people

Shivanand C Mayi, Sachin Shah, Sadashiv R Jidgekar and Arunkumar Kulkarni

Abstract
Background: In India the estimated geriatric population is going to rise from 8% of total population in 2010 to 19% by 2050. Incidence of osteoporosis and associated fractures will rise in coming years with increasing elderly population. Management of fracture neck of femur and unstable intertrochanteric fractures in osteoporotic bone is challenging in elderly as they are more prone for fracture associated complications like pressure sore, deep vein thrombosis and pneumonia.
Aim: The purpose of this study is to evaluate the role of cemented bipolar hemiarthroplasty in management of osteoporotic proximal femoral fractures in elderly people.
Patients and Methods: In this prospective study twenty patients with osteoporosis having proximal femoral fractures (fracture neck of femur/unstable intertrochanteric fracture) were treated by cemented bipolar hemiarthroplasty. Patients were followed up at 3 weeks, 3, 6, and 12 months to evaluate the function outcome. Mean age of the patients in this study was 73.84 years.
Results: Average duration follow up in this study was 14.63 month. Mean Harris Hip Score in the post-operative period was 42.73 ± 8.78 which improved to 81.57 ± 9.11 at 6 months. Average post-operative mobilization duration was 3.84 day and average hospital stay was 11.31 day. At 1 year follow up 85% patients had excellent to fair outcome and 10% had poor outcome.
Conclusion: Treatment of osteoporotic proximal femoral fractures with cemented bipolar hemiarthroplasty gives better functional outcome.

Keywords: Proximal femoral fractures, elderly, osteoporosis, cemented bipolar hemiarthroplasty

1. Introduction

Elder age group is more prone for the fragility fractures of proximal femur mainly fracture of neck of the femur and unstable intertrochanteric fractures. According to United Nation, people more than 60 years of age are considered as elderly people [1]. Elderly people may have fragility fractures after minor trauma. Fracture caused by sideway fall from standing height are defined as fragility fractures [2]. These fractures have a slow initial velocity on the greater trochanter and mainly include trochanteric hip and fractures of femoral neck [3]. Osteoporosis plays a major role among many risk factors which cause fracture of the bone in this age group. Both male and female sexes are prone for osteoporosis in elderly age group but in comparison with females, males develops osteoporosis later in life and osteoporosis-related fractures risk is less [4].

Fractures of proximal femur in elderly patients are associated with impaired mobility, morbidity, mortality and bad effect on the daily living of the patient because of loss of independence [5]. Osteoporosis in these patients with fracture neck of femur or unstable intertrochanteric fractures makes internal fixation difficult with poor out come due to implant and bone related complications such as head perforations, plate pullout, plate breakage, avascular necrosis of femoral head and non-union of femoral neck fracture [6, 7].

Displaced femoral neck fractures in elderly patients give better hip function and lesser reoperation rate if treated with cemented hip arthroplasty in comparison with internal fixation [8, 10]. Bipolar hemiarthroplasty has advantage of reduction of acetabular wear due to dual-bearing system [11].

Cemented bipolar arthroplasty is treatment of choice in freely mobile elderly patients with an intertrochanteric femoral fracture [12].

Most common treatment for displaced femoral neck fractures in elderly is hemiarthroplasty [13] which gives better functional outcome [14]. The aim of this study is to analyze the functional outcome of the proximal femoral fractures in elderly patients with osteoporosis which were treated by cemented bipolar hemiarthroplasty.

2. Materials and Methods

This prospective study was conducted at the Department of Orthopaedics, KBN Teaching and General Hospital attached to KBN Institute of Medical Sciences in Kalaburagi after getting clearance from ethical committee. Between October 2013 and June 2015, 20 elderly patients admitted with either unstable intertrochanteric fracture or fracture neck of the femur with associated osteoporosis were selected for this study. Inclusion criteria were elderly patient (>60 years) with walking ability, unilateral fracture neck of femur / unstable intertrochanteric fracture and Singh's Index < 3 on X-ray of both hips. Poly trauma patients, old contralateral hip fracture, osteoarthritis of hip involved, history of mental illness, pathological fracture and fractures older than 48 hours at admission were not included in the study.

All the 20 patients were admitted to casualty ward and immobilization of the fracture was done by skin traction. X-Ray of the pelvis with both hips and lateral view of the affected hip was taken. Classification of the fracture and assessment of severity of osteoporosis by Singh's index was done. Complete blood investigations were done to know the general health status of the patient. Treatment was started for osteoporosis and other associated medical problems.

Patients were posted for surgery within 48 hours of admission after optimization and pre anesthetic checkup. All the operations were performed by experienced orthopaedic surgeon under spinal anesthesia. Posterior approach was used with the patient in lateral decubitus position. Diameter of extracted femoral head was measured and appropriate size bipolar prosthesis was fixed after reaming the femoral canal with 2nd generation cementing technique (Figure 1). Lesser and greater trochanter fragments in unstable intertrochanteric fractures were reduced to main fragment with SS wire, after which the bipolar prosthesis was fixed with second generation cementing technique (Figure 2). Care was taken to restore the neck length, femoral head offset and anteversion to get a stable hip joint after reduction. Soft tissue repair was done after confirming the stability of the joint and wound closed in layers over suction drain.

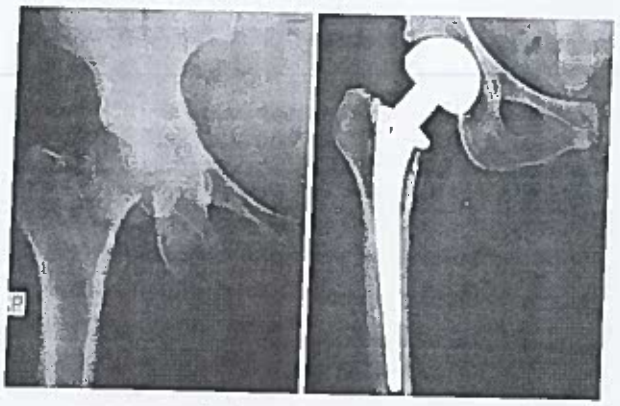

Fig 1: Implant fixation in fracture neck of the femur

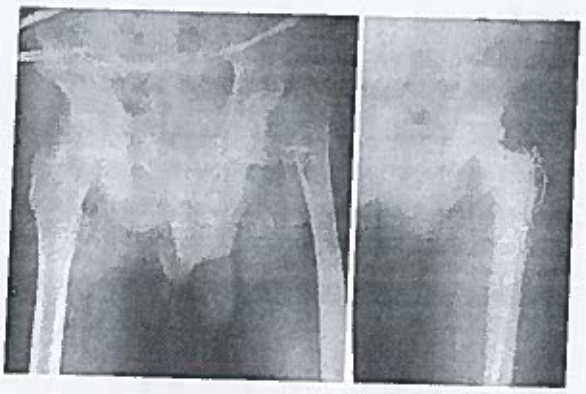

Fig 2: Reduction of trochanteric fragments with SS wire in unstable intertrochanteric fracture.

Post-operative intravenous antibiotics were given for 5 days. Patients were encouraged weight bearing from 2nd post-operative day after drain removal. Sutures were removed on 12th post-op day. Patients were advised to use some type of walking aid (cane/frame) up to 3 months or till they are comfortable to walk without support to avoid falling again. They were also advised to avoid squatting in future. After discharge patients were followed up at 3 weeks, at 3 months, at 6 months and at 12 months for functional evaluation of operated hip joint. Functional evaluation was done by Harris Hip Score and X-ray of the hip joint was taken to note the implant position.

Statistical analysis of the data was done and reported as mean, percentage and standard deviation.

3. Results

20 elderly patients were enrolled in this study having osteoporosis and unilateral proximal femoral fracture (unstable intertrochanteric fracture/ fracture neck of the femur). Average duration of follow up in this study was 14.63 month (12-22 months). One patient expired 1 month after surgery because of other medical condition and was not included in the final assessment. Average age of the study population was 73.84 year (63-96 years). 14 patients were walking without any support before the injury and five with the support of single cane. 18 patients had history of a simple fall at home or while walking on ground and one patient had RTA. Ten patients had fracture neck of femur and 9 had unstable trochanteric fracture. Other patient data is as depicted in table 1.

Table 1: Patient Data

Patients	Numbers/Mean
Total patients	19
Mean Age of patients	73.84 ± 8.75 year
Male : Female	6:13
Hip joint operated	
Right side	9
Left side	10
Fracture neck of femur (Garden's Classification)	10
Type-3	5
Type-4	5
Unstable intertrochanteric fracture (AO/OTA*)	9
32A2.2	2
32A2.3	4
32A3.3	3
Singh's Index (Osteoporosis)	
Grade-3	6
Grade-2	13
Associated medical problems	
Hypertension	5
Diabetes Mellitus (DM)	1
Hypertension with DM	2
Hypertension with IHD*	3
Anemia	2
No medical problems	6

*Orthopedic Trauma Association *Ischemic Heart Disease

Average post-operative mobilization duration was 3.84 day (3-7 days) and average hospital stay was 11.31 day (7-21 days). Mean Harris Hip Score (HHS) in the post-operative period was 42.73 ± 8.78, which improved to 63.84 ± 8.37 at 3 weeks. There was gradual improvement in HHS at 3months, 6 months and up to 1 year after surgery (Table 2). The functional outcome is given in table 3.

Table 2: Mean Harris Hip Score during follow-up

Follow up at	Mean Harris Hip Score
Post-operative period	42.73 ± 8.78
3 weeks	63.84 ± 8.37
3 months	74.10 ± 7.78
6 months	81.57 ± 9.11

Table 3: Functional outcome at 1 year

Harris Hip Score Grading	Number of patients	Percent	Cumulative Percent
Excellent (90-100)	01	5	5
Good (80-89)	15	75	80
Fair (70-79)	01	5	85
Poor (< 70)	02	10	95
Not evaluated (Death)	01	5	100
Total	20	100	

Two patients in the study developed Grade-1 pressure sore which healed with local care and ambulation of the patient. One patient had deep vein thrombosis (DVT) which resolved with low molecular weight heparin therapy for 2 weeks. Two patients had urinary tract infection which responded to antibiotic therapy.

4. Discussion

Since, the elderly population in India is expected to rise from 8% of total population in 2010 to 19% by 2050 [15] an increase in cases of osteoporotic proximal femoral fractures is expected in coming days. Proximal femoral fracture in elderly people with osteoporosis is a big challenge for treating orthopedic surgeon in view of intra & post-operative complications along with functional outcome. Review of the literature shows different opinions about the management of osteoporotic proximal femoral fractures in elderly patients. Early prosthetic replacement decreases morbidity and mortality in geriatric age group with fracture neck of femur, and primary hemiarthroplasty is the recommended treatment option for elderly patients with poor bone stock having unstable intertrochanteric fractures [16]. In our study we have included proximal femoral fractures (fracture neck of femur/unstable intertrochanteric fracture) in elderly patient who are having osteoporotic bone and were managed by cemented bipolar hemiarthroplasty.

A study on unstable osteoporotic intertrochanteric fractures in elderly found that 91% patients had excellent to fair functional results [6]. In our study 85% of patients had excellent to fair functional outcome with HHS which is comparable to above study. Another similar study on proximal femoral fractures in elderly with severe osteoporosis reported excellent to fair results in 92% of study population [17].

Mean HHS after hemiarthroplasty for displaced femoral neck fractures in elderly was 79.3 at 12 months follow-up [11]. Our study result is comparable to above mentioned study with HHS of 84.26 at 12 months follow-up. Another study on cemented bipolar hemiarthroplasty for fracture of femoral neck reported excellent to fair results in 86% of patients [7] with their grading system of patients ambulatory status which is comparable our study results. Different studies have mentioned about the complications associated with hemiarthroplasty in eldery like, wound infection, DVT, pressure sores, joint dislocation, implant loosening and acetabular erosion. Grade-1 pressure sores were reported in 4 patients [18] (n-25) and we had 2 patients (n-19) with grade-1 pressure sores which is less compared to above study because of early mobilization of patients on 3rd post-operative day. In the post-operative period DVT was reported in 9.6% study population [7] compared to our study where 1 patient (5.26%) developed DVT. Mortality rate reported in a study was 5.4% within 6 months of surgery [6] which is comparable with our study result of 5.

The limitation of this study is the short duration of follow up. Further studies are required on management of these fractures with large sample size and long duration of follow up to know the long term outcome of this treatment option.

5. Conclusion

The authors believe that cemented bipolar hemi arthroplasty is a better treatment option for the fractures of proximal femur in elderly people with osteoporotic bones as it helps in early mobilization thus, preventing complications associated with fractures around hip in this age group. Elderly patients treated with cemented bipolar hemiarthroplasty have better functional outcome in osteoporotic proximal femoral fractures.

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the JESS frame after callus becomes visible on radiograph and as pain allows. It is a cost effective treatment option in these patients where non operative treatment or internal fixation becomes difficult. As follow up period in our study is of short duration we could not comment on the limb length discrepancy in our patients. Further studies with similar treatment and longer duration of follow up are required to assess the long term outcome of JESS in these fractures.

CONCLUSION

Our study results shows fractures of the distal third tibial shaft and distal tibial physis with associated soft tissue injury can be well managed by JESS. In these patients who cannot be managed by cast application, JESS helps in the wound care and fracture stabilization without affecting the fracture healing process.

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Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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TDS Centralized Processing Cell | **TRACES** TDS Reconciliation Analysis and Correction Enabling System

Government of India
Income Tax Department

FORM NO. 16A

[See rule 31(1)(b)]

Certificate under section 203 of the Income-tax Act, 1961 for tax deducted at source

Certificate No. SZOMLKA	**Last updated on** 07-Jul-2020
Name and address of the deductor	**Name and address of the deductee**
STAVYA SPINE HOSPITAL & RESEARCH INSTITUTE PRIVATE LIMITED GF, STAVYA SPINE HOSPITAL, NR NAGRI HOSPITAL, ELLISHBRIDGE, AHMEDABAD - 380006 Gujarat neepain@yahoo.com	SHIVANAND C MAYI H.NO 2-910/65/75 NEAR NEW, R T O OFFICE KUSNOOR ROAD, JAYANAGAR DOCTORS COLONY, GULBARGA, KALABURAGI - 585105 Karnataka

PAN of the deductor	TAN of the deductor	PAN of the deductee
AAYCS4340J	AHMS30584B	AWBPM0971D

CIT (TDS)	Assessment Year	Period	
		From	To
The Commissioner of Income Tax (TDS) Room No. 201, 2nd Floor, Navjivan Trust Building, B/h Gujarat Vidhyapith , Ashram Road, Ahmedabad - 380014	2020-21	01-Jan-2020	31-Mar-2020

Summary of payment

Sl. No.	Amount paid/ credited	Nature of payment**	Deductee Reference No. provided by the Deductor (if any)	Date of payment/ credit (dd/mm/yyyy)
1	350000.00	194J		01-01-2020
2	350000.00	194J		01-02-2020
3	350000.00	194J		01-03-2020
4	350000.00	194J		25-03-2020
Total (Rs.)	1400000.00			

Summary of tax deducted at source in respect of Deductee

Quarter	Receipt Numbers of Original Quarterly Statements of TDS Under sub-section (3) of Section 200	Amount of Tax Deducted in respect of Deductee	Amount of Tax Deposited / Remitted in respect of Deductee
Q4	QTZYFIYC	140000.00	140000.00

I. DETAILS OF TAX DEDUCTED AND DEPOSITED IN THE CENTRAL GOVERNMENT ACCOUNT THROUGH BOOK ADJUSTMENT
(The deductor to provide payment-wise details of tax deducted and deposited with respect to the deductee)

Sl. No.	Tax deposited in respect of deductee (Rs.)	Book Identification Number (BIN)			
		Receipt Numbers of Form No. 24G	DDO serial number in Form No. 24G	Date of Transfer voucher (dd/mm/yyyy)	Status of Matching with Form No. 24G
Total (Rs.)					

II. DETAILS OF TAX DEDUCTED AND DEPOSITED IN THE CENTRAL GOVERNMENT ACCOUNT THROUGH CHALLAN
(The deductor to provide payment-wise details of tax deducted and deposited with respect to the deductee)

Sl. No.	Tax deposited in respect of the deductee (Rs.)	Challan Identification Number (CIN)			
		BSR Code of the Bank Branch	Date on which tax deposited (dd/mm/yyyy)	Challan Serial Number	Status of matching with OLTAS*
1	35000.00	6910333	04-02-2020	50140	F
2	35000.00	6910333	05-03-2020	50733	F
3	35000.00	6910333	10-04-2020	50159	F
4	35000.00	6910333	10-04-2020	50159	F
Total (Rs.)	140000.00				

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Joshi's external stabilization system in the management of distal tibial and fibular fractures with associated soft tissue injury in children

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ABSTRACT

Background: Injuries around ankle and distal third of tibial shaft are among common paediatric bone trauma. Some of these cases are associated with soft tissue injury over the lower third of leg or around the ankle joint as tibia is subcutaneous on the anteromedial aspect. This study was conducted to know the outcome of these injuries with minimal invasive external fixation.
Methods: Eleven patients in the age group of 4-14 years were included in this study. All patients had closed fracture of distal third tibial shaft or injury of distal tibial physis with associated soft tissue injury. Joshi's external stabilization system was used to retain the reduction of fracture and appropriate wound care was taken. JESS was removed after radiological signs of fracture union.
Results: Patients were followed up for mean period of 8.9 month. After JESS fixation healing of wound occurred at an average of 12.45 day and external fixator was removed at 6-8 weeks period. Three patients had grade 1 pin tract infection which was controlled by local dressing. No patient had stiffness of ankle at the time of JESS removal. No limb length discrepancy was seen in any of the patients in this study at their final follow up.
Conclusions: JESS gives good results in fractures of distal tibial with associated soft tissue injury. It helps in better management of wound and fracture stabilization.

Keywords: Distal tibial fracture, Epiphysis, Soft tissue injury, External stabilization

INTRODUCTION

Tibial and fibular shaft fractures are the third most common among long bones in children contributing up to 15% after radial/ulnar and femoral fractures.[1] Fifty to 70% of these fractures occur in distal third of tibia.[2] In children from 1 to 4 years of age group bicycle spoke injuries to tibia are common, whereas 4 to 14 years of age are due to sports and road traffic accidents.[2] Nine percent of fractures of tibia in children are open.[2]

These fractures are most commonly associated with concomitant fractures of the ankle. Fractures of the tibia constitutes up to 10-15% of all fractures in children and are also most common lower limb fractures in paediatric age group.[3]

Distal tibial and fibular physeal injuries account for 25% to 38% of all physeal fractures and are second most common to get injured among growth plate injuries.[4,5] Poland in his monograph (1898) pointed out that forces which result in ligament injury in adults causes fractures of the physis in children as ligaments are stronger than the physeal cartilage.[2] Distal tibial physeal fractures are classified according to Salter-Harris anatomical classification.

Closed fractures of tibial shaft in children are usually treated by non-operative methods. Open fractures and fractures with associated soft tissue injury requires operative fixation of fracture for proper wound care.[2] Distal tibial and fibular physeal fractures require accurate reduction and fixation to avoid future growth disturbance.

The aim of this study is to assess the role of Joshi's external stabilization system (JESS) in the management of these fractures associated with soft tissue injury

METHODS

From December 2013 to January 2016, 11 children with injury to the distal tibia and fibula with associated soft tissue injury were surgically managed by JESS. Institutional ethical committee clearance was taken for this study. All patients presented to emergency department with history of trauma to leg and associated wound over the ankle region. Patients were initially stabilized in the casualty department and radiograph of the involved leg was ordered after cleaning and dressing of the wound.

Patients below the age of 18 years with fractures of the distal third tibia and fibular shaft or distal tibial and fibular physeal injury with associated soft tissue injury over the fracture site were included in this study. Closed fractures of shaft of both bones of leg and closed undisplaced fractures of distal tibial and fibular physis without soft tissue injury and patients above 18 years of age were not included in the study.

Relevant patient data was collected after taking informed consent to participate in the study from the parent/guardian of the child. Surgical procedure and wound care process was explained to the attendant of the patient. Radiographs of all the patients were assessed for the fracture site, amount of displacement and type of growth plate injury in ankle fractures. Ankle fractures were classified according to Salter-Harris anatomic classification of physeal fractures.[6]

Patients were taken for surgery within 24 hours of injury after getting clearance from the paediatrician and anaesthetist. Under spinal anaesthesia thorough debridement and irrigation of the wound was performed. Fractures of the distal tibial metaphysis were reduced under image intensifier guidance and stabilized with two kirschner wires (K-wire) of 1.5 mm to 3 mm size both in the proximal and distal fragments as shown in Figure 1. During the surgery care was taken to avoid the wires passing through the injured soft tissue or wound. These wires were interconnected with JESS connecting rods on either side using JESS clamps. Patients with distal tibial physeal injury were also fixed with smooth pins or K-wires after accurate reduction of the fracture fragments under image intensifier. One or two K-wires were passed through the distal tibial epiphysis and physis up to the opposite cortex of metaphysis depending on the fracture pattern as given in Figure 2. Unstable fractures of the fibula after fixation of the tibia were fixed with an intramedullary K- wire. No fixation was done for stable fibular fractures.

In the postoperative period ankle movements were encouraged from day one. Appropriate antibiotics were given by intravenous route. Proper care of the wound and pin tracts were done to avoid infection. Radiographs were taken at 1 week, 3 weeks, and 6 weeks to see the fracture union and retention of reduction. After healing of the wound patients were encouraged partial weight bearing with JESS at 4 weeks or as the pain allowed. JESS was removed after radiological union of the fracture and care of pin tract wound was taken till they healed. Post JESS removal patients were followed up at 3 months and 6 months.

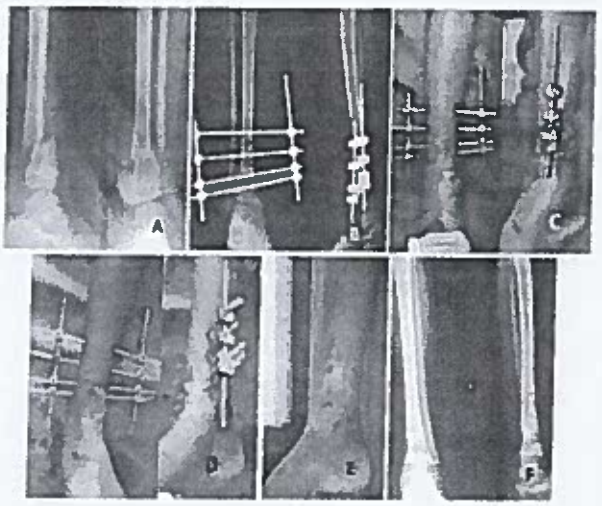

Figure 1: Distal tibial metaphyseal fracture with wound.
A) Pre-op, B) Post-op X-ray (C) Clinical picture of initial wound & (D) Healed wound, (E&F) After JESS removal.

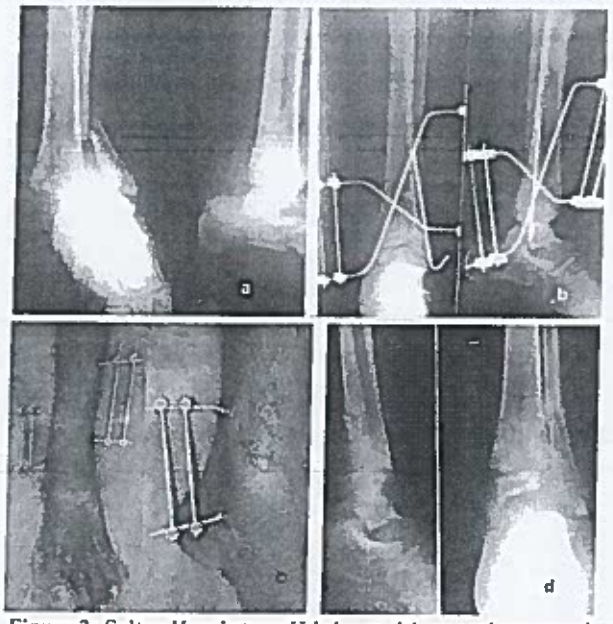

Figure 2: Salter-Harris type II injury with wound managed by JESS.
a) Pre-op & b) Post-op X-ray, c) Clinical picture of healed wound, d) X-ray after JESS removal.

Data analyzed for type of fracture, wound healing period, duration of fracture union and complications.

RESULTS

This study included 11 patients aged between 5-14 years. All the patients had fractures of distal tibial metaphysis or epiphysis and distal fibula with soft tissue injury over lower part of leg and ankle joint. All the patients were managed by JESS apparatus after closed reduction of fracture with appropriate frames. Average age of the study population was 9.27±3.03 year. Males were predominant in this study with road traffic accident (RTA) being the frequent cause of injury. Four patients had fracture of distal metaphysis of the tibia and other seven had distal tibial physeal injury. No patients had any neurovascular injury. Other demographic data of the patients are as given in Table 1.

Table 1: Demographic data of the patients.

Variables	Number (%) (n=11)
Mean Age ± SD	9.27±3.03 year
Sex of the patients	
Male	8 (72.72%)
Female	3 (27.27%)
Fractures operated	
Right side	6 (54.54%)
Left side	5 (45.45%)
Mode of injury	
Road traffic accident	6 (54.54%)
Fall from height	4 (36.36%)
Fall of weight on leg	1 (9.09%)
Fracture type (distal tibial physis)	
Salter-Harris type 2	6 (54.54%)
Salter-Harris type 3	1 (9.09%)
Distal tibial metaphysis fracture	4 (36.36%)

Table 2: Results of JESS.

Variables	Mean ± SD	Range
Duration of wound healing	12.45 ± 3.88	6-21 Days
Partial weight bearing	5.09 ± 0.7	4-6 Weeks
JESS removal	6.63 ± 0.8	6-8 Weeks
Full weight bearing	7.09 ± 0.94	6-9 Weeks

Patients were followed up for an average of 8.9±2.38 months (6-12 months). Duration of wound healing ranged between 8-21 days in these patients with an average of 12.45 day. Time at which partial weight bearing was started ranged from 4 weeks to 6 weeks. JESS fixation was removed at an average of 6.63 week and full weight bearing was started at an average of 7.09 week as shown in Table 2. All the patients had radiological union at the time of full weight bearing. Three patients had grade-I pin tract infection which healed with local care. No patients in the study had limb length discrepancy at their final follow up which ranged from 6 months to 12 months. All the patients had normal range of ankle movements after removal of the JESS.

DISCUSSION

Fractures around the ankle and distal third tibial shaft are common in pediatric age group. Incidence of distal tibial fibular physeal injuries account for 25-38% of all physeal fractures.[4] Another study reported that ankle fractures in children account for 5% of pediatric fractures and 15% of physeal injuries.[6] Physeal injuries are more common than ligament injuries in pediatric age group as ligaments are stronger than open physis.[6] Almost up to 58% of these distal tibial and fibular physeal injuries occurred during sports activities.[7,8] Incidence of physeal ankle fractures is more in male than in females.[9] Commonest age group for tibial physeal fractures is around 8-15 years.[9] Schurz et al found that an adduction trauma to the ankle being the common cause of injury followed by abduction trauma.[10]

Distal tibial physeal injuries require appropriate treatment otherwise which could lead to deformities and limb length discrepancy. Incidence of growth abnormalities is high in Salter-Harris type III and IV injuries and less in type II fractures.[9] Damage to the proliferative layer of cells in the growth plate may occur due to fracture passing through the physis in type III and IV lesions with high risk of growth disturbences.[11] Distal tibial physeal injuries require an absolute anatomical reduction by closed or open technique to decrease the rate of epiphysiodesis and related problems.[11]

Operative treatment is recommended in unstable fractures of distal tibial metaphysis and physis or when these fractures are associated with soft tissue injury.[2] When these fractures are associated with soft tissue injury over the lower part of leg and ankle, appropriate wound care becomes difficult task with plaster cast. External Fixator serves both the purposes of fracture stabilization and soft tissue healing with minimal added trauma to the initial injury. JESS can be used these children with convenient frames according to the fracture stability and type and stiffness of the JESS can be adjusted depending on the K-wire size used.[13] In elder children the axial stability of the JESS can be increased by using thicker K-wires. In JESS as we are using smooth pins in the bone, these can be passed through the physis and connected to the frame to give stable fixation to fracture.

In literature closed reduction and cast application of closed distal tibial fractures and management of open fractures by internal or external fixation is discussed in detail. Not much of literature available on distal tibial fractures with soft tissue injury. Our study was conducted to see the results of these fractures managed with minimal invasive external fixation with JESS. Wound healing is better with JESS fixation and soft tissue injuries resolve faster in these patients. Stiffness of the nearby joints does not occur as we can mobilize the joints earlier. Partial weight bearing can be started along with

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Randomized comparative study to evaluate the role of proximal femoral nail and dynamic hip screw in unstable trochanteric fractures

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ABSTRACT

Background: Treatment of unstable trochanteric fracture is much more challenging than stable fracture. These fractures require stable fixation to minimize the fracture and implant related complications. Need of this study is to assess the suitable implant for stable fixation of unstable trochanteric fracture with less intra and postoperative complications and good functional outcome.

Methods: In this prospective randomized comparative study, 64 patients were distributed into two groups. Group A consisted of patients treated by proximal femoral nail (PFN) (n=32) and group B treated by dynamic hip screw (DHS) (n=32). All the patients were evaluated preoperatively and surgery was done according to the group they were allotted. Post-operative follow up was done at 6 weeks, 3, 6 and 12 months.

Results: Average age of the patients in this study was 51.26±10.24 year. In this study patients were followed up for an average of 10.87±2.61 month. The duration of surgery was shorter in PFN group. Weight bearing was earlier in PFN group than DHS group. Mean functional ability score was better in PFN group with significant gain in function earlier as compared to DHS group.

Conclusions: PFN is a better implant for internal fixation of unstable trochanteric fractures which allows early mobilization and has got better functional outcome score in early postoperative period than DHS.

Keywords: Unstable trochanteric fracture, Proximal femoral nail, Dynamic hip screw

INTRODUCTION

The stability of the trochanteric fracture depends on the amount of contact between the proximal and distal main fragments. Trochanteric fractures with comminution of posteromedial buttress exceeding simple lesser trochanteric fragment or with subtrochanteric extension are termed as unstable. In 3-part fractures stability is inversely proportional to the size of the lesser trochanteric fragment. Instability occurs when more than 50% of the calcar is affected allowing the proximal fragment to collapse into varus with shortening. Reverse obliquity fracture is unstable fracture in which major fracture line extends outward and downward from the lesser trochanter.

Unstable trochanteric fractures are technically much more challenging than stable fractures. Stable reduction of an intertrochanteric fracture requires providing medial and posterior cortical contact between the major proximal and distal fragment to resist varus and posterior displacing forces. For unstable fractures intramedullary implants are (biomechanically) superior.[1] Lag screw cut-out failure following fixation of unstable intertrochanteric fractures in osteoporotic bone remains an unsolved challenge.[2]

The double screw construct provides significantly greater resistance against varus collapse and neck rotation in comparison to a standard DHS lag screw implant.[3] Less sliding of the femoral neck screws was noted with two-femoral neck screw configuration.[2] This study was conducted to assess the suitable implant for stable fixation of unstable trochanteric fracture with less intra and postoperative complications and good functional outcome which should be the goal of every orthopaedic surgeon treating these fractures.

METHODS

Between October 2013 to July 2015, 64 patients with unstable trochanteric fracture were randomised into two groups to be treated with PFN or DHS. Institutional ethical committee was informed and clearance was taken for the study. All the patients admitted to our hospital in the age group of 20-60 years with fresh unstable trochanteric fracture willing to participate in the study were allotted to PFN or DHS group. Random allocation of the treatment modality was done after taking informed consent from the patients. Polytrauma patients, pathological fracture, patients who were not able to walk independently before the injury and patients who refused to give consent were excluded from the study.

After admission relevant blood investigations and plain radiographs of the both hips AP view and involved hip lateral view were taken. Fracture classification was done according to Arbeitsgemeinschaft für Osteosynthesefragen (AO) / Orthopaedic Trauma Association (OTA) classification. The type of treatment was according to randomized table in Microsoft Excel. Pre-operative data about the mode of injury and pre injury ambulatory status of the patient was collected. Patients were taken for surgery within 48 hours of admission after clearance from the anesthetist. All the patients were operated by same surgical team.

All the patients received preoperative antibiotics. Operation was done by standard approach using DHS and PFN. All surgeries were done under the guidance of image intensifier. Lateral approach was used for DHS (Figure 1). PFN was done by standard cephalomedullary approach through the modified medial trochanteric portal (Figure 2).[4] Physiotherapy was started on first postoperative day. Partial weight bearing was started as and when patient is comfortable with walker support. Full weight bearing was allowed after radiological union of fracture and patient was free of pain. Follow up study included clinical examination with functional assessment according to Larson's hip evaluation chart 2 (higher the score better the functional outcome). 1st evaluation was carried out at 6 weeks postoperatively. Subsequent follow up evaluation was carried out at 3 months, 6 months and one year.

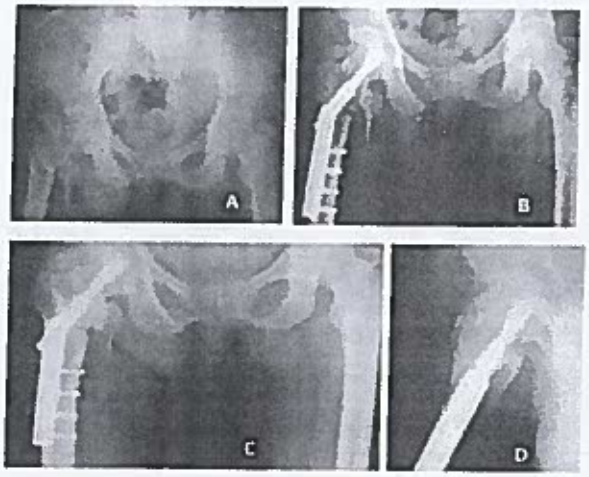

Figure 1: Patient treated by DHS. A) preoperative; B) postoperative; C) X-ray; D) follow up X-ray at 6 months.

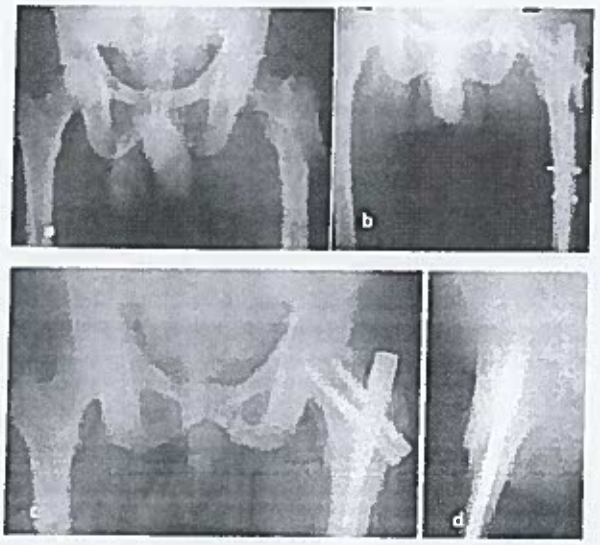

Figure 2: Patient treated by PFN. A) preoperative; B) postoperative; C) X-ray; D) follow up X-ray at 6 months.

RESULTS

In this randomized comparative study consisting 64 patients, DHS was used in 32 and PFN in other 32 patients. The average age of patients in this study was 51.26 ± 10.24 year (22-60 years). Other demographic data of the study individuals and fracture pattern are as given in Table 1. Follow up period ranged from 6 months to 18 months with an average of 10.87±2.61 week. Patients in the age range from 20 years to 50 years had history of high velocity injury (RTA or fall from height) and most of the patients from 51 to 60 years age had history of low velocity injury (simple fall while walking) in this study. Predominant fracture type in this study was 32A2.3 (53.12%) according to AO/OTA classification.

Table 1: Demographic data of the patients.

Variables	Total (n=64)	PFN (n=32)	DHS (n=32)
Mean age±SD	73.84 ± 8.75	50.06 ± 9.86	52.46 ± 10.61
Sex of the patients			
Male	49 (76.56 %)	24(75%)	25(78.12%)
Female	15 (23.44 %)	08(25%)	07(21.87%)
Fractures operated			
Right side	42 (65.62 %)	19(59.37%)	23(71.87%)
Left side	22 (34.38 %)	13(40.62%)	09(28.12%)
Mode of injury			
Simple fall while walking	26 (40.62 %)	09(28.12%)	17(53.12%)
Road traffic accident	23 (35.93 %)	14(43.75%)	09(28.12%)
Fall from height	13 (20.31 %)	09(28.12%)	04(12.5%)
Fall of wall over patient	02 (3.12 %)	00(0%)	02(6.25%)
Fracture type (AO/OTA#)			
32A2.2	17 (26.54 %)	08(32%)	09(28.12%)
32A2.3	34 (53.12 %)	17(53.12%)	17(53.12%)
32A3.1	06 (9.37 %)	04(12.5%)	02(6.25%)
32A3.3	07 (10.93 %)	03(9.37%)	04(12.5%)

Orthopedic trauma association

Table 2: Comparison of PFN with DHS.

	PFN (n=32)	DHS (n=31)	P value (Kruskal-Wallis test)
Mean duration of surgery (minutes)	60.25±10.24	90.78±8.04	P <0.001*
Mean duration after which patient started weight bearing (weeks)	4.96±1.63	8.03±2.26	P <0.001*
Mean shortening of operated limb (cms)	1.06±0.38	1.56±0.43	P <0.001*

*significant

Table 3: Comparison of functional outcome within and between the two groups.

	PFN (n=32)	DHS (n=31)	Between groups (Kruskal-Wallis test)
Pain	Median (SD)	Median (SD)	
6 weeks	20(8.3)	10(7.1)	0.001*
3 months	30(4.5)	30(5.8)	0.009*
6 months	35(3.4)	35(2.3)	0.057
Within groups (Freidman's test)	*P<0.001	*P<0.001	
Functional ability			
6 weeks	8(3.8)	7(3.5)	0.428
3 months	17(5.6)	16(4.2)	0.061
6 months	25(3.8)	22(3.9)	0.263
Within groups (Freidman's test)	*P <0.001	*P <0.001	
Gait			
6 weeks	1(3.0)	1(1.8)	0.002*
3 months	9(2.8)	6(2.8)	0.006*
6 months	12(1.9)	9(2.0)	0.012*
Within groups (Freidman's test)	*P<0.001	*P<0.001	
Anatomic Assessment			
6 weeks	15(1.3)	13(3.0)	0.073
3 months	15(0.6)	15(0.4)	0.543
6 months	15(0.5)	15(0.4)	0.056
Within groups (Freidman's test)	*P<0.001	*P<0.001	

Total Score			
6 weeks	50.5(13.0)	36(11.5)	0.001*
3 months	75(11.1)	66(10.5)	0.002*
6 months	88(8.2)	84(6.4)	0.049*
Within groups (Freidman's test)	*P<0.001	*P<0.001	

significant

Mean duration of surgery in PFN group was 60.25±10.24 minute and 90.78±8.04 minute in DHS group. Mean duration after which patient started weight bearing was 4.96±1.63 week in PFN group and 8.03±2.26 week in DHS group (Table 2). One patient with DHS died 2 months after surgery because of cardiovascular problem and was not included in the final assessment of the functional outcome. One patient in DHS group had superficial wound infection which healed with regular dressing and antibiotic therapy. One patient developed palsy of common peronial nerve after operating with DHS for which foot drop splint was given at the time of mobilisation. Mean shortening of the affected limb in DHS group was 1.55±0.49 cm as compared with 1.21±0.74 cm in PFN group (Table 2).

Three patients in the PFN group and six patients in the DHS group complained of pain in the operated hip region up to 6 months post operatively. Difference in functional outcome between the groups was seen in post-operative pain and gait components of the Larson's chart 2 score. Values in functional ability and anatomic assessment were not significant. Within the groups all the components of Larson's hip evaluation chart 2 were significant when compared at 6 weeks and 3 months. Total score of all four components of scoring system were significant between the two groups at 6 weeks, 3 months and 6 months (Table 3).

DISCUSSION

These days surgical fixation is the preferred mode of treatment option for unstable trochanteric fracture as it decreases the complications and morbidity associated with these fractures. DHS being the implant of choice in the surgical management of trochanteric fractures has given good results in stable fractures as compared to unstable trochanteric fractures.[5] PFN being an intramedullary device gives better fixation of the trochanteric fracture by restoring the anatomy of the hip.[6] PFN gives biomechanically stable construct allowing early weight bearing in unstable trochanteric fractures.[7,8]

Many studies recommended PFN for the surgical treatment of unstable trochanteric fractures as controlled compression of fracture occurs without rotational malalignment of the fracture fragments.[9-11] The patients treated with PFN were able to walk earlier than those treated by DHS as reported by many studies.[6,8,12] This finding was also seen in our study.

Unstable trochanteric fractures treated with DHS were associated with higher incidence of complications.[9] Fractures treated with DHS results in greater impaction of the fracture with shortening of the femoral neck.[6] Many studies reported longer duration of surgery and greater blood loss in DHS group.[6,13,14] In our study shortening was more and weight bearing was started late in patients treated with DHS as compared to patients treated with PFN. DHS is associated with a higher incidence of complications when used in unstable trochanteric fractures.[9]

Functional score in patients treated with PFN was better than DHS in the first 3 months.[15] Patients who were treated by PFN restored walking ability earlier as compared to those treated by DHS.[6] Our study results were similar to above study findings. Restoration of function is better with PFN when compared with DHS. In our study Functional outcome was better in patients treated with PFN compared to the patients treated with DHS in the initial 6 months of postoperative period. The follow up period in this study ranged from 6 months to 18 months because of the non-compliance from the patient side for subsequent follow up. Patients were reluctant to come for follow up once they did not experience pain in the operated hip and have started walking independently.

CONCLUSION

Our study results suggest PFN as better implant for the treatment of unstable trochanteric fractures when compared to DHS. PFN being an intramedullary implant gives stable fixation to these types of fractures and helps in earlier mobilisation of patients thus, minimizing the complications associated with unstable trochanteric fractures. Further studies with longer duration of follow up are required to conclude on the long term outcome of this these implants in unstable trochanteric fractures.

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Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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the JESS frame after callus becomes visible on radiograph and as pain allows. It is a cost effective treatment option in these patients where non operative treatment or internal fixation becomes difficult. As follow up period in our study is of short duration we could not comment on the limb length discrepancy in our patients. Further studies with similar treatment and longer duration of follow up are required to assess the long term outcome of JESS in these fractures.

CONCLUSION

Our study results shows fractures of the distal third tibial shaft and distal tibial physis with associated soft tissue injury can be well managed by JESS. In these patients who cannot be managed by cast application, JESS helps in the wound care and fracture stabilization without affecting the fracture healing process.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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Joshi's external stabilization system in the management of distal tibial and fibular fractures with associated soft tissue injury in children

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ABSTRACT

Background: Injuries around ankle and distal third of tibial shaft are among common paediatric bone trauma. Some of these cases are associated with soft tissue injury over the lower third of leg or around the ankle joint as tibia is subcutaneous on the anteromedial aspect. This study was conducted to know the outcome of these injuries with minimal invasive external fixation.
Methods: Eleven patients in the age group of 4-14 years were included in this study. All patients had closed fracture of distal third tibial shaft or injury of distal tibial physis with associated soft tissue injury. Joshi's external stabilization system was used to retain the reduction of fracture and appropriate wound care was taken. JESS was removed after radiological signs of fracture union.
Results: Patients were followed up for mean period of 8.9 month. After JESS fixation healing of wound occurred at an average of 12.45 day and external fixator was removed at 6-8 weeks period. Three patients had grade 1 pin tract infection which was controlled by local dressing. No patient had stiffness of ankle at the time of JESS removal. No limb length discrepancy was seen in any of the patients in this study at their final follow up.
Conclusions: JESS gives good results in fractures of distal tibial with associated soft tissue injury. It helps in better management of wound and fracture stabilization.

Keywords: Distal tibial fracture, Epiphysis, Soft tissue injury, External stabilization

INTRODUCTION

Tibial and fibular shaft fractures are the third most common among long bones in children contributing up to 15% after radial/ulnar and femoral fractures.[1] Fifty to 70% of these fractures occur in distal third of tibia.[2] In children from 1 to 4 years of age group bicycle spoke injuries to tibia are common, whereas 4 to 14 years of age are due to sports and road traffic accidents.[2] Nine percent of fractures of tibia in children are open.[2]

These fractures are most commonly associated with concomitant fractures of the ankle. Fractures of the tibia constitutes up to 10-15% of all fractures in children and are also most common lower limb fractures in paediatric age group.[3]

Distal tibial and fibular physeal injuries account for 25% to 38% of all physeal fractures and are second most common to get injured among growth plate injuries.[4,5] Poland in his monograph (1898) pointed out that forces which result in ligament injury in adults causes fractures of the physis in children as ligaments are stronger than the physeal cartilage.[2] Distal tibial physeal fractures are classified according to Salter-Harris anatomical classification.

Closed fractures of tibial shaft in children are usually treated by non-operative methods. Open fractures and fractures with associated soft tissue injury requires operative fixation of fracture for proper wound care.[2] Distal tibial and fibular physeal fractures require accurate reduction and fixation to avoid future growth disturbance.

The aim of this study is to assess the role of Joshi's external stabilization system (JESS) in the management of these fractures associated with soft tissue injury

METHODS

From December 2013 to January 2016, 11 children with injury to the distal tibia and fibula with associated soft tissue injury were surgically managed by JESS. Institutional ethical committee clearance was taken for this study. All patients presented to emergency department with history of trauma to leg and associated wound over the ankle region. Patients were initially stabilized in the casualty department and radiograph of the involved leg was ordered after cleaning and dressing of the wound.

Patients below the age of 18 years with fractures of the distal third tibia and fibular shaft or distal tibial and fibular physeal injury with associated soft tissue injury over the fracture site were included in this study. Closed fractures of shaft of both bones of leg and closed undisplaced fractures of distal tibial and fibular physis without soft tissue injury and patients above 18 years of age were not included in the study.

Relevant patient data was collected after taking informed consent to participate in the study from the parent/guardian of the child. Surgical procedure and wound care process was explained to the attendant of the patient. Radiographs of all the patients were assessed for the fracture site, amount of displacement and type of growth plate injury in ankle fractures. Ankle fractures were classified according to Salter-Harris anatomic classification of physeal fractures.[6]

Patients were taken for surgery within 24 hours of injury after getting clearance from the paediatrician and anaesthetist. Under spinal anaesthesia thorough debridement and irrigation of the wound was performed. Fractures of the distal tibial metaphysis were reduced under image intensifier guidance and stabilized with two kirschner wires (K-wire) of 1.5 mm to 3 mm size both in the proximal and distal fragments as shown in Figure 1. During the surgery care was taken to avoid the wires passing through the injured soft tissue or wound. These wires were interconnected with JESS connecting rods on either side using JESS clamps. Patients with distal tibial physeal injury were also fixed with smooth pins or K-wires after accurate reduction of the fracture fragments under image intensifier. One or two K-wires were passed through the distal tibial epiphysis and physis up to the opposite cortex of metaphysis depending on the fracture pattern as given in Figure 2. Unstable fractures of the fibula after fixation of the tibia were fixed with an intramedullary K- wire. No fixation was done for stable fibular fractures.

In the postoperative period ankle movements were encouraged from day one. Appropriate antibiotics were given by intravenous route. Proper care of the wound and pin tracts were done to avoid infection. Radiographs were taken at 1 week, 3 weeks, and 6 weeks to see the fracture union and retention of reduction. After healing of the wound patients were encouraged partial weight bearing with JESS at 4 weeks or as the pain allowed. JESS was removed after radiological union of the fracture and care of pin tract wound was taken till they healed. Post JESS removal patients were followed up at 3 months and 6 months.

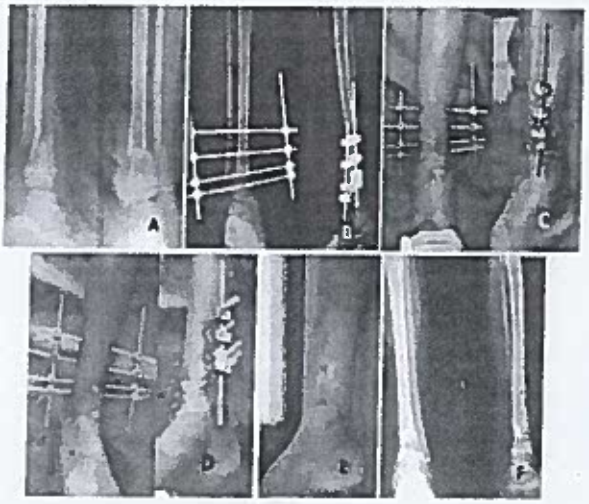

Figure 1: Distal tibial metaphyseal fracture with wound.
A) Pre-op, B) Post-op X-ray (C) Clinical picture of initial wound & (D) Healed wound, (E&F) After JESS removal.

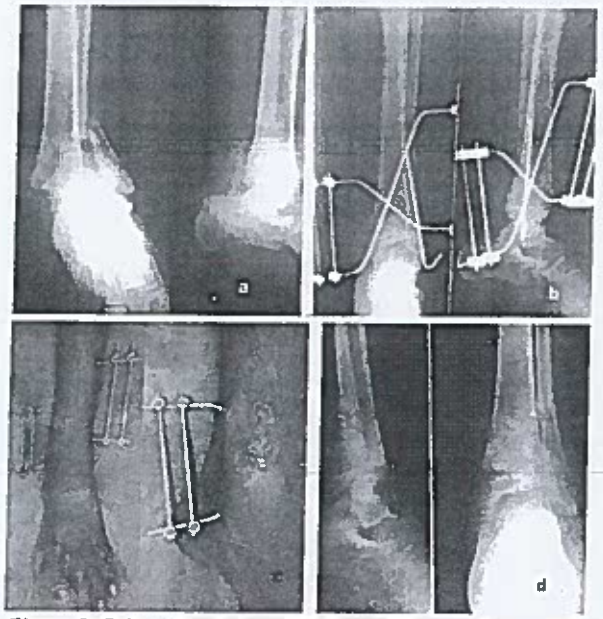

Figure 2: Salter-Harris type II injury with wound managed by JESS.
a) Pre-op & b) Post-op X-ray, c) Clinical picture of healed wound, d) X-ray after JESS removal.

Data analyzed for type of fracture, wound healing period, duration of fracture union and complications.

RESULTS

This study included 11 patients aged between 5-14 years. All the patients had fractures of distal tibial metaphysis or epiphysis and distal fibula with soft tissue injury over lower part of leg and ankle joint. All the patients were managed by JESS apparatus after closed reduction of fracture with appropriate frames. Average age of the study population was 9.27±3.03 year. Males were predominant in this study with road traffic accident (RTA) being the frequent cause of injury. Four patients had fracture of distal metaphysis of the tibia and other seven had distal tibial physeal injury. No patients had any neurovascular injury. Other demographic data of the patients are as given in Table 1.

Table 1: Demographic data of the patients.

Variables	Number (%) (n=11)
Mean Age ± SD	9.27±3.03 year
Sex of the patients	
Male	8 (72.72%)
Female	3 (27.27%)
Fractures operated	
Right side	6 (54.54%)
Left side	5 (45.45%)
Mode of injury	
Road traffic accident	6 (54.54%)
Fall from height	4 (36.36%)
Fall of weight on leg	1 (9.09%)
Fracture type (distal tibial physis)	
Salter-Harris type 2	6 (54.54%)
Salter-Harris type 3	1 (9.09%)
Distal tibial metaphysis fracture	4 (36.36%)

Table 2: Results of JESS.

Variables	Mean ± SD	Range
Duration of wound healing	12.45 ± 3.88	6-21 Days
Partial weight bearing	5.09 ± 0.7	4-6 Weeks
JESS removal	6.63 ± 0.8	6-8 Weeks
Full weight bearing	7.09 ± 0.94	6-9 Weeks

Patients were followed up for an average of 8.9±2.38 months (6-12 months). Duration of wound healing ranged between 8-21 days in these patients with an average of 12.45 day. Time at which partial weight bearing was started ranged from 4 weeks to 6 weeks. JESS fixation was removed at an average of 6.63 week and full weight bearing was started at an average of 7.09 week as shown in Table 2. All the patients had radiological union at the time of full weight bearing. Three patients had grade-1 pin tract infection which healed with local care. No patients in the study had limb length discrepancy at their final follow up which ranged from 6 months to 12 months. All the patients had normal range of ankle movements after removal of the JESS.

DISCUSSION

Fractures around the ankle and distal third tibial shaft are common in pediatric age group. Incidence of distal tibial fibular physeal injuries account for 25-38% of all physeal fractures.[4] Another study reported that ankle fractures in children account for 5% of pediatric fractures and 15% of physeal injuries.[6] Physeal injuries are more common than ligament injuries in pediatric age group as ligaments are stronger than open physis.[6] Almost up to 58% of these distal tibial and fibular physeal injuries occurred during sports activities.[7,8] Incidence of physeal ankle fractures is more in male than in females.[9] Commonest age group for tibial physeal fractures is around 8-15 years.[9] Schurz et al found that an adduction trauma to the ankle being the common cause of injury followed by abduction trauma.[10]

Distal tibial physeal injuries require appropriate treatment otherwise which could lead to deformities and limb length discrepancy. Incidence of growth abnormalities is high in Salter-Harris type III and IV injuries and less in type II fractures.[9] Damage to the proliferative layer of cells in the growth plate may occur due to fracture passing through the physis in type III and IV lesions with high risk of growth disturbences.[11] Distal tibial physeal injuries require an absolute anatomical reduction by closed or open technique to decrease the rate of epiphysiodesis and related problems.[11]

Operative treatment is recommended in unstable fractures of distal tibial metaphysis and physis or when these fractures are associated with soft tissue injury.[2] When these fractures are associated with soft tissue injury over the lower part of leg and ankle, appropriate wound care becomes difficult task with plaster cast. External Fixator serves both the purposes of fracture stabilization and soft tissue healing with minimal added trauma to the initial injury. JESS can be used these children with convenient frames according to the fracture stability and type and stiffness of the JESS can be adjusted depending on the K-wire size used.[13] In elder children the axial stability of the JESS can be increased by using thicker K-wires. In JESS as we are using smooth pins in the bone, these can be passed through the physis and connected to the frame to give stable fixation to fracture.

In literature closed reduction and cast application of closed distal tibial fractures and management of open fractures by internal or external fixation is discussed in detail. Not much of literature available on distal tibial fractures with soft tissue injury. Our study was conducted to see the results of these fractures managed with minimal invasive external fixation with JESS. Wound healing is better with JESS fixation and soft tissue injuries resolve faster in these patients. Stiffness of the nearby joints does not occur as we can mobilize the joints earlier. Partial weight bearing can be started along with

Rapid decalcification technique using tissue floatation bath (TFB) in a tertiary care oncology centre

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Abstract

Background: Decalcification of bone is a very important procedure in pathology especially in an oncology set up for proper staging, chemotherapy response or even in diagnosis of tumors. Objectives- To evaluate the use of tissue floatation bath (TFB) for rapid decalcification of mandibulectomy specimens in an oncology setup.

Materials and Methods: Bony specimens received at pathology department were sliced using bone saw and then placed in 10% formalin at 45 0 C for 4 hours. These sections were then kept overnight in 10% nitric acid at 45 0 C in TFB for decalcification. Decalcification was checked manually next day morning and if decalcification is complete, and then the tissue transferred to tissue processor for routine tissue processing.

Results: Decalcification in tissue floatation bath takes approximately 18-20 hours with better cytomorphological details as compared to routine decalcification process which takes around 7-8 days for complete decalcification.

Conclusion: Tissue floatation bath is a common instrument available in all laboratories performing histopathological examination. Staining quality is comparable and time required for decalcification is improved as compared to routine decalcification technique. It can be used as an alternative to the more expensive microwave technique which requires additional instrument and space. To the best of our knowledge this is the first study using tissue floatation bath for rapid decalcification process.

Keywords: Routine decalcification, Rapid Decalcification, Tissue floatation bath, Bone, Mandibulectomy

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Introduction

Decalcification is a process of complete removal of calcium from bone, teeth and other calcified tissues. It is a very important routine procedure that is employed in nearly all histopathology laboratories but is a very time consuming process and may lead to delay in management of patients. Decalcification is performed to assure that the specimen is soft enough to allow cutting with the microtome knife, so that to avoid damage to tissue as well as to knife.

Decalcification is carried out by various agents which either form soluble calcium salts (acids) or by chelating the calcium ions[1]. Strong acids decalcify tissue faster but can cause deterioration of stainability of tissue section and it increases with acidity of solution and length of decalcification periods[2,3]. Several factors influence the rate of decalcification including concentration and volume of decalcifying agent, temperature at which reaction takes place, size of the specimen, and use of microwave and solution agitation[1]. Thus, the speed of decalcification can be fastened. More concentrated acidic solution and microwave can produce rapid decalcification but damages the morphology of the tissues[4,5]. High temperature can expedite the decalcification process but temperature of more than 60^0C can cause charring of tissues.[5]

Decalcification is particularly important in an oncology setup where it is essential for diagnosis of primary bone tumors and involvement of bone by external malignancy like squamous carcinoma or other tumors. It is also important to know the extent of bone involvement along with the knowledge of margin status. This helps in knowing the staging, completeness of surgery and need for further management like radiotherapy or chemotherapy. Many treatment protocols for bone tumors require a report on an entire slice/grid of resected bone to allow assessment of the benefit or otherwise of preoperative drug treatment.

These all requires a good cellular morphology and a quick result to allow rapid therapeutic intervention for optimal patient care.

Heating is also a method known to accelerate the decalcification process[1,6] and in this study we used tissue floatation bath instead of microwave for rapid decalcification of bone using heat as a source to reduce time of decalcification.

The aim of the present study was to evaluate and compare decalcification of bone by routine method and by using tissue floatation bath with special attention to duration of decalcification and nuclear details.

In India, oral squamous cell carcinoma is one of the most common malignancies and in our institute also we receive many mandibulectomy specimens for histopathological examination. Sections from underlying mandibular bone provide internal control to look for nuclear and cytoplasmic details of squamous carcinoma.

Many studies are there in literature evaluating the role of microwave in rapid decalcification[4-9], but to the best of our knowledge no study has described the role of TFB for the same.

Materials and Methods

This study was performed at pathology department of a tertiary care oncology centre in India. In this study we used TFB as a heat source for rapid decalcification on bony cut margin and underlying bone of mandibulectomy specimens. We also compared the decalcification using TFB with conventional decalcification method with special reference to duration of decalcification and nuclear details.

In this study, a total of twenty hemimandibulectomy specimens were studied. Twenty Sections each of anterior bony cut margin and underlying bone were taken. Bony tissues were sliced using bone saw with a uniform thickness of 2-3 mm and a parallel slice of bone from the same site was taken to prepare another set of specimens. One set of specimens (20 sections of anterior bony cut margins and 20 of underlying bone) was processed through routine decalcification and another set was kept in TFB for rapid decalcification. Thus, we ensured that the two sections under comparison were from the same bone and from the same site. This was done to eliminate bias from other factors that can affect the decalcification process like age and type of bone.

These tissues were then placed in 10% formalin for 4 hours in order to achieve proper fixation. After removing from formalin, these tissues were placed in running water for 30 minutes to remove excess formalin. After that tissues were kept in decalcifying solution (10% nitric acid).

In the routine decalcification method, tissues were placed in a decalcifying agent at room temperature with change of solution at regular intervals till the decalcification is completed. In the method using tissue floatation bath, bony tissues in cassettes are placed in the decalcifying agent in a metal container which was then kept overnight in preheated tissue floatation bath with temperature maintained at around 45^0C. The duration of decalcification and nuclear details of the tissue were noted, compared and tabulated. In both the methods, after completion of decalcification, the tissues were washed using distilled water for 30 minutes and were transferred to ammonia solution to neutralize the remaining acids. Tissues were then subjected to routine processing. Sections were then stained with hematoxylene and eosin stain and submitted for reporting. The stained sections of decalcified bone were assessed for the quality of staining and preservation of nuclear details.

Results

(Table 1) In this study, the average time required for decalcification was approximately 7-8 days by routine decalcification technique while with tissue floatation bath technique the time taken for decalcification reduced to 18- 20 hours for the same set of specimens.

The stained sections of the processed decalcified bone were assessed for the staining quality and preservation of the cytoplasmic and nuclear details. In our study the cellular architecture of the tissue was comparable in both techniques. Decalcification with TFB technique provides a better nuclear staining and nucleo- cytoplasmic differentiation of the stained section with a lesser shrinkage of tissue probably because of lesser duration of contact with the acid. Yellowishness of the stained section was also significantly reduced thus leading to better interpretation. Morphology of soft tissue squamous cell carcinoma was also better preserved then that with conventional methods.

Fig. 1: Showing a common tissue floatation bath showing a metallic container holding the decalcifying fluid

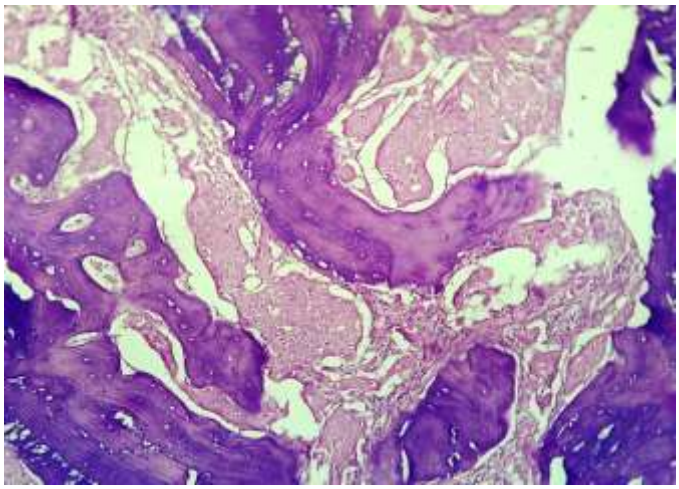

Fig. 2: Showing section of mandibulectomy showing bony trabeculae and a squamous carcinoma infiltrating the bone (100 X)

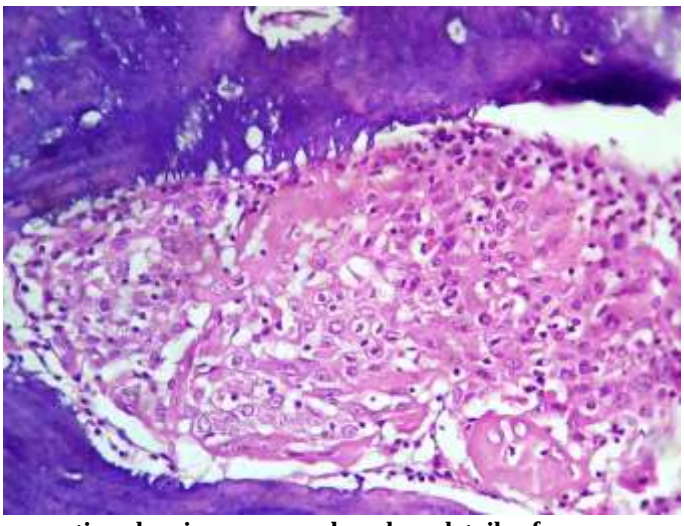

Fig. 3: High power of same section showing preserved nuclear details of squamous carcinoma and decreased eosinophilia (400 X)

Table 1: Comparison of cellular morphology of tissue processed by conventional and TFB method

Parameters	Routine method	TFB method
Yellowishness of tissue section	Present	Significantly reduced
Tissue shrinkage	Present	Less than routine method
Nuclear details	Average	Good
Cytoplasmic eosinophilia	Present	Reduced
Nucleo- cytoplasmic contrast	Blurred	Better
Decalcification time	8-10 days	1day

Discussion

Decalcification is a routine procedure and its aim is to remove calcium salts while preserving the normal architecture of the cells. Bones are one of the important specimen of decalcification in an oncology institute, but other specimens, such as calcified soft tissue tumors, calcified lymph nodes etc. also require this process.

Since the start of decalcification procedure, many studies were conducted for any advances in reagents or procedure with very little change in methodology. This is limited to some additional decalcification solutions and microwave-assisted decalcification. The duration of decalcification is very important for timely diagnosis and management of the patients. In this study we tried decalcification on mandibulectomy sections as they form a majority of specimens in an oncology institute and management of patient also depends on the fast comments on bony cut margins and status of underlying bones. Involvement of underlying bone by squamous carcinoma also requires adequate preservation of the tumor component. Thus, it is very essential to have a correct balance between speed and quality of processing so that ultimate goal of quality patient care is achieved.

Heat is known to expedite the rate of decalcification as it increases the rate of diffusion and increases rate of chemical reaction[9]. In a study performed by Verdenius et al[10] it was observed that time required for decalcification was reduced with increase in temperature. In a study done by Supriya Nikita Kapila et al[11], they have used hot air oven and magnetic stirrer for rapid decalcification process with significant reduction in time of decalcification and improvement in quality of staining. In our study also, there was shortening of time required for decalcification when tissues were continuously exposed to a controlled temperature of 45^0C. When comparing to conventional method of decalcification which require 7-8 days for complete decalcification, our method using TFB require only 18-20 hours for complete decalcification.

Various studies are in literature describing the role of microwave in rapid decalcification. In a study done by R Sangeeta et al[4], microwave was used as for expediting the decalcification process which takes around 2 days for condyles to get decalcified. Pitol et al[5] also mentioned the use of domestic microwave in decalcification with similar results as R Sangeeta et al. It was also suggested that domestic microwave cannot be effectively used for decalcification due to absence of temperature control and temperature beyond 60^0C can damage the tissue[9,12].

These all studies require a separate instrument for this process which require additional space and cost constraints. In our study we have used the tissue floatation bath which is present in nearly every histopathology laboratory which minimizes the requirement for a separate instrument. Also this instrument has an adjustable temperature control up to 110^0C which enables the adequate temperature control throughout the process. In our study it takes about 18-20 hours for decalcification process which is slightly better to that in above mentioned studies.

This instrument which is readily available in all laboratories, fitted with a temperature control provides a rapid decalcification which is comparable to other techniques in respect of duration and staining quality and can be used as an alternative to other methods for decalcification.

Conclusion

The TFB method decalcifies bony tissues much faster than the routine method and is available in nearly all histopathology laboratories. Tissue preservation and staining efficacy is comparable to routine decalcification. It is to emphasize that no separate instrument is required for decalcification process as in microwave technique especially at a tertiary care centre with a lesser workload.

Thus, the TFB is rapid technique as compared to routine methods and is cheaper and easily available technique then microwave with comparable staining quality and preservation.

To the best of our knowledge, this is the first study demonstrating the use of tissue floatation bath in rapid decalcification of bony tissues. Also this can be used for other calcified or bony specimens and further studies are required.

Conflicts of interest: There are no conflicts of interest.

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Bone marrow examination findings in cases of pancytopenia- a study from central India

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Abstract

Background and Objectives: Pancytopenia is one of the most common indications for bone marrow (BM) examination. There are spectrums of condition involving the bone marrow (BM) that can present with pancytopenia and include malignant as well as benign diseases. The objective of this study is to evaluate the BM findings in cases of pancytopenia.

Materials and Methods: This was a retrospective study of 156 cases of pancytopenia presenting over a period of 3 years. Data were retrieved from laboratory and clinical records and were analysed.

Results: Out of 156 cases, the most common cause for pancytopenia in this study was megaloblastic anemia (25.6%), followed by acute leukemia (16%), hypoplastic marrow (14%), metastatic solid tumors (8.9%), myelodysplastic syndrome (MDS) (7.1%), lymphomas (5.7%), plasma cell dyscrasia(3.8%). Along with these there were many benign yet rare causes which may present with pancytopenia like Hemophagocytic syndrome (1.2%), Histoplasmosis (0.6%), Leishmaniasis (0.6%) and Gaucher's disease (0.6%). Bone marrow examination (combining both aspirate and biopsy) alone was sufficient in diagnosing 55% of cases, while remaining cases require additional details like clinical findings (for cases of MDS, viral infection, hypersplenism, autoimmune, septicemia) and special investigations like hemoglobin electrophoresis for hemoglobinopathy. In only 3.8% cases, BME was inconclusive.

Conclusion: BME is an important investigation in diagnostic work up of cases of pancytopenia. In majority of cases, it can provide an accurate diagnosis or at least can guide the approach towards diagnosis and management. Thus, it should be performed in all cases of persistent pancytopenia and should be evaluated in light of clinical details and supportive investigations.

Keywords: Pancytopenia, Bone marrow aspiration biopsy, Causes, Clinical presentation

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Introduction

Pancytopenia is an important clinical entity which is defined as reduction in the number of all the three series (WBC's, RBC's and platelets) in peripheral blood[1].

Pancytopenia is a clinical outcome of many diseases that involve bone marrow either primarily or secondarily. Management of pancytopenia cases depends on the severity of pancytopenia and treatment of the underlying pathology[2].

There are various mechanisms for development of pancytopenia and this include reduced or ineffective hematopoiesis and increased destruction by either sequestration or destruction by antibodies[3].

In cases of pancytopenias, patient usually presents with clinical features attributable to decreased number of RBC's, platelets or WBC's i.e., pallor, easy fatiguability, bleeding, weight loss, or repeated infections leading to fever[4].

Bone marrow examination not only helps in final diagnosis but can also help in indicating the approach to diagnosis based on various parameters like cellularity (hypocellular or hypercellular), Blasts (for leukemias), abnormal cells (lymphoma, plasma cells, carcinoma cells, histiocytes), organisms (fungus, parasite), dysplastic changes in cells (MDS) or megaloblastic maturation.

Correlation with bone marrow biopsy is also important in cases where aspirate is hemodiluted or in hypocellular marrows. Biopsy also helps in many conditions which focally involve the bone marrow like metastatic carcinomas or lymphomas or tuberculosis.

This study is performed at a tertiary care centre and medical college in India and is intended to look at BM findings in cases of pancytopenia so that one should keep in mind various differentials that can present with pancytopenia.

Materials and Methods

This was a retrospective study performed at a tertiary care centre and medical college over a period of three years in Department of pathology. Laboratory data from all the cases who presented with pancytopenia (hemoglobin< 10gm/dl total leukocyte count < 4000/mm^3 and platelet count /150,000/mm^3) were retrieved. Clinical details were obtained from patient's case file and was tabulated, analyzed and correlated with that of laboratory parameters. Cases of

chemotherapy induced pancytopenia (whether benign or malignant) were excluded from this study. Bone marrow aspiration was performed from posterior superior iliac spine. Slides were prepared and stained with leishman stain. Biopsy was processed as per laboratory protocol for bone marrow. Special stains were performed wherever required.

Results

In our institute we receive a total of 610 bone marrow specimens over 3 year duration of which we studied around 156 cases who presented with pancytopenia (Table 1). Male: female ratio was 1.6:1 with 97 males and 59 females. The age of the patients ranged from 2 months to 70 years. Out of 156 cases of pancytopenia, 41 patients (26.3%) were in pediatric age group (<18 years) and remaining 115 patients (73.7%) were adults (>18 years).

Most common presentation (Table 2) was pallor (70.5%) followed by fever (30.1%), splenomegaly (23.1%), hepatomegaly (19.8%) and associated lymphadenopathy (17.3%) while only 5.7% cases were asymptomatic.

Peripheral smear findings (Table 3) in most of the cases show presence of anisocytosis (41%) followed by lymphocytosis (32.1%), nucleated red blood cells (31.4%), and poikilocytosis (20.5%). Blasts were seen in 15.4% cases.

Table 1: Bone marrow aspiration findings in pancytopenia (n= 156)

Diagnosis	Total number of cases				Total
	<18 year		>18 year		
	Male	Female	Male	Female	
Megaloblastic anemia	6	4	20	10	40 (25.6%)
Acute leukemias	5	4	14	2	25(16%)
Hypoplastic marrow	8	1	5	8	22(14%)
Metastasis	1	0	7	6	14(8.9%)
Myelodysplastic syndrome	0	0	3	8	11(7.1%)
Lymphoma infiltration	0	0	8	1	9(5.7%)
Plasma cell dyscrasia	0	0	3	3	6(3.8%)
Viral	1	1	1	0	3(1.9%)
Hypersplenism	0	1	1	1	3(1.9%)
Autoimmune (ITP, SLE)	0	2	0	1	3(1.9%)
Hairy cell leukemia	0	0	2	0	2 (1.2%)
Haemophagocytic syndrome	0	0	2	0	2(1.2%)
Myelofibrosis	0	0	1	1	2(1.2%)
Septicemia	0	0	1	1	2(1.2%)
Leishmaniasis	0	0	1	0	1 (0.6%)
Histoplasmosis	0	0	1	0	1(0.6%)
Malaria	0	0	1	0	1(0.6%)
Gauchers Disease	0	1	0	0	1(0.6%)
Tuberculosis	1	0	0	0	1(0.6%)
Hemoglobinopathy	0	1	0	0	1(0.6%)
Inconclusive	3	1	1	1	6(3.8%)
Total	25	16	72	43	156

Table 2: Clinical findings in cases of pancytopenia

Diagnosis	Pallor	Fever	Petechiae	lymphadenopathy	Splenomegaly	Hepatomegaly	Asymptomatic
Megaloblastic anemia (40)	40	1	0	0	0	0	0
Acute leukemias (25)	20	15	2	12	20	24	0
Hypoplastic marrow (22)	22	13	2	0	0	0	1
Metastasis (14)	0	0	0	0	0	0	2
Myelodysplastic syndrome (11)	3	0	0	0	2	2	0
Lymphoma infiltration (9)	6	2	0	9	0	0	0
Plasma cell dyscrasia (6)	2	1	0	0	0	0	3

Viral (3)	0	3	0	2	0	0	0
Hypersplenism(3)	3	0	0	0	3	0	0
Autoimmune (ITP, SLE) (3)	3	1	0	0	0	0	0
Hairy cell leukemia (2)	2	0	0	1	2	0	0
Haemophagocytic syndrome(2)	2	2	0	0	2	1	0
Myelofibrosis(2)	2	1	0	0	2	2	0
Septicemia (2)	0	2	0	0	0	0	0
Leishmaniasis (1)	0	1	0	0	1	1	0
Histoplasmosis(1)	1	1	0	1	1	0	0
Malaria (1)	1	1	0	0	1	0	0
Gauchers Disease (1)	1	0	0	1	1	1	0
Tuberculosis (1)	0	1	0	1	0	0	0
Hemoglobinopathy (1)	1	0	0	0	0	0	0
Inconclusive (6)	1	2	0	0	1	0	3
Total (156)	110 (70.5 %)	47(30.1%)	4 (2.5%)	27 (17.3%)	36 (23.1%)	31 (19.8%)	9 (5.7%)

Table 3: Peripheral blood findings in cases of pancytopenia

Diagnosis	Anisocytosis	Poikilocytosis	Nucleated RBC's	Blasts	Lymphocytosis
Megaloblastic anemia (40)	35	25	15	0	0
Acute leukemias (25)	10	2	10	23	0
Hypoplastic marrow (22)	0	0	3	0	20
Metastasis (14)	10	0	10	0	4
Myelodysplastic syndrome (11)	1	0	6	1	0
Lymphoma infiltration (9)	0	0	0	0	7
Plasma cell dyscrasia (6)	0	0	0	0	6
Viral (3)	0	0	0	0	3
Hypersplenism(3)	3	3	0	0	0
Autoimmune (ITP, SLE) (3)	0	0	0	0	3
Hairy cell leukemia (2)	0	0	0	0	2
Haemophagocytic syndrome(2)	0	0	2	0	0
Myelofibrosis(2)	0	0	0	0	2
Septicemia (2)	1	0	1	0	0
Leishmaniasis (1)	0	0	0	0	0
Histoplasmosis(1)	0	0	1	0	0
Malaria (1)	1	1	0	0	0
Gauchers Disease (1)	0	0	0	0	1
Tuberculosis (1)	1	0	0	0	1

Hemoglobinopathy (1)	1	1	0	0	0
Inconclusive (6)	1	0	1	0	1
Total (156)	64 (41%)	32 (20.5%)	49 (31.4%)	24 (15.4%)	50 (32.1%)

Discussion

Pancytopenia is a common hematological finding seen in many diseases and diagnosis still remains a challenge for pathologist as well as to clinician. Accurate diagnosis is very crucial for management of patient. Bone marrow examination is very important investigation in patients of pancytopenia and should be looked carefully to achieve proper diagnosis. Even in the absence of a final diagnosis, BME can help clinician in approach to diagnosis and management of the patient.

In our study, out of total 610 cases of BME performed, 25.6% cases presented with pancytopenia which is slightly higher than that in literature.[5-7]

Male: Female ratio in our study was 1.6:1 which is comparable to some studies[6,8] while few study showed slightly female preponderance[9].

In this study most common isolated cause of pancytopenia was megaloblastic anemia which is comparable to many studies performed[8,10-13] while few studies found hypoplastic marrow as the most common cause of pancytopenia[6,14-16].

In a study[17], they found neoplastic diseases as most common cause of pancytopenia. In our study also, combined total of all neoplastic cases exceed that of megaloblastic anemia because this medical college has a separate cancer unit that caters predominantly to cancer patients and many cancers when involve bone marrow, presents with pancytopenia.

In our study second most common cause was acute leukemia which includes both acute myeloid and acute lymphoblastic leukemias. Blasts were seen in peripheral blood smears in 23 cases while two showed absence of blasts on PBS (aleukemic leukemia). These two cases turned out to be acute promyelocytic leukemia (APML) with few promyelocytes on PBS and around 80% promyelocytes and 10% blasts on BME. Out of 23 cases, 8 cases showed mildly reduced count with few blasts on PBS (5-10%) and bone marrow in all these cases show features of acute leukemia with > 50% blasts.

Hypoplastic marrow was 3rd most common cause and all these cases were confirmed on biopsy. Majority of these cases (20) show reduced count with predominantly lymphocytes on peripheral blood smears and similar findings on BME. The diagnosis was confirmed on bone marrow biopsy and was in correlation with aspirate findings.

In our study metastasis of solid tumors (Fig. 1) was seen as reason for pancytopenia in 14 cases with lung, breast and prostate as the most common site of primary in adults while in a single pediatric case ewing's sarcoma was the primary tumor producing pancytopenia. In most of these cases (10) peripheral blood showed circulating nucleated RBC's.

In this study, Myelodysplastic syndrome was found as a cause of pancytopenia in 11 cases, lymphoma infiltration in 9 cases and marrow plasmacytosis in 6 cases.

We found 2 cases of hairy cell leukemia presenting with pancytopenia and one was diagnosed outside as hypocellular marrow with marrow fibrosis on biopsy. He was referred to our hospital with worsening symptoms and marrow was repeated and showed hypocellular marrow with atypical lymphoid cells (Fig. 2). Flow cytometry was asked for and it showed features of Hairy cell leukemia. This is important to discuss that irrespective of myelofibrosis on biopsy, if atypical lymphoid cells are seen on aspirate; special investigations like flow cytometry must be performed as Hairy cell leukemia can frequently cause bone marrow fibrosis.

We found 2 cases presented to us with pancytopenia, persistent fever, splenomegaly. On laboratory work up one case showed blood culture positive for pseudomonas and other patient was a known case of carcinoma ovary with suspected metastasis to bone marrow in view of decreasing counts. Bone marrow from both these cases showed scattered histiocytic cells showing hemophagocytosis (Fig. 3). No metastasis was found in cases suspected of metastatic carcinoma. In view of significant histiocytes showing hemophagocytosis serum ferritin was asked for and was raised in both the cases. Thus, the final diagnosis was made as hemophagocytic syndrome (HPS) as these cases fulfilled 5 criteria of the hemphagocytic syndrome as mentioned in literature[18]. One patient succumbed to the disease irrespective of treatment. It is important to discuss that this is a very severe disease and prognosis and survival is very poor if treatment is not initiated early. Thus, patient with presence of hemophagocytosis in BM should be evaluated for HPS.

Other causes which we found as a cause of pancytopenia were viral induced, autoimmune (idiopathic thrombocytic purpura- 2cases and systemic lupus erythematosus- 1 case), myelofibrosis, septicemia, leishmaniasis (Fig. 4), histoplasmosis (Fig. 5), Hypersplenism, malaria, tuberculosis, Gaucher's disease (Fig. 6) and thalassemia.

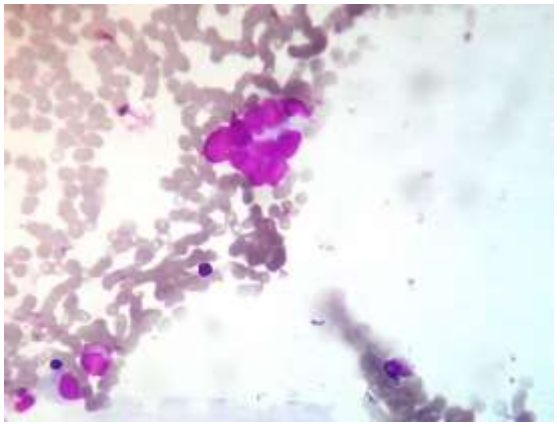

Fig. 1: Smears showing clusters of small round cells in a known case of small cell carcinoma (BM, 400x)

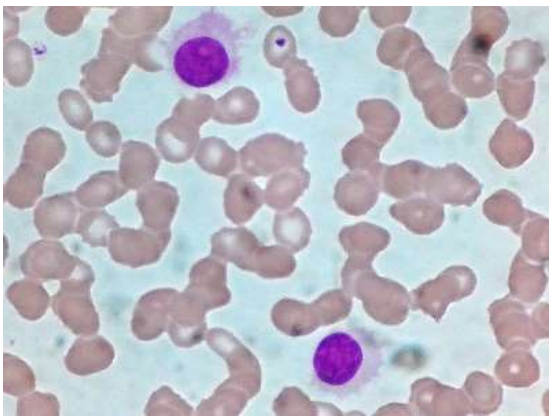

Fig. 2: Hypocellular marrow showing scattered atypical lymphoid cells with cytoplasmic projections (BM, 1000x)

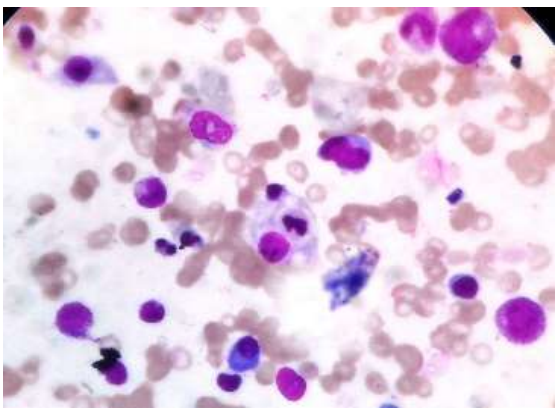

Fig. 3: Histiocytic cells showing phagocytosis of nucleated red blood cells (BM, 1000x)

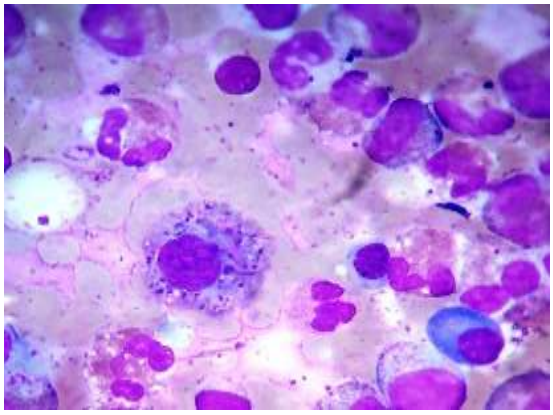

Fig. 4: Scattered and intra-cytoplasmic parasite consistent with leishmaniasis (BM, 1000x)

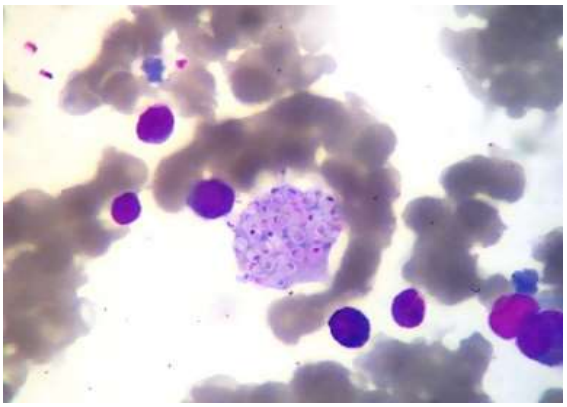

Fig. 5: Cytoplasmic fragment showing intracellular histoplasma organisms (BM, 1000x)

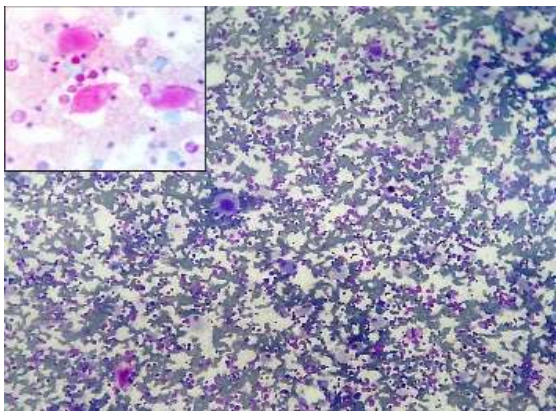

Fig. 6: Gaucher's cells with inset showing PAS positive intacellular accumulation (BM, 1000x)

Conclusion

Bone marrow examination is an important investigation to be performed in cases of pancytopenia. Diagnosis can be made in majority of cases and in few cases it can direct the clinician to approach the disease. Most common cause of pancytopenia are megaloblastic anemia, leukemias and lymphomas, hypoplastic marrow and metastasis. In addition, specific causes of pancytopenia (e.g. Hemophagocytic syndrome, storage disorders, Hairy cell leukemia, fungal or parasitic

infections) should be kept in mind as some of them can be life threatening. Correlation of clinical, peripheral smear finding and bone marrow aspirate findings are required to arrive at final diagnosis.

Conflicts of interest: Nil

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Section Pathology

Original Article

Distribution of ABO and Rh types in Voluntary Blood Donors in a Tertiary Care Center in a Southern District of Rajasthan

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ABSTRACT

Background: *Despite the long list of several other blood groups discovered, the knowledge and distribution of ABO and Rh-D blood group are essential for blood transfusion purposes, population genetic study and healthcare planning.* ***Aims:*** *This study is aimed to determine the distribution pattern of the ABO and Rh blood groups among blood donors in Southern Rajasthan and compare it with other data from similar studies within and outside India. The importance of the study lies in maintaining the blood bank inventory so that no patient dies due to the deficient supply of blood.*
Methods: *It is a retrospective study carried out at blood bank, Ananta Institute of Medical Sciences and Research centre, Rajsamand, Rajasthan over a period of 2 years from January 1, 2016, to December 31, 2017. Blood group of the blood donors was determined by commercially available standard monoclonal antisera by test tube agglutination technique accompanied by reverse grouping.*
Results: *Out of 1142 subjects, 1117 (97.81%) were male and 25 (2.19%) were female subjects. 279 (24.43%) donors were voluntary and 863 (75.56%) donors were replacement donors. On studying the ABO blood group system, the most frequent group was B (33.97%) followed by O (31.96%), A (22.06%), and AB (6.91%) in blood donors while in Rh system, 1084 (94.92%) donors were Rh positive and 58 (5.07%) were Rh negative.* ***Conclusions:*** *The knowledge of distribution of blood group is very important for blood banks and transfusion services which play an important role in the patient's health care. The study has a significant implication regarding the inventory management of blood bank and transfusion services and will also throw light on the reasons of deficiency of a particular group in a particular area so that deficient group donors may be encouraged to donate more frequently.*

Keywords: *ABO, blood bank, Rhesus, blood donors*

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INTRODUCTION

Blood is a very important and life-saving component of the body and hence its transfusion for various ailments is a landmark for improving health. Timely transfusion of blood saves millions of lives.

In recent times, transfusion medicine has gained immense importance and the use of specific components of blood rather than whole blood has gained importance. But there has been a shortage of sufficient blood units. An increase of 10.7 million blood donations from voluntary unpaid donors has been reported from 2008 to 2013. In total, 74 countries collect over 90% of their blood supply from voluntary unpaid blood donors; however, 71 countries collect more than 50% of their blood supply from family/replacement or paid donors[1].

Human red blood cells contain on their surface a series of glycoproteins and glycolipids, which constitute blood group antigens. Development of these antigens is genetically controlled, inherited in a mandelian fashion.[2] Erythrocyte antigens are organized into more than 30 blood group systems by the International Society of Blood Transfusion.[3] The ABO blood group system was the first human blood group system to be discovered by Landsteiner in 1901.[4] Later Landsteiner and Wiener defined the Rh blood group in

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1941.[5] Together these two systems have proved to be the most important, for blood transfusion purposes.

All human populations share the same blood group systems; although they differ in the frequencies of specific types. The incidence of ABO and Rh groups varies markedly in different races, ethnic groups, and socio-economic groups in different part of the world.[6]

Discovery of ABO blood group system opened the way for discoveries in the field of immunohaematology, blood transfusion among humans irrespective of their natives, unmatched pregnancy, legal medicine, anthropology and the discovery of other blood group systems.[7]

The ABO blood group system is divided into four blood types on the basis of presence or absence of A and B surface antigens. The blood groups are ABO and AB. ABO blood group system is important because of the fact that A and B are strongly antigenic and anti A and anti B are naturally occurring antibodies present in the serum of persons lacking the corresponding antigen. These antibodies are capable of producing intravascular hemolysis in case of incompatible transfusion.[8]

ABO and Rh blood groups are useful in blood transfusion practice, population genetic studies, analyzing population migration patterns as well as resolving certain medicolegal issues, for example, disputed paternity cases.[9]

Blood banks usually have a problem of ever-changing stock position and it being very difficult to predict the prevalence of a particular blood group at a particular time hence the knowledge of distribution of ABO and Rh blood group is essential for effective management of inventory, be it a facility of a smaller local transfusion service or a regional or national transfusion service.[10]

The present study was done to assess the prevalence of blood groups in the region and to compare the results with other studies conducted in India and elsewhere in the world and its multipurpose future utilities for the health planners.

METHODS

This study was carried out at blood bank, Ananta Institute of Medical Sciences and Research centre, Rajsamand, Rajasthan, during the 2 years period from 1 January 2016 to 31 December 2017. Total 1,142 donors were considered medically fit and accepted for blood donation during the study period.

All were of age between 18 and 60 years. After blood donation, blood group was determined by forward blood grouping (cell grouping) by test tube agglutination method. Commercially available standard antisera A, antisera B, and antisera D were used after validation at blood bank. Reverse blood grouping (serum grouping) was performed by test tube agglutination method with pooled known A, B, and O cell that are being prepared daily at the blood bank. Final blood group is confirmed only if both forward group (cell group) and reverse group (serum group) are identical. The donor blood group data were recorded on specially formed pro forma, tabulated, analyzed, and compared with the similar studies by other authors.

RESULTS

Total number of donors was 1,142. The voluntary and replacement donors constituted 24.43% and 75.56% respectively. The frequency of ABO and Rh blood groups was compared. In ABO system, our study shows the highest frequency of blood group “B” (35.72%), followed by “O” (33.8%), “A” (23.38%), and “AB” (7.09%). Incidence of Rh positive and Rh-negative donors was 94.92% and 5.07% respectively. Percentage of male and female donors was 97.81% and 2.18% respectively.

Table 1. Distribution of different types of blood donors according to sex and donation type (voluntary/replacement).

Donation type	Male	Female	Total	Percent of Total
Voluntary	261	18	279	24.43%
Replacement	856	7	863	75.56%
Total	1117	25	1142	
Percent of Total	97.81%	2.18%		

Table 2: Distribution of blood donors according to group.

	Rh+				Rh-			
	A positive	B positive	O positive	AB positive	A negative	B negative	O negative	AB negative
Number of donors	252	388	365	79	15	20	21	2
Percentage	22.06	33.97	31.96	6.91	1.31	1.75	1.83	0.17

Table 3: Comparison of frequency percentage of ABO and Rhesus blood groups in various studies of India and with different countries

Study	A	B	O	AB	Rh+	Rh-
Chandra and Gupta [11]	21.73	39.84	29.10	9.33	95.71	4.29
Girish et al [14]	24.27	29.43	39.17	7.13	94.93	5.07
Kaur et al [12]	18.01	38.06	34.31	9.62	91.28	8.72
Giri et al [16]	28.38	31.89	30.99	8.72	95.36	4.64
Periyavan et al [20]	23.85	29.95	39.82	6.37	94.20	5.80
Wadhwa et al [18]	23.30	35.50	32.50	8.80	94.20	5.80
Nag et al [19]	23.90	33.60	34.80	7.70	94.70	5.30
Mallikarjuna et al [17]	26.15	29.85	31.76	7.24	94.80	5.20
Khattak et al [21]	27.92	32.40	29.10	10.58	90.13	9.87
Patel et al [15]	21.94	39.40	30.79	7.86	95.05	4.95
Garg et al [13]	28.70	32.07	28.70	10.53	94.49	5.51
Agrawal et al [23]	22.88	32.26	37.12	7.74	94.61	5.39
Pramanik and Pramanik[22]	34	29	33	4	96.70	3.30
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Mwangni J [28]	21.60	21.40	54.20	2.80	95.20	4.80
Australian Red Cross Society [27]	38	10	49	3	NA	NA
Present Study	22.06	33.97	31.96	6.91	94.92	5.07

DISCUSSION

Total 1,142 subjects were included in the study. Replacement donors (75.56%) were much more than voluntary donors (24.43%).

In ABO system, our study shows the highest frequency of blood group “B” (33.97%), followed by “O” (31.96%), “A” (22.06%), and “AB” (6.91%) (Table 3). Blood group frequency with respect to ABO with Rh positive was found to be in sequence of B > O > A > AB (Table 2) which is in accordance with other studies.[11,12] The frequency for ABO with Rhesus negative comes out to be in sequence of O > B > A > AB (Table 2) which matches with study done by Kaur et al[12] but is in contrast with study done by Garg et al[13]

where the sequence of B > A > O > AB was given. As observed in Table 3, these figures are similar to the other studies carried out in India.[11-21,23]

Many studies have suggested that outside India, "A" group is much more common than "B". The most common blood group in the studies conducted in Britain, the USA, Australia, Nigeria, and Saudi Arabia is "O" group followed by "A," "B," and "AB".[24-28] In a study from Nepal, "A" group was the most common followed by B, O, and AB.[22]

Rh negativity status was found to be 5.07% in our study (Table 4) which is in accordance with the studies conducted at other places in India and is in contrast with western studies[24,25] where it was reported to be as high as 15-17%.

Table 4: Percentage of male and female donors in and outside India

	Male donors (%)	Female donors (%)
Inside India		
Present Study	97.81	2.18
Garg et al [13]	99.71	0.23
Patel et al [29]	99.05	4.95
Agarwal et al [30]	87.4	12.6
Giri et al [16]	95.75	4.25
Bala et al [31]	94.79	5.21
Koram et al [32]	97.73	2.27
Singh et al [10]	91.73	8.27
Outside India		
Nigeria [33]	90.1	9.9
Iran [34]	95	5
Italy [35]	67	33
Spain [36]	50.3	49.7
Great Britain [34]	45	55
USA [37]	54.5	45.5

It has been observed that female donors (2.18%) are very less compared to male donors (97.81%) (Table 1, 4). Similar results have been seen in many studies conducted in India [10,13,16,29,30,31,32] and some developing countries for example in Iran [34] and Nigeria [33]. This may be attributed to taboos related to blood and its loss, fear of blood donation, low level of awareness regarding the importance of blood donation, lack of motivation and increased deferral in female donors which are obviously accentuated in developing countries. In contrast, female donors show significant participation in developed countries.[34,35,36,37]

The significance of such studies which analyze the prevalence of blood groups is manifold. The group-wise availability of blood will eventually reflect the prevalence of blood group in the general population in that territory. It helps the doctor to plan the treatment of patients in a better way, for example, at the time of emergencies such as trauma, Rh incompatibility, and postoperative care.

This type of studies also allows blood banks to identify and maintain records of donors of blood groups which are rare in that particular area. In case of any unavailability during any emergency, the donor could be contacted and requested if he/she would like to donate in a good cause.

The data generated can be useful in population genetic studies giving useful information for instance, about population migration patterns. It may also prove important for other studies of various geographical regions of India which will be useful to health planners while making efforts to face the future health challenges in the particular region.

CONCLUSION

In conclusion, blood group 'B' was most common in the study followed by 'O', 'A' and 'AB'. Proportion of Rh positive donors was 94.92% while Rh negative was 5.07%. Blood donation by females was very low (2.18%) compared to males (97.81%) and it needs to be increased by improving health status of females and generating awareness about importance of blood donation.

These studies generate a database of blood groups at local and regional level. It is important to conduct similar studies in other regions in order to present a broader picture which can have significant implications for doctors, patients, transfusion services and health planners.

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Section Pathology

Original Article

Distribution of ABO and Rh types in Voluntary Blood Donors in a Tertiary Care Center in a Southern District of Rajasthan

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ABSTRACT

Background: *Despite the long list of several other blood groups discovered, the knowledge and distribution of ABO and Rh-D blood group are essential for blood transfusion purposes, population genetic study and healthcare planning.* ***Aims:*** *This study is aimed to determine the distribution pattern of the ABO and Rh blood groups among blood donors in Southern Rajasthan and compare it with other data from similar studies within and outside India. The importance of the study lies in maintaining the blood bank inventory so that no patient dies due to the deficient supply of blood.*
Methods: *It is a retrospective study carried out at blood bank, Ananta Institute of Medical Sciences and Research centre, Rajsamand, Rajasthan over a period of 2 years from January 1, 2016, to December 31, 2017. Blood group of the blood donors was determined by commercially available standard monoclonal antisera by test tube agglutination technique accompanied by reverse grouping.*
Results: *Out of 1142 subjects, 1117 (97.81%) were male and 25 (2.19%) were female subjects. 279 (24.43%) donors were voluntary and 863 (75.56%) donors were replacement donors. On studying the ABO blood group system, the most frequent group was B (33.97%) followed by O (31.96%), A (22.06%), and AB (6.91%) in blood donors while in Rh system, 1084 (94.92%) donors were Rh positive and 58 (5.07%) were Rh negative.* ***Conclusions:*** *The knowledge of distribution of blood group is very important for blood banks and transfusion services which play an important role in the patient's health care. The study has a significant implication regarding the inventory management of blood bank and transfusion services and will also throw light on the reasons of deficiency of a particular group in a particular area so that deficient group donors may be encouraged to donate more frequently.*

Keywords: *ABO, blood bank, Rhesus, blood donors*

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INTRODUCTION

Blood is a very important and life-saving component of the body and hence its transfusion for various ailments is a landmark for improving health. Timely transfusion of blood saves millions of lives.

In recent times, transfusion medicine has gained immense importance and the use of specific components of blood rather than whole blood has gained importance. But there has been a shortage of sufficient blood units. An increase of 10.7 million blood donations from voluntary unpaid donors has been reported from 2008 to 2013. In total, 74 countries collect over 90% of their blood supply from voluntary unpaid blood donors; however, 71 countries collect more than 50% of their blood supply from family/replacement or paid donors[1].

Human red blood cells contain on their surface a series of glycoproteins and glycolipids, which constitute blood group antigens. Development of these antigens is genetically controlled, inherited in a mandelian fashion.[2] Erythrocyte antigens are organized into more than 30 blood group systems by the International Society of Blood Transfusion.[3] The ABO blood group system was the first human blood group system to be discovered by Landsteiner in 1901.[4] Later Landsteiner and Wiener defined the Rh blood group in

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1941.[5] Together these two systems have proved to be the most important, for blood transfusion purposes.

All human populations share the same blood group systems; although they differ in the frequencies of specific types. The incidence of ABO and Rh groups varies markedly in different races, ethnic groups, and socio-economic groups in different part of the world.[6]

Discovery of ABO blood group system opened the way for discoveries in the field of immunohaematology, blood transfusion among humans irrespective of their natives, unmatched pregnancy, legal medicine, anthropology and the discovery of other blood group systems.[7]

The ABO blood group system is divided into four blood types on the basis of presence or absence of A and B surface antigens. The blood groups are ABO and AB. ABO blood group system is important because of the fact that A and B are strongly antigenic and anti A and anti B are naturally occurring antibodies present in the serum of persons lacking the corresponding antigen. These antibodies are capable of producing intravascular hemolysis in case of incompatible transfusion.[8]

ABO and Rh blood groups are useful in blood transfusion practice, population genetic studies, analyzing population migration patterns as well as resolving certain medicolegal issues, for example, disputed paternity cases.[9]

Blood banks usually have a problem of ever-changing stock position and it being very difficult to predict the prevalence of a particular blood group at a particular time hence the knowledge of distribution of ABO and Rh blood group is essential for effective management of inventory, be it a facility of a smaller local transfusion service or a regional or national transfusion service.[10]

The present study was done to assess the prevalence of blood groups in the region and to compare the results with other studies conducted in India and elsewhere in the world and its multipurpose future utilities for the health planners.

METHODS

This study was carried out at blood bank, Ananta Institute of Medical Sciences and Research centre, Rajsamand, Rajasthan, during the 2 years period from 1 January 2016 to 31 December 2017. Total 1,142 donors were considered medically fit and accepted for blood donation during the study period.

All were of age between 18 and 60 years. After blood donation, blood group was determined by forward blood grouping (cell grouping) by test tube agglutination method. Commercially available standard antisera A, antisera B, and antisera D were used after validation at blood bank. Reverse blood grouping (serum grouping) was performed by test tube agglutination method with pooled known A, B, and O cell that are being prepared daily at the blood bank. Final blood group is confirmed only if both forward group (cell group) and reverse group (serum group) are identical. The donor blood group data were recorded on specially formed pro forma, tabulated, analyzed, and compared with the similar studies by other authors.

RESULTS

Total number of donors was 1,142. The voluntary and replacement donors constituted 24.43% and 75.56% respectively. The frequency of ABO and Rh blood groups was compared. In ABO system, our study shows the highest frequency of blood group “B” (35.72%), followed by “O” (33.8%), “A” (23.38%), and “AB” (7.09%). Incidence of Rh positive and Rh-negative donors was 94.92% and 5.07% respectively. Percentage of male and female donors was 97.81% and 2.18% respectively.

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Present Study	22.06	33.97	31.96	6.91	94.92	5.07

DISCUSSION

Total 1,142 subjects were included in the study. Replacement donors (75.56%) were much more than voluntary donors (24.43%).

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Outside India		
Nigeria [33]	90.1	9.9
Iran [34]	95	5
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The data generated can be useful in population genetic studies giving useful information for instance, about population migration patterns. It may also prove important for other studies of various geographical regions of India which will be useful to health planners while making efforts to face the future health challenges in the particular region.

CONCLUSION

In conclusion, blood group 'B' was most common in the study followed by 'O', 'A' and 'AB'. Proportion of Rh positive donors was 94.92% while Rh negative was 5.07%. Blood donation by females was very low (2.18%) compared to males (97.81%) and it needs to be increased by improving health status of females and generating awareness about importance of blood donation.

These studies generate a database of blood groups at local and regional level. It is important to conduct similar studies in other regions in order to present a broader picture which can have significant implications for doctors, patients, transfusion services and health planners.

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Original Research Article

Aspiration Cytology of Metastatic Cervical Lymph Node: A Tertiary Health Centre Based Study

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ABSTRACT

Objective: the present study was conducted to assess the prevalence and cytological pattern of various metastatic cervical lymph nodes in the southern part of Rajasthan, India.
Material and Methods: The prospective study was conducted in a tertiary healthcare centre of southern Rajasthan, India during the period of 1 year from August 2018 to August 2019. 100 patients with cytologically diagnosed metastatic cervical lymph node were included in the study. Review of all cytological reports were done according to standard guidelines and the diagnosis was classified and correlated with patient age and sex to explore the pattern and association.
Results: Age of the patients' ranges from 29 to 70 years with the mean age of 54.16 years. Maximum patients (80%) were from the age group > 50 years. Among the 100 study participants, 83% were male and 17% were females (Male: Female ratio- 4.89:1). Primary site was known in 89% cases while primary was occult in 11% cases. Out of 89 cases of known primary, 32 cases had primary in oral cavity followed by 24 cases having primary in larynx. On cytological examination, squamous cell carcinoma was found to be the most common type of tumour type (71%) followed by Adenocarcinoma (20 %).
Conclusion: Fine needle aspiration cytology is an effective, economical and reliable method in diagnosing metastasis with good degree of certainty. Squamous cell carcinoma is most common type of metastatic tumour which commonly affects older individuals after the fifth decade with male preponderance.

Keywords: Metastasis, Carcinoma, Lymph Node, cytology, Cytology.

INTRODUCTION

Lymphadenopathy is a sign of inflammation, infections, primary or metastatic tumours. This is commonly seen involving the head, neck and inguinal region. [(1)] Carcinoma metastatic from the head and neck region is the most important of these and must remain prominent in the mind of the clinician. [(2)] Even though the cause of cervical lymphadenopathy may vary, enlarged cervical nodes in an elderly patient must be considered as metastatic until proved otherwise. [(3)]

Fine needle aspiration of neck lymph nodes is quick, safe, very cost effective and simple technique, well tolerated by the patients, without any complication, done on an outpatient basis and repeatable. India is eminently suited for this procedure. [(4)] Metastatic lesions confirmed by FNAC also give clue to the nature and site of primary. [(5)] A correct diagnosis helps in early management thus reducing mortality and morbidity. The present study was performed to know the prevalence of various metastatic cervical lymph nodes in our region. As there is paucity of literature on these matters from

our region, this study will highlight for the same the cytomorphological patterns of neck node metastasis.

MATERIAL AND METHODS

Nature of study and study population: The present study was a prospective study performed in the department of Pathology of Ananta Institute of Medical Sciences, Rajsamand, Rajasthan during the period of 1 year from August 2018 to August 2019. 100 slides of cytologically diagnosed metastatic cervical lymph nodes among the various suspected patients referred for FNAC were included in the present study.

Study period: 1 year from August 2018 to August 2019

Sample size: 100 cases of metastatic cervical lymph nodes

Procedure: A well informed and written consent was taken from all the study participants before starting the study. Approval from institutional ethical committee was also taken. Brief clinical history including age, sex, site, side were taken from all the participants and thorough clinical examination was also carried out. The FNAC was performed by experienced faculty using 20-24 gauze needles without local anaesthesia. Needle was inserted up to the desired depth into the lymph node and adequate quantity of cellular material was withdrawn. A minimum of two well labeled glass smears were prepared. The smears were air dried and stained with Romanowsky stain according to standard procedure. Review of all cytological reports were done according to standard guidelines and the diagnosis was classified and correlated with patient age and sex to explore the pattern and association. All the information collected from the results of present study was correlated with previous studies done in the similar field and results were compared & correlated.

Patients with the diagnosis other than metastatic lymph node and those who refused to give consent were excluded from the study.

RESULTS

100 patients with metastatic cervical lymph nodes were included in present study. Age of the patients ranges from 29 to 70 years with the mean age of 54.16 years. Maximum patients were from the age group > 50 years. (Table 1)

Table 1 Age wise distribution of the study participants

S.No.	Age-group	Number	Percentage
1	< 30 years	01	01
2	31-50 years	19	19
3	>50 years	80	80
	Total	100	100

Among the 100 study participants, 83% were male and 17% were females (Male: Female ratio- 4.89:1). Primary site was known in 89% cases while primary was occult in 11% cases. Out of 89 cases of known primary, 32 cases had primary in oral cavity followed by 24 cases having primary in larynx. (Table 2)

Table 2 Distribution of primary site of the metastatic tumour

S.no.	Primary site	Number of cases	Percentage
1	Oral cavity	32	35.99
2	Larynx	24	26.96
3	Oropharynx	11	12.35
4	Nasopharynx	7	7.86
5	Lung	7	7.86
6	Breast	6	6.74
7	Thyroid	1	1.12
8	Prostate	1	1.12
	Total	89	100%

On cytological examination, squamous cell carcinoma was found to be the most common type of tumour type (71%) followed by Adenocarcinoma (20 %). (Table 3)

Table 3 Cytological diagnosis of cervical lymph node metastasis.

S.No.	Tumour type	Number of cases	Percentage
1	Squamous cell carcinoma	71	71
2	Adenocarcinoma	20	20
3	Undifferentiated carcinoma	6	6
4	Small cell carcinoma	2	2
5	Follicular carcinoma	1	1
	Total	100	100

DISCUSSION

In present study, age of the patients' ranges from 29 to 70 years with the mean age of 54.16 years and maximum number of patients were from the age group > 50 years.

Similar results were obtained in similar studies done in the past. In a study performed by Mehrotra et al in 2005, the commonly affected age group was 50-60 years. [(6)] Ghartimagar et al studied the utility of FNAC in metastatic lymph node in 2011 and found that most commonly affected age group was > 60 years. [(4)] Similarly, in a study by Virendra T et al, the most commonly affected age group was 50-60 years. [(7)]

The male: female ratio in present study was 4.89:1. In the study by Virendra T et al the ratio was 4:1. [(7)]The ratio was 2.9: 1 in the study done by Bhattacharjee et al in 2006. [(8)] The male: female ratio was almost equal in another study done by Engzell et al in 1971 (1.07:1). [(9)]

The most common primary site for metastasis in present study was oral cavity (32%). Izhar N. Bhagwan (2007) and Karabi Kohar et al (2008) also found the oral cavity as the most common primary site for cervical lymph node metastasis. [(10, 11)] In a study performed in china by Chih Hsu et al in 1971, the most common site for cervical lymph node metastasis was nasopharyngeal carcinoma. [(12)] We all know; the incidence and mortality of nasopharyngeal carcinoma are highest in china because of their specific diet and genetic inheritance. In a study performed by Malika Afroz, the most common primary site was larynx. [(13)]

In present study, the most common type of tumour was squamous cell carcinoma (71%) followed by adenocarcinoma (20%). Other types were undifferentiated carcinoma (6%), small cell carcinoma (2%) and follicular carcinoma (1%).

In squamous cell carcinoma, tumour cells are seen arranged in sheets or scattered singly. The cells had dense cytoplasm with hyperchromatic nuclei owhile cynophilic cytoplasm with pyknotic nuclei in PAP stain. Necrotic material is often present in the background and keratinization may also be found.

In adenocarcinoma, the tumour cells are arranged in acinar or papillary arrangements or singly scattered. Cells are cuboidal to columnar with moderate amount of cytoplasm and pleomorphic nuclei with prominent nucleoli. Intracellular mucin secretion is present.

In undifferentiated carcinoma, there is pattern less solid, sheet like growth of tumour cells. There are no nests, papillae, glands, trabeculae or spindle pattern, no squamous or mucinous metaplasia, no or minimal neuroendocrine differentiation. In present study, the undifferentiated carcinomas were mainly from the nasopharynx.

Metastatic small cell carcinoma was seen in 2 cases of present study where the primary was found to be in lungs. In small cell carcinoma, the cells have scanty cytoplasm with large nuclei. Nuclei usually demonstrate the classical “salt and pepper” chromatin with indistinct nucleoli and frequent molding.

One case of metastatic follicular carcinoma with suspected primary in thyroid was also encountered in present study.

Squamous cell carcinoma has been found as the most common verity in other studies done in the past by Ustun et al, [(14)] Izhar N. Bhagwan [(10)] and Kiran Alam et al. [(15)] In contrary to our result, adenocarcinoma was the most common variety in a study performed by Ghartimagar D. et al. [(4)]

CONCLUSION

Fine needle aspiration cytology is an effective, economical and reliable method in diagnosing metastasis with good degree of certainty. Squamous cell carcinoma is most common type of metastatic tumour which commonly affects older individuals after the fifth decade with male preponderance. Unnecessary use of invasive methods like surgical biopsy can be avoided with the use of FNAC.

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A study of histomorphology and immunohistochemical profile in breast cancer in a tertiary care hospital

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Abstract
The most common cancer among women in the urban Indian population is breast cancer and it is second only to cancer of the cervix in the rural population. Breast cancer is no longer seen as a single disease but rather a multifaceted disease comprised of distinct biological subtypes with diverse natural history, presenting a varied spectrum of clinical, pathologic and molecular features with different prognostic and therapeutic implications. One important aspect of the role of Pathology in the evaluation of breast cancer is biomarker testing, specifically the accurate assessment of the Estrogen receptor (ER), progesterone receptor (PR), and Her2 neu status of a patient's breast cancer. Biomarkers can be prognostic, predictive, or both. Prognostic biomarkers are independent measures of prognosis such that the presence or absence of the biomarker is associated with a patient's overall clinical outcome.

Keywords: Breast carcinoma, ER, PR, Her2 neu, triple negative

Introduction
Breast carcinoma is a malignant proliferation of the epithelial cells lining the ducts and lobules of breast. Breast cancer is the most common malignancy in women, affecting one in 12 in the western world. Advances in imaging techniques and the increased use of aspiration needle biopsy have greatly assisted preoperative evaluation of breast lesions; however, in a large proportion of cases, differentiation between benign and malignant lesions still rests on histologic examination. Currently, routine clinical management of breast cancer incorporates specific molecular markers; namely ER (Estrogen receptor), PR (progesterone receptor), Her 2 neu (human epidermal growth factor receptor 2 gene) that have been proven to provide therapeutic, predictive and prognostic value.

Aims and Objective
1. To analyse histomorphology and lymph node status in breast carcinomas.
2. To study Estrogen receptor (ER), progesterone receptor (PR) and human epidermal growth factor receptor 2 (Her2 neu) in all these breast carcinomas

Materials and methods
All the lumpectomy, simple mastectomy and modified radical mastectomy specimens of carcinoma breast submitted to the Department of Pathology in a tertiary care hospital in 1 year were enrolled. A total of 50 cases were included in this study. H&E sections from the tumour were analysed for histomorphology and corresponding tumour section was used for immunohistochemistry analysis of ER, PR and Her2neu.

Observation and results
The present study comprised of 50 cases of breast carcinoma over a period of 24 months. The age of the patients range from 32 to 77 years with a mean age of 51.10 years (SD 10.869).
Majority of patients were in age group of 40-49 years. Modified radical mastectomies (96%) comprised the maximum load of specimens received followed by small biopsies (4%).
Most of the lesions were in the Right breast (64%). The most common location of tumour was in upper outer quadrant with 22 cases (44%) followed by upper inner quadrant with 11

cases (22%). In our study, the size of the tumour ranged from 1 to 9 cm with majority of the tumours (50%) in the size range of 2 to 5 cm. Most common histologic type was Infiltrating Ductal Carcinoma (Not otherwise Specified) with 66% cases (Table 1) (Figure1). Majority of the cases were of Grade II with 39 (78%) cases (Table 2). Lymph node positivity was seen in 24 cases (48%) and in 4 cases (8%) more than 10 positive lymph nodes were found.

ER, PR, Her 2neu status (Figure 2-4)
The immunohistochemical analysis revealed 54% (27 cases) positivity for ER with Allred score of 3-8. Majority (62.96%) of the ER positive cases had the Allred score of 7 or 8. PR positive cases were 23 (46%) with Allred score of 7 or 8 in most of the positive cases. Her2 neu was positive in 11 (22%) cases. Equivocal score was seen in 3 (6%) cases.

Lymph node status and Allred score for ER: In 24 cases (48%) lymph nodes were involved in which 12 cases (50%) were ER negative (Allred Score: 0,2). Lymph nodes were not involved in 24 cases (50%) in which 13 cases (54%) had ER positivity (Allred score: 3-8) (Table 3). Significant association was noted with ER score and lymph node involvement (p value < 0.05).

Lymph node status and Allred score for PR: In 24 cases (48%) lymph node status was positive with 13 cases (54.2%) being PR negative. In lymph node negative cases, 10 cases (41.6%) were PR positive (Allred score 3-8) (Table 4).

Lymph node status and Her2 neu score: In 36 (72%) cases Her2 neu score was negative. In HER2 neu negative cases, lymph nodes were involved in 17 patients (47.22%). Equivocal status was seen in 3 cases in which 1 case was positive for lymph nodes. In 11 patients HER2 neu score was 3+ out of which 6 cases (54.5%) had lymph node involvement (Table 5).

Allred score for Pr with her2/NEU score
In 11 cases (22%) HER2/neu was positive in which 10 cases (90.9%) were negative for PR with Allred score of 0 or 2. HER2/neu score inversely correlated with the Allred Score for PR (Table 6). Pearson Chi Square test showed significant association between HER2 neu score and Allred score for PR.

Triple negative status and histologic grade: The study had 13 triple negative cases, of which 12 cases (92.3%) were grade II or grade III, thus emphasising that Triple negative status is associated with higher grade (Table 7).
Pearsons Chi Square test showed significant correlation among triple negative status and tumour grade (p value < 0.05).

Discussion

Age: The age range of present study with mean age of 51.10 years was comparable with various other studies (Table 8).

Laterality: The present study had majority of tumours in the right breast while the studies by Sofi *et al.* and Nisa *et al.* have left predominance. (Table 9)

Tumour Size: In the present study the size of tumour ranged from 1 to 9 cm. The mean tumor size was 3.52 cm and is comparable to the studies by Mudduwa *et al*. [1] and Sofi *et al*. [2] (Table 10). Also it is noted in the present study that 72% of cases showed more than 2 cm tumor size which is similar to the results observed by Bhagat Vasudha *et al.* [3] (91.38%), Azizun *et al.* [4] (88%), Moses *et al.* [5] (91.6%) and Mona *et al.* [6] in their study. While study from western country, Adedayo *et al.* [7] showed 71.4% cases with ≤ 2cm size, this could be due to early cancer detection programs. In India owing to the lack of awareness of this disease and absence of a breast cancer screening program, the majority of breast cancers are diagnosed at a relatively advanced stage. In our study 14.3% of tumours which were less than 2 cm in size showed HER2/neu positive staining, 20% cases in the size range of 2-5 cm were HER2/neu positive and 36.4% cases in which tumour size was more than 5 cm were HER2/neu positive. Significant association between increasing tumor size and HER-2/neu expression was seen in our study. Tumors larger than 2 cm size had higher rates of Her-2/neu expression than those of tumors less than 2 cm size. Similar result was observed by Bhagat *et al.* [3] in their study.

Histologic type: The most common histologic type in the present study was IDC-NOS which is comparable to the findings of other studies (Table11).

Tumour grade: The most common tumour grade in the present study was grade II with 78% cases followed by grade II with 16% cases. This was similar to findings by Sofi *et al.* [2] and Ayadi *et al*. (Table 12).

Lymph node status: In 24 (48%) cases lymph nodes were positive for metastasis. In 2 cases lymph nodes were not retrieved. Lymph nodes were not involved in 24 (48%) cases. In the studies by various authors like Zubair Ahmed *et al*. [8], Mudduwa *et al*. [1]., Seho Park *et al*. [9], Lobna Ayadi *et al*. [10] and Lokuhetty [11] documented lymph nodes positive for metastasis as 74.77%, 57.7%, and 27.8%, 65% and 41% respectively.

ER/PR and HER2/neu status: Comparison of ER/PR and HER2/neu status in various studies is shown in the table 13**.** Out of total 50 cases, 22 cases (44%) showed positive staining for both ER and PR and 21 cases (42%) were negative for both ER and PR. Our findings were in concordance with study of R. Kumawat [12], who demonstrated 33% cases showed positive staining for both ER and PR while 45% cases showed negative staining for both estrogen and progesterone receptors. The negative ER PR status in IDC-NOS was comparable to study by Kumavat *et al.* [12].

HER2/neu score and Histologic Type: We compared our results with previously published international data. In the Sloan-Kattering study HER-2 positivity was limited to infiltrating breast carcinoma of the ductal and lobular morphology. None of the special type carcinomas like mucinous, medullary or papillary showed HER-2 positivity. These findings were similar to our study.

Histologic Grade with ER/PR and HER2/neu expression: The comparison of molecular marker expression in different studies are given in the table 14. Our findings were in concordance with Bird P *et al*. [13] who demonstrated that increasing tumour grade is associated with decreased PR expression

Triple Negative Breast Carcinoma (TNBC): The present study had 26% of triple negative breast carcinomas (TNBC). A major proportion (30.7%) of TNBC had tumour size >5cm as compared to 18.91% in other cases. The finding that *TNBC present with larger size* compared to other group is consistent with findings by Bauer *et al*. [14], Li *et al*. [15], Somali *et al*. [16]

Also the rate of node positivity was found in TNBC was high (53.84%) compared to node positivity in other group of carcinomas (45.94%). This is consistent with findings of Bauer *et al*, Li *et al*. The majority of TNBC were of *grade III*, the finding being consistent with Carey *et al*. [17], Bauer *et al*. [14], Somali *et al*. [16].

There are conflicting reports in literature regarding lymph node status in TNBC. While some publication report a higher rate of node positivity (Bauer *et al*. 2008; Li *et al*. 2013) [14, 15] Some report node negativity more common in TNBC (Foulkes *et al*, 2003; Cheang *et al*., 2008; Somali *et al*. 2013) [18, 19, 16]. In our study a high rate of node positivity was found in TNBC compared to other group (53.84% vs 45.94%). Comparing the histological subtypes, IDC NOS comprised maximum number of cases in both the study groups (61.53% vs 67.56%). Similar results were observed in other studies (Carey *et al*. 2006; Somali *et al*. 2013) [17, 16].

Conclusion

The study of ER, PR and HER2 neu expression in breast carcinomas by IHC is a very important diagnostic tool in deciding the treatment strategy and the prognosis. The study throws a light on lack of adequate screening programs and awareness regarding breast carcinoma in India compared to western countries. The study establishes a significant correlation between lack of estrogen receptors and lymph node involvement and also that expression of HER2 neu receptors are inversely related to the expression of progesterone receptors. Triple negative status of tumours significantly associated with higher tumour grade and tumour size.

Table 1: Distribution of breast carcinomas according to histologic type

Histological type	Frequency	Percentage
IDC-NOS	33	66.0
IDC with DCIS	5	10.0
Multicentric IDC	1	2.0
IDC with medullary component	2	4.0
Invasive papillary carcinoma	1	2.0
Invasive lobular carcinoma	3	6.0
Invasive medullary carcinoma	1	2.0
IDC with paget's disease	1	2.0
Mucinous carcinoma	2	4.0
DCIS	1	2.0
Total	50	100.0

Table 2: Distribution of breast carcinomas according to histologic grade

Histological grade	Frequency	Percentage
Grade 1	4	8
Grade 2	39	78
Grade 3	7	14
Total	50	100

Table 3: Lymph node status and Allred score for ER

Allred score for ER		Lymph Node status			Total
		Not retrieved	Negative	Positive	
0,2	Frequency	0	11	12	23
	%	0.0	45.8	50.0%	46.0%
3	Frequency	1	0	0	1
	%	50.0	0.0	0.0%	2.0%
4-6	Frequency	0	6	3	9
	%	0.0	25.0	12.5%	18.0%
7-8	Frequency	1	7	9	17
	%	50.0	29.2	37.5%	34.0%
Total	Count	2	24	24	50
	%	100.0%	100.0%	100.0%	100.0%

Table 4: Lymph node status and Allred score for PR

Allred score for PR		Lymph Node status			Total
		Not retrieved	Negative	Positive	
0,2	No. of Cases	0	14	13	27
	%	0.0	58.3	54.2	54.0
3	No. of Cases	0	1	1	2
	%	0.0	4.2	4.2	4.0
4-6	No. of Cases	1	5	2	8
	%	50.0	20.8	8.3	16.0
7-8	No. of Cases	1	4	8	13
	%	50.0	16.7	33.3	26.0
Total	No. of Cases	2	24	24	50
	%	100.0	100.0	100.0	100.0

Table 5: Lymph node status and Her2/neu score

Lymph node status		Her2 neu				Total
		Negative	Negative 1+	Equivocal 2+	Positive 3+	
Not retrieved	No. of Cases	2	0	0	0	2
	%	5.9	0.0	0.0	0.0	4.0%
Negative	No. of Cases	17	0	2	5	24
	%	50.0	0.0	66.7	45.5	48.0%

Positive	No. of Cases	15	2	1	6	24
	%	44.1	100.0	33.3	54.5	48.0%
Total	No. of Cases	34	2	3	11	50
	%	100.0	100.0	100.0	100.0	34.0%

Table 6: Allred Score for PR with HER2/neu Score

Allred Score for PR		Her2 neu				Total
		Negative	Negative 1+	Equivocal 2+	Positive 3+	
0,2	No. of Cases	15	1	1	10	27
	%	44.1	50.0	33.3	90.9	54.0%
3	No. of Cases	1	1	0	0	2
	%	2.9	50.0	0.0	0.0	4.0
4-6	No. of Cases	7	0	1	0	8
	%	20.6	0.0	33.3	0.0	16.0%
7-8	No. of Cases	11	0	1	1	13
	%	32.4	0.0	33.3	9.1	26.0%
Total	No. of Cases	34	2	3	11	50
	%	100.0	100.0	100.0	100.0	100.0

Table 7: Triple negative status and histologic grade

ER, PR & Her2/neu status		Histologic grade			
		Grade I	Grade II	Grade III	Total
Triple Negative	No. of Cases	1	8	4	13
	%	25	20.5	57.14	26.0
Others	No. of Cases	3	31	3	37
	%	75	79.5	42.8	74.0
Total	No. of Cases	4	39	7	50
	%	100.0	100.0	100.0	100.0

Table 8: Age range and Mean age of carcinoma breast in various studies

Study	No. of cases	Age range (years)	Mean age (years)
Present Study	50	32-77	51.10
Ahmed *et al.* [8]	157	16-80	43.75
Cadman *et al.* [20]	103	31-83	59
Mudduwa *et al.* [1]	151	31-85	52.5
Konofaos *et al.* [21]	119	36-86	50
Faheem *et al.* [22]	1226	27-84	48.04
Mohsin *et al.* [23]	1042	25-80	45.6

Table 9: Tumour laterality in various studies

	Left	Right	Bilateral
Present study	36%	64%	-
Sofi *et al.* [2]	50.8%	48.5%	0.7%
Nisa *et al.* [24]	57%	43%	-

Table 10: Tumour Size in various studies

Study	Mean tumour size (in Centimeter)
Present study	3.52
Mudduwa *et al.* [1]	3.52
Sofi *et al.* [2]	3.56
Cadman *et al.* [20]	2.1

Table 11: Comparison of various histologic types in other studies

	IDC	ILC	IMC	IPC
Present Study	84%	6%	2%	2%
Zoppi *et al.* [25]	95%	2%	-	1%
Malaviya *et al.* [26]	97.5%	0.5%	-	1%
Stalhammer *et al.* [10]	80%	18%	-	-

Table 12: Histologic grade in various studies

Study	Grade I	Grade II	Grade III
Present Study	6%	78%	10%
Ahmed *et al.* [8]	25.3%	55.2%	19.5%
Mudduwa *et al.* [1]	14.6%	36.4%	49%
Sofi *et al.* [2]	7.6%	52.1%	40.3%
Ayadi *et al.* [10]	10.9%	63.2%	25.8%

Table 13: Comparison of ER, PR and HER2/neu status in various studies

S. No	Study	ER + (%)	PR + (%)	Her2/neu + (%)
1	Present study	54.0	46.0	22.0
2	Faheem *et al.* [22]	62.2	60.9	38.9
3	Mostafa *et al.* [27]	69.0	72.3	28.4
4	R.Kumawat *et al.* [12]	52.0	34.0	-
5	K Rathod *et al.* [28]	32.7	25.3	24.7

Table 14: Histologic Grade with ER/PR and HER2/neu expression

	Grade I		Grade II		Grade III	
Study	Present Study	K Rathod *et al.* [28]	Present Study	K Rathod *et al.* [28]	Present Study	K Rathod *et al.* [28]
ER	66.6	68.7	59	27.02	0	28.5
PR	66.6	62.5	46.2	27.02	20.0	28.5
Her 2 neu	0	6.25	38.5	18.9	0	71.42

Table 15: Triple Negative Breast Carcinoma (TNBC) in various studies

Study	TNBC cases (%)
Present Study	26
Syeda Zubeda *et al*. [29]	46
Ghosh *et al*. [30]	29.80
Rakha *et al*. [31]	16.30
Dunwald *et al*. [32]	25
Bauer *et al*. [14]	12.5

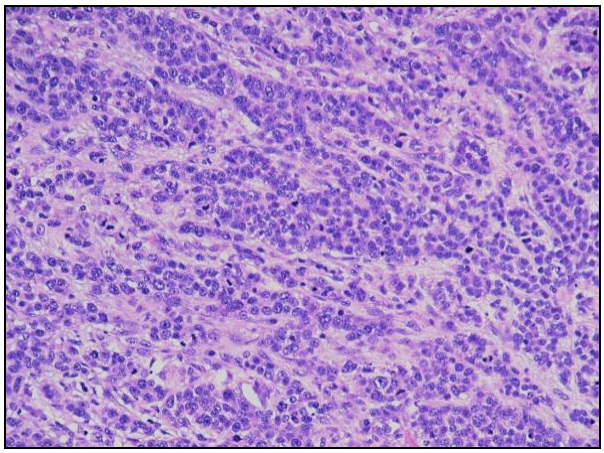

Fig 1: Infiltrating ductal carcinoma (grade III) [H&E, 100X]

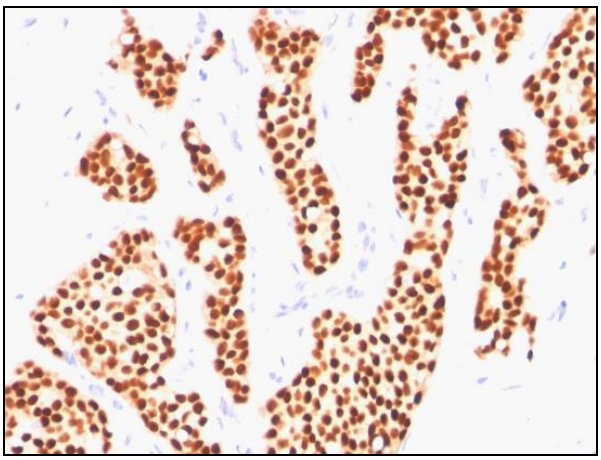

Fig 2: Strong nuclear staining for ER (Allred score: 8) [IHC-ER, 400X]

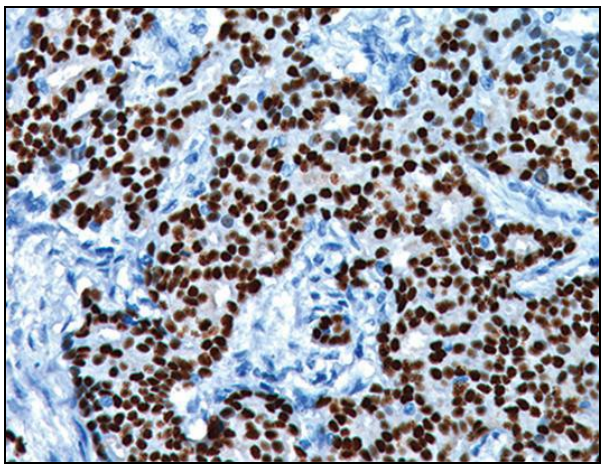

Fig 3: Strong nuclear staining for PR in infiltrating ductal carcinoma (Allred score: 8), [IHC- PR, 400X

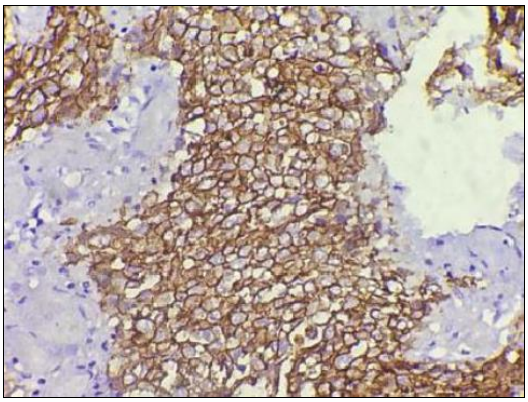

Fig 4: Strong complete membrane staining for HER2/neu (3+), [IHC-HER2/neu, 400X]

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Original Research Article

Aspiration Cytology of Metastatic Cervical Lymph Node: A Tertiary Health Centre Based Study

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ABSTRACT

Objective: the present study was conducted to assess the prevalence and cytological pattern of various metastatic cervical lymph nodes in the southern part of Rajasthan, India.
Material and Methods: The prospective study was conducted in a tertiary healthcare centre of southern Rajasthan, India during the period of 1 year from August 2018 to August 2019. 100 patients with cytologically diagnosed metastatic cervical lymph node were included in the study. Review of all cytological reports were done according to standard guidelines and the diagnosis was classified and correlated with patient age and sex to explore the pattern and association.
Results: Age of the patients' ranges from 29 to 70 years with the mean age of 54.16 years. Maximum patients (80%) were from the age group > 50 years. Among the 100 study participants, 83% were male and 17% were females (Male: Female ratio- 4.89:1). Primary site was known in 89% cases while primary was occult in 11% cases. Out of 89 cases of known primary, 32 cases had primary in oral cavity followed by 24 cases having primary in larynx. On cytological examination, squamous cell carcinoma was found to be the most common type of tumour type (71%) followed by Adenocarcinoma (20 %).
Conclusion: Fine needle aspiration cytology is an effective, economical and reliable method in diagnosing metastasis with good degree of certainty. Squamous cell carcinoma is most common type of metastatic tumour which commonly affects older individuals after the fifth decade with male preponderance.

Keywords: Metastasis, Carcinoma, Lymph Node, cytology, Cytology.

INTRODUCTION

Lymphadenopathy is a sign of inflammation, infections, primary or metastatic tumours. This is commonly seen involving the head, neck and inguinal region. [(1)] Carcinoma metastatic from the head and neck region is the most important of these and must remain prominent in the mind of the clinician. [(2)] Even though the cause of cervical lymphadenopathy may vary, enlarged cervical nodes in an elderly patient must be considered as metastatic until proved otherwise. [(3)]

Fine needle aspiration of neck lymph nodes is quick, safe, very cost effective and simple technique, well tolerated by the patients, without any complication, done on an outpatient basis and repeatable. India is eminently suited for this procedure. [(4)] Metastatic lesions confirmed by FNAC also give clue to the nature and site of primary. [(5)] A correct diagnosis helps in early management thus reducing mortality and morbidity. The present study was performed to know the prevalence of various metastatic cervical lymph nodes in our region. As there is paucity of literature on these matters from

our region, this study will highlight for the same the cytomorphological patterns of neck node metastasis.

MATERIAL AND METHODS

Nature of study and study population: The present study was a prospective study performed in the department of Pathology of Ananta Institute of Medical Sciences, Rajsamand, Rajasthan during the period of 1 year from August 2018 to August 2019. 100 slides of cytologically diagnosed metastatic cervical lymph nodes among the various suspected patients referred for FNAC were included in the present study.

Study period: 1 year from August 2018 to August 2019

Sample size: 100 cases of metastatic cervical lymph nodes

Procedure: A well informed and written consent was taken from all the study participants before starting the study. Approval from institutional ethical committee was also taken. Brief clinical history including age, sex, site, side were taken from all the participants and thorough clinical examination was also carried out. The FNAC was performed by experienced faculty using 20-24 gauze needles without local anaesthesia. Needle was inserted up to the desired depth into the lymph node and adequate quantity of cellular material was withdrawn. A minimum of two well labeled glass smears were prepared. The smears were air dried and stained with Romanowsky stain according to standard procedure. Review of all cytological reports were done according to standard guidelines and the diagnosis was classified and correlated with patient age and sex to explore the pattern and association. All the information collected from the results of present study was correlated with previous studies done in the similar field and results were compared & correlated.

Patients with the diagnosis other than metastatic lymph node and those who refused to give consent were excluded from the study.

RESULTS

100 patients with metastatic cervical lymph nodes were included in present study. Age of the patients ranges from 29 to 70 years with the mean age of 54.16 years. Maximum patients were from the age group > 50 years. (Table 1)

Table 1 Age wise distribution of the study participants

S.No.	Age-group	Number	Percentage
1	< 30 years	01	01
2	31-50 years	19	19
3	>50 years	80	80
	Total	100	100

Among the 100 study participants, 83% were male and 17% were females (Male: Female ratio- 4.89:1). Primary site was known in 89% cases while primary was occult in 11% cases. Out of 89 cases of known primary, 32 cases had primary in oral cavity followed by 24 cases having primary in larynx. (Table 2)

Table 2 Distribution of primary site of the metastatic tumour

S.no.	Primary site	Number of cases	Percentage
1	Oral cavity	32	35.99
2	Larynx	24	26.96
3	Oropharynx	11	12.35
4	Nasopharynx	7	7.86
5	Lung	7	7.86
6	Breast	6	6.74
7	Thyroid	1	1.12
8	Prostate	1	1.12
	Total	89	100%

On cytological examination, squamous cell carcinoma was found to be the most common type of tumour type (71%) followed by Adenocarcinoma (20 %). (Table 3)

Table 3 Cytological diagnosis of cervical lymph node metastasis.

S.No.	Tumour type	Number of cases	Percentage
1	Squamous cell carcinoma	71	71
2	Adenocarcinoma	20	20
3	Undifferentiated carcinoma	6	6
4	Small cell carcinoma	2	2
5	Follicular carcinoma	1	1
	Total	100	100

DISCUSSION

In present study, age of the patients' ranges from 29 to 70 years with the mean age of 54.16 years and maximum number of patients were from the age group > 50 years.

Similar results were obtained in similar studies done in the past. In a study performed by Mehrotra et al in 2005, the commonly affected age group was 50-60 years. [(6)] Ghartimagar et al studied the utility of FNAC in metastatic lymph node in 2011 and found that most commonly affected age group was > 60 years. [(4)] Similarly, in a study by Virendra T et al, the most commonly affected age group was 50-60 years. [(7)]

The male: female ratio in present study was 4.89:1. In the study by Virendra T et al the ratio was 4:1. [(7)]The ratio was 2.9: 1 in the study done by Bhattacharjee et al in 2006. [(8)] The male: female ratio was almost equal in another study done by Engzell et al in 1971 (1.07:1). [(9)]

The most common primary site for metastasis in present study was oral cavity (32%). Izhar N. Bhagwan (2007) and Karabi Kohar et al (2008) also found the oral cavity as the most common primary site for cervical lymph node metastasis. [(10, 11)] In a study performed in china by Chih Hsu et al in 1971, the most common site for cervical lymph node metastasis was nasopharyngeal carcinoma. [(12)] We all know; the incidence and mortality of nasopharyngeal carcinoma are highest in china because of their specific diet and genetic inheritance. In a study performed by Malika Afroz, the most common primary site was larynx. [(13)]

In present study, the most common type of tumour was squamous cell carcinoma (71%) followed by adenocarcinoma (20%). Other types were undifferentiated carcinoma (6%), small cell carcinoma (2%) and follicular carcinoma (1%).

In squamous cell carcinoma, tumour cells are seen arranged in sheets or scattered singly. The cells had dense cytoplasm with hyperchromatic nuclei owhile cynophilic cytoplasm with pyknotic nuclei in PAP stain. Necrotic material is often present in the background and keratinization may also be found.

In adenocarcinoma, the tumour cells are arranged in acinar or papillary arrangements or singly scattered. Cells are cuboidal to columnar with moderate amount of cytoplasm and pleomorphic nuclei with prominent nucleoli. Intracellular mucin secretion is present.

In undifferentiated carcinoma, there is pattern less solid, sheet like growth of tumour cells. There are no nests, papillae, glands, trabeculae or spindle pattern, no squamous or mucinous metaplasia, no or minimal neuroendocrine differentiation. In present study, the undifferentiated carcinomas were mainly from the nasopharynx.

Metastatic small cell carcinoma was seen in 2 cases of present study where the primary was found to be in lungs. In small cell carcinoma, the cells have scanty cytoplasm with large nuclei. Nuclei usually demonstrate the classical “salt and pepper” chromatin with indistinct nucleoli and frequent molding.

One case of metastatic follicular carcinoma with suspected primary in thyroid was also encountered in present study.

Squamous cell carcinoma has been found as the most common verity in other studies done in the past by Ustun et al, [(14)] Izhar N. Bhagwan [(10)] and Kiran Alam et al. [(15)] In contrary to our result, adenocarcinoma was the most common variety in a study performed by Ghartimagar D. et al. [(4)]

CONCLUSION

Fine needle aspiration cytology is an effective, economical and reliable method in diagnosing metastasis with good degree of certainty. Squamous cell carcinoma is most common type of metastatic tumour which commonly affects older individuals after the fifth decade with male preponderance. Unnecessary use of invasive methods like surgical biopsy can be avoided with the use of FNAC.

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Pattern and Prevalence of Congenital Malformation of Fetus: Autopsy Based Study

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Abstract

Introduction: Autopsy is an important aspect of clinical service, providing clinicians with critical feedback regarding diagnostic accuracy, therapeutic efficacy, and medical complication [1]. Rajasthan has reportedly the second Indian state having highest number of child marriages in the country with more than 60 percent of girls getting married before 18 [1]. The practice of child marriage is common in Rajasthan. Along with cultural incest marriage leads to one most important causes of fatal anomalies. Early diagnosis of life threatening congenital malformation can pave the way for surgical correction or palliation of these infants [1].

Material and Method: We studied 217 cases of fetal autopsies from January 2017 to October 2018 duration of one year retrospective study. Purpose of study is pathological and legal correlation in aspect of M:F ratio, age of termination of pregnancy, fetal anomalies & its pattern In Pacific Institute of Medical Sciences (PIMS) and M.R. Medical College, Gulbarga, Karnatka.

Results: Total fetal autopsies done are 217, out of which 51 are anomalous.Among them 22 are male and 28 are female babies and 1 sex is not determined {ambiguous}. In our study M:F ratio is 1:1.35. Most common cause of death found in autopsy examination is meconium aspiration in male fetus and placental insufficiency in female fetus. And mean age of gestation is 29 week and 30 weeks respectively. Mean age of the mother is 29 years.

Conclusion: Fetal autopsies provide us an important information about pattern of anomalies, their incidence and cause of death in relation with sex and age of fetus, maternal age, along with socio-economical status. Legal implications regarding fetal autopsies is still a field of interest.

Keywords: Fetal Autopsy: Fetal Anomalies: Legal Aspects.

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Introduction

Fetal autopsy includes external, internal and histopathological examination of dead fetus along with placental examination [2].

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There are two types of fetal autopsy.

1. Medico-legal autopsy
2. Academic autopsy

Medico legal Autopsy– is conducted on requisition of police under section Crpc -174 to know the cause of death, age, sex and viability of fetus for which police inquest& panchnama is required [2].

Academic Autopsy / Clinico-pathological Autopsy– is conducted on request of obstetrician, pediatrician, radiologist or family members of fetus to know the cause of congenital malformation if any and cause of repeated abortions, where in the detail pre and post natal history of mother and consent of parents /relatives with the collaboration of concerned department is necessary [2]. Placental examination is done to know the cause of death to certain extent and placental pathology explains the cause of prematurity.

In our study we performed 217 cases of fetal autopsy to rule out cause of death and associated anomalies, which is helpful in future family planning for couples and improvement of management of anomalous babies

Etiological diagnosis in unexplained fetal deaths is possible with detailed evaluation of fetus. Fetal autopsy is confirmative in 28.6-89%, diagnostic in 10-38%; it provided additional information in 3.9-24% cases; it changed the predicted probability in 18% cases In addition, the data pertaining to demography, socio-economic status, and maternal health is helpful to pinpoint the factors behind the occurrence of fetal loss.

Congenital anomalies were estimated to be the fifth largest cause of neonatal deaths in India after preterm births (34.7%), intrapartum complications (19.6%), pneumonia (16.3%) and neonatal sepsis (15%) Despite this ranking, in absolute numbers, congenital anomalies were estimated to contribute to 60699 neonatal deaths in India in 2013, which accounted for the highest global burden of neonatal mortality due to congenital anomalies India lacks national birth defects surveillance, indicating that there is no data on the magnitude of congenital anomalies in the country [7,8]. Thus, systematic data on the magnitude of congenital anomalies, the most prevalent types of congenital anomalies, their healthcare impact and their impact on neonatal health are required, especially as India has announced a program me for the management of children born with selected birth defects like cleft palate lips etc. [9,10].

Materials and Method

We studied 217 cases The present study of congenital anomalies in fetal and neonatal deaths was done at PIMS. Study conducted over a time period of 8 month from January 2017 to october 2018. Consent for autopsy in requested compassionately, respectfully and was fully informed. Autopsy was within the scope of the autopsy permit and all the legal requirements are met before it is conducted. The dissecting instruments required for fetal and neonatal (perinatal) autopsy are small scissors and forceps and scalpels. The autopsy protocol was including space for recording specific measurements and norms for particular gestational ages.

Measurements

The crowns heal length (CHL) and crown rump (CRL) length determined to the nearest 0.5 cm. Chest and abdominal circumferences were taken at the level of the nipple and umbilicus respectively. Both limb measurements has been taken. The metric documentation of changes in the face is often a valuable component of the autopsy. So the distances between the inner canthi and outer canthi, nasal height and width, philtrum height, mouth width and ear length are obtained and compared with published norms. Weights: Scales accurated to 0.1 gm.in perinatal specimens. All major organs weighed (i.e. thymus, heart, lungs, liver, spleen, kidney, adrenal glands, brain and placenta) and the date recorded in the autopsy protocol along with expected values. Photographs were taken which provide indisputable evidence of findings and study of dysmorphic face images, for important diagnostic information [3].

Inclusion and exclusion criteria

The present study included dead fetus and neonates with gestational age 18 to 40 weeks of intra uterine life. All fetuses of gestational age <12 weeks and all neonates above 7 days of age were excluded from the study. Autopsy was performed by standard technique adopted by Edith L. Potter.

Procedure

1-External examination

Done for inspection of cyanosis, injuries and maceration, skin lesions, all major and minor developmental anomalies were described. The y shaped incision was taken which extend from the anterior aspect of each shoulder to the xiphoid process. Umbilical vein examined for signs of inflammation, vernix, rupture (or) thrombus. The two umbilical arteries are examined and inspected in their entirety. The arteries and urachus examined for patency and the arteries for hemorrhage (or) thrombosis. Single umbilical artery was an important anomaly noted. The autopsy protocol included the removal of thoracic, cervical, abdominal and pelvic organs en block and subsequently dissected into organ blocks [3].

2- Internal examination

All internal organs position and size and weight were examined. The internal genitalia are inspected. As the testis will be undescended in younger fetuses, are removed with abdominal contents. Prior to opening of the pleural cavities

the possibility of pneumo thorax is ruled out. on entering the chest each cavity inspected for fluid. Each lung was examined for developmental changes carefully. The integrity and tension of the pericardium are ascertained and the pericardial cavity is looked for the presence of free gas (or) fluid and fibrinous deposition. Heart examined in situ, while anatomic relationship with structures were intact, inspected externally and internally, in a systematic fashion that follows the flow of blood. All major veins and arteries were examined. The diagnosis of premature closure of foramen ovale if any are noted. The configuration of tricuspid valve, right ventricle, and main pulmonary artery were studied. The endocardium, myocardium, and configuration of trabeculae, pectinate and papillary muscles and chordae tendineae were examined. After opening the left part of heart, the interior of the left atrium [3] pulmonary venous orifices, mitral valve and left ventricle were inspected, followed by examination of the aortic valve and ascending aorta All other organs were removed en bloc by the rokitansky methods of evisceration. Neck structures trachea and esophagus were examined. The scalp, fontanels, and cranial sutures were examined by palpation and any changes were documented. The fontanels, sutures, and glia were examined and any changes were documented. brain has been exposed and examined in situ. Then the brain was removed and examined on all sides and placed in fixative. Attention to the cranial base and dural sinuses was given [3].

3- Dissecting the viscera

Examination begins with the most posterior structures and moved anteriorly layer by layer. Aorta, inferior vena cava, adrenal glands and posterior surface of the urinary system exposed and examined. Adrenal glands, kidneys, ureters and urinary bladder were examined. The vagina and uterus were opened in the anterior midline and examined. The liver, gallbladder and structures of the porta hepatis, portal vein, hepatic artery and common bile duct were identified and dissected as indicated [3].

The esophagus was opened in the posterior midline while intact with trachea. In this way a trachea-esophageal fistula can be identified and opened. Next the incision carried into the stomach. After major hilar structures of the lungs have been opened and inspected, attention was turned to the lungs. Lobation and condition of the visceral pleura were presumably ascertained. In case of bladder outlet obstruction, the entire urethra is examined for posterior urethral valves (or) other abnormalities (i.e., anterior urethral valves, mega urethra). Placenta was available in only few cases [3].

4-Histopathological examination

The organs after evisceration and external examination were fixed in 10% formalin. Blocks of tissues for microscopic examination were taken, one block from each lobe of both lungs. One block each from thymus, heart, stomach, liver, spleen, pancreas, small intestine, large intestine, kidneys, adrenals, and any doubtful lesions were taken. Sections were studied in the routine way with Haemato-xylin and Eosin (H&E) stains. Special stains were done whenever necessary and studied. Autopsy findings were compared with ultrasound findings whenever available.

Results

In present study out of 217 patients 213 (98%) were fetal death and 4 (2%) cases of neonatal death were included in present study. Among 217 cases 51 found to anomalous. Relation between maternal age and neonatal death mean age of mother was 29 years. 99 (45.6%) fetal death seen in maternal age group was 20-24 years. While in neonatal death maternal age most commonly involved was 25-29 years.

External anomalies most commonly seen in present study was Neural and spinal malformations that included 77% of external anomalies. While Lymphatic system & Circulatory system involvement was only 5.5% in present study.

In Internal congenital anomalies diaphragmatic hernia (40%) was most common anomaly seen followed by atelectasis of lung i.e. 33% in present study. Cardiac and genitourinary anomalies involvement was 13% respectively.

Relationship between anomalous fetus and weight of fetus reveals that 47 anomalous fetus had weight of 1000 gm, 800 gm & 750 gm respectively while 4 fetus had normal weight range 2.5 to 3.5 kg. And 30-34 year of maternal age involved maximum number of anomalous fetus which was 47% seen in present study.

Anomalous pattern in 22 male fetus involved Neural and spinal Malformation (8 cases) > Pulmonary malformation (6 cases) > cardiac malformations (3 cases) > genitourinary & Renal malformation (1 case) and in miscellaneous 4 cases

2 cases diagnosed as Edwards syndrome. while anomalous pattern in female fetus included no of cases were 28, female fetus it s bit higher incidence as compare to male fetus anomalies ratio of anomalies in study was 1:1.3, Neural and spinal Malformation (8 cases) > Pulmonary malformation (7 cases) > Genitourinary & Renal malformation (6 cases) > cardiac malformations (1 case). In miscellaneous category total number of cases were 6 cases among them 2 cases diagnosed as Klipilfeil Syndrome & 2 cases diagnosed as Achondrodysplasia in present study. Thanatropic dysplasia seen in 1 case (sex was not determined). As we mentioned consensual marriage incidence in our study is 83%, 180 cases had history of consensual marriage a great significance in formation of anomalous fetus pattern and preventable cause by spreading awareness among population subgroups. There is no toxicological study done in present study due to lack of any relevant significance because cause of death known in all cases as malformation.

Table 1: Percentage of fetal deaths (FD) and early neonatal death (END).

Classification	No. of cases	Percentage (%)
Fetal death (FD)	213	98
Neonatal death (ND)	04	2
Total		

Table 2: Relation of maternal age (yrs) with no of fetal/neonatal deaths

Maternal age (years)	fetal death		Neonatal Death	
No.	No	%	No	%
19	3	1.38		
20-24	99	45.6		
25-29	81	37.3	3	1.38
30-34	23	10.5	1	0.5
s35-39	07	3.22		
Total	213		4	

Table 3: External congenital anomalies

System affected	Type of anomaly	No	%
Neural &spinal malformation	Anencephaly	5	28
	Omphalocele	1	5.5
	Meningocele	5	28
	Hydrocephalus	2	11
	acephalus	1	5.5
Lymphatic system	Hamartoma nape of neck	1	5.5
Skeletal system	Achondroplasia	2	11
Circulatory system	Single umbilical artery	1	5.5.
Total		18	

Table 4: Internal congenital anomaly

	Type of anomaly	No.	%
Respiratory system	Atelectasia of lungs	5	33
Genitourinary system	Polycystic kidneys	2	13
Cardiac system	Tetrology of Fallot	1	6.6
	Hypoplastic heart	1	6.6
others	Diaphragmatic hernia	6	40
Total		15	

Table 5: Relation between Maternal age , Fetal weight and fetal anomaly

Total anomaly	Mother Age (Yr)	Fetal anomaly	Fetal weight (Mean wt)	
51 cases			Total no case-47	Total no of case – 04 case
	25-29	20	1000 gm	
	30-34	24	800gm	2.8 kg
	35-39	07	750gm	

* 04 Cases Having Normal Weight Range 2.5 -3.0

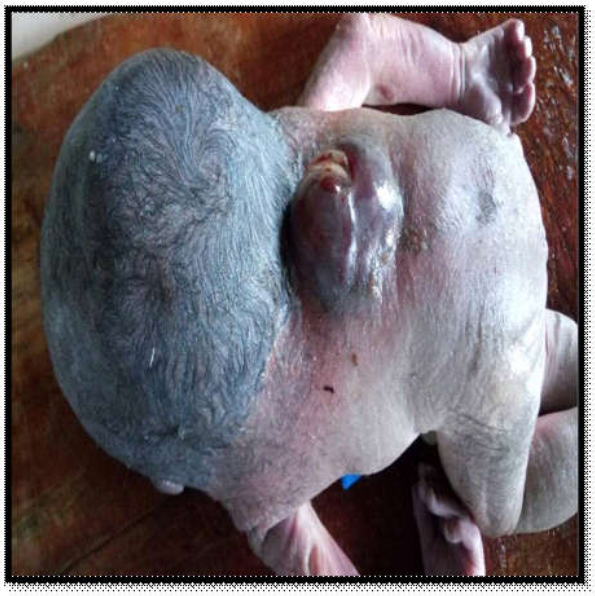
Table 6: Fetal Anomaly Pattern According to Sex Distribution Anomaly Pattern in male fetus-22 Cases (Study of 217 Cases)

Sno.	Neural & Spinal Malformation 8 Cases	Cardiac Malformation 3 Cases	Pulmonary Malformation 6 Cases	Genitourinary / Renal Malformation 1 Case	Miscellenous 4 Cases
1	Anencephaly -1	Myocarditis-1	Atelectasis – 3 cases	Poly cystic Kidney -1	Hydrops Fetalis-1
2	Anencephaly with Spinabifida-1	Tetrology of Fallot -1	Diaphragmatic Hernia – 2cases		Chlongiomatous placenta-1
3	Omphalocele-1	Hypoplastic Heart -1	Congenital Adenoid Cystic Malformation-1		Edward syndrome (Trisomy – 18) – 2 cases
4	Meningocele -1				
5	Meningocele-Myelocele-1	-	-	-	-
6	Meningocele Encephocele-1	-	-	-	-
7	Hydrocephalus-1	-	-	-	-
8	Hydrocephalus with Spinabifida-1	-	-	-	-

Table 7: Anomaly pattern in female fetus study of (total 217 cases) – 28 cases

S.No.	Neural & Spinal Malformation -8 Cases	Cardiac Malformation-1 Case	Pulmonary Malformation-7 Cases	Genitourinary / Renal Malformation-6 Cases	Miscellenou-6 Cases
1	Anencephaly – 3cases	Ebstein Anomaly	Partial Atelectasis – 2cases	Uretheral Stenosis	Sacrococcygeal teratoma
2	Anencephaly with Spinabifida- 2case		Diaphragmatic Hernia – 2cases	Extrophy Bladder	Hamartoma of Nape of neck
3	Anencephaly with spinal deformity		Diaphragmatic Hernia with CCAM Type II– 2cases	Winters Syndrome – Renal Dysplasia	Achondrodysplasia – 2cases
4	Acephalous		Congenital Adenoid Cystic Malformation TYPE III	Bilateral Renal Cystic Diseases	Klipilfeil Syndrome – 2 cases
5	Meningocele-occipital			Mermaid – Renal Agenesis	
6				Renal – Hepatic -Splenic Dysplasia	

* Thanatropic dysplasia – 1 case (sex not determined), m:f- 1 :1.3 , Total anomalous – 51 cases



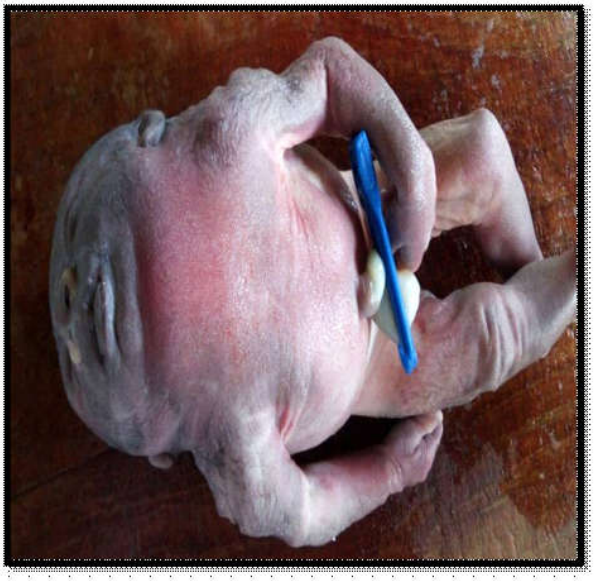


Fig 1: Gross – fetus with short neck (web neck) and meningocele

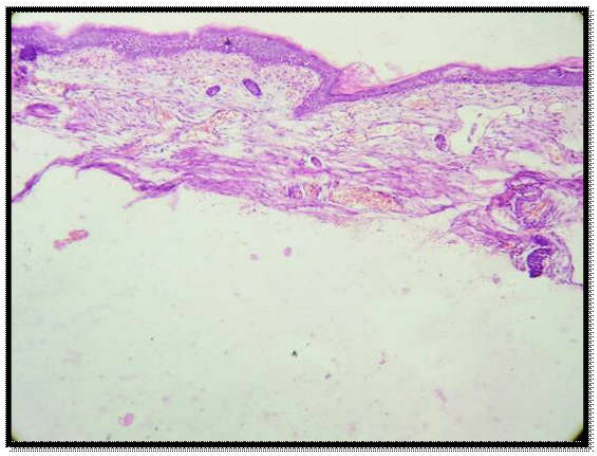


Fig. 2: H & E (400x) section reveals meninigocele-showing kertinized stratified squamous epithelum with neural tissue

Fig. 3. Gross–lung showing multiple cystic lesion

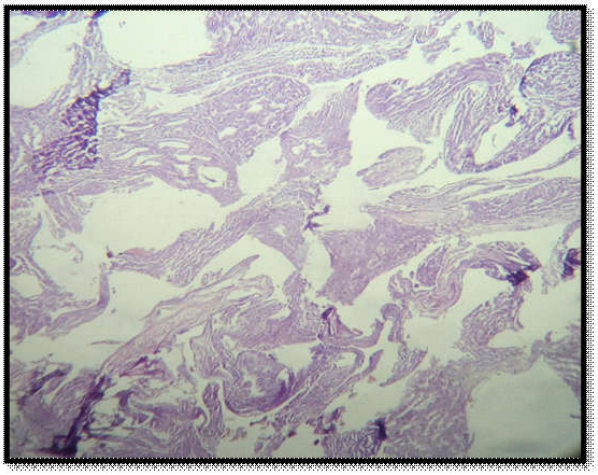


Fig.4: H & E (400x) section showing congnital cystoid malformation type-1

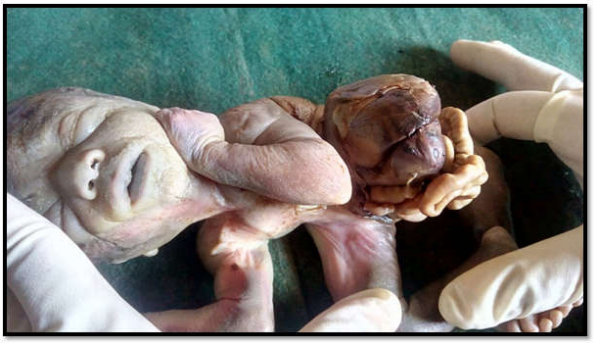


Fig. 5: Gross - fetus showing polycystic kidney &omphelocele

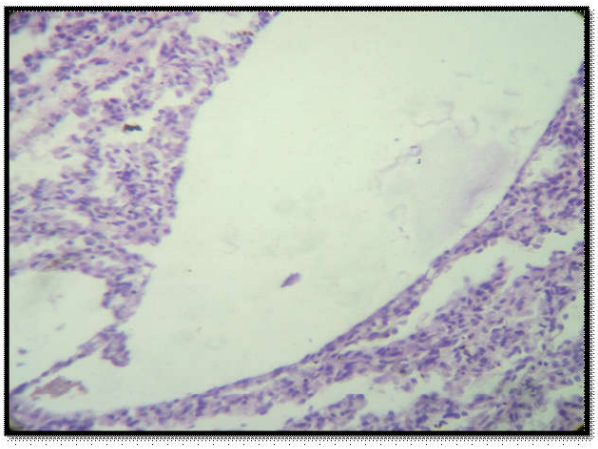


Fig. 6: H&e (400 x) section showing multiple cystic lesion - polycystic kidney

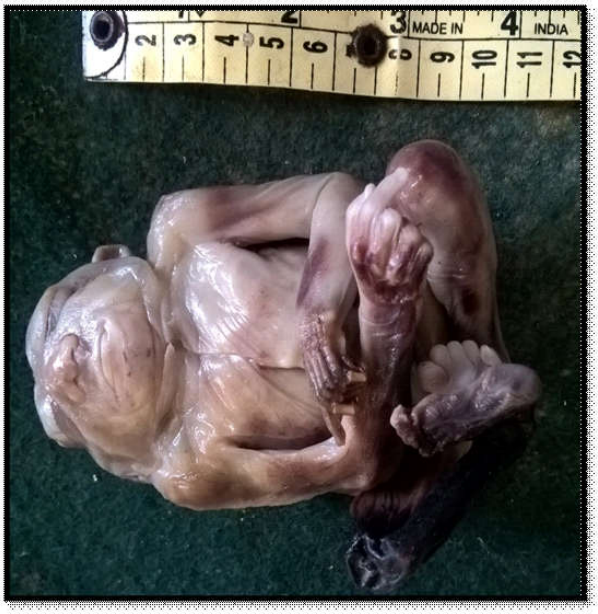


Fig. 7: Gross picture fetus showing microcephaly

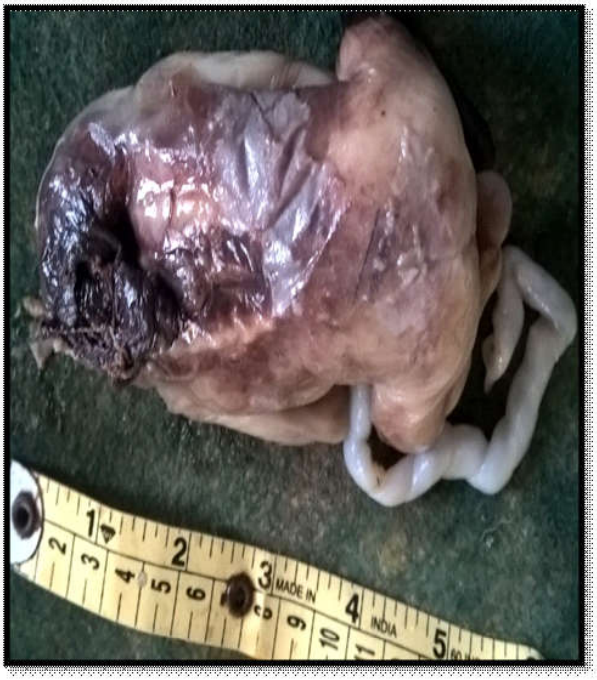


Fig. 8: gross picture fetus showing meningocele

Discussion

Fetal autopsy significantly contributes to the diagnosis of intrauterine fetal death and congenital anomalies are a major cause of perinatal death. Congenital malformations in fetal and neonatal deaths vary in different studies. The study of malformations greatly helpful in genetic counseling

and prenatal diagnosis in successive pregnancies1.

In the present study 217 fetal and neonatal autopsies were carried out among 213 fetal and 04 neonatal deaths that occurred in PIMS, during the period from Jan 2018 to Oct 2018. Prevalence of Congenital malformations account for 23.5% of fetal and neonatal deaths. This incidence matches with the study by Rabah M. Shawky, Nermine S. Elsayed

Maternal Factors

In present study, the incidence of congenital malformations were higher in mother's age group of 25 to 39 years. In 25 to 29 years out of 217 fetal and neonatal deaths 20 (9.2%) cases got anomalies. In 30 to 34 years of maternal age group, 24 (11.05%) cases got anomalies. In 35-39 years of maternal age group, 07 (3.2%) cases got anomalies many authors have shown higher incidence of malformations in the babies born to maternal age between 20 to 35 years. The observations in the present study is that 90% of the cases belong to multi gravid and 10% cases belong to primi gravida. In our study the incidence of congenital anomalies were increased with the increase in maternal age

Fetal Factors

In present study, the incidence of congenital malformations were higher among the low birth weight infants (<1500 gm) in comparison to the normal weight accounting for 04 cases. The association of low birth weight and malformations has been well documented. Many studies have documented male predominance amongst congenital malformed babies. However, in the present study we observe 22 male babies and 28 female babies with congenital malformation. In a five year study on major congenital anomalies in Turkey by Tomtair et al., 14 there were 183 cases (2.9/1000) of single (or) multiple congenital Anomalies among 63,159 live births. The most common anomalies were related to the nervous system (31.1%), cleft palate and lip (18.6%), musculoskeletal system disorder (14.2%) and chromosomal anomalies (13.1%). Both genders were found to have greater anomalies related to the nervous system (34.9% of girls and 28.3% of boys) while amongst.

In present study CNS malformation is the most common. (17cases 8%) in 217 cases. Among them most common follows the order Meningocele > Anencephaly > Hydrocephalus. Second most common malformation is pulmonary malformation (13 cases 6%) in 217 cases ,most common is Diaphragmatic Hernia than Atelectasis of Lung. Urogenital malformation (7 cases 3.2%) in 217 cases – with female predominance.

Benefits of Autopsy

The direct benefits of autopsy to parents are not limited to refining the risk of recurrence. Even after autopsy, sometimes a definitive final diagnosis cannot be made and information given to parents may cover a range of possible diagnoses. In such cases the storage of fetal samples for possible future genetic analysis provides the hope of an accurate diagnosis (which may have ramifications for the wider family) at a much later date. In most cases in which the scan findings are confirmed parents can gain comfort that their baby had the prenatally suspected condition. The finding of additional malformations, as well as in some cases changing the diagnosis, may be helpful in targeting tests in a subsequent pregnancy. A wider importance of autopsy is in its value for quality control for prenatal diagnosis, teaching, and research [5].

The decline in autopsy rate and issues surrounding the retention of tissues and organs for diagnostic studies, teaching, and research has been the subject of much debate since the adverse publicity concerning autopsies and organ retention Parents should be provided with full information and not be coerced into accepting an autopsy examination. It is important that those advising them at such a sensitive time do not take what may be the superficially kinder route of avoiding detailed discussion about the autopsy. Parents need full information about the potential benefits of the examination, including details both about the procedures involved and about the benefits in providing information about risks of recurrence if they are to make a truly informed decision. This discussion should be with an appropriately trained professional [5].

Our study provides important information for parents. If a termination has been carried out because of anomalies detected by ultrasound scan, by declining an autopsy, parents will remain ignorant of information of recurrence risk.

Conclusion

The study of dead is to save the livings. Congenital malformations have become important cause of fetal and neonatal mortality in developed countries and would very soon be increasingly

important determinants of fetal and neonatal mortality in developing countries like India and of various states- like Rajasthan, Karnataka & Andhra Pradesh where consensual marriage is common which is known cause of congenital malformation This study was undertaken with the purpose of finding out cause of death during the perinatal & neonatal period at PIMS Udaipur, to see pattern and prevalence of congenital anomalies and implication of legal aspects of fetal autopsy.

Confliction of interest: No

Ethical clearance: Not necessary.

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Section Pathology

Original Article

Cyto-Histopathological Correlation of Breast Lump as a Part of Internal Quality Control

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ABSTRACT

Background: *Breast malignancy is the most widely recognized tumor in females around the world. With the advent of fine needle aspiration cytology (FNAC), the approach to diagnosis and management of breast lesions has been revolutionized. Its accuracy in many situations can approach that of histopathology in providing an unequivocal diagnosis.*
Hence a review was undertaken with the following objectives.
1. To correlate cytological and histopathological diagnosis of breast lesions as a part of internal quality control.
2. To know the incidence of false positive and false negative cases.
3. To find out the sensitivity and specificity of FNAC of breast lesions.
Methods: *This study was conducted for a period of 2 year and 102 aspirations of breast lumps studied. Out of which 82 cases were followed- up by histopathological correlation.*
Results: *Cytological diagnosis in general was divided into four categories, benign (76.29%), malignant (18.29%), suspicious (2.44%), and unsatisfactory (00). Age of the patient was range from 16 - 62 years with mean age of 32 years. There were 76 female patients and 06 male patients. Fibroadenoma (54.87%) was most common benign neoplasm. The two cases which were categorized as "Epithelial Hyperplasia, Suspicious" by cytology turned out to be malignant lesions on histopathology. Sensitivity and specificity of FNAC in breast lesions were reported to be 88.24 % and 100% respectively, with 100% positive predictive value and 97.01% negative predictive value.*
Conclusion*: Considering the high specificity and sensitivity of aspiration cytology in the cases of breast lesion, it can be established as an internal quality control at tertiary centre to minimize economical stress demanded for EQAS (External Quality Assessment Scheme).*

Key words: *FNAC; Breast lumps; Quality Control*

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INTRODUCTION

A palpable breast lump is a common diagnostic problem both to the general practitioner and to the surgeon.[1] In addition to enormous reservoir of benign pathology, breast cancer is the most common form of cancer among women and the second most common cancer in the world, trailing only lung cancer.[2] Women have a lifetime breast cancer risk of approximately 1 in 8 (12%) and is one of the leading causes of cancer mortality among woman.[3]

Traditional management of breast lumps has been surgical biopsy. As the number of biopsies has increased, the cost of screening for breast cancer is also increased. The need for cost containment has led to interest in alternative methods to open biopsy that could provide definitive diagnosis of breast cancer. Fine needle aspiration represents such an alternative technique.

FNAC can reduce the number of open breast biopsies.[4] It has been shown that, clinical examination in conjunction with fine needle aspiration cytology and mammography, also known as "triple approach" can divide almost all breast

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lesions preoperatively into benign and malignant categories. This technique was suggested by Kreuzer and Boquoi (1976)[5] and Hermansen et al (1987).[6]

The concept of quality control, which is deeply rooted in most other disciplines of laboratory medicine, is relatively young in the histopathology department. Unlike in other disciplines of laboratory medicine, assessment of analytical aspects in histopathology is not easy given the subjectivity of the reports. Error detection and avoidance in histopathology has been written about very often.[7-11]

The present study was undertaken with the aim of cyto-histopathological correlation to understand the lesion more clearly and if it can be used as one of the objective criteria for Internal Quality Control.

METHODS

The present study was carried out at Ananta institute of Medical science and research Centre, Rajasthan. FNAC was done on 107 patients with breast lesions, among which cyto-histopathological correlations were obtained in 82 cases. FNAC was done by standard procedure on palpable breast lumps. Palpable axillary lymph nodes, wherever indicated, were aspirated to exclude metastases. The slides were stained with Papanicolaou stains. Correlation with imaging studies, including mammography, was done.

The surgical specimens received were fixed in 10% formalin. The gross and cut section findings were noted. Several bits were taken from appropriate sites for processing and paraffin embedding. From each block, sections were cut at 4-5 microns thickness and stained by H&E.

The breast samples from FNAC were further sub-classified into definite breast disease entities. The final histopathological diagnosis of each case was then compared with the cytological diagnosis.

Results thus obtained were subjected to statistical analysis.

RESULTS

A total of 107 cases of FNAC were analyzed into the study. Out of 107 cases, 82 (76.63%) histopathology correlations was done in the department. The 6 (7.32 %) cases were male while 76 (92.68%) were female. Age of the patient was range from 16 - 62 years with mean age of 32 years.

Table 1: Age incidence of breast lesions (of 82 cases)

Age range	No. of cases	Percentage
0-10	00	0 %
11-20	22	26.83 %
21-30	31	37.80 %
31-40	18	21.95 %
40-50	07	8.54 %
>50	04	4.88 %
Total	82	100 %

Table 2: Sex incidence

Sex	Total no. of cases	Percentage
Female	76	92.68 %
Male	06	7.32 %

Cytological diagnosis of 82 aspirations was reviewed and lesions were classified into four diagnostic classes revealing 65 (79.26 %) benign lesions, 15 (18.29%) malignant, 02 (2.44%) suspicious and nil inadequate.

Tab 3: Cytological findings in breast FNA smears in general

Cytological diagnosis	No. of cases	Percentage
Benign	65	79.26 %
Malignant	15	18.29 %
Suspicious	02	2.44 %
Unsatisfactory	00	00 %
Total	82	100 %

Table 4: FNAC diagnosis of Breast Lump

Cytological diagnosis	No. of cases	Percentage
Fibroadenoma	45	54.87 %
Chronic Mastitis	04	4.87 %
Granulomatous Mastitis	02	2.44 %
Galactocele	02	2.44 %
Fibrocystic Disease	05	6.10 %
Gynecomastia	06	7.31 %
Phyllodes tumor	01	1.22 %
Epithelial Hyperplasia, Suspicious	02	2.44 %
Carcinoma Breast	15	18.29 %

In our study we have recorded 45 (54.87%) cases of Fibroadenoma. The 91 % of fibroadenoma cases were seen in the age group of 15-35 yrs. Histopathology available in all 45 cases of Fibroadenoma which shows 100% sensitivity and specificity for FNAC.

This study documented the fact that benign breast lesions were the most common lesions in young females, among which the Fibroadenoma was the commonest one. The malignant lesions were common in fourth and fifth decades of life. The two cases which were categorized as “Epithelial Hyperplasia, Suspicious” by cytology turned out to be malignant lesions on histopathology and they were diagnosed as Invasive ductal carcinoma. Rest of all cases showed good correlations between FNAC and histopathology.

Following cyto-histopathological correlation, sensitivity, specificity, positive predictive values were calculated in accordance with Park. There were two false negative cases and no false positive cases in this study. In the present study, the sensitivity in diagnosing malignant lesions was 88.24%, specificity was 100 %. PPV and NPV were 100 % and 97.01 % respectively.

DISCUSSION

FNAC of breast lumps is an accepted and established method for determining the natures of breast lumps with a high degree of accuracy.[12,13] Most of the patients with breast lumps are in a state of anxiety. So, in reducing anxiety and unnecessary surgical procedures as well as in minimization of delay in the diagnosis, FNAC proves very fruitful. FNA procedure is a safe method with only a few reported complications. It has been reported in the literature that the incidence of tumour transplantation along the needle track by FNA procedure is only about 0.0045%, and even much lower in superficially located tumours.[14]

In the present study, all the 15 cytologically diagnosed malignant cases were confirmed as malignant on subsequent histopathological examinations. So, in our study, a 100% cyto-histopathological correlation was observed for malignant lesions. Khemka et a,l[15] Ramesh S et al[16], Tiwari M[17] had also observed the same results in their studies.

Table 5: Cyto-Histopathological Correlation (n=82)

FNAC↓	Histopathological Diagnosis →						
	Inflammatory Lesion	Fibroadenoma	Fibrocystic disease	Phyllodes tumor	Galactocele	Gynecomastia	Breast carcinoma
Inflammatory Lesion	06						
Fibroadenoma		45					
Fibrocystic Disease			05				
Phyllodes tumor				01			
Galactocele					02		
Epithelial Hyperplasia, Suspicious							02
Gynecomastia						06	
Carcinoma Breast							15

Table 6: Calculation of statistical value

FNAC	Histopathology	
	Benign	Malignant
Positive for Malignancy	00	15 (TP)
Negative for Malignancy	65 (TN)	02 (FN)
Total	65	17

Table 7: Statistical indices of present study

Statistical indices	TP	TN	FP	FN	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
	15	65	00	02	88.24%	100%	100%	97.01%

Table 8: Comparison of sensitivity, specificity, positive predictive value and negative predictive value by various authors

Author	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
Khemka et al [15]	96	100	100	95.12
Ramesh S et al [16]	88.24	100	100	93.2
Tiwari [17]	83.3	100	-----	-----
Pandit et al [18]	83	100	100	91
Norton et al [19]	89	100	100	90
Bojia F et al [22]	94.3	78.6	68.8	96.5
Watson DP et al [23]	74	99.6	68.8	96.5
Clive et al [24]	92	100	100	85
Kline et al [25]	86	100	100	95
Wanebo et al [26]	99	100	100	99
Present Study	88.24	100	100	97.01

In the present study, 2 cases which were cytologically diagnosed as lesions "suspicious for malignancy" were confirmed as malignant lesions on doing histopathological studies. Other studies also noted an increase in rate of malignancy on histopathology in lesions which were previously diagnosed under the category of "suspicious lesions for malignancy". The sensitivity of our study is 88.24% similar results has been observed with other studies.[16-19]

A difference was noted in the incidences of benign and malignant breast lesions amongst various studies, which may be explained on the basis of variables like the duration of study period, number of cases studied, age group of patients, etc.

In developing countries like ours, economical restrictions, low budget for health care and screening program put the patients at a disadvantage because of the high cost of sophisticated diagnostic methods, thus we recommend that FNAC be used as a routine diagnostic method because of its low cost compared with the others and this policy maximizes the availability of health care to women with breast cancer.

CONCLUSION

FNAC is an initial diagnostic modality in breast lumps. It is fairly safe procedure and it gives reasonably accurate results, thereby helping the clinicians to plan the best line of treatment. The high specificity and a high negative predictive value for malignancy illustrates the high accuracy of FNAC in the diagnosis of malignancy in the breast. Hence the cyto-histopathological correlation can be used as one of the criteria for internal quality control.

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Section Pathology

Original Article

Relationship of Platelets Count and Serological Marker of Dengue Infection: A Prospective Study

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ABSTRACT

Background: *Dengue fever is a mosquito-borne virus disease of humans. In terms of numbers of individuals infected, it is by far the most devastating of all the recognized arthropod-transmitted virus diseases. It is estimated that more than 3 billion humans live in dengue endemic regions of the world, and currently, more than 50 million infections occur annually with at least 500,000 individuals requiring hospitalization.*

Methods: *This study was conducted in Department of Pathology, Ananta Institute of Medical Sciences and Research Centre, Rajsamand. A total of 160 serum positive samples from clinically suspected dengue patients attending outdoors, causality services and indoor patients were included in this study. Five milliliter of blood was collected from all suspected cases of dengue fever.*

Results: *In our study, 525 total samples were included in this study. 160 samples were positive out of 525 samples. In the present study, 53.7% were males and 46.3% were females. In this study showed relationship between Platelet count and other parameters. From which notice that, 110 patients had less than 1 lakh count.*

Conclusion*: Thrombocytopenia found in case of fever which is more constantly in dengue positive sooner than dengue negative cases. It correlates well when NS1 & IgM are found simultaneously.*

Key words: *febrile illness, Dengue virus, endemic, IgM, IgG, NS1*

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INTRODUCTION

Dengue is an acute febrile illness which is endemic to the Indian subcontinent. It is one of the most significant mosquito-borne viral diseases transmitted to humans by the *Aedes aegypti* mosquitoes.[1,2]

It is caused by the Dengue virus (DENV) belonging to the family *Flaviviridae*. On the basis of the neutralization assay data, four serotypes (DENV-1, DENV-2, DENV-3, and DENV-4) have been distinguished. DENV infection is a major cause of sickness in tropical and subtropical countries.[3-6]

Each year almost 100 million people are infected. Out of these, 5,00,000 people suffer from dengue hemorrhagic fever (DHF) and dengue shock syndrome (DSS) with 30,000 fatalities, mostly of children.[7]

There are three basic methods for the diagnosis of dengue virus infection. These are viral isolation, detection of the viral genomic sequence by a nucleic acid amplification technology assay (Reverse transcription polymerase chain reaction (RT-PCR)), and detection of dengue virus-specific IgM antibodies by the IgM-capture enzyme-linked immunosorbent assay (MAC-ELISA) and/or the rapid dengue immunochromatographic test (ICT).

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The laboratory methods should be rapid and sensitive to reduce the morbidity and mortality of the dengue.[8] The antibody (IgG/M) detection is the most commonly used method for diagnosis of dengue infection but it is not a rapid method because time needed for appearance of IgM antibody is approximately 4-6 days.[9] Dengue non-structural 1 antigen (NS1) is highly conserved glycoprotein produced in both membranes associated and secretory forms is a new biomarker which is used for early diagnosis of dengue infection.[10]

Besides the dengue specific parameters, platelet count is the only other accessory lab test that can support the diagnosis of DHF or DSS. The platelet counts can be rapidly, easily and roughly estimated by microscopy even in the remotest of the areas.[11]

With this background it was planned to study correlation of the platelet count and microbiological laboratory tests of detection of NS1 antigen and IgG/M antibody tests in dengue suspected patients attending hospital.

METHODS

This study was conducted in Department of Pathology, Ananta Institute of Medical Sciences and Research Centre, Rajsamand. A total of 160 serum samples from clinically suspected dengue patients attending outdoors, causality services and indoor patients were included in this study. Five milliliter of blood was collected from all suspected cases of dengue fever. Serum was separated from all blood samples and was further tested for NS1 Ag and the presence of IgM and IgG Dengue antibody by dengue day1 test (J. Mitra) according to manufacturer s instructions.

Platelet Count:-

EDTA blood samples were collected and the platelet count was done by automated analyzer and cross checked by microscopy in the Department of Pathology, AIMSRC.

Ethical Considerations:

This was a analysis of routine laboratory diagnostic work thus ethical approval was not necessary.

RESULTS

In our study, 1052 total samples were included in this study. 160 samples were positive and 892 samples were positive out of 1052 samples. In the present study, 53.7% were males and 46.3% were females. In this study showed relationship between Platelet count and other parameters. From which notice that, 110 patients had less than 1 lakh count.

Table 1. Positive sample found from total number of sample

Sample	No. of sample	Percentage
Positive	160	15.2%
Negative	892	84.7%
Total	1052	100%

Table 2:- Gender-wise distribution

Gender	No. of Patients	Percentage
Male	86	53.7%
Female	74	46.3%
Total	160	100%

Table 3:- Various dengue Parameters in diagnosis of dengue cases

Parameters	No. of Patients	Percentage
NS1	48	30%
IgM	80	50%
IgG	5	3.1%
NS1 & IgM	17	10.6%
NS1 & IgG	1	0.6%
IgG & IgM	9	5.6%
TOTAL	160	100%

Table 3:- Relationship of platelets count with other parameters

Parameters	No. of Patients	Platelets less than 1 lakh	Percentage
NS1	48	35	31.8%
IgM	80	48	43.6%
IgG	5	4	3.6%
NS1 & IgM	17	16	14.5%
NS1 & IgG	1	1	0.9%
IgG & IgM	9	6	5.4%
TOTAL	160	110 (68.75)	100%

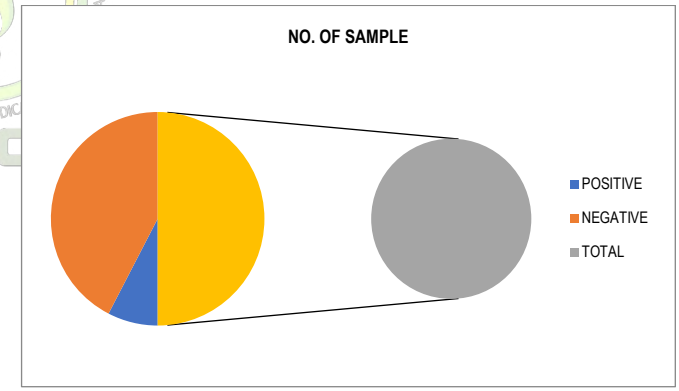

Fig:-1 This chart showed number of positive and negative sample

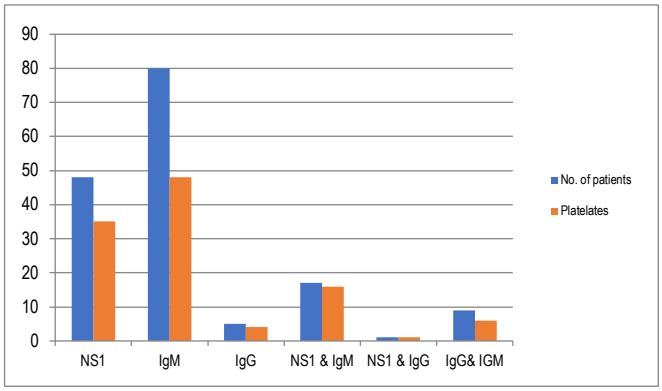

Fig:-2 This chart showed relationship between palates count and other parameters

DISCUSSION

The detection of dengue-specific antibodies IgG/M has been the main diagnostic modality of DI for a long. The dengue-specific antibodies appear from fifth day of fever in primary infection[5] and from third day in the most secondary infections.[9] Thus, both in primary and secondary DI, there is a window period when only antibodies can be tested. On the other hand, the NS1 antigen can be detected from first day of fever both in primary and secondary infections. NS1 antigen test has been reported to be highly specific viral marker and an extremely reliable parameter for the diagnosis of DI from first day of the fever.[10] Out of the 160 cases reported in the present study, 48 cases (30%) were positive only for NS1 antigen indicating if the NS1 antigen test had not been included in the study, the 30% cases of DI had been missed.[11,12] Almost the similar findings were reported by Datta and Shrivastava in their studies.[10,13] In the present study, NS1 alone or in combination with IgM/G was positive in 66 cases (41.25% cases). IgG has been reported to be a less reliable marker in the diagnosis of DI between the two dengue antibodies test.[5] It has been found that antibody IgG can be produced both in clinical and sub-clinical infections and may persist even for several years.[14] High levels of IgG in endemic areas can be attributed to the bites of infected mosquitoes.

On the contrary, dengue-specific IgM is a good indicator of recent DIs. Along with primary, it can also be detectable in secondary DI. In antibodies test, the diagnosis of DIs mainly depends on rising titers while in NS1 antigen test, there is no need of repeat testing as it is a highly specific marker of DI.[5] Out of the 160 cases reported in the present study, 110 (68.75%) were having thrombocytopenia. Out of 66 cases positive for NS1, thrombocytopenia was evident in 52 cases. Contrary to this, thrombocytopenia was present only in 117 (61.6%) cases out of 190 cases positive only with antibodies tests. The association of thrombocytopenia with NS1 showed higher SEP test = 5.01, Z=3.51 and *P* value <0.001 (highly significant).

On analysis of NS1 only group (73.68%) with NS1 plus IgM (94.12%) group, thrombocytopenia was found to be associated more with NS1 plus IgM group (SEP = 6.06, Z=3.37, *P*<0.001, highly significant).

It has been reported that platelet counts are decreased in some other conditions such as some viral infections other than DI, drug induced thrombocytopenia, collagen vascular diseases, idiopathic thrombocytopenia etc.[3]

In the present study, On statistical analysis (SEP = 4.55, Z=8.51, *P*<0.001), it was found that the association of thrombocytopenia and dengue parameter was significantly higher in comparison to thrombocytopenia and dengue negative cases.

CONCLUSION

In the diagnosis of dengue, presence of NS1 antigen increases the detection rate significantly. Thrombocytopenia found in case of fever which is more constantly in dengue positive sooner than dengue negative cases. It correlates well when NS1 & IgM are found simultaneously.

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Section Pathology

Original Article

The Prospective Study on Acute Leukemia in Tertiary Care Teaching Hospital in Rajsamand

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ABSTRACT

Background: *Acute leukemia are characterized by clonal expansion of immature myeloid or lymphoid precursors (blasts). The blasts cells are known to replace the normal hematopoietic tissues and to invade other organs of the body as well. Anemia, hemorrhage and infections occurring due to bone marrow failure are the top three complications of acute leukemia.*
Methods: *This study was carried out in the Department of Pathology, Ananta Institute of Medical Sciences and Research Centre, Rajsamand*
Results: *In The present study, 32 cases of different patterns of acute leukemia were reported. According to hematological parameters, 25 cases (78.1%), 2 cases (6.25%), 3 cases (28.1%) and 2 cases (6.25%) were reported as acute leukemia, AML, ALL and bi-lineage leukemia respectively.*
Conclusions: *The present study showed that AML is more prevalent than ALL. It is observed that ALL is more common in children. The incidence of AML is higher in adults in comparison to children and decreases towards older age.*

Keywords: *acute leukemia's, heterogeneous, hematological ,ALL, ALM*

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INTRODUCTION

It is a known fact that acute leukemias are heterogeneous group of hematological malignancies. Acute leukemias are characterized by clonal expansion of immature myeloid or lymphoid precursors (blasts). The blasts cells are known to replace the normal hematopoietic tissues and to invade other organs of the body as well. Anemia, hemorrhage and infections occurring due to bone marrow failure are the top three complications of acute leukemia[1-3] and may even be fatal. Acute leukemias are among the most common childhood cancers. The percentage of blasts should be more than 20% in the marrow or peripheral blood for diagnosing as per WHO classification.[4]

Acute leukemias are classified morphologically, in two types acute myeloid leukemia (AML) and acute lymphoblastic leukemia (ALL). AML is the most common type of leukemias in adults while ALL, accounting for 80% of the total cases, is the most common type in children.[5,6] ALL is further subclassified in three subtypes L1-L3 while AML in eight subtypes M0-M7.[7] some cytoplasmic and surface proteins known as cluster differentiation (CD) antigens are expressed by every blood cell. A unique set of CD antigens is expressed at every level of differentiation. The identification and quantification of cellular antigens through fluorochrome labeled monoclonal 7 antibodies are known as immunophenotyping.[8]

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METHODS

Study population:- A total of 32 cases of acute leukemia's were reported in the Haematology section.

Study Area:- This study was carried out in the Department of Pathology, Ananta Institute of Medical Sciences and Research Centre, Rajsamand.

Data Collection:- The complete haemograms were determined according to standard laboratory procedures. Slides were prepared with peripheral blood and in selected cases bone marrow aspirates which were stained by 'Leishman stain' and 'Giemsa stain' to find out the blast cells morphology in peripheral blood and bone marrow. Diagnosis of acute leukemia was made in cases where blast percentage was ≥20% (WHO guideline) and then Flow cytometric immunophenotyping was performed to distinguish between AML & ALL.

Data analysis:-Data were analyzed by using Microsoft excel.

RESULTS

In The present study, 32 cases of different patterns of acute leukemia were reported. According to hematological parameters, 25 cases (78.1%), 2 cases (6.25%), 3 cases (28.1%) and 2 cases (6.25%) were reported as acute leukemia, AML, ALL and bi-lineage leukemia respectively. The lowest blast percentage was 18.7% and highest was 31.25%. The hematological diagnosis (by means of complete blood count (CBC) / peripheral blood smear (PBS) / bone marrow aspirates (BMA)) and the number of cases that fall in different ranges of haemoglobin (Hb) level, total leucocyte count (TLC), platelet count (Plt.) and blast percentage are detailed in chart 3-7.

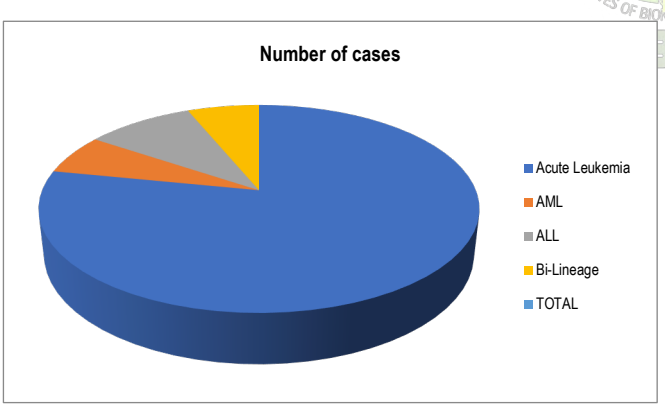

Chart 1: Distribution of hematological diagnosis

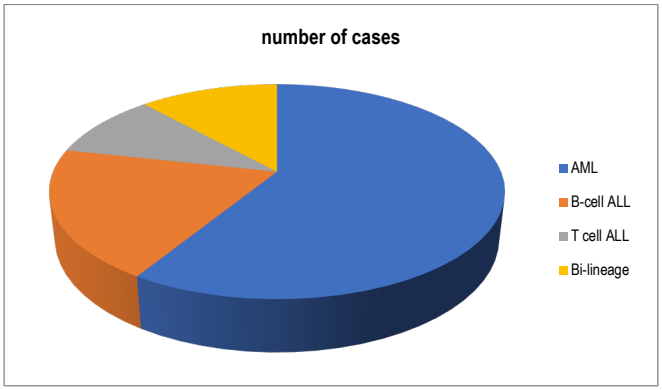

Chart 2: Distribution of Immunophenotypical diagnosis

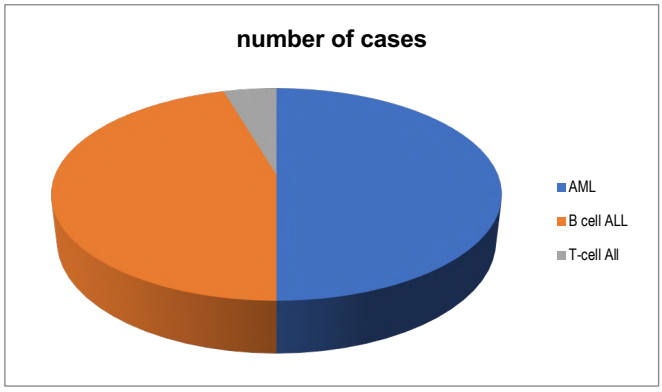

Chart 3: Distribution of Immunophenotypical diagnosis

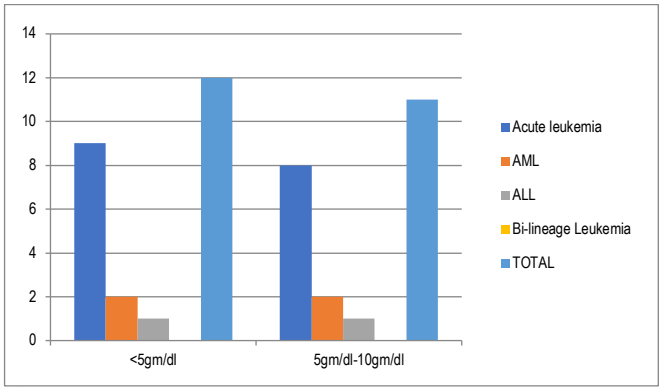

Chart 4: Hemoglobin findings of all cases presenting as acute form of leukemia

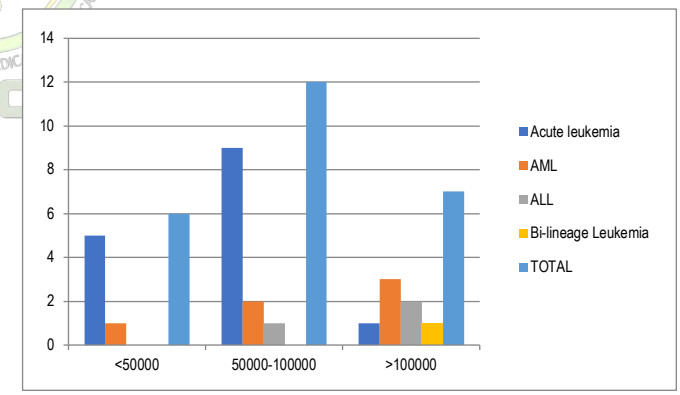

Chart 5: Total leucocyte count findings of all cases presenting as acute form of leukemia

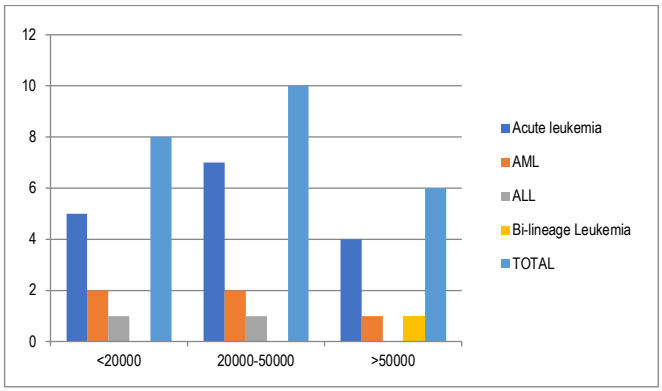

Chart 6: Platelets count findings of all cases presenting as acute form of leukemia

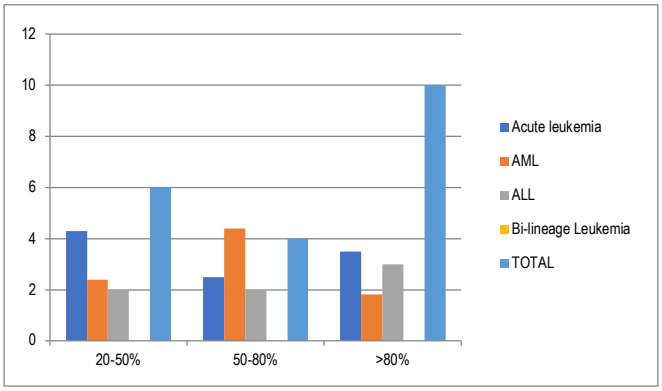

Chart 7: Platelets count findings of all cases presenting as acute form of leukemia

DISCUSSION

In the present study, anaemia was diagnosed in all cases and 37.5% of the total cases presented with severe anaemia with less than 5.0 g/dl of haemoglobin concentration. TLC was found to be more than 50,000/ cu.mm in 25% of patients, while such high TLC was present in only forty to fifty percent of cases in western studies.[9] 18.75% of the patients presented with less than 50,000/cu.mm platelet counts while 25% of patients had severe thrombocytopenia with platelet count less than 20,000/cu.mm. The results of the present study were almost similar to the local studies but on comparison with western studies, the results are more manifested. These marked results can be attributed to the late presentation as the degree of anaemia; leucocytosis and thrombocytopenia are directly proportional to severity of bone-marrow failure.[10] Immunophenotypic observations of AML (HLA-DR, CD13, CD33, MPO) in the presented study were supported by other studies.[11-12] On the other hand, B-cell and T- cell ALL were diagnosed in immunophenotypically cases. These findings were supported by observations of Shanta V et al. and Magrath I et al.[13-14] The results of the present study of the aberrant expression of lymphoid antigens (CD22, CD79a) in AML were also similar to the findings of the Ghosh S et al studies. Considering the different types of acute leukemia it was observed that AML was more common than ALL . These results are closely resembled to results reported from Kenya in Africa.[15]

CONCLUSION

The present study showed that AML is more prevalent than ALL. It is observed that ALL is more common in children. The incidence of AML is higher in adults in comparison to children and decreases towards older age.

In morphologically challenging cases, it is also concluded that immunophenotyping is an important diagnostic tool to differentiate between AML and ALL. It is possible to subtype as well as to establish the lineage of the leukemia from immunophenotyping. It is also essential to monitor the progress of patients after chemotherapy in detection of minimal residual disease.

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ImprInt Cytology: A rellAble AlternAtIve to Frozen SeCtIon

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AbStrACt

background: There are instances when either we do not perform pre-operative biopsy due to the fear of spread of malignancy, or needle aspiration cytology is inconclusive. During surgical exploration for a benign pathology if surgeons find suspicious lesions, per-operative cytological diagnosis becomes important to rule out malignancy. The frozen section facility is available only at few large volume centres. So there is always a need for an easy and cheap alternative to frozen section that can help surgeons at low volume centres as well.

Aim: Aim of the study was to assess the reliability of imprint cytology in per-operative (immediate) diagnosis of malignancy.

material and methods: The present study was a prospective analysis of 69 specimens from suspected or diagnosed cancer patients that were sent for per-operative (or urgent) imprint cytology (IC) from July 2012 to Feb. 2014, at surgical oncology unit of our institute. All the specimens were then subjected to paraffin section (PS) and final reports were compared.

results: Out of 69 specimens 61 were found to be malignant, and five were found to be benign by both IC and PS. In all such situations IC helped us a lot in decision making regarding change in treatment plan further. The sensitivity and specificity of imprint cytology were 96.8 % and 83.3% respectively. The positive predictive value (PPV) of IC was 98.3 %.

Conclusions: The imprint cytology is a cheap and reliable method for per-operative diagnosis of malignancy. It can be used for per-operative confirmation of parathyroid glands before auto-implantation.

Key Words: Frozen section, Imprint cytology, Per-operative cytology, Touch cytology

INTRODUCTION

For past many years it has become a trend to have definitive diagnosis before surgery, as it helps in surgical planning, planning of neo-adjuvant therapy and in patient counselling. This practice has decreased the numbers of surgical explorations. Surgeons feel difficulty in planning out the extent of resection of lesion whenever initial tissue diagnosis is not available. Still there are instances when we do not perform pre-operative biopsy or cytology due to the fear of capsular rupture, needle tract seedling or spread of malignancy. Sometimes fine needle aspiration cytology (FNAC) or needle biopsy is inconclusive and we have to take surgical (excision) biopsy, and then plan the definitive procedure after biopsy report, thus making it a 2 stage procedure. Many times during surgical exploration for a benign pathology if surgeons find suspicious lesions, per-operative cytological diagnosis becomes important to rule out malignancy, as this may change the intra-operative surgical plan further. Since a long time frozen section (FS) and imprint cytology (IC) are considered as two methods of per-operative cytological diagnosis. After popularity of frozen section in practice, pathologists have given up interest towards imprint cytology. The frozen section facility is available only at few centres in India as compared to large number of hospitals and patients. So there is always a need for an easy and cheap alternative to frozen section that can help surgeons at low volume centres as well. The aim of this study was to assess the reliability of imprint cytology in per-operative (immediate) diagnosis of malignancy.

MATERIAL AND METHODS

The present study was a prospective analysis of 69 specimens from suspected or diagnosed cancer patients that were sent for per-operative (or urgent) imprint cytology

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from July 2012 to Feb. 2014, at surgical oncology unit of our institute. In all these situations it was important to confirm (or to rule out) malignancy, as this would make a major difference in treatment plan or extent of resection or in initiating a specific treatment. At our hospital we did not have facility for frozen section. Many times we felt difficulty in decision making where per-operative cytological diagnosis was needed. So we started doing imprint cytology as an alternative to frozen section based on previous literature, along with systematic recording of data.

Slides were either made in operation theatre or fresh adequate tissue samples were taken and wrapped in saline soaked cotton gauss pieces and, sent to pathology laboratory for urgent imprint cytology. The imprint cytology slides were then prepared in pathology lab by standard technique, fixed and stained. The reporting was done by a senior pathologist who was expert in cytological diagnosis of malignancy. All the specimens were then subjected to paraffin section (PS) and final reports were compared.

RESULTS

The results are shown in table 1.

From various surgical explorations (or excision biopsies) suspicious 12 metastatic nodules, six breast lumps, two encapsulated ovarian masses and 14 lymph nodes (including celiac, pelvic or para-aortic lymph nodes) were examined and all found to be positive by IC and PS as well. In all such situations IC helped us a lot in per-operative decision making.

The sensitivity and specificity of imprint cytology were 96.8 % and 83.3% respectively. The positive predictive value (PPV) of IC was 98.3 %. The average time taken in reporting was 23 minutes.

The only false positive result of IC was a specimen of lower uterine fibroid protruding out of cervix with surface erosions. It was giving appearance of defined cervical cancerous mass clinically (including imaging), but showing only dysplasia in cervical biopsy. We did radical hysterectomy and send specimen for imprint cytology to rule out malignancy in cervical mass before pelvic lymph node dissection (PLND). The IC reported it as malignant and we did bilateral PLND. Later on in final PS report it was found to be a uterine fibroid with surface dysplasia, all nodes negative.

Now let me discuss with you the two false negative cases. There was a confirmed case of carcinoma cervix, confined to cervix only in imaging, opened for radical hysterectomy. On exploration there was a significantly large, hard, round right pelvic lymph node (LN), which was sent for imprint cytology. The IC reported it as granulomatous disease and we proceeded to radical hysterectomy. The LN was finally found to harbour metastatic cancer.

The second false negative report was from a per-operative biopsy of stomach suspicious of linitus plastica. Multiple endoscopic biopsies were negative for malignancy, but clinically patient was not improving and CT (computed tomography) scan was constantly showing a diffuse wall thickening. Surgery with per-operative cytology was planned. The tumour was inoperable on exploration, as it was infiltrating into porta and transverse mesocolon. A small full thickness stomach wall biopsy was taken and sent for IC, which was negative for malignancy. We took a large full thickness biopsy and based on clinical judgement closed the abdomen. Finally both showed carcinoma stomach.

In a known case of laryngeal malignancy, 'wide field laryngectomy' surgery was planned. During surgery all four parathyroid glands were isolated and cut. One fourth part of each was sent for confirmation by IC. In the report three were normal parathyroids (auto-implanted) and one was found to be metastatic LN (discarded), which were confirmed by final PS.

The sub typing of malignancy (although it was not a predecided criterion to report) was given in 22 IC reports, but it was changed finally in nine patients. This makes IC unreliable for diagnosis of specific subtype (PPV 59 % only).

DISCUSSION

Imprint cytology (IC) and frozen section (FS) are renowned techniques of per-operative cytology and the diagnostic accuracy of both is comparable. Liu et al have investigated the utility of intraoperative touch preparation with comparison of frozen section in 122 cases. The rate of correct diagnosis for touch preparation was 88.5% as compared to 86.1% for frozen section. The rate of incorrect diagnosis for touch preparation was 4.1% as compared to 2.5% for frozen.[1]

Scucchi et al compared 2,250 intraoperative cytology with frozen section with the final diagnosis achieved on paraffin sections. The diagnostic accuracy of each technique alone was 94.9%. For frozen section the sensitivity was 89.9% and specificity 97.9% as compared to the touch cytology, which had a sensitivity of 94.9%, and specificity of 96.8%.[2]

Guarda et al carried out a comparative study of the two techniques and found the accuracy of cytology and frozen section 98.4% and 99.2% respectively.[3]

The greatest advantage of IC examination is of not having artifacts, resulting in superb nuclear and cytological details.[1] IC provides better and crisp cellular morphological details and even some tissue architecture.[4] Very small fragments of tissue provide sufficient cells for IC, but difficult to process and report on FS. The diagnosis of very small lesions is therefore facilitated and tissue is saved for permanent section.[5] Certain tissues that cannot be studied by frozen section i.e. bone, necrotic tissue and fat etc. give accurate results on touch preparations.[1] IC was found to be more valuable in the field of neuro-pathology, lymph node and most of the epithelial tumours.[3] Parathyroid glands are correctly identified by IC, slightly more sensitive than FS.[5]

Used intraoperatively, the imprint method can provide valuable information when frozen-section interpretation is equivocal. IC is particularly valuable in the diagnosis of certain neoplastic lesions which can simulate inflammatory lesions on FS eg. Well differentiated Pancreatic cancer, metastatic signet ring cell carcinoma in LN (can be mistaken for reactive sinus histiocytosis on FS). Certain benign inflammatory lesions can simulate malignancy on FS e.g. Organizing pneumonia (anaplastic carcinoma), intense sinus histiocytosis (can simulate metastatic carcinoma) that can be diagnosed with IC.[5]

Well-differentiated tumours and tumours with a dense fibrous stroma cannot be diagnosed by imprint cytology method.[5]

On the other hand Frozen Sections provided more tissue architectural details. It is well recognized, however, that the freezing and sectioning techniques of frozen section results in unavoidable distortions and artifacts, rendering diagnosis difficult in many instances.[1]

The diagnostic accuracy in distinguishing benign from malignant lesions by combined procedures was 100%. There were no false positive or false negative cases.[4] To increase diagnostic accuracy many people recommend the combined use of imprints and frozen sections.[5]

For diagnosing specific subtypes of malignancy, the diagnostic accuracy of each method alone was 96.6% with a sensitivity of 86% and specificity of 100% and the combined sensitivity 90%. The benefit of frozen section is that the tissue architecture closely approximates permanent histology sections.[4]

By virtue of our experience from this study, we would like to emphasize upon these few points:-

1. Imprint cytology is a reliable method to rule out malignancy in a short time. It may help surgeons to make changes in the previously made treatment plan. The confirmation of malignancy can help an oncologist to start therapy earlier without waiting for the results of final biopsy.
2. This method can be used to find out adequacy of biopsy specimen. Many times we are not sure while taking core biopsies (may be sonography or CT guided) that correct specimen is retrieved or not. Immediate imprint cytology from biopsy specimen will tell us that the tissue contains viable tumour, necrosed tissue or normal tissue. If the biopsy is not representative of disease we can take more samples immediately, hence to save time, patients' comfort and cost.
3. The imprint cytology can differentiate between a normal parathyroid gland and a lymph node with or without metastasis. This may help head and neck surgeons in per-operative confirmation of normal parathyroid glands before using them for auto-implantation. Now days, it is highly emphasised not to implant parathyroid glands without histological confirmation.
4. The imprint cytology is not a reliable investigation for sub-typing of cancer. It cannot differentiate between the grades of differentiation from well to poorly differentiated cancers. Its reliability on differentiating lung cancer into various subtypes like small cell, squamous cell or adenocarcinoma is not acceptable. Also it can't differentiate among various grades of dysplasia and early invasive cancer. This limitation should always be kept in mind.
5. Frozen section needs a good cryostat and other specialized materials along with experienced pathologist and technician. The cost of the setup ranges from Rupees 4 lac to 20 lac. There are problems regarding maintaining low temperature in the range of minus 15 to 20 ^{0} centigrade (sometimes even lower) with the cheaper cryostats along with issues regarding wastage of precious sample and poor quality of slides with cheaper devices. To make frozen section cost effective a centre should have at least 5 specimens for frozen section per day. This is the basic reason why frozen section is not available in majority of the hospitals even in big cities.

CONCLUSION

Imprint cytology is a cheap and reliable method for per-operative diagnosis of malignancy, and can be used in place of frozen section, where such facility is not available. It can be used for per-operative confirmation of parathyroid glands before auto-implantation.

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Table 1: The results are shown with categorization of various specimens.

S. No.	Tissue of origin of specimen	Total No.	Positive for malignancy by Imprint Cytology (IC)	Positive for malignancy by Paraffin Section (PS)
1	Metastatic nodules	13	12	12
2	Breast lump	6	6	6
3	Ovary	2	2	2
4	Cervix/uterus	2	2	1
5	Lymph nodes (LN)	15	14	15
6	Parathyroid gland for confirmation	4	3	3
7	CT/ USG guided biopsies	25	22	22
8	Stomach cancer	2	1	2
	Total	69	62	63

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A histopathological analysis of colorectal cancer

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Abstract
Background: Carcinoma of the colon or rectum is a common and lethal disease. The present study was conducted to assess histopathology of colorectal cancer.
Materials & Methods: The present study was conducted on 112 rectum specimens. Tumor invasion depth, surgical margin status, lymph vascular/perineal invasion, presence/absence of metastatic lymph nodes, neoadjuvant therapy, and regression rates were assessed.
Results: Out of 112 specimens, 64 were of males and 48 of females. There was mild treatment response in 21, moderate in 15, high in 14 and complete regression in 10 cases. Tumor type was adenocarcinoma in 76, mucinous adenocarcinoma in 23, malign melanoma in 6, signet ring cell carcinoma in 4, and gastrointestinal stromal tumor in 2 and endometriosis in 1 case.
Conclusion: Authors found that histopathology revealed that maximum cases were of adenocarcinoma followed by mucinous adenocarcinoma.

Keywords: Adenocarcinoma, colorectal cancer, histopathology

Introduction
Worldwide, colorectal carcinomas are the third most common carcinomas in men and the second most common carcinomas in women. A study conducted in 2014 reported that there are approximately 10 000 new cases of colon cancer and nearly 40000 new cases of rectal carcinoma annually in the United States. Deaths due to colorectal cancers account for approximately 9% of all cancer-related deaths. With changes in oncological treatments over the years, care should be taken to accurately perform pathological and clinical staging of these cases [1].
Carcinoma of the colon or rectum (colorectal cancer [CRC]) is a common and lethal disease. Approximately 145,600 new cases are diagnosed each year in the United States, of which 101,420 are colon and the remainder are rectal cancer [2]. Annually, approximately 51,020 Americans die of CRC, accounting for approximately 8 percent of all cancer deaths. Global, country-specific data on incidence and mortality are available from the World Health Organization (WHO) [3].
Surgical resection is the primary treatment modality for early stage CRC (stage I through III) and the most powerful tool for assessing prognosis following potentially curative surgery is pathologic analysis of the resected specimen. Although the parameters that determine pathologic stage are the strongest predictors of postoperative outcome, other clinical, molecular, and histologic features may influence prognosis independent of stage. Among patients with stage IV disease, prognosis is more closely tied to the location and extent of distant metastatic disease [4]. The present study was conducted to assess histopathology of colorectal cancer.

Materials & Methods
The present study was conducted to in the department of General pathology. It comprised of 112 rectum specimens. The study protocol was approved from institutional ethical committee.
Demographic data, etiology, and physiological and surgical parameters were collected from medical records. Tumor invasion depth, surgical margin status, lymphovascular/perineural invasion, presence/absence of metastatic lymph nodes, neoadjuvant therapy, and regression rates were assessed. When performing lymph node dissection, adipose tissue specimens were kept in alcohol overnight and were dissolved and solidified into adipose tissue components.

Results thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

Results

Table 1: Distribution of patients

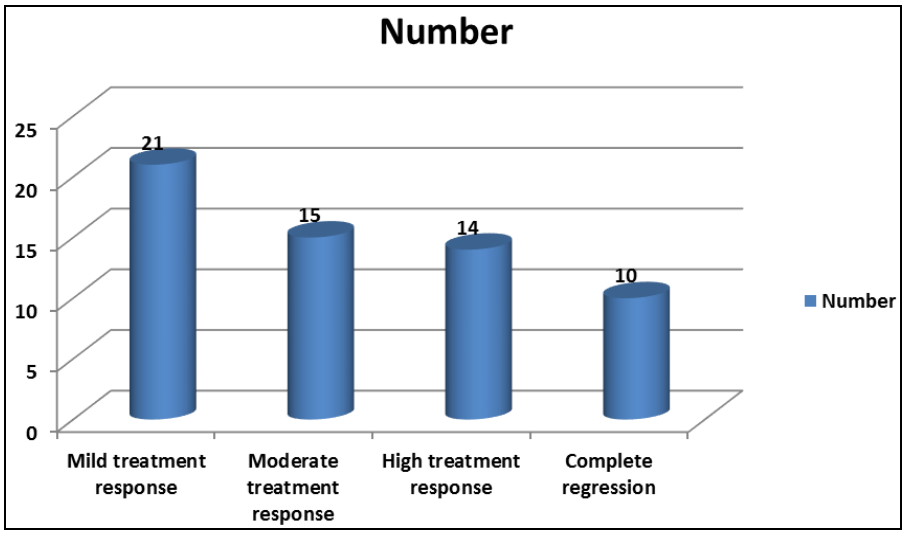
Total- 112		
Gender	**Males**	**Females**
Number	64	48

Table I shows that out of 112 specimens, 64 were of males and 48 of females.

Table 2: Regression responses of neoadjuvant treated patients

Response	Number	P value
Mild treatment response	21	0.12
Moderate treatment response	15	
High treatment response	14	
Complete regression	10	

Table II, graph I shows that there was mild treatment response in 21, moderate in 15, high in 14 and complete regression in 10 cases.

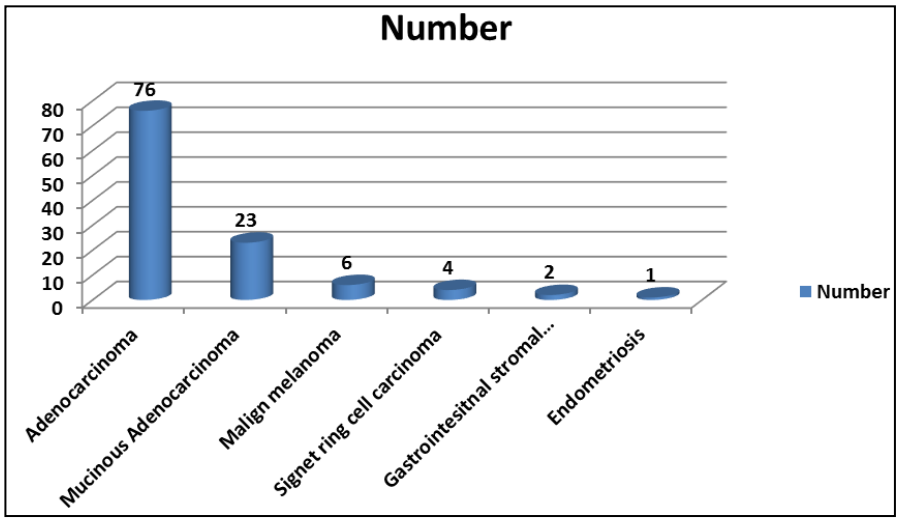


Graph 1: Regression responses of neoadjuvant treated patients

Table 3: Distribution of cases

Tumor type	Number	P value
Adenocarcinoma	76	0.01
Mucinous Adenocarcinoma	23	
Malign melanoma	6	
Signet ring cell carcinoma	4	
Gastrointesitnal stromal tumor	2	
Endometriosis	1	

Table III, graph II shows that tumor type was adenocarcinoma in 76, mucinous adenocarcinoma in 23, malign melanoma in 6, signet ring cell carcinoma in 4, gastrointestinal stromal tumor in 2 and endometriosis in 1 case.



Graph 2: Distribution of cases

Discussion

Colorectal cancer (CRC) is one of the most common malignancies and usually ranks high in incidence and mortality among all malignancies in the Western world.[5] Carcinoma of the rectum and sigmoid is one of the most sites of gastrointestinal tract malignancy and accounts for 20% of all gastrointestinal malignancies. The age-adjusted incidence rates of CRCs in all the Indian cancer registries are very close to the lowest rates in the world [6].

Pathological examination of rectum specimens requires special attention for correctly evaluating many prognostically important factors. Careful pathological examination is extremely important with respect to tumor invasion depth, surgical margin status, presence of lymphatic/vascular/perineural invasion, presence/absence of metastatic lymph nodes, presence of neoadjuvant therapy, and regression rates [7]. The present study was conducted to assess histopathology of colorectal cancer.

In present study, out of 112 specimens, 64 were of males and 48 of females. There was mild treatment response in 21, moderate in 15, high in 14 and complete regression in 10 cases. A *et al*. [8] found that of the 173 specimens, 15 (8.7%) were APR and 158 (91.3%) were LAR specimens. Ninety-four patients (54.3%) were males and 79 patients (45.7%) were females. The mean age of the patients was 63.5 years (range 26–90 years). In the histopathological examination, malignant neoplasm was detected in 172 of the cases (99.4%) and benign endometriosis was detected in 1 of the cases (0.6%). There were 151 (87.2%), 8 (4.6%), 5 (2.9%), 1 (0.6%), 1 (0.6%), 1 (0.6%), 1 (0.6%), 1 (0.6%), and 4 (2.3%) patients with adenocarcinoma, mucinous adeno-carcinoma, intramucosal adenocarcinoma in the setting of a high-grade tubulovillous adenoma, synchronous colon/prostate adenocarcinoma, malignant melanoma, signet ring cell carcinoma, gastrointestinal stromal tumor, endometriosis, and adenocarcinoma diagnosed by the examination of colonoscopic biopsy specimens that showed complete regression with neoadjuvant therapy, respectively.

In present study tumor type was adenocarcinoma in 76, mucinous adenocarcinoma in 23, malign melanoma in 6, signet ring cell carcinoma in 4, gastrointesitnal stromal tumor in 2 and endometriosis in 1 case. Singla *et al*. [9] found that rectum was the most common site of involvement followed by the recto-sigmoid involvement. Metastasis was observed in 5 cases out of the 31 malignant cases. Five of the 7 cases were correctly staged as T1 & T2 lesions on CT having a sensitivity of 83.3%, specificity of 92%, and positive predictive value of 71.4% and a negative predictive value of 95.8% in the diagnosis of T1 and T2 lesions. 15 of the 16 cases were correctly staged as T3 lesions. CT had a sensitivity of 88.2%, specificity of 93.8%, and positive predictive value of 93.8% and a negative predictive value of 86.7% in the diagnosis of T3 lesions. All the 8 cases were correctly staged as T4 lesions. CT had a sensitivity of 100%, specificity of 100%, and positive predictive value of 100% and a negative predictive value of 100% in the diagnosis of T4 lesions.

A study done by Pereira *et al*. [10] described that pericolic fat stranding is commonly seen in inflammatory conditions of the colon. Adjacent organ infiltration was seen in 8 cases (25.8% of total cases); however, the rest of the 23 cases did not show any involvement of viscera which means that the rate of detection of infiltration was 100%.

Conclusion

Authors found that histopathology revealed that maximum cases were of adenocarcinoma followed by mucinous adenocarcinoma.

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Original Research

A histopathological analysis of appendectomy specimens

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ABSTRACT:

Background: Appendicitis is a common acute surgical emergency. The present study was conducted to assess histopathology of appendectomy specimens. **Materials & Methods:** The present study was conducted on 89 appendix specimens. Data such as age, gender etc. was recorded in performa. Histopathological assessment was performed. **Results:** Out of 89 specimens, 52 were of males and 47 of females. Specimens found to be of appendicitis in 14, unusual pathology in 28, carcinoid tumor in 30 and mucinous lesion in 17 cases. The difference was found to be significant (P< 0.05). Age group 0-10 years had 6, 11-20 years had 17, 21-30 years had 24, 31-40 years had 21, 41-50 years had 13 and >50 years had 7 specimens. The difference was significant (P< 0.05). **Conclusion:** Authors found maximum case in age group 21-30 years with male predominance. Maximum cases found to be of carcinoids tumor.

Key words: Appendix, Histopathology, carcinoid tumor

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INTRODUCTION

Appendicitis is a common acute surgical emergency with over 40,000 cases in the UK every year and the estimated life time risk of appendicitis in the USA is 8.6% and 6.7% for males and females respectively. The diagnosis of appendicitis is largely clinical and appendectomy is the treatment of choice.[1] Delayed diagnosis of appendicitis could lead to complications like perforated appendix, peritonitis, sepsis, increased morbidity and mortality. Right iliac fossa pain can be a presenting complaint of different pathologies that may mimic appendicitis especially in the female population causing diagnostic difficulties and often leads to negative appendectomies.

Acute abdominal pain is one of the most common earliest indicators of any clinical issues. The earliest known case of an appendiceal tumor dates back to 1882. Appendiceal tumors constitute 0.2% to 0.5% of all primary neoplasms seen in the gastrointestinal tract. This type of tumor is rare compared to other tumors that affect the gastrointestinal tract.[2]

Obstruction of lumen is the dominant factor in acute appendicitis and although faecoliths and lymphoid hyperplasia are the usual cause of obstruction, some unusual factors could be involved.[3] Unusual causes of obstructions are enterobiasis, ascariasis, tuberculosis, carcinoid tumor ,primary or secondary adenocarcinoma, lymphoma, dysplastic changes, mucocele, gastro-intestinal stromal tumor, eosinophilic granuloma etc. Even though, there are many case reports in English written medical literature, reports with meticulous analysis of all cases with appendicitis are small in number.[4] The present study was conducted to assess histopathology of appendectomy specimens.

MATERIALS & METHODS

The present study was conducted to in the department of General pathology. It comprised of 89 appendix

specimens. The study protocol was approved from institutional ethical committee.
Data such as age, gender etc. was recorded in performa. Histopathological assessment was performed. Results thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I Distribution of specimens

Total- 89		
Gender	**Males**	**Females**
Number	52	47

Table I shows that out of 89 specimens, 52 were of males and 47 of females.

Table II Histopathological findings in appendectomy specimens

Specimens	Number	P value
Appendicitis	14	0.05
Unusual pathology	28	
Carcinoid tumor	30	
Mucinous lesion	17	

Table II, graph I shows that specimens found to be of appendicitis in 14, unusual pathology in 28, carcinoid tumor in 30 and mucinous lesion in 17 cases. The difference was found to be significant (P< 0.05).

Graph I Histopathological findings in appendectomy specimens

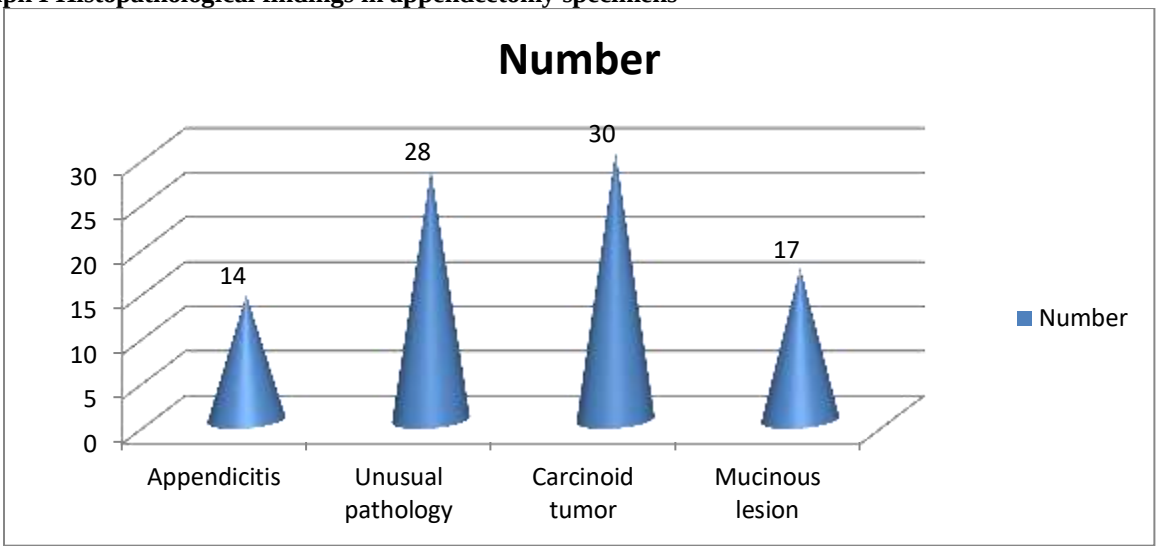

Table III Distribution of cases according to age group

Age group (Years)	Number	P value
0-10	6	0.04
11-20	17	
21-30	24	
31-40	21	
41-50	13	
>50	7	

Table III shows that age group 0-10 years had 6, 11-20 years had 17, 21-30 years had 24, 31-40 years had 21, 41-50 years had 13 and >50 years had 7 specimens. The difference was significant (P< 0.05).

DISCUSSION

There is variation in the practice of routine histopathological examination of appendectomy specimens. Arguments against the practice include the rarity of incidental pathologies that may impact on treatment and also the financial implications of routine histopathological assessments.[5]Acute appendicitis is the most common surgical emergency for a number of decades and the appendectomy is the most frequently performed abdominal operation. Obstruction of the lumen seems to be the essential for developing an appendiceal infection. Although faecoliths and lymphoid hyperplasia are the usual causes of the obstruction, some unusual factors could also be involved.[6] The present study was conducted to assess histopathology of appendectomy specimens.

In present study, out of 89 specimens, 52 were of males and 47 of females. Specimens found to be of appendicitis in 14, unusual pathology in 28, carcinoid tumor in 30 and mucinous lesion in 17 cases. Memon et al[7] found that a total of 238 appendectomies were performed during the study period. The mean age of the patients was 32 years (range, 7-81 years). Adult patients (>16 years) represented 79.4% of the study population. The female sex accounted for 46.6% of all the patients. Of the 238 resected appendix, 211 (88.7%) had histopathology findings consistent with appendicitis. Approximately 1.7% of the 238 specimens were abnormal pathologies other than inflammation of the appendix. The negative appendectomy (normal appendix on histology) rate was 11.3%. The female sex accounted for 59.1% of the negative appendectomies. Adults (>16 years) represented 77.8% of the negative appendectomies.

We found that age group 0-10 years had 6, 11-20 years had 17, 21-30 years had 24, 31-40 years had 21, 41-50 years had 13 and >50 years had 7 specimens. Emre et al[8] found that out of 790 appendectomy specimens, acute appendicitis accounted for 302 (38.2%) with peak occurrence in the age group 11-20 years (38.9%) and 21-30 years (27.7%) with male predominance (2.34:1). Unusual findings were noted in 44 (5.6%) cases by histopathology. Most common findings included obliterative appendicitis (77.3%), followed by eosinophilic appendicitis (6.8%) and granulomatous appendicitis (4.5%).Other unusual findings include diverticulum, mucocele, carcinoid and signet ring adenocarcinoma of the appendix.

Shrestha[9] reported the findings of a retrospective analysis of 261,134 patients who underwent non-incidental appendectomies with a NAR of 15.3%. When compared with patients with appendicitis, negative appendectomy was associated with a significantly longer length of stay (5.8 vs. 3.6 days, P<0.001), infectious complications rate (2.6% vs. 1.8%, P<0.001) case fatality rate (1.5% vs. 0.2%, P<0.001) and total charge-admission. An estimated $741.5 million in total hospital charges resulted from admissions in which a negative appendectomy was performed. Hence NAR has been recognized as a quality metric in the management of acute appendicitis.

The histological criterion for the diagnosis of acute appendicitis is polymorphonuclear leucocytic infiltration of the muscularis mucosa. The incidence of primary chronic appendicitis as a pathologic or clinical entity has been greatly disputed. Much more frequently recurrent acute attacks may be inappropriately referred to as chronic appendicitis.[10] Extensive fibrosis of the appendiceal architecture implies a chronic inflammatory reaction within the wall, supports the diagnosis of chronic obliterative appendicitis. The appendectomy resolves the chronic appendicitis.

CONCLUSION

Authors found maximum case in age group 21-30 years with male predominance. Maximum cases found to be of carcinoids tumor.

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Body mass index, waist hip ratio and body fat percentage as early predictors of pre-diabetes and pre-hypertension in adolescents.

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Abstract

Objective: The study aimed to assess the relationship between Body mass index (BMI), body fat percentage(BFP) and waist hip(WH) ratio in predicting Pre-Diabetes and Pre-Hypertension.

Methods: A total of 389 adolescents aged 11–17 years were recruited from Doddaballapura government school. Body Mass Index and Waist Hip Ratio were determined using standard equipment's. Body fat percentage was derived from a body fat analyser. Fasting blood glucose was determined by glucometer method, Blood pressure was recorded using sphygmomanometer.

Results: Compare to students with normal BMI, those who are overweight had 7.19 times [95% CI: (2.25-22.96)] high odds to have pre hypertension or hypertension. Similarly compare to normal BMI students, obese students were 28.76 times high odds [95% CI: (2.5-330.27)] to have pre hypertension or hypertension. There was no significant difference between normal BMI students and underweight students in terms of Pre hypertension/ Hypertension. Compare to students with normal WH ratio, low WHR students didn't have any significant correlation in developing Pre hypertension or hypertension. Compared to students with normal Body fat percentage, those who had a high BFP were 6.02 times high odds to have pre hypertension or hypertension similarly those who had very high BFP were 21.25 times high odds to have pre hypertension or hypertension in respect to predicting pre diabetes, BMI and waist to hip ratio were not significantly correlated, whereas high Body fat percentage had 1.46 high odds as compared to normal BFP.

Conclusion: These data suggest the importance of the BMI, Body fat percentage and waist to hip ratio in adolescents, in prevention and early intervention of Obesity, Hypertension and Pre-diabetes since it may be the most cost-effective way of reducing the complications related with them.

Keywords: Hypertension, Obesity, Childhood, Body mass index.

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Introduction

The unabated rise in the prevalence of overweight in children and adolescents is one of the most alarming public health issues facing the world today [1]. Among Indian children, various studies reported the magnitude of overweight to be from 9 to 27.5% and that of obesity from 1 to 12.9% [2-6]. Obesity increases the risk for many chronic diseases including diabetes mellitus, cardiovascular disease and non-alcoholic fatty liver disease, which, further decreases the overall quality of life [7-9]. Therefore, it is imperative to identify the individuals at risk at an early stage. Increasing evidence suggests that this epidemic of childhood obesity as a causative agent for premature onset of hypertension, resulting in, increased risk for adult coronary heart diseases [10,11]. The landmark Global Burden of Disease Study showed that the hypertension is leading the list of risk factors for death and disability worldwide [12].

Since the late 1990s, both the World Health Organization

(WHO) and the National Heart, Lung, and Blood Institute (NHLBI) have proposed that abnormal body weight be classified according to the body mass index (BMI) and body fat distribution, measured by the abdominal circumference (AC) or the waist circumference (WC) [13,14] It is widely accepted that being overweight, traditionally defined as having a body mass index 25 kg/m², is a major risk factor for a wide range of chronic diseases and injuries including cardiovascular disease (CVD), type II diabetes and certain site specific cancers including colorectal and breast cancer [15,16]. A recent report from the Prospective Studies Collaboration, which was based on 466 000 deaths, estimated that optimal survival is achieved at a BMI of 22.5–25 kg/m² with reductions in life expectancy of 3 and 10 years in individuals with moderate (BMI 30–35 kg/m²) and extreme obesity (BMI 40–50 kg/m²), respectively, the latter being equivalent to the years lost by lifetime smoking (Prospective Studies Collaboration, 2009) [17-20].

Although some cohort studies have shown that the higher the BMI, the greater the likelihood of developing hypertension in adults, The WHO recommends the use of the AC, taken at half-distance between the iliac crest and the lower rib cage rim, on the horizontal plane as a measurement of obesity [17-23]. However, the NHLBI prefers using the WC, measured at the highest portion of the right iliac crest as an indicator of obesity. The guide for identification and treatment of obesity in adults, published in 1998, refers to several prospective studies showing that abdominal fat correlates with increased mortality rate and risk for diabetes, hyperlipidemia, hypertension, coronary artery disease and cerebral and peripheral disease [24]. In spite of the need to establish cut off points of WC/AC for risk prediction of obesity related complication in children and adolescents, this was not proposed until 2004, although some articles reported percentile distributions in different populations [25]. So far, the cut-off points proposed for adults by the NHLBI7 were used, with 88 centimetres for women and 102 cm for men as standards.

Paediatric hypertension is increasing along with the paediatric obesity epidemic. Blood pressure measurement neither have been included in elementary school children health examination schedule, nor have blood pressure check-up been required during paediatric medical visits in India. This has led to under diagnosis of paediatric hypertension in clinical settings [26]. Hypertension is classified as essential (primary) or secondary to underlying cause, e.g. disease of renal parenchyma, reno-vascular or endocrine disorders. Screening studies suggest that essential hypertension is in increase trend during late childhood and adolescence. There is increasing evidence that essential hypertension tracks into adulthood, resulting in considerable cardiovascular morbidity [27]. The objective of this present article was to assess the sensitivity and specificity of anthropometric body fat measurements in predicting hypertension and pre diabetes in a sample of school going children of Karnataka.

Materials and Methods

Study Design and Size

A cross sectional study was carried out in Doddaballapura Government school, Karnataka, in December 2015, by Department of Paediatrics of Kempegowda Institute of Medical Sciences. A total of 389 students comprising of male and female adolescents, aged 11 to 17 years. Children with chronic disease like renal, hepatic or endocrine disorders or taking treatment for the same were excluded.

Data Collection Procedure

An informed consent was taken from all the subjects/ Principal of the school and institutes ethics committee permission was obtained. School was visited 1 day prior to the pre-arranged date and instructed for overnight fasting.

Anthropometric Parameters

The study protocol included anthropometric parameters, body weight, height, waist circumference (WC) and hip circumference (HC). Adolescents weight was measured (to the nearest 0.5 kg) with the child standing motionless on the weighing scale with feet 15 cm apart and weight equally distributed on each leg. Height was measured with adolescent being bare foot (to the nearest 0.5 cm) with the child standing in an erect position against a vertical scale of portable stadiometer with the participants feet placed together with heels, buttocks and shoulder blade against the stick head positioned in Frankfurt horizontal plane. Waist circumference was measured with a non-stretchable tape (exerting the same standard pressure on the tape) at the midpoint of the lowest rib cage and the iliac crest, to the nearest 0.1 cm. Hip circumference was measured at the level of greater trochanters with the subject in standing position and both feet together. For all measurements, tape was positioned parallel to the floor.

BMI was computed by dividing weight (kg) by height square (m²). BMI categories were defined as (a) Normal weight, (b) Overweight and (c) Obese according to contemporary Indian data. Height for age, weight for age and BMI for age z-scores were computed using Indian reference data [28].

Blood pressure was measured on left arm by auscultatory method using mercury sphygmomanometer. The individual was made comfortable and seated at least for five minutes in the chair before measurement. Hypertensive and Pre-Hypertensive children considered and were checked again half an hour apart and the average of two reading was taken. Pre-Hypertension and Hypertension are diagnosed if Systolic or Diastolic blood pressure or both are >90th to <95th and >95th centile as per age and height, respectively.

Fasting plasma glucose was measured with One Touch Glucometer (Johnson & Johnson Co.) in all the subjects after an overnight 10 h fast. Later students were provided with breakfast. Pre-diabetes was defined as fasting plasma glucose between 100 mg/dl to 125 mg/dl.

Body fat percentage was measured using commercially available digital monitor Omron HBF-306 body fat monitor incorporating bioelectrical impedance(BI) analyser.

Statiscal Analysis

Data were analyzed using SPSS version 19.0.Data was expressed as mean +/- SD for quantative variables or numbers and percentage for categorical variables. Data was compared using student t-test for 2 groups and ANOVA for more than 2 groups. Multivariate regression analysis was done to estimate effect of each variable on obesity. For all test p value<0.05 was considered statically significant.

To detect the Sensitivity and Specificity of each anthropometric parameter to detect Prehypertension and Pre-diabetes ROC curve was plotted.

Results

In the present study, total 389 adolescents investigated, 45% were girls and 55% were boys (Tables 1 and 2).

The area under the curve for waist hip ratio, waist circumference, hip circumference, weight, body fat and BMI are 0.54, 0.43, 0.43, 0.43, 0.48 and 0.42, respectively. Of these values the waist hip ratio which had relatively higher area under the curve, at the cut of 0.84, it has 61% sensitivity and 54% specificity in suspecting an individual for pre-diabetes (Table 3 and Figures 1-3).

The area under the curve for waist hip ratio, waist circumference, hip circumference, weight, body fat and BMI are 0.43, 0.46, 0.54, 0.60, 0.60 and 0.66, respectively (Table 4 and Figure 4) for hypertension in boys.

The area under the curve for waist hip ratio, waist circumference, hip circumference, weight, body fat and BMI for hypertension in girls is 0.54, 0.69, 0.79, 0.81, 0.79 and 0.78, respectively (Table 5 and Figure 5).

Interpretation

Compared to students with normal BMI, those who were overweight had 7.19 times [95% CI: (2.25-22.96)] high odds to have pre hypertension or hypertension (Table 6).

Similarly compared to normal BMI students, obese students were had 8.76 times high odds [95% CI: (2.5-330.27)] to have pre hypertension or hypertension.

There was no significant difference between normal BMI students and underweight students in terms of Pre hypertension/Hypertension.

Compared to students with normal WH ratio, low WHR students did not have any significant correlation in developing pre-hypertension or hypertension.

Compared to students with normal body fat percentage, those who had a high BFP had 6.02 times high odds to have pre-diabetes or diabetes similarly those who had very high body fat percentage who were at 21.25 times high odds to have pre-diabetes and diabetes (Figure 3).

Table 1. Association of anthropometric parameters with hypertension status of the students

Anthropometric parameters	Prehypertension/Hypertension N (%)	Normotensive N (%)	Odds Ratio (95% CI)	P value
BMI				
Normal	21 (6.5)	302 (93.5)	1 (Ref)	
Underweight	48 (100.0)	0 (0.0)	4.57 (0)	1
Overweight	5 (33.3)	10 (66.7)	7.19 (2.25-22.96)	0.001
Obese	2 (66.7)	1 (33.3)	28.76 (2.5-330.27)	0.007
Waist hip circumference ratio				
Normal	14 (12.8)	95 (87.2)	1 (Ref)	
Low	11 (4.6)	226 (95.4)	0.33 (0.14-0.75)	0.009
High	3 (7.0)	40 (93.8)	0.51 (0.14-1.87)	0.309
Body fat				
Normal	4 (2.3)	170 (97.7)	1 (Ref)	
Low	1 (1.8)	54 (98.2)	0.79 (0.09-7.19)	0.832
High	18 (12.4)	127 (87.6)	6.02 (1.99-18.23)	0.001
Very high	5 (33.3)	10 (66.7)	21.25 (4.93-91.62)	<0.001
Total	28 (7.20)	361 (92.80)	-	-

Table 2. Association of anthropometric parameters with diabetes status of the students

Anthropometric Parameters	Impaired FBS N (%)	Normal FBS N (%)	Odds Ratio (95% CI)	P value
BMI				
Normal	40 (12.4)	283 (87.6)	1 (Ref)	
Underweight	7 (14.6)	41 (85.4)	1.21(0.51-2.87)	0.669
Overweight	1 (6.7)	14 (93.3)	0.51 (0.06-3.95)	0.515
Obese	0 (0.0)	3 (100)	4.52 (0)	0.992
Waist hip circumference ratio				
Normal	15 (13.8)	94 (86.2)	1 (Ref)	
Low	32 (13.5)	205 (86.5)	0.98 (0.51-1.89)	0.948
High	1 (2.3)	42 (97.7)	0.15 (0.02-1.17)	0.070
Body fat				
Normal	19 (10.9)	155 (89.1)	1 (Ref)	
Low	6 (10.9)	49 (89.1)	1.01(0.38-0.64)	0.998
High	22 (15.2)	123 (84.8)	1.46 (0.76-2.82)	0.260
Very high	1 (6.7)	14 (93.3)	0.58 (0.07-4.68)	0.611
Total	28 (7.20)	361 (92.80)	-	-

Table 3. Interpretation ROC curve for prediabetes among girls

Anthropometric parameter	Cut off point to predict pre diabetes among girls	Sensitivity at this cut-off point to predict pre-hypertension	Specificity at this cut-off point to predict pre-hypertension
Weight	41.5	68%	46
Hip circumference	80.5	68%	33%
BMI	18.5	72%	56%
Body fat	22.7	72%	54%

Table 4. Interpretation ROC curve for pre-hypertension for boys

Anthropometric parameter	Cut off point to predict hypertension among boys	Sensitivity at this cut-off point to predict pre-hypertension	Specificity at this cut-off point to predict pre-hypertension
Weight	45.50	85%	59%
Waist circumference	68.5	92%	63%
Hip circumference	81.5	89%	59%
Waist hip ratio	0.82	92%	35%
BMI	17.9	92%	58%
Body fat	22.2	85%	70%

Table 5. Interpretation ROC curve for pre hypertension among girls

Anthropometric parameter	Cut off point to predict hypertension among girls	Sensitivity at this cut-off point to predict pre-hypertension	Specificity at this cut-off point to predict pre-hypertension
Weight	43.5	87%	53%
Waist circumference	64.5	87%	29%
Hip circumference	84.5	73%	63%
Waist hip ratio	80.5	73%	47%
BMI	18.7	80%	60%
Body fat	23.6	80%	58%

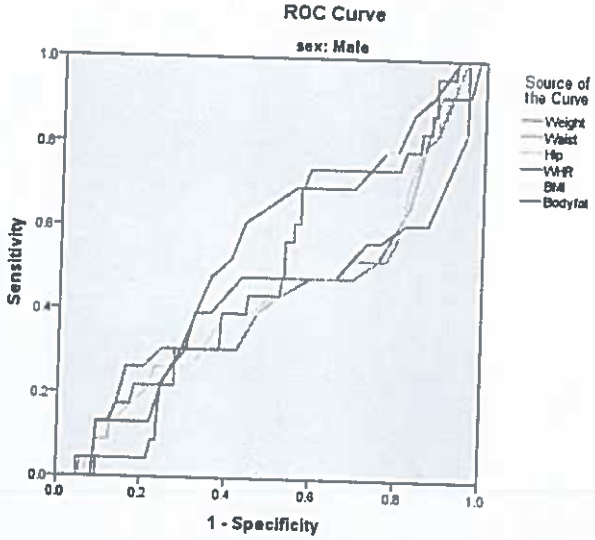

Figure 1. ROC curve for prediabetes among boys

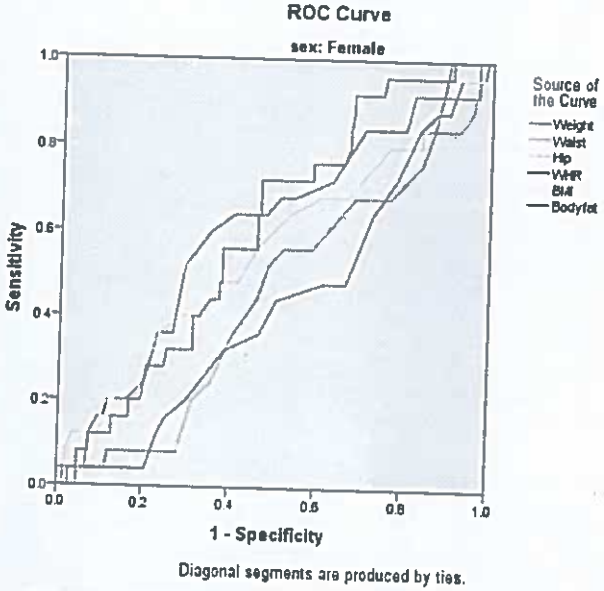

Figure 2. ROC curve for prediabetes among girls

Discussion

Vague was first to realize that different body morphology or types of fat distribution were related to various risks associated with obesity [29]. Our study comprising of 214 males and 175 females showed the prevalence of overweight and obesities among preparatory adolescents in government school of Karnataka was 3.9% and 0.8%, respectively.

There is a high incidence of Diabetes in India which is increasing rapidly. International Diabetes Association has estimated that there would be around 70 million cases of Diabetes mellitus in India by the year 2025 [30,31]. Also, studies have shown that diabetes sets in a decade earlier in Indians than West [32]. Abnormal anthropometric indicators like WHR and BMI are associated with a

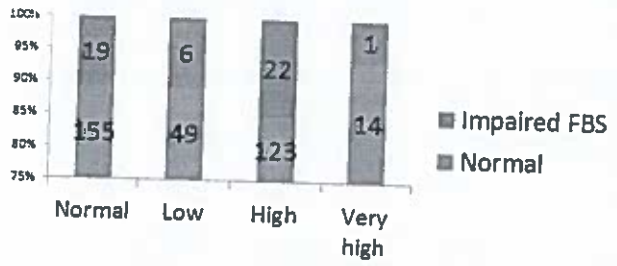

Figure 3. Body fat with FBS status

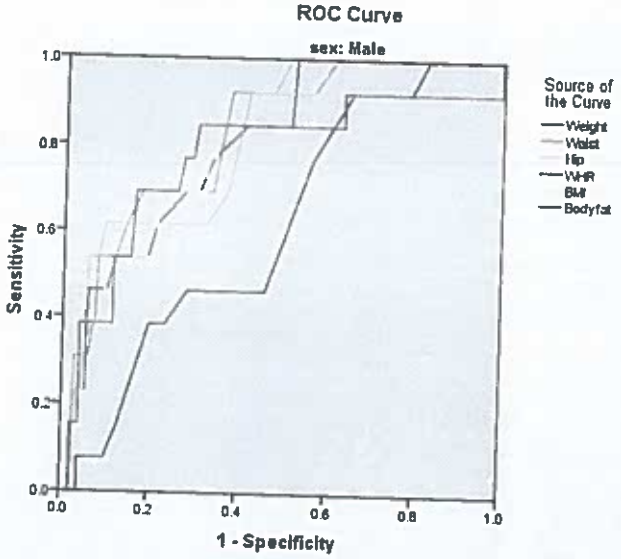

Figure 4. ROC curve for pre-hypertension for boys

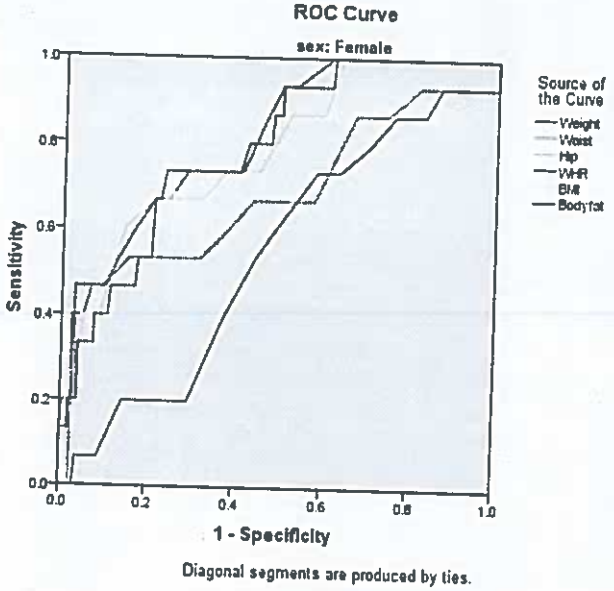

Figure 5. ROC curve for pre hypertension among girls

greater possibility of development of DM and metabolic syndrome. Students having a WHR of more than 0.8 were categorised as having high WHR. However, cut-off values of WHR are not prescribed by WHO for children. But previous studies have shown WHR values for children whose weight for age was between 50th to 97th percentile

Table 6: Similar studies

Study	Year of Study	Place of Study	Prevalence of Hypertension in Obesity
Gupta et al. [42]	1990	India	0.34%
Verma et al. [36]	1994	Punjab, India	13.7%
Anand et al. [37]	1996	Amritsir ,India	0.23%
Macedo et al. [38]	1996	North Portugal	5.2%
Sorof et al. [39]	2002	Texas, USA	19.4%
Present study	2015	Banglore, India	7.2%

were between 0.8-0.9, which is closer to the WHR cut-off values for adults as per WHO guidelines [33]. In our study, number of students with high waist-hip-ratio especially was 11.1% (43 participants). Significant correlation was found between WHR and pre-diabetic status (p value=0.07) (Table 6). As overweight condition and obesity are risk factors for diabetes, a high waist measurement and a high WHR might serve as a good indicator in recognizing cases at high risk that might progress to pre-diabetic state and later Diabetes mellitus. No correlation was found between pre-diabetes with overweight or obesity. This might be due to the fact that insulin resistance is a common feature even in non-obese Asian Indian subjects with a specific "Asian Indian Phenotype" that refers to certain unique clinical and biochemical abnormalities in Indians which include increased insulin resistance, greater abdominal adiposity, i.e., higher waist circumference despite lower body mass index, lower adiponectin and higher high sensitive C-reactive protein levels. This phenotype makes Asian Indians more prone to diabetes and premature coronary artery disease. At least a part of this is due to genetic factors. This observation is also in accordance with the study done by Narayanappa et al. [32,34,35]. However, the primary drive for the epidemic of diabetes is the rapid epidemiological transition associated with changes in dietary patterns and decreased physical activity as evident from the higher prevalence of diabetes in the urban population which in recent times is also seen in rural areas.

At third screening, a total of 28 cases (7.2%) had abnormal blood pressure of which 5.1% were in pre-hypertension group and 2.1% in hypertension. The prevalence in various other studies ranged from 0.46% to 19% as shown in. This wide difference could be due to different standards used for the diagnosis of hypertension and also, due to variations in the regions. Also, there is higher prevalence of hypertension in southern India probably because of influencing factors like genetic inheritance, dietary habits and lifestyle factors.

According to NHBPEP, pre-hypertension defined if BP is between 90th and 95th percentile. Stage I hypertension is BP from 95th percentile to <99th percentile plus 5 mm of Hg. Stage II hypertension is BP more than 99th percentile plus 5 mm of Hg. Prehypertension and stage I hypertension need only weight and dietary management. Stage II hypertension needs pharmacological therapy in addition to weight and diet management. Our cases were managed accordingly.

Anthropometric Risk Factors

Pre-hypertension and hypertension were directly proportional to weight for age ($p<0.05$). Also it was noted that, high body fat had significant association to incidence of pre hypertension and hypertension. Hypertension in obese children could be due to increased cardiac output, increased blood volume, excessive sodium intake, increased steroid production and alteration in receptors for various presser substances [40].

Body mass index and increased weight and height had a significant association with hypertension in our study ($p \leq 0.001$), similar results obtained in Anand et al. [37] Chadha et al. [40] study. The results also showed that lower the BMI, lessen the chances of hypertension. Obesity in childhood is a well-established risk factor for hypertension. In our study, prevalence of HTN in obese children is 11.1% which is statistically significant. Sorof et al. [39] Verma et al. [36] have shown that 19.4% and 13.7% of obese children had hypertension, respectively.

No association was found between waist hip ratio and hypertension, it correlates with studies done by Chaddha et al. and Moussa et al. [40,41].

Limitations

The sample size in the present study was small and there are no standard charts available for the local population from which the sample has been taken. Blood pressure is also influenced by various other factors such as ambience, fasting vs. non fasting state, psychological stress, which could not be controlled in our study.

Recommendations

Regular anthropometric and blood pressure monitoring at least once in a year on an outpatient basis or in routine school health check-up should be incorporated in early life.

Serial blood pressure measurements are required to diagnose hypertension than single reading and children with significant clinical history should be screened at the earliest.

Studies involving a larger population are required to prepare standard centile charts for the local population.

What is Already Known?

Extensive studies have been done to establish relation between waist hip ratio with pre-hypertension and prediabetes in western country. These studies correlate faulty food habits and sedentary lifestyle with obesity associated comorbidity.

What this Study Adds?

So far very few similar studies have been done in school going children in India, and study in rural parts of India are very rare. Among the studies which are done, many of them do not include BMI, Waist hip ratio and Body Fat percentage all together to correlation for pre-hypertension and pre-diabetes in a single subjected population sample. Our study establishes this relation in school going children of rural part of Karnataka. It was an extensive study which concluded BMI, Waist hip ratio and Body Fat percentage are early Predictors of Prehypertension and hypertension. Our results are comparable to studies done in urban scales. Early incidence can prevent this epidemic rise in obesity and associated comorbidities in new India.

Conclusion

Hypertension and Diabetes is a significant problem in the school going adolescents of developing countries. Obesity, waist hip ratio, and increased body mass index are significant anthropometric risk factors for hypertension and diabetes. Using simple screening methods in younger ages itself like measuring BMI, Waist and FBS, it is possible to identify individuals at high risk at an early age and accordingly lifestyle modifications can be adopted to postpone the onset of the disease and reduce the burden on the community and the nation.

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Original Article

SERUM MAGNESIUM LEVEL IN FEBRILE CONVULSION

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ABSTRACT

Aim

To study relation between serum magnesium levels and febrile convulsion and to compare serum magnesium level in children with febrile convulsion.to febrile children with no convulsion.

Material and Methods

A prospective case control study done in Kempegowda Institutes of Medical science, Bangalore between October 2015- October 2016 where 2 groups were made of 45 children each as case and control group. Informed consent was taken by all parents and detailed history, past , birth and family history was taken and serum magnesium levels were done by Roche 9180 electrolyte analyser.

Results

Mean age of cases with febrile convulsion and febrile patients without seizures were 1.97years (+/-) 1.33years and 2.01years (+ /-)1.02 years respectively. there were 24 male and 21 female babies in group 1 and 23 male and 22 females in other group. the mean age and sex were similar in both groups. Mean level of magnesium were 1.97+_0.24 and 2.19 +_ 0.20 in cases with febrile convulsion and febrile patients without seizures respectively and there was significant differences.

Conclusions

Febrile convulsion is the most common type of convulsion in children. We got a positive co relation between levels of serum magnesium and febrile convulsion. However more studies at a larger level required to establish a strong correlation between the two.

KEYWORDS: *Serum Magnesium Levels, Febrile Convulsion & Convulsion*

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INTRODUCTION

Febrile convulsion are the most common type of seizures and occur in 2-4 % of children [1] Factors like genetics, neurotransmitters level changes and few trace elements have been introduced as a possible cause [2-4], however, the main cause not known yet. Because 30-40% of children who experience a febrile convulsion will have a recurrence, it makes febrile convulsion an important issue to understand and prevent [5]In the past, blood tests like electrolytes were not suggested, but recently several studies have shown the effect of GABA, ZN, and Fe in developing febrile convulsion offering possible interference of other trace elements. Magnesium is the fourth most common cation in the body and the third most intra cellular cation .50-60% of body magnesium is in bone where it serves as reservoir because 30% is exchangeable, allowing movement to extra cellular space. Most intra

cellular magnesium is bound to protein, of about 25% is exchangeable. Because cells with higher metabolic rate have higher magnesium, most of it is present in muscle and lever. The normal plasma magnesium is 1.5-2.3 mg/dl. Magnesium is essential for membrane utilization and nerve conduction [1].By definition by AAP criteria , the child should have a febrile illness or certainly fever, neurologically healthy between 6 month to 5 years of age whose seizure is brief (<15min) , generalized and occurs only once (simple febrile convulsion) or more times(complex febrile convulsions) during a 24 hour period during a fever[6].The following objectives to correlate the hypothesis , to find co relation between serum magnesium level and febrile convulsion and to compare level of serum magnesium between children with febrile convulsion and febrile children with no convulsions.

METHOD

This was a prospective case-control study done in Kempegowda Institute of Medical Science, Bangalore between October 2015 to October 2016 which included two groups of patients with 6-60 month of age with febrile convulsion and fever without seizure respectively. Forty five cases were enrolled in each groups.

Inclusion Criteria

- Patients between 6 month to 5 years of age of either sex.

Exclusion Criteria

- Electrolyte imbalance due to gastrointestinal disease
- CNS infections (encephalitis , meningitis)
- Metabolic disorder

Detailed history of presenting complaints, type and duration of seizure, past history, birth history and family history was taken . Thorough physical examination was done. Children with congenital or acquired illness were excluded. 2ml of blood was drawn under aseptic precaution and serum magnesium level were measured using Roche 9180 electrolyte analyser. The analysis was done by STATA11.1, data were analysed using T test and Chi square

RESULTS

Mean age of cases with febrile convulsion and febrile patients without seizures were 1.97years +_ 1.33 years and 2.01years + _ 1.02 years respectively. There were 24 male and 21 female babies in group-I and 23 male and 22 females in group-II. The mean age and sex were similar in both groups.

Mean level of magnesium were 1.97+_0.24 and 2.19 +_ 0.20 in cases with febrile convulsion and febrile patients without seizures respectively and there was significant difference (p=0.001)

Table 1

VARIABLE	GROUP 1	GROUP 2
Serum Mg	1.97+_0.24	2.19 +_ 0.20

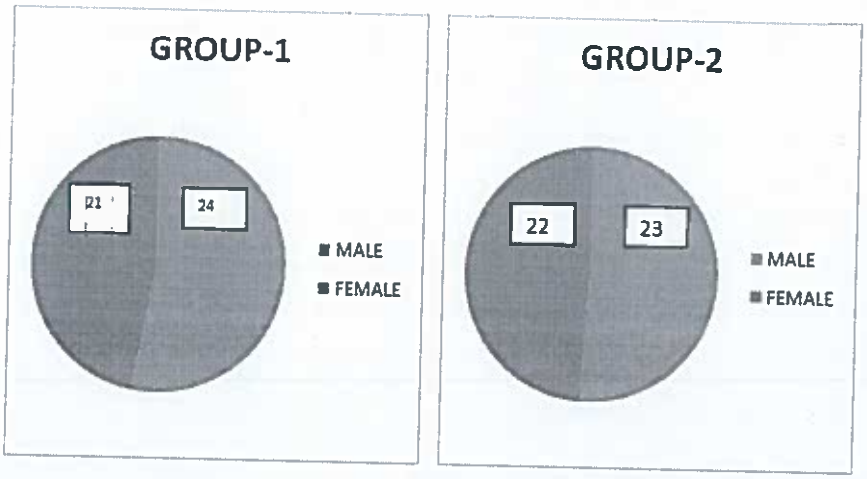

Figure 1

DISCUSSIONS

Action of magnesium level on nervous system is that, it reduces the release of acetyl choline at the neuromuscular junction by antagonizing calcium ions at presynaptic junction, reduced excitability of nerves, and acts as anticonvulsants, reverses cerebral vasospasm [7].It is suggested that alteration in magnesium concentration in plasma and intracellular matrix give rise to functional impairment of the cell membranes, which might trigger seizures. Recent evidences indicate that the deficiency of magnesium play a significant role in febrile convulsion [7, 8].Magnesium plays an important role in establishing electrical potential across cell membrane. It also affects calcium metabolism the production of cyclic adenosine monophosphate is magnesium dependent which in turn controls release of parathyroid hormone. [7, 9]. Our study showed difference in magnesium level in between two groups which is similar to Studies done by Prakash, Talebian and Sadinegad [10-12]. However studies done by Burhanoglu, Donalson, Rutter and Heipertz showed no difference in magnesium level [3, 13-15].A recent study done in Egypt in 2013 in Ain Shams University and National research centre Egypt to asses blood levels of trace elements in familial febrile convulsion concluded that serum selenium and magnesium levels were significant low and logistic regression model in their study showed that selenium and magnesium have protective effect in children with febrile convulsion [16].

CONCLUSIONS

Febrile convulsion is the most common type of convulsion in children. In our study, a positive correlation was found between levels of serum magnesium and febrile convulsion. Hence children with low serum Magnesium level are more prone to get febrile convulsions than children with normal Magnesium levelsHowever more studies at a larger level required to establish a strong co relation between the two.

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Prevalence of attention deficit hyperactivity disorder in school going children aged between 5-12 years in Bengaluru.

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Abstract

Background: Attention deficit hyperactivity disorder (ADHD) is one of the most common childhood psychiatric disorders that affect 2% to 14% of school age children. It is characterized by age inappropriate level of inattention with or without motor over activity and impulsivity in academic and social spheres. Boys are more affected than girls and male female ratio is 4:1. Although ADHD is the most common condition, the evidence from Indian studies is very less. Many studies are required in India to see the magnitude of ADHD. Evaluation of the prevalence of this condition in our country will help clinicians to consider the diagnosis of ADHD and related disorders. This study aims to determine the prevalence of ADHD among school going children (5 years to 12years) and to know the difference between government and private schools as well as to determine male to female ratio in Bengaluru.

Methods: This was a cross-sectional study done in Bengaluru city by convenience sampling method. A total 18 schools comprising of both private and government were selected. 3120 Children aged between 5-12years studying in these schools were included in the study. Introduction about ADHD was given by Paediatrician to the teachers followed by screening for ADHD was done by teachers using Conner's teachers rating scale for all children. Positive cases in these were screened with Parents and Paediatrician by using Conner's parent rating scale. Children who were positive in Parents and Paediatrician rating scale were interviewed by the Psychiatrist at KIMS Hospital and ADHD was diagnosed by using DSM V criteria along with IQ assessment and treatment was started for the needy.

Results: The prevalence of ADHD in our study was 1.3%. Male to female ratio was 1.6:1. Among the positive cases, children belonging to Hyperactivity type were 34.1%, inattention was 9.8% and combined type was 56.1%. Prevalence in private school was 1.25% and government school was 1.37%. Total dropouts were 2.5% who did not reach the hospital for the final diagnosis.

Conclusion: ADHD is prevalent worldwide and it is also one of the emerging disorders in our country. It constitutes a significant mental health disorder in children and 50% of this disorder will be carried to adulthood. In our study we had prevalence of 1.3% ADHD and 2.5% dropouts due to lack of awareness of this disorder, their work pressure, distance, social and financial constricts. It is high time to identify the disorder and creating wide spread awareness about ADHD by the Paediatrician's among the Teachers, Parents and Primary care Physicians, in order to prevent the social and academic impact of the disorder. By introducing an ADHD standard screening methods in all schools along with the regular health check-ups will bring awareness in the society for the healthy future of the children. Lastly every school should have a counsellor to overcome ADHD and other related problems.

Keywords: Hyperactivity, Children, Schools.

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Introduction

Attention Deficit Hyperactivity Disorder (ADHD) has been described all around the world and is the most common neurobehavioral disorder of childhood and one among the most common chronic health conditions affecting school-age children [1,2]. It is characterized by inattention, increased distractibility with difficulty sustaining attention, poor impulse control and decreased self-inhibitory capacity, motor over activity and motor restlessness [3].

The first example of a disorder that appears to be similar to ADHD was given by Sir Alexander Crichton in 1798. George still, conducted study on a group of 20 children whom he described as having a deficit in "volitional inhibition [4]. He reported that there was an overrepresentation of male subjects, a family history of alcoholism, criminal conduct, and depression, a family predisposition and the possibility that the condition may arise from an injury to the nervous system. Still's observations are quite common and have been corroborated in later research.

Later, it was stated that mild forms of brain damage in infancy, although unnoticed at that time, could lead to behavioural sequelae, which becomes first apparent at school [5,6].

In 2008, it was defined as a "persistent pattern of inattention, hyperactivity and impulsivity, that is more frequent and severe than is typically observed at a comparable level of development" affecting approximately 5% of school-age children and frequently persisting into adulthood [7-9].

Population surveys suggest that ADHD occurs around the world in about 5% of children and it is carried to about 2.5% of adults. These reported rates vary depending upon the nature of the population sampled and the method of ascertainment [3]. Many studies across the globe have reported the prevalence of ADHD in 5% to 10% of school aged children. Most of them are western studies and there is a little information about the same from India.

ADHD is often undiagnosed in children. This is usually due to lack of awareness of ADHD among parents and teachers. Children with ADHD have difficulty in performing scholastically to their optimum levels. This translates to stress on the family and in turn has an emotional impact on the child. Hence, there is an urgent need for continued teamwork on prevalence of ADHD in our country.

This study provides the much needed epidemiologic data on ADHD as well as understands the influence of socioeconomic factors in the same which in turn would help in designing the programme to increase the awareness of ADHD in parents as well as teachers.

This study also helps in differentiating the prevalence of ADHD between Private and Government schools by including the socio-economical and educational factors causing impact on children's mental health. Finally, this study will throw light on the male female ratio in the prevalence of ADHD.

Aims and Objectives

1. To study the Prevalence of ADHD in children aged 5-12 years in urban schools of Bengaluru.

2. To compare the Prevalence of ADHD in Government and Private Schools.

3. To create awareness among the teachers and parents about ADHD in children.

Materials and Methods

Study Area

The study was conducted in Bengaluru South block schools.

Study Design

Cross sectional-descriptive.

Study Duration

Time period of two year, i.e., October 2014 to October 2016.

Study Population

School children in the age group 5 to 12 years in Bengaluru city.

Exclusion Criteria

- Children <5 years and >12 years.
- Children with conduct disorders and oppositional disorders.
- Children studying in schools outside Bengaluru city limits.

Statistical Analysis

Descriptive statistics-percentages and proportion.

Ethical Clearance

The study protocol was submitted to the ethical committee of Kempegowda Institute of Medical Sciences and clearance obtained before the study was commenced.

Method of Collection of Data (Including Sampling Procedure)

Sampling procedure: Convenience sampling

Sample size: N=3120, Sample size has been calculated taking prevalence of ADHD among school going children as 5% at 5% significance level and 10% allowable error.

Collection of Data

The collection of data was done in 4 phases. These rating

scales assist in determining whether children between the ages 5 to 12 years might suffer from ADHD. Details are presented in presented in supplementary file.

Study Instruments

Semi-structured Performa was prepared after discussion with the psychiatrist. It is a questionnaire with 12 simple questions from DSM-V criteria related to the ADHD symptoms. It has 6 questions related to inattention, 6 questions related to hyperactivity and impulsivity. It was translated to kannada for easy understanding and use in kannada medium schools.

Conner's Rating Scale, Revised (CRS-R): Developed by C. Keith Conners, Ph.D., CRS-R is used as part of a comprehensive examination and is designed to be easily administered and scored. CRS-R is the widely used rating scale and has set the standard for assessing ADHD and related problems. CRS-R is available in long and short versions for both parents and teachers. Short version (each comprising of 27 items) of both parent and teachers rating scale was used in our study.

Based on the types of symptoms, three kinds (presentations) of ADHD can occur:

1. Combined Presentation: if enough symptoms of both criteria inattention and hyperactivity-impulsivity were present for the past 6 months

2. Predominantly Inattentive Presentation: if enough symptoms of inattention, but not hyperactivity-impulsivity, were present for the past six months

3. Predominantly Hyperactive-Impulsive Presentation: if enough symptoms of hyperactivity-impulsivity but not inattention were present for the past six months.

Results and Observations

We found 41 children with ADHD, which translates to a prevalence rate of 1.3 % in school going children of age group 5 to 12 years. The prevalence was 1.6% in boys and 1% in girls.

The above Table 1 also shows the sex distribution of the children screened which was 56.7% boys and 43.3% girls (1.30:1) whereas the boys: girl ratio among ADHD children is 1.6:1 and is significant (p value<0.001).

Table 2 shows the prevalence of ADHD in different age groups. The prevalence is highest in 6-8 years group and lowest in 5 years age group. The prevalence tends to decrease as age progresses.

Figure 1 shows the prevalence of ADHD subtypes in our study sample. In this study, the prevalence of hyperactivity subtype was 34.1%, the inattention type was 9.8% and combined type was 56.1%. Combined type was more predominant in our study closely followed by hyperactivity type.

Table 3 shows distribution of ADHD children based on different subtypes of disorder. In children of 5 years prevalence of ADHD is 7.14%. The hyperactivity type is 2.38%, combined type is 4.76% and inattention type is 0%. In children of 6-8 years prevalence of ADHD is 1.06%. The hyperactivity type is 0.47%, combined type is 0.35% and inattention type is 0.23%. In children of 9-10 years prevalence of ADHD is 0.96%. The hyperactivity type is 0.35%, combined type is 0.52% and inattention type is 0.09%.

In children of 11-12 years prevalence of ADHD is 1.65%. The hyperactivity type is 0.46%, combined type is 1.10% and inattention type is 0.09%.

This Table 4 shows that in our study 53.66% of the children with ADHD belonged to Government school, 46.34% to private. The difference was not significant in statistical analysis.

This Table 5 shows the academic performance of children who were diagnosed to have ADHD. This academic

Table 1. Prevalence rate of ADHD by gender

ADHD	Gender		Total
	Female	Male	
No	1337 (99%)	1742 (98.4%)	3079 (98.7%)
Yes	13 (1%)	28 (1.6%)	41 (1.3%)
Total	1350 (100%)	1770 (100%)	3120 (100%)

Table 2. Prevalence rate based on age

Age in Years	ADHD	Non ADHD	Total
5	3 (7.14%)	39	42 (1.3%)
6-8	9 (1.06%)	839	848 (27.2%)
9-10	11 (0.96%)	1131	1142 (36.6%)
11-12	18 (1.65%)	1070	1088 (34.9%)
Total	41 (1.3%)	3079	3120 (100%)

Table 3. Distribution of ADHD children based on different subtypes of disorder

Type of ADHD	No. of Patients (n=41)	%
Hyperactive	14	34.1
Combined	23	56.1
Inattentive	4	9.8

Table 4. ADHD children and type of school

Type of school	Frequency	%
Private	19	46.34%
Government	22	53.66%
Total	41	100

Table 5. Academic performances of ADHD children

Academic Performance	Frequency	%
Good (>70%)	0	0%
Average (40-70%)	31	76%
Poor (<40%)	10	24%
Total	41	100

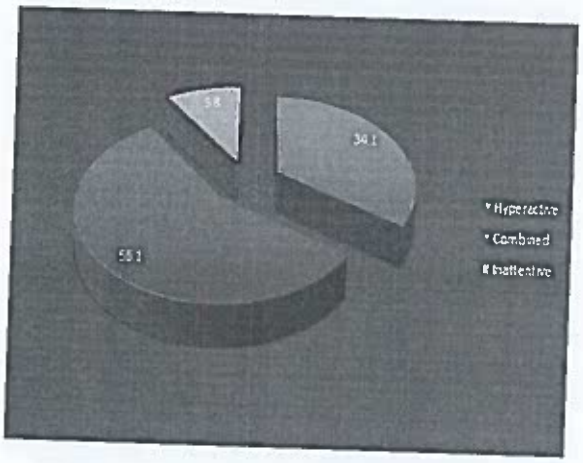

Figure 1. *Prevalence of ADHD subtypes*

performance was based on the marks obtained in the tests and exams in school. Out of 41 children only 31 children were having average grades and 10 children having poor grade, none of them were having good grades.

Discussion

Our study shows 1.3% prevalence of ADHD. Other studies which have prevalence of 2-15% Dropouts were 2.56%. Among these, most of them were having significant scores in Teachers, Parents and Pediatrician's scale and were unavailable for follow up at the KIMS hospital. The probable reasons behind this is lack of knowledge and false beliefs about ADHD in our country and in a metropolitan city like Bengaluru, many could not approach us to the hospital during working hours for final follow up with all their work pressure, distance, social and financial constricts.

This study examined the prevalence of ADHD in 3120 school age children of age group 5 to 12 years by cross sectional survey in Bengaluru city in Karnataka. Although the prevalence of 1.3% is low when compared with the studies in western countries and some studies in India, it is consistent with some Indian studies in school age children [3,10,11].

A review of 17 studies conducted in all continents showed a wide range of prevalence ranging from 0.2% to 23%. These studies were done using different criteria (DSM and ICD) and strategy adopted to collect information were different (i.e., only parents or teacher or both, whether functional impairment required, whether child was interviewed). Studies based on information from either only parents or teachers have higher prevalence than the studies which collect information from both parents and teachers, which in turn will be higher compared to studies which includes interview in addition to the information from both parents and teacher

According to Kurtzke et al., epidemiological studies with a higher prevalence should be considered as estimated or screening prevalence because many false positives may be included. That may explain part of the differences observed between the results obtained from different studies [12].

More recent community based epidemiological studies have reported much lower prevalence figures. The Great Britain office of national statistics conducted a survey of more than 10,000 children and found a DSM-IV based prevalence of 1.4% in 1999 and 1.5% in 2004. A similar profile is seen in recent studies conducted in developing countries. In Brazil DSM-IV based prevalence of 1.8%, 2% in Bangladesh and 1.6% in India were noted. In our study, the prevalence is 1.3% and is consistent with these recent studies. [13].

Epidemiological surveys in western countries have reported a greater incidence in boys than in girls; the ratio ranging from 2:1 to 10:1 [14,15]. Whereas Indian studies have reported ADHD to be 3.3 to 7.7 times more common in boys than girls.

Our study gives the sex ratio of 1.6:1 which is (low) compared to above studies, but a recent meta-analysis of studies done in last decade gives a pooled prevalence of (2.4:1) which is consistent with the present study [16].

According to Goodman et al. [16] the gender differences strengthens the evidence for a biologically based, often genetically transmitted etiology of hyperkinetic disorder.

This difference may be due to the fact that girls have ADHD with higher predominance of inattention type, causing less trouble to the family and at school, and are therefore less easily identified.

Our study shows higher prevalence in the age groups 11-12 years. This is consistent with the findings of Mullick et al. [17] which also showed a higher prevalence of ADHD in age groups 9-10 years and 11 to 12 years. This difference may be due to increased demands of attention both in school as well as home as the child grows.

In our study, ADHD was associated with poor academic performance in 24.4%, average performance in 75.6% and none in good performance (based on marks obtained in tests and examinations). This is in accordance with the fact that there is functional impairment in children with ADHD.

Our study shows higher prevalence of ADHD among children whose mothers were homemakers and is not consistent with the hypothesis that homemakers are in a better position to look after their children at home both socially and psychologically [18].

High proportions of mothers in this study were either had primary education or illiterate, which puts more weight on education as a contribution factor. ADHD is one of the best investigated child mental health disorders. ADHD has received a great deal of clinical, scientific and public attention in recent years. In the last decade, western literature on this syndrome has grown but in India only a few studies have been done. Hence this study was done to fill this void.

There is lack of awareness about ADHD in parents, teachers and even among treating clinicians to create necessary awareness about ADHD, study results were discussed in parent – teacher meet conducted monthly in the school. Early detection and intervention about ADHD were explained. Teachers were also trained on classroom management of ADHD children.

Conclusion

Our study aim was to find the prevalence of ADHD among 5-12years old school going children in Bengaluru. We found a prevalence of 1.3% with male: female ratio of 1.6:1. Although the prevalence in our study is low compared to studies in western countries and also some Indian studies, it still constitutes a major public health problem. Epidemiological survey of ADHD is important in planning health services. Therefore further interview based studies assessing the prevalence of ADHD as defined by DSM-V criteria are required in different parts of the country to get a clearer picture of its burden in our country. The knowledge of ADHD is lacking in teachers, parents and also in the society, by this study we would like to recommend the ADHD screening should be done regularly along with routine health check-ups done annually in every government and private school, counsellors should be there in every government and private school to help students to overcome these type of issues.

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Neck circumference measurement as a screening tool for obesity in children

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ABSTRACT

Background: Childhood obesity is a rising epidemic and a major public health problem with the risk for type 2 diabetes mellitus, hypertension and cardiovascular disorders in later life. Neck circumference (NC), a marker of upper body subcutaneous adipose tissue distribution can predict higher metabolic risk. The aim of the present study was to evaluate the association between neck circumference (NC) and obesity.

Methods: This cross-sectional prospective observational study was conducted in Bangalore in the month of October 2016. 172 male and 161 female students, aged 13-17 years were screened. Anthropometric markers of obesity measured included body mass index (BMI), waist circumference (WC), hip circumference (HC), waist-to-hip ratio (WHR), and compared with neck circumference (NC) of the same subjects. Pearson's correlation coefficient was calculated between neck circumference and other obesity indices, and receiver operating characteristic curve analysis was used to determine the best cutoff value of neck circumference in predicting high BMI.

Results: Overall, 13.2% boys and 9.9% girls were found overweight/obese. The mean BMI was 25.27±2.09kg/m^2 and25.17±2.23kg/m^2, mean neck circumference was 33.43±2.3cm and 31.50±1.4 in overweight/obese boys and girl respectively. All of the anthropometric parameters were found to be significantly higher in overweight/obese children than with their normal weight peers and higher in boys compared to girls. The neck circumference in boys was significantly greater than girls and higher in overweight/obese with P<0.001. The best cut-off value of neck circumference by ROC to identify boys with a high BMI was 32cm with sensitivity of (81.82%), specificity (89.06%), and for girls was 30cm with sensitivity of (84.85%), specificity (87.5%). Neck circumference had a strong positive correlation with other anthropometric measures BMI, WC, waist hip ratio in both boys and girls (p <0.001).

Conclusions: Neck circumference significantly correlated with other indices of obesity. It can be used with great reliability to screen overweight and obesity in children. NC can be considered as a simple, time saving and inexpensive clinical tool for detection of obesity in large population-based studies in children and adolescents.

Keywords: Body mass index, Neck circumference, Overweight, Obesity, Waist Circumference, Waist hip ratio

INTRODUCTION

The prevalence of childhood obesity is rapidly increasing worldwide. Obesity is associated with increased risk of cardiovascular and metabolic disturbances in later life. In children, the prevalence of obesity increased 300% over approximately 40 years. The National Health and Nutrition Examination Survey (2009-2010) found 32% of children between 2-19 year-old to be overweight or obese.[1]

BMI is the most widely used tool for defining overweight and obesity in both adults and children. But BMI is a suboptimal marker for total body fat and less suitable to

assess body fat distribution. Regional deposition of fat, especially in the upper body segment, is a better predictor of obesity related complications, such as hypertension, diabetes, and cardiovascular diseases.[2]

In assessing central obesity, anthropometric measures used are waist circumference (WC), waist/hip ratio (WHR), sagital abdominal circumference, etc, and skinfold thickness like triceps/subscapular skinfold thickness are measures of subcutaneous adiposity. But these measurements may not be of practical to use in winter and busy primary day to day practice. Other techniques like DEXA (dual-energy X-ray absorptiometry), USG, CT and MRI imaging procedures are expensive procedures to measure visceral/subcutaneous adiposity and are limited to research purposes. So there is a need to develop a simple, quick and reliable method of assessing obesity in primary care practices, to control obesity and related metabolic consequences. Free fatty acids release from upper body subcutaneous fat was found to be larger than that from lower body subcutaneous fat, a fact that further strengthens the relevance of measuring upper body subcutaneous adipose tissue depot.[3] Neck circumference measurement has been suggested as an index of the upper body fat distribution and can be used as a simple and time-saving screening measure to identify overweight/obesity.

The purpose of this study was to determine whether neck circumference alone can be used to identify overweight and obese children and to find out the correlation between neck circumference and BMI, WC, WHR to evaluate obesity.

METHODS

The present study was a prospective cross sectional observational study conducted in 2016 in the month of October in an urban school in Bangalore. After institutional ethical committee approval, we screened 333 children who were aged between 13 to 17 years. Parents were informed and consent was taken from the adolescent children in this study. Inclusion criteria were all adolescents aged between 13 to 17 years and who gave consent. Exclusion criteria were children with goiter, cervical lymphadenopathy or other neck masses, neck deformity, diabetes, cushings disease, medication use (like steroids etc) or procedures like tracheostomy or use of cervical collar were excluded from this study.

Anthropometric measurements

Measurements were taken by trained research assistant, height was measured by using a stadiometer, child standing with barefoot and head held in Frankfurt horizontal plane to the nearest 0.1 cm. Weight was measured by using a calibrated electronic weighing scale, to the nearest 0.1 kg. BMI was calculated by dividing weight in kilograms (kg) by the square of their height in meters (kg/m^2). WC was measured by using flexible measuring tape to the nearest 0.1 cm with the child standing, and at the end of normal expiration at a point midway between the inferior margin of the lowest rib and the iliac crest. Hip circumference (HC) was measured at the maximum circumference around the buttocks. WHR was calculated by dividing WC by HC. Neck circumference was measured by using a flexible tape, with the child in the standing position, head held erect and eyes facing forward and the neck in a horizontal plane at the level of most prominent portion, the thyroid cartilage.

Classification of BMI (WHO -2004): Underweight < 18.5 kg/m^2, normal 18.5 - 22.9 kg/m^2, over weight- 23 - 27.4 kg/m^2, Obese >_27.5 kg/m^2.[4] WHR values (WHO) for males was 0.9 and for females was 0.85.[5]

According to this classification 77 (23.1%) were with BMI >23kg/m^2 and 256 (76.9%) were with BMI <23kg/m^2.

Descriptive statistical analysis has been carried out in the present study. Continuous measurements were computed as Mean±SD, categorical measurements were presented in number (%).The calculations were performed by SPSS version 21 software and the results were considered statistically significant with $P \leq 0.05$. Student t-test (two tailed) has been used to find the significance of study parameters on continuous scale between two groups. Pearson correlation was used to study association between various anthropometric measurements to find the degree of relationship. Cutoff values of neck circumference to identify overweight and obesity were obtained by analyzing the ROC (receiver operating characteristic) curves. A perfect score will have an AUC of 1, whereas AUC of 0.5 means that test performs no better than chance. The best cutoff values were established for male and female children separately.

RESULTS

A total of 333 children who met the inclusion criteria were included in this study. Based on BMI, 44(13.2%) boys and 33(9.9%) girls were identified as overweight/obese. Table 1 shows mean anthropometric measurement values in both boys and girls. The mean weight, height, BMI, WC, HC, WHR were 63.16±10.03 kg, 158.33±8.2 cm, 25.27±2.09 kg/m^2, 81.05±10.41 cm, 88.14±10.4 cm, 0.92±0.05 cm respectively in obese/overweight boys. The mean weight, height, BMI, WC, HC, WHR were 59.00±7.3 kg, 153.14±7.1, 25.17±2.23 kg/m^2, 78.36±10.07 cm, 87.03±10.3cm, 0.90±0.10 respectively in obese/overweight girls. All of the anthropometric parameters were found to be significantly higher in overweight/obese children than with their normal weight peers and higher in boys compared to girls. The mean neck circumference in overweight/obese boys and girls was 33.43±2.3 and 31.50±1.4 cm respectively. The neck

circumference in boys was significantly greater than girls and higher in overweight/obese with P <0.001. Table 2 presents the Pearson's correlation coefficients between neck circumference and other anthropometric parameters for boys and girls. Neck circumference showed a strong positive correlation with BMI, WC and waist hip ratio in both boys and girls.

Table 1: Comparison of anthropometric measurements between controls and overweight/obese in boys and girls.

Boys (mean)	controls(normal/underweight)	Over weight-obese	P value
Age (years)	14.84±1.1	15.23±1.4	0.065
WT(kg)	44.48±7.0	63.16±10.03	<0.001
HT(cm)	157.11±7.5	158.33±8.2	0.366
BMI (kg/m^2)	17.89±2.0	25.27±2.1	<0.001
HC(cm)	80.29±7.0	88.14±10.4	<0.001
WC(cm)	67.02±7.4	81.05±10.4	<0.001
WHR	0.83±0.1	0.92±0.1	<0.001
NC(cm)	29.53±3.2	33.43±2.3	<0.001
Girls (mean)			
Age (years)	14.93±1.3	14.97±1.2	0.889
WT(kg)	42.91±5.6	59.00±7.3	<0.001
HT(cm)	153.26±5.9	153.14±7.1	0.918
BMI(kg/m^2)	18.32±2.0	25.17±2.2	<0.001
HC(cm)	81.95±5.9	87.03±10.3	<0.001
WC(cm)	65.93±6.1	78.36±10.1	<0.001
WHR	0.80±0.0	0.90±0.1	<0.001
NC(cm)	28.71±1.5	31.50±1.4	<0.001

Table 2: Pearsons correlation(r) between neck circumference and other anthropometric parameters.

	NC-BMI (r)	NC-WHR (r)	NC-WC (r)	BMI-WHR (r)	P value
Boys	0.57	0.39	0.55	0.64	<0.001
Girls	0.7	0.46	0.66	0.55	<0.001

Table 3: ROC curve analysis for neck circumference.

Neck circumference	ROC results to predict obesity				Cut-off	AUROC	SE	P value
	Sensitivity	Specificity	LR+	LR-				
Boys	81.82%	89.06%	7.48	0.20	>32	0.885	0.032	<0.001
Girls	84.85%	87.50%	6.79	0.17	>30	0.912	0.028	<0.001

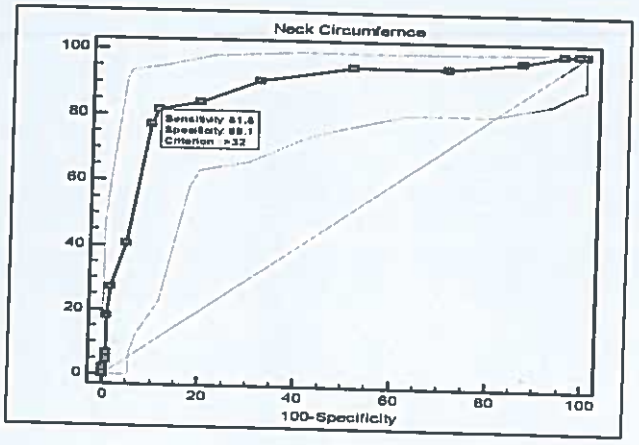

Figure 1: ROC for NC in boys

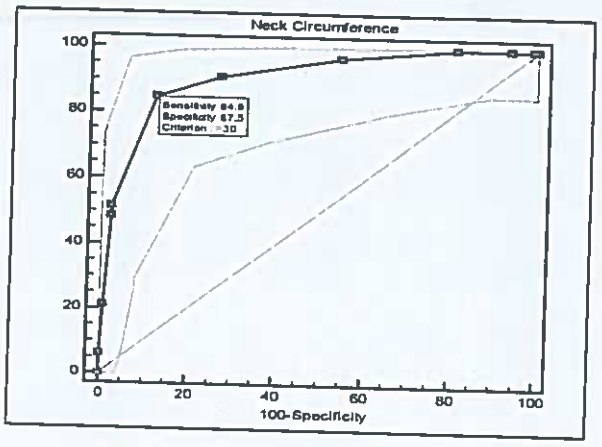

Figure 2: ROC for NC in girls.

Table 3 shows the AUC (area under curve) including the optimal NC cutoffs. Neck circumference cutoff value in boys was 32cm with the corresponding sensitivity of (81.82%), specificity (89.06%), positive LHR (7.48) and negative LHR (0.20). Neck circumference cutoff value in girls was 30cm and the corresponding sensitivity was (84.85%), specificity (87.5%), positive LHR (6.79) and negative LHR (0.17)

DISCUSSION

The present study conducted on children aged 13 - 17 years had shown a significant association between neck circumference and other anthropometric measurements of obesity in both boys and girls.

Childhood obesity has become a major public health problem in children. Many studies had shown increased adverse health outcomes of childhood obesity both short-term as well as long-term consequences.[6,18] Controlling the epidemic of childhood obesity, detection, early prevention and treatment of childhood obesity are important priorities that need accurate diagnostic measures. Screening and monitoring tools must be low-cost, quick and easy to use, and generally acceptable to both patients and health practitioners.

Several methods are available for assessing obesity in children and include weight, WC, WHR, BMI and weight height ratio. BMI may not reflect body fat distribution and waist circumference measurement though reflect central obesity it is time consuming, cumbersome and may be effected by post prandial abdominal distension, bowel dysfunction etc. Direct measurement of body fat by USG, DEXA, CT etc are expensive and not feasible and hence anthropometric measures which are reliable and easy to perform at point of care should be used.

Studies conducted in adults had shown that neck circumference can be used as a simple screening tool for identifying individuals with high BMI with good inter and intrarater reliability and various studies had found an association between neck circumference with other obesity indices.[7-9] However, there are limited studies on the neck circumference measurement as an index of obesity in the paediatric age group.

Vague J was the first person to suggest that different body morphology and type of fat distribution are associated with the health risk of obesity and used a neck skin-fold to assess upper body fat distribution.[10]

Hatipoglu et al suggested NC can be used as an additional measure to screen children with overweight and obesity and also found a positive correlation between NC and BMI, WC. The cut-off values that showed higher sensitivity and specificity for NC to detect overweight in pre-pubertal and pubertal period were 28 -31 cm for girls and 29-32.5cm for boys respectively.[11]

A study conducted by Nafiu et al on 1102 children aged between 6-18 years had shown that NC correlated with age, BMI, and waist circumference in both boys and girls and NC cutoff values were given according to age, optimal NC cutoff indicative of high BMI in boys ranged from 28.5-39 cm, in girls 27-34.6 cm respectively.[12] Similar results were also found in other studies by Roberta de et al and Mozaffer et al.[13,14]

Some studies shown association between neck circumference and increased risk of adverse health consequences of excess weight. Renata et al shown association of neck circumference and high blood pressure in children and adolescents.[15] Katz et al had shown that neck to waist ratio, an index of body fat distribution predicts obstructive sleep apnoea in overweight/obese children.[16] Another study conducted in 324 Greek children aged 9 - 13 years found that NC was associated with most cardiovascular disease (CVD) risk factors. The study showed that the association of NC and CVD was comparable to the observed co-relations of BMI, WC, hip circumference (HC), waist-to-hip ratio (WHR) and WHtR with CVD.

The present study had similar results with other studies. Neck circumference cutoff value in boys was 32 cm with sensitivity of (81.82%), specificity (89.06%), in girls was 30cm with sensitivity was (84.85%), specificity (87.5%). Neck circumference is a reliable and inexpensive, quick and easy to measure than other indexes of adiposity.

The study had some limitations that it was a cross-sectional observation study with small sample size and limits its interpretation as to causality of associations. Although neck circumference had a strong correlation with various obesity parameters there is a need to derive and validated neck circumference cutoff for different pubertal stages, different BMI catagories and different age groups for our Indian population.

CONCLUSION

The findings of the present study are consistent with other studies in children and adolescents, so we conclude that neck circumference could be a useful, simple screening measure for identifying overweight/obese children.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Post Graduates,

Department of Pediatrics,

KIMS Hospital and Research Centre,

Bangalore, India.

Dear Dr. Goutham A S,

Subject: Acceptance of research paper for publication in our International Journal – Reg.

This is to inform you that the original research article titled **"CURRENT ALCOHOL USE AMONG SCHOOL GOING CHILDREN IN BANGALORE"** authored by **"Goutham A S, Pragyee Dhingra, & Poornima Shankar"** submitted us to for an evaluation by you on **Feb 11 2017** has been accepted by the review board for publishing in **TJPRC: International Journal of General Pediatrics and Medicine (TJPRC: IJGPM)**, Bearing Paper Id: TJPRC: IJGPMJUN20174, Volume - 2, Issue -1.

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Junior Resident,,

Department of Pediatrics,

KIMS Hospital and research centre,

Bangalore, India.

Dear Dr. Prarthana. B,

Subject: Acceptance of research paper for publication in our International Journal – Reg.

This is to inform you that the original research article titled **"TO STUDY THE PREVALENCE OF CIGARETTE SMOKING BY MALE AND FEMALE STUDENTS STUDYING IN 8-10th STANDARD IN BENGAEURU"** authored by **"Prarthana. B, Goutham. A. S, & Poornima Shankar"** submitted us to for an evaluation by you on **Feb 13 2017** has been accepted by the review board for publishing in **TJPRC: International Journal of General Pediatrics and Medicine (TJPRC: IJGPM)**, Bearing Paper Id: TJPRC: IJGPMJUN201776, Volume - 2, Issue -1.

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Section Paediatrics

Original Article

Value of Neck Circumference and Waist Circumference Measurement in Assessment of Overweight/Obesity in Adolescent Children

SK Tak[1], Anup Paliwal[2*], Sameer Jagrwal[3]

[1]Associate Professor; [2]Assistant Professor; [3]Senior Resident, Department of Paediatrics, Ananta Institute of Medical Sciences and Research Centre, Rajsamand, Rajasthan, India.

ABSTRACT

Background: *To measure neck circumference and waist circumference, to compare it between normal and overweight/obese adolescents and to validate these with body mass index.*

Methods: *A cross-sectional study was conducted in 500 school going children/adolescents. Body mass index, waist circumference and neck circumference were measured. Independent samples t-test and Pearson's correlation were used as tests of significance to analyse quantitative data.*

Results: *A positive correlation of neck circumference and waist circumference with body mass index was observed. The neck circumference and waist circumference in overweight/obese adolescents were significantly higher than adolescents with normal body mass index (P<0.001). Area under curve of waist circumference was more than area under curve of neck circumference. Cut off value of neck circumference for screening adolescent obesity in boys and girls were 30.73 cm, and 29.73 cm, respectively, and waist circumference cut off value were 70.73 cm for boys and 69.23 cm for girls at fairly good levels of sensitivity and specificity.*

Conclusion: *Neck circumference and waist circumference may be used in clinical practice and epidemiological studies as an index of overweight/obesity among school-going adolescents.*

Key words: *Anthropometry, Body mass index, Neck circumference (NC), Waist circumference (WC), Area under curve (AUC).*

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INTRODUCTION

Overweight and obesity used to be the problems of developing countries, but recently it is on increasing trends in developing countries too, due to cross cultural interactions, aggressive marketing by food industries and increasing sedentary life style.[1] Central obesity being main predicter of obesity related disorders, body mass index (BMI) may not be the best indicator of functional consequences of obesity.[2] Calculation and interpretation of BMI is difficult & time consuming by field worker sometimes and varying with age. Neck circumference (NC) on contrary may be a good marker to judge subcutaneous fat& obesity, a new concept in the anthropometry. Measuring NC and Waist circumference(WC) by tape is easy and can be taken by health staff and social worker, has not been much explored. Thus present study was conducted to evaluate NC & WC as anthropometric measurement for judging overweight/obesity among adolescent and correlate them with BMI.

METHODS

This school and Hospital based study was conducted in Rajsamand district of Rajasthan. For selection of cases, one school was chosen from low (Government school) and high (Public school) socioeconomic status each and cases

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attending hospital OPDs. Total 500 students were selected by random sampling following student list in attendance register. Ethical clearance was obtained from institution's ethical committee with permission from Principal/ Headmaster of the school prior to study.

Healthy children were included in the study. Children with any condition affecting the measurement of NC such as Goitre, swelling/cyst neck, cranio-vertebral diseases/ anomalies were excluded. The cases with Cushing Syndrome/steroid ingestion (Nephrotic syndrome, Bronchial asthma, Collagen vascular disease), Malnutrition, HIV, Malignancies and chronic illnesses were also excluded.

Weight was taken in light clothes without shoes from digital weighing machine. Height was measured by vertical scale, without shoes. Children were categorised according to their BMI, using BMI percentile of Indian Children from 5-17 years with 3rd, 10th, 25th, 50th, 75th and 95th percentile and at 18 years two more percentiles (23 & 28 kg/m^2) were also added.[3] WC was measured by non-stretchable tape at midpoint between costal margin and iliac crest in midaxillary line in standard position at the end of gentle expiration.[4] NC was measured by same tape in standing position with head erect at the level of thyroid cartilage.[5] Anthropometry was performed by trained Paediatric nurse/resident. Data were analysed by using independent t test and Pearson's correlation. Receiver operating characteristics (ROC) analysis was done to find optimal and maximal sensitivity & specificity for NC/WC against BMI. The cut off value of these were determined by Yonden Index (Sensitivity + Specificity – 1). A p-value of <0.05 was considered to be statistically significant.

RESULTS

The age of adolescents recruited in the study (n=500; 55% boys) varied from 10-16 years with a mean SD age 13 (1.4) years. The study sample consisted of 390(78%) with normal BMI, 60(8%) with overweight/ obesity and 50(6.66%) with underweight children. The mean (SD) BMI of boys and girls were 18.4(4.5) and18.6(4.3) kg/m^2 respectively. The mean (SD) waist circumference (WC) for boys and girls were 68.6(12.4) and 66.3 (9.4) cm respectively. There was significant difference (P<0.001) in WC & NC between adolescents with normal and high BMI for both sexes (Table 1).

Table 1: Anthropometric Measurements in Adolescents in the study

BOYS	With (N) BMI	Overweight/ Obese	P Value
Height (cm)	151.6 (13.09)	155.2 (13.05)	<0.001
Weight (Kg)	38.5 (9.87)	59.78 (14.19)	-
WC	64.5 (8.58)	80.48 (12.57)	-
NC	28.9 (2.56)	32.65 (2.68)	-
GIRLS			
Height	147.6(8.3)	148.9(9.3)	<0.05
Weight	36.89(7.0)	54.29(10.1)	<0.001
WC	63.00(7.48)	74.5(8.5)	<0.001
NC	28.18(2.2)	31.06(2.4)	<0.001

All values in Mean (SD)

All values in Mean (SD); for (N) BMI, n =215 for boys and n=175 for girls; and for overweight/obese n=33 for boys and n= 27 for girls.

BMI was positively correlated with NC (r=0.644 for boys, 0.613 for girls) and WC(r=0.691 for boys, 0.681 for girls) at significant level (p=<0.001). For boys 3rdpercentile of NC was 24.9 cm & 97th percentile was 35.95 cm and for girls, 3rd percentile was 24.1 cm and 97th percentile was 34.9 cm.

Table 2 shows values of area under the curve (AUC) and cut off values for WC and NC with their respective sensitivity & specificity levels in identifying children with overweight/ obesity.

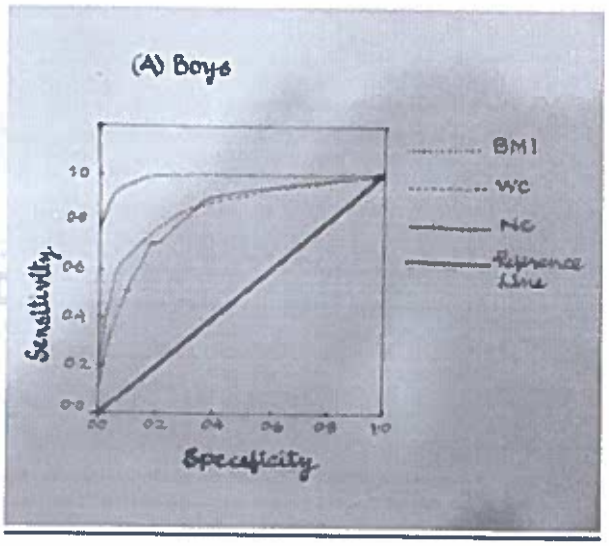
Table 2 also shows the comparison of NC as a tool for detection of overweight/obesity as compared to WC.

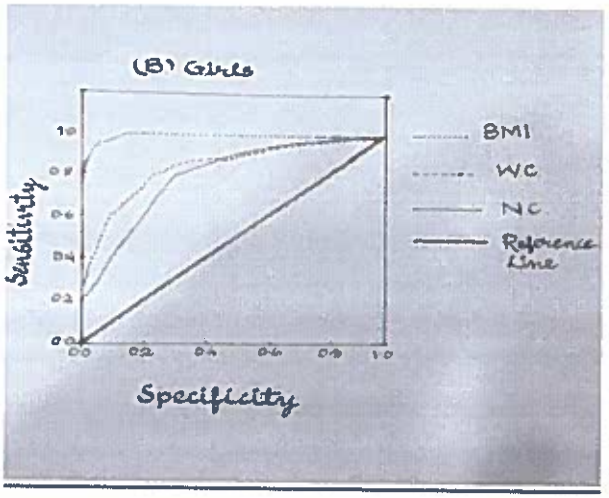
Table 2: Performance of NC in detecting overweight/ obesity

	AUC	95% CI	Cut off	Sensationally	Specificity
WC	Boys 0.885	0.837, 0.894	70.73	82.7	77.2
	Girls 0.849	0.821, 0.879	69.23	74.4	81.0
NC	Boys 0.821	0.793, 0.852	30.73	78.9	68.6
	Girls 0.815	0.784, 0.844	29.73	71.9	77.0

Fig. 1 ROC curve comparing neck circumference and waist circumference with body mass index (BMI) in boys (A), and girls (B).

WC-waist circumference and NC- neck circumference.





DISCUSSION

In this study, it is found that a significant difference in WC & NC among normal and overweight/obese children detected by BMI(p=<0.001) in both boys and girls. Also there was a strong positive correlation of NC as well as WC with BMI.

Limitations of the present study includes enrolments of adolescents from small geographic area, sample size and lack of validations of these measurements with functional consequences of obesity.

It was found that cut off values of NC for screening adolescent obesity in boys and girls was 30.73 cm & 29.73 cm. respectively while for WC 70.73 cm. and 69.23 cm. for boys and girls respectively. These results are close to estimates from previous studies.[1,2] Small differences between cut off could be explained by ethnic variations.[5,7] Correlation of NC & WC with BMI has also been reported in studies.[5,7,8] It was observed that AUC of >80% for both NC & WC in boys and girls including its accuracy to detect adolescents with increased BMI. Further AUC for WC was found to be more as compared to NC in girls (0.849 vs 0.815) and boys (0.885 vs 0.821) indicating WC may be better measure for obesity in adolescents, however several limitations have been documented in the literature either related to its measurements,[7] specially among the adolescents owing to body changes they experience during puberty or due to its variations throughout the day according to bowel function or menstrual period.[9] Measurement of NC may be relatively simple, convenient and nonintimidating specially for adolescents. As compared to BMI, Waist to hip ratio, Neck &Waist circumference have been shown to have high accuracy in predicting the risks of atherosclerosis in middle aged adults.[10]

CONCLUSION

Thus, we conclude that both NC & WC are useful screening tools for adolescents with overweight/obesity and have a potential to be used as screening tool for adolescent overweight/obesity.

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Section Paediatrics

Original Article

Bacteriological Profile and Antibiotic Sensitivity Pattern in Community Acquired Neonatal Sepsis in Rajsamand – A Hospital Based Prospective Study

SK Tak[1], Anup Paliwal[2*], Sameer Jagrwal[3]

[1]Associate Professor, [2]Assistant Professor, [3]Senior Resident, Department of Paediatrics, Ananta Institute of Medical Sciences and Research Centre, Rajsamand, Rajasthan, India.

ABSTRACT

Background: *To isolate the pathogenic bacteria and to know the antibiotic sensitivity in the community acquired neonatal sepsis.*
Materials & Methods: *It was a prospective study undertaken on 120 neonates suspected of community acquired neonatal sepsis admitted in Pediatrics Department of AIMSRC over a period of two year. All these cases fulfilled the inclusion criteria required for the study. Blood culture of these cases was performed by Mackie and McCartney method and antibiotic sensitivity by Kirley-Baner's disc diffusion method.*
Results: *Out of 120 cases, 88 cases showed positive blood culture. Gram negative isolates (N=55) were more frequent than gram positive isolates (N=33). Most common isolate was Klebseilla, Pneumoniae followed by Staphylococcus Aureus, E. Coli, Pseudomonas Aeroginosa, Acinetobacter. Both gram negative as well as gram positive isolates showed high resistance to ampicillin and gentamycin. Gram negative isolates were highly sensitive to Colistin Sulphate and Meropenem whereas gram positive isolates were highly sensitive to Linezolid and Vancomycin.* ***Conclusion:*** *Gram negative bacteria were more frequent causes of community acquired neonatal septicemia than gram positive isolates. Both gram positive and negative isolates showed poor sensitivity towards conventional first line antibiotics, rather were mainly susceptible to higher antibiotics. So, the knowledge of the pattern of bacteriological isolates and their antimicrobial susceptibility pattern can be very helpful for prompt treatment of such patients, to decrease neonatal morbidity and mortality as well as reducing the emergence of multi-drug resistant organisms.*

Key words: *Antibiotic susceptibility; Bacterial isolates; Bacterial resistance; Neonatal sepsis.*

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INTRODUCTION

Neonatal Sepsis refers to the invasive bacterial infection occurring in the first 4 weeks of life. It encompasses various infections of the new born like septicemia, meningitis, arthritis, osteomyelitis and urinary tract infection but excludes superficial infections like conjunctivitis and oral thrush.[1] It can be early onset sepsis(EOS) presenting within 72 hours of life with maternal genital tract being the main source of infection or it can be late onset sepsis (LOS) which usually presents after 72 hours of life and the main source of infection is nosocomial (hospital acquired)or community acquired infection.[2,3] Neonatal sepsis, the commonest cause of neonatal morbidity and mortality is responsible for 30-50% of total neonatal deaths each year in the developing countries.[4-6] According to the World Health Organization (WHO) estimate, there are about 5 million neonatal deaths per year in the world, 98% of these occurring in the developing world. Neonatal mortality rate in developing countries from various causes is about 34 per 1000 live births, most of the deaths occurring in the first week of life. Globally, major causes of the neonatal deaths are due the prematurity (28%), sepsis (26%), and birth asphyxia (23%).[7] The incidence of the neonatal sepsis according to the Neonatal and Perinatal Database (NNPD) is 30 per 1000 live births. The NNPD network comprising of the 18 tertiary care neonatal units across India found sepsis to be the commonest cause of neonatal mortality contributing to 19%

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of all neonatal deaths.[8] In India, sepsis has been reported as a cause of neonatal deaths in 20-50% of cases in the community based studies.[9,10] The gold standard for the diagnosis of neonatal sepsis is isolation of bacterial agents from the blood culture.[11] Both gram negative and gram positive bacteria have been isolated from the blood and predominance of one type over the other varies from place to place and even in the same place over the time to time.[12] In most of the developing countries, gram negative sepsis remains the major cause of the neonatal septicemia. Commonly isolated organisms include Klebseilla Pneumonia, Escherichia Coli, Enterobacilli, Pseudomonas Aeruginosa, Staphylococcus Aureus, Streptococcal Species, Citrobacter Species and Coagulase Negative Staphylococcus (CoNS).[13,14] So, this study was undertaken with the aim to determine the bacteriological profile and its antibiotic susceptibility pattern in the community acquired neonatal sepsis. Following a rational antibiotic therapy, we can minimize the risk of severe neonatal morbidity and mortality as well as decrease the development of multidrug resistant bacteria.

METHODS

It was a hospital based prospective study conducted in the department of Pediatrics, AIMSRC, Rajsamand. It included 120 neonates admitted with clinically suspected community acquired sepsis during the period of two year. Only those neonates were included who were less than 28 days of life, had clinically suspected septicemia and presented after 72 hours of birth. Neonates of more than 28 days of life or presenting before 72 hours of life or already on antibiotics were excluded from the study. Sepsis was suspected from the clinical history of one or more of the symptoms like refusal to feed, lethargy, fever, abdominal distension, loose stools, vomiting, features of hypoglycemia, hypothermia, tachypnea, tachycardia, grunting, chest retractions, cyanosis, apnea, pallor, shock, excessive crying, body mottling, poor cry, prolonged capillary time, bleeding from any site, neck retractions and vacant stare. With all the recommended aseptic precautions, 1ml of blood was drawn from each neonate and collected in a sterile bottle containing 1%glucose broth and inoculated at 37^{0}C. Subcultures were made on blood agar and Mac-Conkey agar after 24 hours, 48 hours, 72 hours and 7 days which were further inoculated at 370C for 18-24 hours. The plates were observed the next day. If no growth was observed even after 7th day, sample was reported negative for bacterial isolate. The growth of isolates were identified by colony morphology, gram staining and standard biochemical tests described in Mackie and McCartney Practical Medical Microbiology.[16] For identification of gram positive isolates catalase and coagulase tests were done; for gram negative organisms, Simons's citrate test, motility indole test, urea (MIU) test and triple sugar test (TST) were done. Antibiotic susceptibility test was performed on the and identified isolates using commercially prepared antibiotics disks (High media Co. Mumbai, India) on Muller Hinton agar by Kirby-Baur Disk Diffusion method as recommended in the Clinical Laboratory Standard Institute (CLSI) guidelines.[15]

RESULTS

Out of 120 study cases, 73 (61.24%) were males and 47 (38.76 %) were females. Three most frequent features suggestive of septicemia were refusal to feed (n= 92; 77%), lethargy (n= 80; 66.66%) and fever (n= 59; 49 %) followed by other clinical features. 88 (73.33%) showed positive blood culture and 32 (26.66 %) showed no bacterial growth. Gram negative isolates (n =55; 62.5 %) were more frequent than gram positive growths (n=33; 37.5 %). The most common pathogen isolated was Klebseilla pneumoniae (n= 28) followed by other organisms and CONS was the least common bacterial isolate [Table 1]. The gram-negative isolates showed high resistance to Ampicillin and Gentamycin but were highly sensitive to Colistin Sulphate and Meropenem [Table 2]. Gram positive isolates were also quite resistance to Ampicillin and Ceftazidime but were highly sensitive to Linezolid and Vancomycin [Table 3].

Table 1: Organisms Isolated.

Organisms Isolated	Number(N=88)	Percentage
Gram Negative (55)		
Klebseilla Pneumonia	28	31.81
Escherichia Coli	14	18.33
Pseudomonas	12	16.12
Acinetobacter	3	3.62
Gram Positive (33)		
Staphylococcus Aureus	22	28.85
Enterococcus	1	1.28
Coagulase Negative Staphylococci (CoNS)	7	

Table 2: Antibiotic Susceptibility Pattern of Gram Negative Isolates. (n=55)

Antibiotic	Gram Negative	Percentage
Amikacin	34	61.8
Gentamicin	21	38.1
Ceftriaxone	24	43.6
Piperacillin-Tazobactam	23	41.8
Imipenem	53	96.36
Colistin Sulphate	54	98.18
Ceftazidime	25	46.28
Ciprofloxacin	36	65.4
Ampicillin	2	3.63
Cefotaxime	25	46.28
Cefoperazone	26	46.78

Table 3: Antibiotic Susceptibility Pattern of Gram Positive Isolates. (n=33)

Antibiotic	Gram Positive	Percentage
Amikacin	30	90.9
Gentamicin	14	42.4
Ceftriaxone	16	48.4
Linezolid	32	96.9
Amoxycillin- Clavulanate	15	45.4
Ceftazidime	4	12.1
Vancomycin	31	93.9
Ciprofloxacin	18	54.5
Ampicillin	2	6
Cefotaxim	17	51.5
Methicillin	29	87.8
Cefoperazone	18	54.5

DISCUSSION

Neonatal Sepsis is a life-threatening emergency and any delay in its treatment may lead to mortality.[4,7] Bacteriological profile of community acquired neonatal sepsis changes from region to region and time to time. In addition, there is increasing multidrug resistance over the last few years.

Therefore, knowledge of pattern of the bacteriological profile and its antimicrobial susceptibility pattern can be very helpful for prompt empirical treatment of neonatal sepsis. This study was undertaken keeping these objectives in mind.

Out of 120 study cases; male to female ratio 1.5:1 which is comparable to other studies like by Begums et al.[16] Reason for male preponderance may be Social and Sex dependent factors as X-linked immunoregulatory genes may play some protective roles in females.[17] Positive blood culture was observed in 73% cases in the present study which is comparable to study by Premlata et al.[18] showing blood culture positivity in 82% cases although the results are higher as compared to Karthikeyan et al.[19] showing blood culture positivity in 51% cases. The difference may be due to variable incidence of neonatal sepsis from place to place and due to many other factors like perinatal care, birth weight etc. Gram negative isolates (62.50%) were more frequent than gram positive (37.50%). These results were consistent with the NNPD data. Out of all culture positive cases, Klebseilla pneumonia was most frequent (31.81%) gram negative isolate and Staphylococcus Aureus was the most common (28.85%) gram positive isolate. These results are similar to many other Indian studies. Most of the gram-negative isolates in the present study were resistant to the routinely used first line empirical antibiotics with 96.15% resistant to Ampicillin and 58.34% to Gentamicin. But all the negative organisms showed 100% sensitivity to Colistin Sulphate to Imipenem. Our findings correlate well to those of Mustafa et al and many other studies.[20] Out of gram positive isolates, again 93.82% were resistant to routinely used first line antimicrobial Ampicillin and 42.40% were resistant to Gentamicin whereas 96.90% gram positive isolates were sensitive to Linezolid, 90.90% were sensitive to Amikacin and 93.90% to Vancomycin. Our findings again correlate well with those reported by Mustafa et al and Kaistha et al.[20,21] Increasing resistance by both gram positive and gram negative isolates to routinely used antimicrobials may be due to inappropriate use of antibiotics.

CONCLUSION

Gram negative organisms were more frequent causes of community acquired (CA) neonatal septicemia than gram positive isolates. Klebseilla Pneumoniae was the most common, Staphylococcus Aureus was the second most common and CoNS was the least common organisms isolated. Both gram negative and gram positive showed poor sensitivity towards routinely used first line antimicrobials like Ampicillin and Gentamicin. Gram-negative organisms were highly sensitive to Colistin Sulphate, Imipenem, Ciprofloxacin, Amikacin and third generation Cephalosporins in the descending order. Gram-positive isolates were mainly sensitive to Linezolid, Amikacin, Vancomycin, Methicillin, Ciprofloxacin and third generation Cephalosporins in descending order. Therefore, the bacteriological profile and the sensitivity pattern of Community acquired neonatal septicemia in a particular geographical area must be considered before deciding the empirical antibiotic treatment of community acquired neonatal septicemia.

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Original Article

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Knowledge, Attitude and Practice Study About Use of ORS in Diarrhea in Mothers with Children 02-05 Year Age Group Residing in Various Urban Slums of Bhopal City

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Abstract

Background: KAP study for use of ORS in Diarrhea in mothers with children 02-05 year age group. The objective of the study was to assess the Knowledge, Attitude and Practice use of ORS in Diarrhea among mothers at various Urban Slums of Bhopal City. **Subjects and Methods:** A cross sectional descriptive study was conducted among mothers having children 02-05 year age group. All mothers were interviewed through a self designed pretested structured questionnaire regarding use of ORS in Diarrhea of their infants and socio demographic profile. **Results:** Majority of the mothers were illiterate, and not aware about benefits of use of ORS. Although mother's knowledge was lacking but most of mother use of ORS in Diarrhea in their children. **Conclusion:** Most of mothers do not follow practice of use of ORS in Diarrhea and had lack of knowledge. The knowledge regarding method of use of ORS for management of diarrhoea was found to be inadequate in this study. Though many mothers are aware that it is useful most are not aware of its method of use. More measures need to be adopted to improve this knowledge and make mothers aware about the method of use and availability of ORS.

Keywords: ORS, Diarrhea, Knowledge, Attitude, Practice, Urban Slums.

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Introduction

Diarrhoea is defined as the passage of three or more loose or liquid stools per day (or more frequent passage than is normal for the individual). Frequent passing of formed stools is not diarrhoea, nor is the passing of loose, "pasty" stools by breastfed babies. Diarrhoeal disorders in childhood reported in large proportion (18%) of childhood deaths, with an estimated 1.8 million deaths per year globally. The World Health Organization (WHO) suspects that there are >700 million episodes of diarrhea annually in children < 5 years of age in developing countries.[1]

The objective of this study was to see the change in knowledge and behavior of the mother acute diarrhea in children 02-05 years of age group. Because almost three decades have passed since commercially available ORS was launched and continued feeding during diarrhea is being stressed.[2,3]

Diarrhoeal disease is the 2nd principal cause of death in children under 05 years old, & is responsible for killing around 760 000 children every year. Diarrhoea can last several days, & can leave the body without the water & salts that are necessary for survival.[4] Most people who die from diarrhoea die from severe dehydration & fluid loss. Children who are malnourished or have impaired immunity as well as people living with HIV are most at risk of life-threatening diarrhoea. It is usually a symptom of an infection in the intestinal tract, which can be caused by a variety of bacterial, viral and parasitic organisms. Infection is spread through contaminated food or drinking-water, or from person-to-person as a result of poor hygiene.[5]

Subjects and Methods

This study was conducted at various Urban Slums of Bhopal City. This cross sectional study was carried out from September 2018 to August 2019. All mothers who have 02-05 years of age group child with diarrhea were enrolled. Total 300 consecutive mothers with written informed consent were taken.

A predesigned & pretested questionnaire was prepared comprising of nearly 20 questions, most of the questions were close ended. Besides literacy, socioeconomic status was also noted. Questions pertained to practices towards diarrhea, nutrition during diarrhea and awareness of ORS. A single interviewer interviewed all 300 mothers who have 02-05 years of age group child for diarrhea and related diseases.

It took nearly 15-20 minutes to finish one interview & on a single day, not more than 5 interviews were carried out. At the end of each interview, the mothers were provided with health education to improve their knowledge of diarrhea, nutrition during diarrhea and oral rehydration therapy, with practical demonstration of correct ORS preparation. Also, the mothers were handed over a health education pamphlet in Hindi pertaining to diarrhea and ORS at various Urban Slums of Bhopal City, to improve their knowledge and management skills in the future. The data was calculated in Microsoft Excel and interpreted as mean and percentages.

Inclusion Criteria:

Mothers with children of 02 to 05 yrs age group, who are permanent residents of urban slums.

Exclusion Criteria:

1. Mothers with either less than 02 years or more than 05 yrs age group children.
2. Mothers with children who are critically ill, hospitalized or on medication.
3. Mothers who are guests or temporary residents of urban slums.

Results

Table 1: Age of Mothers

Age of mother	No. of mother (n = 300)	Percentage of mother
Below 25 years	53	17.66
25-35 years	179	59.66
35 years and above	68	22.68

In our study, 59.66% were in age group of 25-35 years, followed by 22.68 were 35 years & above & 17.66% were below 25 years.

Table 2: Education of Mothers

Education of mothers	Number of mothers (n = 300)	Percentage of mother
Intermediate	21	7.00
Primary	97	32.34
Illiterate	182	60.66

In our study, 60% were Illiterate mothers, followed by 32.34 Primary & 7% were Intermediate.

Table 3: Knowledge, Attitude and Practice study about use of ORS in Diarrhea in mothers

S. No.	Parameter	Number of mothers (n = 300)	Percentage of mothers
1	Did not know the exact definition of diarrhoea	267	91%
2	Aware that diarrhoea leads to dehydration	79	26.33%
3	Food contamination causes diarrhea	98	32.66%
4	Rice based feeds are best in diarrhea	112	37.34%
5	Oral fluids should be increased in diarrhea	96	31.88%
6	Aware of ORS but not practising it	217	72.53%
7	Unaware of ORS	179	59.66%
8	Wrongly preparing ORS	193	64.29%

193 mothers said that they one or the other time used wrong commercial preparation like Sporolac/Lactrol as ORS. Nearly 91% of the mothers did not know exactly how much ORS is to be given with each loose stool.

Discussion

Diarrhoea stays one of the main worldwide reasons for death among youngsters younger than two years. ORS is straightforward, exceedingly compelling, economical and suitable treatment for diarrheal drying out and since the presentation of ORS in 1979, there has been an unfaltering decrease in passing because of diarrheal ailments6. Diarrhoea is the frequent (typically characterized as at least three times in multi day) passage of liquid or soft stool7,8. It is the most widely recognized clinical indication of gastrointestinal infection and the second driving reason for death on the planet among kids under two years old. Unfortunately, particularly in creating nations, because of absence of legitimate information in mother, with respect to accessibility, planning and utilization of ORS, this objective is a long way from accomplished.

Although use and availability of ORS can reduce the morbidity and mortality associated with diarrhoeal diseases it is far from being highly effective especially in developing countries due to lack of awareness about availability and use of oral rehydrating solution for management of diarrhoeas.9 Also complicating the issue is lack of understanding regarding the role of sanitation and hygiene in reducing the incidence of diarrhoea.[10] In present study, although 75% of the mothers were educated, only 156 knew the correct method of ORS preparation and its use whereas out of the remaining mothers who knew about ORS did not know the correct method of using ORS.[11] In fact, people adopt a wait and watch approach as it is believed the consumption of food and water increases the bulk of stools and does not provide rest to the intestine which is necessary for recovery from diarrhoea. Even some of the educated people do the same thing.[12]

Conclusion

Most of mothers do not follow use of ORS in Diarrhea practices and had lack of knowledge was found. The

knowledge regarding method of use of ORS for management of diarrhoea was found to be inadequate in this study. Though many mothers are aware that it is useful most are not aware of its method of use. More measures need to be adopted to improve this knowledge and make mothers aware about the method of use and availability of ORS.

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Original Article

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Knowledge, Attitude and Practice Study about Complementary Feeding in Mothers with Children Upto 02 Years Age Group in Urban Slums across Bhopal City

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Abstract

Background: Objective of our study was to assess the knowledge, attitude and practice of complementary feeding among mothers in various Urban Slums across Bhopal City. **Subjects and Methods:** A cross sectional study was done about knowledge of mothers with children below 2 years of age with help of pretested self designed questionnaire based interview who are attending Anganwadi Centre & Slum Areas. **Results:** In our study most of mothers did not know correct time of starting complementary feeding, they also did not know what food can be given, frequency and amount of complementary feed. **Conclusion:** Knowledge of Mother's concerning timing of complementary feeding is inadequate and practice and attitude are inappropriate. Majority of them are not aware of the current recommendations. Health education about correct feeding should be given to mothers and family members including appropriate time for complementary feeding initiation, complementary foods, it's preparation and practices to give on proper time and amount and hygiene. It will help to prevent malnutrition, infant and under 5 mortality and morbidity and improve the health status of children. Correct information and guidelines about complementary feeding is not reaching the target population. False beliefs, customs and attitude of the mother tend to wean the child late. Poor breastfeeding and inappropriate complementary feeding practices are the principal proximate causes of malnutrition during the first two years of life. Study Design: Cross Sectional Study

Keywords: KAP, Complementary, Breast Feeding, Knowledge, Attitude, Practice, Urban Slums.

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Introduction

World Health Organization (W.H.O), Complementary feeding is the process starting when breast milk alone is no longer adequate to meet the nutritional requirements of infants, & consequently other foods and liquids are needed, along with breast milk. The change from exclusive breast feeding to family food referred to as complementary.[1]

Breast feeding is well renowned while early age to be the best feeding for a neonate. Early breastfeeding within 01 hour and for first 06 months related to child malnutrition & mortality respectively.[2] In India effective implementation of these interventions is yet to be achieved. Proper initiation & continuation of breast feeding in children under 06 months is only 46.4%.[3] To formulate any effective strategy to improve infant nutrition it is imperative to have an insight into existing knowledge, attitude and practices about infant feeding practices existing in the community.[4]

Subjects and Methods

A cross sectional study was conducted at Anganwadi Centre & Slum Areas of Bhopal between August 2018 to July 2019. Mothers of children age below 2 year of various Urban Slums across Bhopal City were included in the study. Well informed written consent was taken by all mothers, Mothers with older children and non willing to participate were excluded. During study 300 mothers were interviewed through a self designed pre tested structured questionnaire based on extensive literature search and WHO and national guidelines. The questionnaire included socio-demographic variables, starting time for complementary feeding, complementary food, frequency and amount of feed, liquid, semisolid and solid food, homemade or readymade food, their knowledge about hygiene in food preparation and feeding, finger foods. Total thirty two questions were asked in interview. The questions had single as well as multiple correct options, some were open ended and others were with

options all questions asked by doctors after explaining mother about study.

Inclusion Criteria-

All mothers living in urban slums, with up to 2 yrs age group child.

Exclusion Criteria-

1. Visitors to the slums.
2. Mothers with child who is more than 2 yrs of age
3. Sick children, children with serious illnesses or children on medication.

Statistical analysis

Statistical analysis was done by using descriptive and inferential statistics using chi square test. Software used in analysis was SPSS 20.0 version. P Value < 0.05 is considered as level of significance.

Results

Table 1: Comparison of demographic profile to Knowledge of Mothers about Complementary feeding

Table 1A: Education of mothers

Education of mothers	Number of mothers	Knowledge of mothers about complementary feeding			P-Value
		Good	Average	Poor	
Primary	84	29	33	22	0.031 Significant
Illiterate	216	27	109	80	

P Value is less than 0.05, hence it is significantly associated.

Table 1B: Number of children

Number of children	Number of mothers	Knowledge of mothers about complementary feeding			P-Value
		Good	Average	Poor	
One child	104	15	47	42	0.042 Significant
More than one child	196	24	110	62	

P Value is less than 0.05, hence it is significantly associated.

Table 1C: Age of Mother

Age of mother	No. of mother	Knowledge of mothers about complementary feeding			P-Value
		Good	Average	Poor	
Below 30 years	186	16	91	79	0.032 Significant
30 years and above	114	23	58	43	

P Value is less than 0.05, hence it is significantly associated.

Table 1D: Income / Month

Income / Month	Number of mothers	Knowledge of mothers about complementary feeding			P-Value
		Good	Average	Poor	
Above 10,000 Rs	89	09	47	33	0.96 Not Significant
Below 10000 Rs	211	18	112	81	

P Value is greater than 0.05, hence it is not significantly associated.

Table 2: Knowledge of mothers about complementary feeding

S. No.	Complementary feeding Knowledge	Good	Average	Poor
1	Meaning of complementary feeding	64	156	80
2	Time to start	42	184	74
3	Amount of feed	62	174	64
4	Frequency of feed	104	114	82
5	Food can be given	82	152	66
6	Hygine practices	56	116	128
7	Liquid, Semisolid and solid diet	40	196	64

Discussion

Exclusive breastfeeding is recommended worldwide as the ideal feeding for first six months of life. For successful lactation, timely initiation of breastfeeding i.e. within ½ hr of normal delivery and within 4 hrs of caesarean delivery is essential. In fact a recent study from Ghana found that 22% death among newborn can be prevented if they are given breastfeeding within one hr of birth.[5] In present study only half of the total mothers knew about this fact (57% urban and 46.7% rural). Likewise only 63.3% urban and 40% rural mothers knew about correct period of exclusive breastfeeding. As far as maximum period of breastfeeding (i.e. up to 2 years) is concerned, only 40% of urban and 36% of rural mothers were knowledgeable about it.

The women who had history of antenatal care visit during pregnancy period and post natal visit initiate complementary feeding timely. A study in Ghana, Harar, Tigrai found out that timely initiation of complementary feeding is become higher with antenatal and Post natal, maternal education, antenatal care and Post natal care.[6,7] Mothers who have No post natal visit in Health institution were start early complementary feeding as compared to mothers who have follow up. These finding is supported by study conducted by South West Ethiopia.[8] This is explained Mothers who get Health education and advice on complementary feeding during Post natal visit has great effect t on the timely initiation of complementary feeding. In this study more than two third 139 (69.5%) of mothers had history of ante natal care visit during their pregnancy period from which the majority (59.0%) have had more than three times. This is higher than study in Uganda that only 47% of women receive antenatal care coverage.[9] This may be due the low overall antenatal care coverage of in the country.

Conclusion

Knowledge of Mother's concerning timing of complementary feeding is inadequate and practice and attitude are inappropriate. Majority of them are not aware of the current recommendations. Health education about

correct feeding should be given to mothers and family members including appropriate time for complementary feeding initiation, complementary foods, it's preparation and practices to give on proper time and amount and hygiene. It will help to prevent malnutrition, infant and under 5 mortality and morbidity and improve the health status of children. Correct information and guidelines about complementary feeding is not reaching the target population. False beliefs, customs and attitude of the mother tend to wean the child late. Poor breastfeeding and inappropriate complementary feeding practices are the principal proximate causes of malnutrition during the first two years of life.

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Original Research Article

Observation on hypothermia among infants less than 2 months in urban slums of Indore City

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Abstract

Aim: To study Hypothermia in infants of less than 2 months of age in urban slums of Indore city. **Methods:** Retrospective, cross-sectional observational study of 411 infants of below 2 months of age. **Period of study:** 1 year (August 2015 to August 2016) **Results:** Infants below 2 months of age when studied in home deliveries; conducted by Trained Birth Attendant's- 19% were having 'hypothermia by maternal perception' Immediately after birth only 47% were covered fully, 52% were only partially covered, while 1% were not at all covered. Immediately post delivery only 24% were kept in skin-to-skin contact with mother. First bath immediately post birth was given in 57% infants. **Conclusion:** In urban slums of Indore city, in home deliveries 19% of newborns were suffering from hypothermia even when deliveries were attended by Trained Birth Attendant. This can be attributed to faulty newborn care practices.

Keywords: Hypothermia, Neonatal care, Newborn, Urban slums

Introduction

Many practices in midwifery care are prevalent without ever having been properly assessed. Perinatal routine care in urban slums seems to be in particular need of assessment. Birth asphyxia and hypothermia are common antecedents of excessive morbidity and mortality in the neonatal period. The prevention of neonatal hypothermia in uncompromised newborns is dependent on the degree of adherence to simple routines after birth. These routines are- wiping and wrapping the baby, keeping the delivery room warm and giving opportunities for early breast feeding. The newborn responds differently to hypothermia-by 'non shivering thermogenesis'- a metabolic process whereby oxygen consumption is raised independently of muscle activity; occasionally transient shivering can be observed [1] but mostly newborn responds to cold stress by changing its position in an attempt to decrease its body surface.

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First bath and hypothermia: Bathing the newborn is a common routine mostly to remove the 'dirty skin'- the 'vernix caseosa'. Vernix is actually a product of fetal skin representing physiological and sterile coverage of parts of the fetal body beyond 34 to 36 wks of normal pregnancy. It has no infected material and on the contrary it has got antibacterial properties that may contribute to the protection of the newborn from bacterial infections.

Methods

This study was conducted over a period of 1 year at the Aanganwadi centres of various urban slums of Indore city at M.P. state. For these purpose 411 subjects of age 0-2 months were randomly selected.

Inclusion criteria: All term Neonates and infants up to age 2 months who are permanent residents of urban slums of Indore city

Exclusion criteria: More than 2 months old preterm or sick newborns who needed admission in NICU within 7 days after birth or who were delivered in institutes and children of guests or relatives from other places were excluded from the study. Mothers were explained about the aims, objectives and type of study. They were asked if they understand the term 'hypothermia by maternal perception'. Only those mothers were included who had home delivery conducted by Trained Birth Attendant. Mothers who had recollection of perceiving body temperature of infants less than 2 months old, were included.

Pre-conceived and printed questionnaire was used as proforma and filled by both the investigators themselves; based on mothers interview.

Data was collected, tabulated and analysed statistically. As this is a one-time single observation study, Confidence Interval (CI) was chosen as the best tool to gather reliable data; narrower the range, more the confidence in the data. The calculation of 95% CI was done by method described by J.E.Park [2]

95% Confidence Interval (CI): it is the range of 95% confidence in any data To calculate CI, SEP (Standard Error of Proportion) is calculated as follows: SEP= $\sqrt{(pq/n)}$
Where,

P= proportion of parameter for which 95% CI is to be calculated

Q= proportion of the rest of the parameters

N= sample size

95% CI= SEP×1.96±p

i.e. (SEP ×1.96CI)+p to (SEP×1.96 CI)-p

For every parameter 95% CI is calculated.

Results

In home delivery 19% newborns were hypothermic by maternal perception (95% CI-0.15-0.22). Only 47% newborns were fully covered with cloth (95% CI-0.43-0.51) and only 24% were kept in skin contact with mother (95%CI-0.19-0.28), most of the babies (57%) were given bath immediately (95%CI-0.52-0.61).

Table-1: Distribution according to Hypothermia by maternal perception (Home delivery)

Hypothermia	No.	%	95% CI
Yes	78	19	(CI-0.15-0.22)
No	333	81	(CI-0.77-0.84)
Total	**411**	**100**	

Hypothermia was present in 19% of subjects (95%CI-0.15-0.22)

Table-2: Distribution according to way of covering the baby

Baby covered as	No.	%	95% CI
Head covered	8	2	(CI-0.006-0.03)
Head +body covered	193	47	(CI-0.42-0.51)
Only body covered	206	50	(CI-0.45-0.54)
not covered	4	1	(CI-0.0004-0.02)
Total	**411**	**100**	

Only 47% were covered fully (95%CI-0.43-0.51)

Table-3: Distribution according to status of Baby-Mother skin-to-skin contact

Whether kept in skin-to-skin contact with mother	No	%	95% CI
YES	99	24	(CI-0.91-0.28)
NO	312	76	(CI-0.71-0.80)
TOTAL	411	100	

Only 24% were kept in contact with mother (95% CI-0.19-0.28)

Table-4: Distribution according to time since birth for first bath

First bath after how many hrs since birth	No.	%	95% CI
Immediately	234	57	(CI-0.52-0.61)
B/w 12-24 hrs	116	28	(CI-0.23-0.32)
B/w 24-48 hrs	35	9	(CI-0.06-0.11)
B/w 48-72 hrs	26	6	(CI-0.03-0.08)
Total	**411**	**100**	

Majority of the newborns (57%) were immediately bathed (95% CI-0.51-0.61)

Discussion

In our study overall incidence of Hypothermia was found to be 19% by maternal perception. Hands and body both were covered in only 47% newborns while 50% were kept with only body covered, 2% only head covered and 1% were not covered at all. Only 24% were kept in skin – to-skin contact with mother, 57% were bathed immediately, 28% between 12-24hrs, 9% within 24-48 hrs and 6% were given bath within 48-72hrs.

A similar study in Zambia [3] found that 30.64% neonates were completely wrapped, which is similar to our study, 20.96% were incompletely wrapped; which is less than our study and 8% were not wrapped at all; which is more than our study. A similar study on uncomplicated newborn infants in Nepal [4] found that hypothermia was present in 2.9% of hospital deliveries; which is less than our study.

A similar study in Shimla [5] found that hypothermia was present in 81% of newborns on first day after birth, which is more than our study. In a community based study in Ambala city [6] incidence of hypothermia was 11.1% which is less than our study. A cross-sectional community based study of care of newborns in Nepal [7]; found that in home deliveries only 4% newborns were wrapped, which is less than our study.

In Uganda: A randomized, controlled trial [8] found that 83% neonates were hypothermic after 1 hour, which is more than our study.

A study was conducted by UHRC[9] with 15025 mothers across 45 slums in Meerut city of UP found that the incidence of hypothermia was 12%, which is similar to our study, 26.5% were kept in contact with mother and 18.8% were wrapped completely; these findings are less than our study.71.5% were wrapped partially, which is more than our study. 32% were bathed immediately, which is less than our study.

A similar study conducted in urban slums of Lucknow city, UP [10] found that 79.7% newborns were bathed immediately, which is more than our study. A study among slum dwellers in Rachna Town, Lahore [11] found that 37.2% newborns were bathed immediately, which is less than our study; 18.8% were wrapped completely, which is less than our study and only 26.5% were kept in contact with mother, which is similar to our study.

A systemic review on similar topic [12] found out that in home deliveries; range of prevalence of hypothermia was from 11 to 92.3%. 92.3% in Sarlahi, Nepal, 82% in Kathmandu, 43% in Uttar Pradesh and 25% in Delhi, which are more than our study and 11% in Haryana, 17% in Gadchiroli; which is less than our study.

Conclusion

The incidence of Hypothermia varies in different regions and seasons. The incidence of hypothermia reported in this study should be taken as minimum as lower environmental temperatures in the night might have increased the incidence during night hours.

Since the relation between neonatal temperature and mortality is shown to be linear; appropriate practices

like-warm delivery room, immediate drying and skin to skin contact with mother for first hours after birth and delaying first bath must be followed. While promoting the programme for prevention of neonatal hypothermia, caution should be taken to modify the guidelines according to the specific environmental situation.

Funding: Nil, **Conflict of interest:** Nil
Permission from IRB: Yes

What is already known?: Hypothermia is a common cause of excessive morbidity and mortality in neonatal period.

What this study adds?: In urban slums of Indore city incidence of hypothermia is high in home deliveries even while they are being conducted by Trained Birth Attendants. Hypothermia can fully be attributed to faulty newborn care practices.

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ORIGINAL ARTICLE

Clinico-etiological Profile and Developmental Status of Infants Aged 1–24 months with Epilepsy

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Abstract

Objective To study the clinico-etiological profile of epilepsy in children aged 1–24 mo attending a tertiary-care public hospital.

Methods All infants aged 1–24 mo with epilepsy (as per International League Against Epilepsy, 2014) presenting between April 2016 and March 2017 were enrolled. Detailed history and examination were done in all children, and developmental assessment was done using Developmental Assessment Scale for Indian Infants (DASII). Electroencephalography and neuroimaging (CT/MRI) were done for all subjects.

Results Sixty children (39 males) were consecutively enrolled after informed written consent. The mean (SD) age at seizure onset was 4.3 (4.14) mo. Perinatal asphyxia (45%) and malformations of cortical development (18.3%) were the commonest etiologies. Neurological examination was abnormal in 68.3%, and a neuroimaging abnormality was present in 76% of children. Fifteen patients (25%) had West syndrome, which was symptomatic in the majority (73.3%). Developmental delay (DQ < 70) was the commonest co-morbidity (81.7%); 28.3% had profound delay. Odds of having developmental delay were 13-times higher in those with an abnormal neurological examination [OR 13.5 (2.82–64.67), $P = 0.001$], and nearly 9-times higher with abnormal neuroimaging [OR 8.9 (2.11–37.9), $P = 0.003$].

Conclusions Epilepsy in children <2 y is symptomatic in the majority, with sequelae of birth asphyxia as the commonest etiology. High prevalence of co-morbid developmental delay underscores the need for routine evaluation and early intervention in all high-risk infants.

Keywords Electroencephalography · Neuroimaging · Outcome · Seizures

Introduction

Epilepsy is the most common disabling neurological problem among children worldwide [1], and has a varying prevalence and etiological profile across the life-cycle. Onset of epilepsy prior to two-year age is more common than later in childhood [2]. It more commonly has a symptomatic cause [3–6], and poor long-term outcome with respect to seizure-control [5–7] and cognition [2–5]. A recent community-based study in this age-group in UK identified the highest incidence among Asian children [3]. Previous work from India on epilepsy in infants has either focused on a single etiology [8], on one particular epilepsy syndrome [9, 10], or on single seizure rather than epilepsy [11]. As there is a paucity of literature on infantile epilepsy from India, and because etiological correlates and types of epilepsy are likely to be different across regions [12]; the present study was conducted to delineate the clinico-etiological profile of epilepsy in infants aged between 1 and 24 mo at a public hospital in India.

Material and Methods

This descriptive study with prospective data-collection was conducted from April 2016 through March 2017, after Institutional Ethics Committee clearance. Consecutive infants aged 1 mo to 24 mo with epilepsy [13], who presented on pre-specified weekdays to the Pediatric department of authors' institution, were assessed for inclusion. Both incident and prevalent cases were enrolled after taking written informed consent from the parents. Infants diagnosed with febrile seizures were excluded.

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Details regarding seizure-onset and semiology, duration of seizure, frequency, current treatment, any precipitating factors for seizures, current seizure control and current medications, antenatal/perinatal/neonatal history, and developmental status were recorded in a structured proforma. Developmental assessment was done by a single trained examiner in all children by using Developmental Assessment Scale for Indian Infants (DASII) [14]. Developmental delay was defined as the development quotient (DQ) score ≤ 70 on either the mental or motor scales [14]. Based on the development quotient, infants were classified as No delay (DQ ≥ 85), Borderline delay (DQ, 71–84), Mild delay (DQ, 50–70), Moderate delay (DQ, 35–49), Severe delay (DQ, 20–34) and Profound delay (DQ < 20).

Results of neuroimaging (either Computed tomography of head or Magnetic Resonance Imaging of brain) and electroencephalography (EEG) were recorded, if already done. For others, these were carried out at the study institution. Neuroimaging investigations were reported by a single radiologist for all infants. Evaluation for neuro-metabolic disorders (serum ammonia and lactate, blood sugar, urine for reducing substances, Tandem Mass Spectroscopy and urinary Gas Chromatography – Mass Spectrometry), and any additional investigations were carried out as per clinical suspicion.

Seizure and epilepsy classification, and etiology were labelled for each child by two experts in consultation, on the basis of the clinical history, reviewing parent-recorded video of the episode (if available), and incorporating the diagnostic data. These were re-classified as per the recent classification for the purpose of this publication [15–17]. Seizure outcome was described as 'seizure-free' (with/without antiepileptic drugs), 'controlled seizures' (<1 seizure per mo on any antiepileptic drug), and 'poorly controlled' seizures despite treatment, in last three months [18]. 'Diagnostic delay' was defined as an interval of one month or greater from second seizure to epilepsy diagnosis [19]. Birth asphyxia was labeled if there was a history of delayed cry, with either features suggestive of hypoxic-ischemic encephalopathy (lethargy, hypotonia, history of seizure) or documented low APGAR scores.

General physical examination and detailed systemic examination to document co-morbidities was done in all participants. The neurologic examination was considered abnormal if any abnormalities were evident on examination of the cranial nerves, motor system and sensory system, cerebellar functions, or gait.

All data were compiled on Excel spreadsheet and analyzed. Proportion of children with developmental delay, and in various etiological groups was calculated. The authors used a univariate analysis to compare the odds of having developmental delay in those with abnormal neuroimaging, abnormal neurological examination, and abnormal EEG. *P* value less than 0.05 was considered significant.

Results

Of the 82 infants approached, 60 infants [median age (range), 14.5 (4.8–24) mo; 39 males] were finally enrolled (Fig. 1). Seizures were observed (by a researcher or on a video-recording) in 39 (65%);15 (25%) infants were seeking medical attention for the first time. The mean (SD) age at seizure onset was 4.3 (4.14) mo. Diagnostic delay was seen in 21 (35%) infants, with the median delay (range) in presentation being 1.5 (1–18) mo. Microcephaly (30, 50%) and neurological abnormalities (41, 68.3%) were present in majority of the infants (Table 1).

Predominantly generalized seizures were present in 56.7% infants (generalized tonic-clonic, 21; myoclonic, 9; and tonic, 4), focal seizures in 11 (18.3%) and epileptic spasms in 15 (25%). Multiple type of seizures were present in 10 children. West syndrome (15), Dravet syndrome (1) and Lennox-Gastaut syndrome (1) were the epilepsy syndromes identified. Majority of the infants (42, 67%) had a structural etiology; sequelae of perinatal asphyxia (46.7%) and malformations of cortical development (18.3%) were the commonest etiologies found (Table 2). Neuroimaging had a high diagnostic yield, with an MRI abnormality being present in 76% infants (35 of 46 infants in whom MRI was done).

Complete seizure control was seen in only 22 (36.7%) infants with median (range); 2 (1–2) drugs. Remaining two-third had continuing seizures despite multiple antiepileptic drugs [median (range); 3 (1–3)]; 17/38 (44.7%) of these had daily seizures. The number of antiepileptic drugs being used in those with persisting seizures was higher than those in whom seizure were controlled [2.6 (0.74) *vs.* 1.9 (0.6); $P < 0.001$]. Non-pharmacologic modalities (Ketogenic diet, vagal nerve stimulation) for seizure management were not being used in any of the patients. The odds of having a good control of epilepsy was significantly higher among those with an unknown etiology than those with a structural etiology [OR (95% CI): 2.6 (1.44–4.87), $P = 0.004$].

Development delay (DQ ≤ 70) was the commonest co-morbidity (81.7%), with 28.3% having profound delay. Developmental delay was significantly more likely in those with an abnormal neurological examination [OR 13.5 (2.82–64.67), $P = 0.001$] or abnormal neuroimaging [OR 8.9 (2.11–37.9), $P = 0.003$]; though, not associated with an abnormal EEG ($P = 0.18$) (Table 3).

Discussion

In this descriptive study of 60 consecutively enrolled 1–24 mo-old infants with epilepsy at a public hospital in India, an underlying etiology was found for more than three-fourth infants. Perinatal asphyxia and malformations of cortical

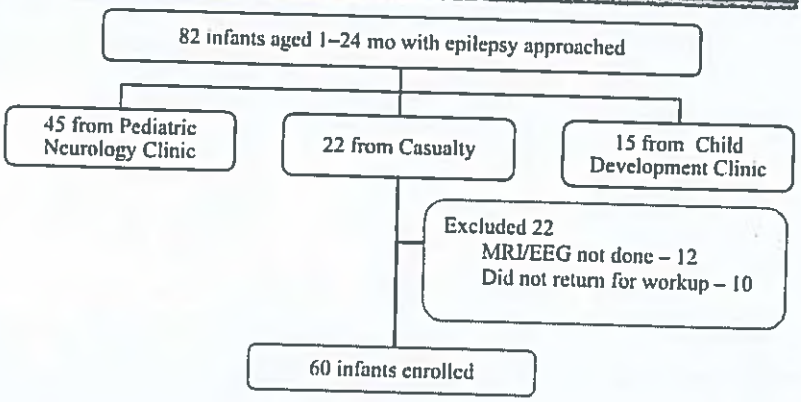

Fig. 1 Flow of participants in the study

development were the commonest etiologies, with 75% patients having an abnormal MRI. Development delay was the commonest co-morbidity, and two-third had abnormalities on neurological examination. West syndrome (WS) was the commonest epilepsy syndrome identified.

Table 1 Disease characteristics of children (< 2 y) with epilepsy (N = 60)

Disease characteristic	No. (%)
Co-morbidities	
Visual impairment*	29 (48.3)
Hearing impairment#	9 (15)
Feeding difficulties	16 (26.7)
Microcephaly	30 (50)
Neurological abnormalities$	41 (68.3)
Spasticity	25
Dystonia	9
€Others	7
¥*Seizure type*	
Generalized	34 (56.7)
Focal	11 (18.3)
Epileptic spasms	15 (25)
Abnormal EEG	38 (63.3)
Hypsarrhythmia	15 (39.5)
Generalized discharges	13 (34.2)
£Others	10 (16.7)
Etiology^	
Structural	42 (67)
Perinatal factors	28 (46.7)
Malformations of cortical development	11 (18.3)
Others	3
Genetic	3
Metabolic	1
Infectious	3
Unknown	13
Developmental status (DQ)	
Mild delay (50–69)	8 (13.3)
Moderate delay (35–49)	16 (26.7)
Severe delay (20–34)	8 (13.3)
Profound delay (<20)	17 (28.3)

$ Some infants had multiple abnormalities; *Delayed P wave latency in Visual evoked potentials in 17, clinically in the rest; # Delayed/absent wave V on Brain evoked response audiometry in 4, clinically in the rest; ^Few patients classified in more than one etiological category; ¥ 10 patients had multiple seizure types, classified as per predominant seizure type; € Hemiparasis-2, Paraparesis-1, Chorea-1; £ Generalized slowing-2, multi-focal discharges-4, focal abnormalities-4

Symptomatic epilepsy is reported in a high proportion (45%–82%) of infants of this age-group [3–6, 20–22]. Related finding has been the high proportion with MRI abnormalities (57%–72%) in this age-group in both community-based and hospital-based populations [3, 23]. Although, a study from this region [21] even reported 71% of CT scans

Table 2 Investigation results in children (< 2 y) with epilepsy (N = 60)

Neuroimaging	No. (%)
Magnetic resonance imaging of brain	46
Normal	11 (23.9)
Abnormal	35 (76.1)
Sequelae of Hypoxic ischemic encephalopathy	18
Malformations of cortical development	9
Corpus callosum dysgenesis	2
Focal cortical dysplasia	2
Lissencephaly	2
Polymicrogyria	1
Congenital hydrocephalus	1
Arachnoid cyst	1
Encephalitis sequelae	2
Leukodystrophy (Alexander disease)	1
Infantile stroke	1
Sequelae of Bilirubin induced neurological dysfunction	1
Propionic acidemia^	1
Congenital Cytomegalovirus infection*	1
Sturge Weber syndrome	1
Computed tomography scan of head	21
Normal	5 (23.8)
Abnormal	16 (76.2)
Sequelae of Hypoxic ischemic encephalopathy	10
Communicating hydrocephalus	2
Sub Dural hemorrhage	1
Infantile stroke	1
Encephalitis sequelae	1
Congenital Cytomegalovirus infection*	1

7 patients has both MRI and CT scan; ^diagnosed on clinical, TMS and MRI finding; * Same patient, diagnosed on serology & neuroimaging

Table 3 Factors associated with developmental delay in children (< 2 y) with epilepsy ($N = 60$)

	*Developmental delay		Total	Odds Ratio (95% CI)	*P* value
	Present, $n = 49$	Absent, $n = 11$			
Neurological examination					
Normal	4	6	10	13.5 (2.82–64.67)	0.001
Abnormal	45	5	50		
Neuroimaging					
Normal	8	7	15	8.9 (2.11–37.9)	0.003
Abnormal	41	4	45		
Electroencephalography					
Normal	16	6	22	2.5 (0.66–9.34)	0.18
Abnormal	33	5	38		

*Developmental delay: Developmental Quotient (DQ) ≤ 70 on DASII

to be abnormal, the same had been done selectively rather than in all infants. In consonance with the bulk of the literature, the current recommendations for evaluation of epilepsy in infancy also suggest MRI in all such infants [24].

Previous hospital-based studies [4, 5, 25, 26] have reported the proportion of infants with developmental delay to range between 65 and 80%, which is similar to present findings; although, a recent community-based study [3] in the UK reported subnormal cognitive functioning in around 60% of their subjects. Developmental delay in this population has been reported to be associated with abnormal neurological examination [3, 4, 27] and abnormal neuroimaging [3], similar to the present post hoc analysis. Association of developmental delay has also been reported with an abnormal neonatal [3] or current [4, 22] EEG, but authors did not find any such association, similar to other reports [27], which could have been due to the small numbers in this study.

Almost half the participants had predominantly generalized seizures, although studies have reported both generalized [21, 26, 27] or focal [20] seizures to be commoner. The proportion of children with WS in this study is in consonance with the reported 20–53% in previous studies from different regions [6, 20, 25], though lower numbers have also been reported [21, 26]. The present findings in the West syndrome sub-group were similar to the previous Indian studies [9, 10], except for an older mean age of onset in those studies, possibly due to these studies done at referral centers or the smaller numbers in the present study.

The study results are limited by its tertiary hospital-based enrolment, with majority referred from the neurodevelopment clinic. This could likely have led to enrolment of more children with associated neurodevelopmental disorders, especially global developmental delay and cerebral palsy. The generalizability of the study findings are also limited by the small numbers in this study. The authors did not collect anthropometric data, which could have helped in identifying co-existent failure to thrive in this sub-group of patients. Extensive and complete work-up of a large number of consecutively enrolled patients is the strength of the study.

This study has documented that most of the epilepsy in infants less than two years in a developing country setting is symptomatic in nature, with sequelae of birth asphyxia being the commonest etiology. This is a potentially preventable entity, likely to be amenable to better perinatal care, and early identification and management of seizures. High prevalence of co-morbid developmental delay again underscores the need for follow-up of all high-risk infants, and early identification and management of seizures. The need for further studies from different regions is highlighted so as to better elicit the various etiologies and co-morbidities of infantile epilepsy in India, especially with respect to genetic causes.

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Authors' Contribution PKS, DM, MJ, KT: Study planning; PKS, DM: Subject assessment and evaluation; DM, KT: Statistical analysis; PKS, KT, DM: Manuscript writing. All authors made important intellectual contribution to study planning, data analysis, and manuscript writing. All authors approved the final manuscript. DM would be the guarantor.

Compliance with Ethical Standards

Conflict of Interest None.

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Original Research Article

Screening for Gaucher's Disease in unexplained splenomegaly and/or thrombocytopenia: An observational study

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Abstract

Introduction: Gaucher's disease is a hereditary disease that can be diagnosed by determination of acid β glucosidase enzyme activity on leucocytes but it's diagnosis is mostly delayed due to limited availability of test.To determine prevalence of Gaucher's disease in patients of unexplained splenomegaly and/or thrombocytopenia using dried blood spot filter test.**Methodology:** This prospective cross sectional study was conducted after approval from Institutional ethical committee in 222 subjects, assuming 3.6% prevalence of the disease among unexplained cases of splenomegaly with 95% confidence interval, 0.05 α error, 80% power and with an absolute allowable error of 2.5%. After implementation of the diagnostic algorithm, samples from the patients were collected on dried blood pot filter paper and sent for analysis. Patients who tested positive by screening test were confirmed through mutational analysis done from the same sample. Data was expressed as mean, proportions and percentages. Mann Whitney test,Chi square test and Fisher's exact test were used for analysis.**Results:**The prevalence of Gaucher's disease in our study population was 2.7% (CI 0.54 to 4.86) with the odds ratio for gender calculated as 3(95% CI 0.344 to 26.134).**Conclusion:**The results of this study show that the use of an appropriate diagnostic algorithm and DBS filter test facilitate early diagnosis and management of a rare disease, thereby saving a lot of medical resources while simultaneously improving the quality of life in patients.

Key-words:Gaucher's disease, Dried blood spot filter test, Splenomegaly, Thrombocytopenia.

Introduction

Gaucher's disease(GD), the most common lysosomal storage disorder, is an autosomal recessive hereditary disease due to the congenital deficiency of lysosomal enzyme acid β-Glucosidase. It leads to accumulation of non-degraded glycosphingolipids (gluco cerebroside) in the macrophagic cells of the reticulo-endothelial system. The disease incidence in patients with Ashkenazi Jewish heritage varies from 1 in 450 to 1 in 1000, while in the rest of populations the incidence is estimated at 1:40000 to 1:60000.[1,2] Gaucher's disease is progressive and if not treated, it may lead to increased morbidity and mortality due to liver failure, pulmonary hypertension, skeletal complications, haemorrhage and sepsis.[3] Splenomegaly and thrombocytopenia are the two most typical and frequent manifestations of GD.[4] Though, GD can be easily diagnosed by determination of acid β glucosidase enzyme activity (<30% compared to healthy subjects) on leucocytes, taken from a peripheral blood sample, it's diagnosis is mostly delayed due to availability of test only at limited centres.[5]We hypothesised that a novel screening method of dried blood spot filter test can be used to screen Gaucher's disease in patients with unexplained splenomegaly and/or thrombocytopenia after implementation of an appropriate diagnostic algorithm. The primary aim of this study is to determine the prevalence of Gaucher's disease in patients of unexplained splenomegaly and/or thrombocytopenia using dried blood spot filter test and appropriate diagnostic algorithm. This method will eliminate the diagnostic delay, creating opportunities for the patient to receive treatment with enzyme replacement therapy(Imiglucerase) in the reversible phase of the disease and hence, reducing overall morbidity.[6]

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Materials and Methods

This cross sectional observational study was carried out in the department of pediatrics at our institute after approval from institution's ethical committee. A written and informed consent was taken from the patient's relatives after explaining the procedure to the patient. Assuming 3.6% prevalence of GD among unexplained cases of splenomegaly, sample size was calculated to be 222 with 95% confidence interval, 0.05 α error, 80% power, with an absolute allowable error of 2.5%.[7]

Inclusion criteria comprised of patients with unexplained splenomegaly and persistent thrombocytopenia(Table 1).

Exclusion criteria was defined as the cases where causes of splenomegaly and/or thrombocytopenia have been ascertained e.g. haematological malignancies, splenomegaly due to portal hypertension, haemolytic anaemia, haemoglobinopathies, acute and chronic infections.After implementation of Gaucher's disease diagnostic algorithm proposed by Mistry et al, samples from the patients were collected on Dried Blood Spot (DBS) filter paper and sent for analysis of β-glucosidase enzyme levels. The normal reference range for β-glucosidase enzyme activity, estimated by fluorometric assay on DBS samples was taken as 2.3 – 14.1 nmol/ml/hr, and patient range as 0 – 2 nmol/ml/hr.[8] Level of chitotriosidase enzyme was also measured in the patients with normal range considered as <150 nmol/ml/hr. Patients who tested positive by

screening test were confirmed through mutational analysis done from the same sample.

Statistical Analysis was done with SPSS-16 and MS-Excel. Data was expressed as mean, proportions and percentages. Mann Whitney U test was used to calculate difference of means between two groups. Chi square test and Fisher exact test were used to demonstrate association between two variables, as appropriate.

Table 1: Inclusion criteria

S.no	Inclusion criteria	
1.	Unexplained splenomegaly	Clinically palpable spleen ≥ 2 cm from the costal margin
		Splenomegaly diagnosed by Ultrasonography
2.	Persistent thrombocytopenia	Platelet count<100,000/mm^3 on 2 occasions at least 4 weeks apart alongwith bone pain or Hemogobin<10g/dl
		Platelet count<100,000/mm^3 with history of splenectomy

Results

Two hundred twenty two patients with unexplained splenomegaly and/or thrombocytopenia were enrolled in this study. Out of 222 patients, 129 patients had both splenomegaly and thrombocytopenia, 68 had only splenomegaly while 25 had only thrombocytopenia. Among the 222 patients, 6 had low(< 2 nmol/ml/hr) levels of β-glucosidase enzyme level and high chitotriosidase level (>150 nmol/ml/hr). GD patients had significant growth retardation as compared to other patients included in the study(p value- 0.005). Average Spleen size of GD patients was significantly more than other patients(p value – 0.001). Platelet count was found to be on lower side in GD patients (p value- 0.045). GD patients had higher Serum iron than other patients (p value- 0.036). On performing ultrasongraphy, GD patients had increased liver and spleen size, with p value of 0.002 and 0.016, respectively.(Table 2)

Table 2: Comparison of patient's characteristics with and without Gaucher Disease

Characteristics	Gaucher's disease present(n=6)	Gaucher's disease absent(n=216)	p value
Age	57.60±47.548	55.26±57.925	0.472
Weight For Age	13.22±7.823	14.01±10.443	0.718
Height Deficiency For Age	-2.67±0.516	-1.41±1.057	0.005
Spleen Size	11.42±3.26	5.60±3.88	0.001
USG Spleen Size	15.28±3.45	9.68±3.79	0.002
USG Liver Size	12.87±2.60	10.03±2.51	0.016
TLC	5340.00±2169.98	9207.76±7724.76	0.381
TRBC	2.67±0.67	2.82±1.08	0.794
Platelet Count	0.46±0.29	1.28±1.50	0.045
Haemoglobin	5.68±1.33	6.18±2.44	0.864
S. Iron	134.67±31.53	95.34±53.81	0.036
S. Ferritin	299.72±258.19	266.71±260.84	0.778
TIBC	260.00±22.83	283.24±78.00	0.619
SGOT	62.00±30.20	72.96±69.84	0.882
SGPT	28.67±26.74	49.79±62.418	0.079
S. Vitamin B12	370.17±113.547	370.69±239.85	0.370
Folic Acid	12.38±5.60	10.72±5.54	0.441
Beta Glucosidase Enzyme Level	1.05±0.52	5.37±4.05	0.000
Chitotriosidase Level	502.93±466.24	46.55±45.61	0.003

**Mean± SD*

Discussion

Gaucher's disease is the most common lysosomal storage disorder with the estimated prevalence of 1:60,000 to 1:40,000 in non-Ashkenazi jews population. There have been no prevalence studies in India, so the actual prevalence is not yet known. Some studies suggest overall prevalence to be 1:105, while others suggest higher number depending on the demographic profile.[9,10] As GD is a rare disease, involving multiple organs with variable clinical manifestation, it is accompanied by delayed diagnosis and delayed commencement of enzyme replacement therapy. Only twenty percent haematologist/oncologist considers GD in the differential diagnosis of a patient with a history of anaemia, thrombocytopenia, hepatomegaly, splenomegaly and bone pain.[11] Many a complex algorithm have been proposed for screening of patients with GD. Screening algorithm proposed by Maja et al uses five indicators i.e. skeletal erlenmeyer flask(EF) deformity, growth retardation, strabismus and/or oculomotor palsy, serum ferritin levels and tartrate resistant acid phosphatase(TRAP) levels.[12] Serum ferritin or TRAP levels are not part of routine laboratory investigations and not many

GD patients present with characteristic skeletal EF deformity, strabismus and oculomotor palsy. Therefore, relatively simple diagnostic algorithm described by Mistry et al, which uses splenomegaly and thrombocytopenia for screening was used in our study. The diagnostic algorithm proposed by Mistry et al has already been successfully applied in previous studies.[7]

The gold standard for diagnosis of Gaucher's disease is acid β-glucocerebrosidase enzyme assay in blood leucocytes but its regular use is hampered by its inaccessibility. So, we used DBS filter test for diagnosis of GD. Though DBS filter test is not the gold standard but it has been well validated in previous studies for the diagnosis of GD.[8]The prevalence of GD in our study population i.e. patients with unexplained splenomegaly and/or thrombocytopenia, was 2.7% (CI 0.54 to 4.86) with the odds ratio for gender calculated as 3(95% CI 0.344 to 26.134). There were 3 males and 1 female. Our results were similar to the study conducted by Motta et al who found the prevalence of GD in the same patient group to be 3.6% (CI 95% 1.4–7.2) with 5 females and 2 males.[13] In our study, the mean age at presentation was 55.27 ± 5.75 months (4.6 ± 0.475 years) while the mean age of diagnosis of GD was 57.60 ± 2.26 months (4.8 ± 0.188 years). Lei et al had also observed similar findings in their study. Out of 73 children, four (three boys and one girl) were diagnosed with GD, with a median age of 1.5 years, and the prevalence in that specific population was ascertained to be 5.5% (1.5-13.4%). [8,14,15]In our study, 100% of GD cases had hepatosplenomegaly (66.67% had moderate splenomegaly and 33.33% had severe splenomegaly) and thrombocytopenia. 83.3% of patients with GD had anaemia, 66.67% had growth retardation, 33.3% had bone pain but none had radiologic bone disease. These findings were consistent with ICGG Registry as 66.67% GD cases in our study were younger than 6 year. Among the six GD patients in our study, thrombocytopenia and anaemia were observed more frequently when compared with the ICGG registration which showed 50% of children with severe or moderate platelet count, and about 40% with anaemia.[4] Genotype data from the ICGG Registry indicate that four common mutations constitute 72% of all GD alleles: N370S, L444P, IVS2+1, and 84GG.[4] Depending on the allele involved the presentation and the average age of diagnosis is highly variable. At the time of diagnosis, patients with the L444P/L444P genotype had median age of 1 year. All other allele groupings had a median diagnosis age ranging from 3 to 7 years. In our study, 50% (3) had L483P/L483P genotype, 33.33% (2) had L444P/L444P genotype and 16.67% (1) had L444P/A456P genotype. 2 out of 3 L444P genotype had neurological manifestation and 1 out of 3 L483P mutation had neurological manifestations.(Table 3)

Table 3: Comprehensive evaluation of six patients with positive DBSresult

S.no.	Chitotriosidase level	β glucosidase enzyme level	Mutation Analysis*
Patient 1	239	0.46	[L444P]+[L444P]
Patient 2	228.52	1.01	[L444P]+[A456P]
Patient 3	1051.1	1	[L444P]+[L444P]
Patient 4	789	1.63	[L483P]+[L483P]
Patient 5	1041.26	1.9	[L483P]+[L483P]
Patient 6	1232.67	0.9	[L483P]+[L483P]

**The mutations are described according to the traditional amino acid residue numbering*

The relevance of the combined approach based on Mistry et al's algorithm and the use of DBS filter test to assess the β-glucosidase enzyme activity is that it can be made easily accessible, permitting earlier diagnosis and management. Although the number of GD cases in our study was small, our findings expect paediatricians to be increasingly suspicious for diagnosis of GD in children with thrombocytopenia and/or anaemia, especially those accompanied with hepatosplenomegaly.There should be a high index of suspicion in order to diagnose rare genetic disorders in children presenting with common clinical manifestation. The diagnostic algorithm was proved to be appropriate to make an early diagnosis of GD patients with mild symptoms or atypical symptoms and avoid diagnostic delay. DBS filter test is convenient for preparation, storage and transport, and can effectively screen GD patients, hence it can be used as a preliminary screening method for GD diagnosis. These results show that the use of an appropriate diagnostic algorithm and a simple, relevant diagnostic method, such as DBS filter test, are important tools to facilitate early diagnosis and management of a rare disease, thereby saving a lot of medical resources while simultaneously improving the quality of life in patients.

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Original Research Article

Effect of phototherapy on serum calcium levels in neonates receiving phototherapy for neonatal jaundice

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ABSTRACT

Background: To study the occurrence of hypocalcaemia in neonates with physiological unconjugated hyperbilirubinemia after 48 hours of phototherapy or at the end of phototherapy, in case duration of phototherapy was less than 48 hours.
Methods: This prospective study was conducted on 100 term neonates (61 males and 39 females) admitted to Neonatal intensive care unit of Teerthankar Mahaveer Medical College, Moradabad with unconjugated hyperbilirubinemia and requiring phototherapy. Total Serum bilirubin levels and serum calcium levels were checked before and after phototherapy. Neonates were assessed for clinical features of hypocalcemia i.e. jitteriness, irritability/excitability, lethargy and convulsions.
Results: After phototherapy, there was hypocalcemia in 35.0% neonates. The difference between pre and post phototherapy serum calcium levels were found to be statistically significant ($p < 0.001$). 2.86% of neonates developed jitteriness among those who had hypocalcemia. Hypocalcemia was more in subjects who received phototherapy for longer duration.
Conclusions: Hypocalcaemia is a common complication of phototherapy. Therefore, calcium supplementation should be done in all neonates undergoing phototherapy.

Keywords: Hyperbilirubinemia, Hypocalcemia, Phototherapy, Term neonates

INTRODUCTION

Neonatal jaundice is a common and benign problem in neonates. Jaundice is observed during first week of life in approximately 60 % of term neonates and 80 % of preterm neonates.[1] Untreated severe unconjugated hyperbilirubinemia is potentially neurotoxic.

Phototherapy is one of the routine method for management of hyperbilirubinemia. However, it is not a harmless intervention. It can produce adverse effects such as dehydration, temperature instability, skin rashes, loose stools, retinal damage, hypocalcemia, bronze baby syndrome, redistribution of blood flow and genotoxicity. It causes photo oxidation of bilirubin into water soluble or less lipophilic colorless form of bilirubin which is readily excreted in bile, feces and urine.

Hypocalcemia is one of the lesser known adverse effects of phototherapy. It is defined as total serum calcium concentration of <7mg/dl (1.75mmol/L) in preterm and serum calcium <8mg/dl (2mmol/L) in term neonates. It can cause serious complications like neuromuscular irritability, myoclonic jerks, jitteriness, convulsion, cyanosis, apnea and laryngospasm.[2] Cardiac

manifestations like tachycardia, heart failure, prolonged QT interval and decreased contractibility are also seen due to hypocalcemia.[2]

Aims and objectives was to study the occurrence of hypocalcaemia in neonates with physiological unconjugated hyperbilirubinemia after 48 hours of phototherapy or at the end of phototherapy, in case duration of phototherapy is less than 48 hours.

METHODS

This study was conducted in Neonatal Intensive Care Unit (Department of Pediatrics) at Teerthankar Mahaveer Medical College and Research Centre, Moradabad. Ethical approval for the study was obtained from the Institutional Ethical Review Committee.

It was Hospital based prospective study and 100 term neonates was there.

Inclusion criteria

Full term neonates (37 completed weeks to 41 weeks) with unconjugated hyperbilirubinemia requiring phototherapy.

Exclusion criteria

New borns

- To a diabetic mother
- With onset of jaundice within 24 hrs of age
- With perinatal asphyxia (Apgar <4 at 1 minute of birth)
- Whose mother had history of taking Anti-convulsants
- Fed with cow's milk
- Who had exchange transfusion
- With jaundice lasting more than 14 days of life
- With sepsis
- With jaundice having hypocalcemia prior to the start of phototherapy
- Babies born with apparent major congenital anomalies
- ABO incompatibility.

Written informed consent was taken from parents/guardians of all eligible subjects in their preferred language. Complete maternal history was taken and maternal risk factors like hypertension, diabetes mellitus, oligohydramnios, anaemia, epilepsy, fever, any rash, any drug intake during pregnany other than iron and folic acid supplementation were ruled out.

Complete history and physical examination was carried out in all neonates included in the study. Dermographic and clinical variables were recorded. It included birth weight, sex, gestational age, mode of delivery, time of appearance of icterus in hours, maternal blood group and Rh status, baby blood group and Rh status, anthropometric measurements (weight, length and head circumference) of infant at the time of admission and duration of phototherapy.

Total serum bilirubin (TSB), serum calcium, serum albumin, G6PD, Direct Coombs Test (DCT), Reticulocyte count and thyroid profile were sent in all cases. TSB and Serum calcium levels before and at the end of phototherapy were recorded. The first sample was considered as control. Hypocalcemia was considered as total serum calcium of <8mg/dl. Neonates were clinically assessed for features of hypocalcemia.

A conventional phototherapy equipment, containing four blue light fluorescent lamps with wavelengths of 410-470nm, was placed at a distance of 25-35cm from the skin surface of neonates under standard protocol with eyes and genitals completely covered. The irradiance during phototherapy was measured and maintained consistently at 15μW/cm²/nm at the level of infant's skin.

Statistical analysis

Data were analysed using SPSS version 17 software. Descriptive statistical analysis was done and continuous variables were described as mean and standard deviation and categorical variables in number and percentage. Students paired t test and unpaired t test had been used to assess continuous variables for pair matched samples with 95% confidence limit. p value less than 0.001 was considered statistically significant.

RESULTS

The study group included 100 neonates, 61 boys (61.0%) and 39 girls (39.0%), with mean gestational age of 38.16±0.95 weeks and mean birth weight of 2.66±0.33 kilograms. 57.0% neonates were delivered by normal vaginal delivery and 43.0% by lower segment caesarean section. Mean time of appearance of icterus and duration of phototherapy was 102.60±48.10 hours and 42.48±10.15 respectively (Table 1).

Table 1: Dermographic features of newborns.

Variable	Mean and number (%)
Gestational age (weeks)	38.16±0.95
Birth weight (kilograms)	2.66±0.33
Time of appearance of icterus (hours)	102.60±48.10
Duration of phototherapy (hours)	42.48±10.15
Type of delivery	
Normal vaginal delivery	57 (57.0%)
Lower segment caesarean section	43 (43.0%)

Mean total serum bilirubin levels before and at the end of phototherapy was 19.48±2.78mg/dl and 11.18±3.11mg/dl

respectively. Mean serum calcium levels before phototherapy was 9.14±0.78mg/dl and it reduced to 8.53±0.77mg/dl after phototherapy. It was found that there was significant reduction ($p<0.001$) in mean total serum bilirubin and mean serum calcium levels after phototherapy as compared to pre phototherapy levels (Table 2).

Table 2: Comparison between mean total serum bilirubin and serum calcium levels before and after receiving phototherapy.

Test	Admission time	After phototherapy	p-value
Total serum bilirubin (mg/dl)	19.48±2.78	11.18±3.11	0.000
Total serum calcium (mg/dl)	9.14±0.78	8.53±0.77	0.000

Serum calcium levels after phototherapy was >8mg/dl in 65.0% of subjects and hypocalcemia i.e. serum calcium levels <8mg/dl was noted in 35.0% of subjects (Table 3, Figure 1).

Table 3: Descriptive data of serum calcium levels post phototherapy.

Variable	N=100
Hypocalcemia (<8mg/dl)	35/100 (35.0%)
Normal calcium (>8md/dl)	65/100 (65.0%)

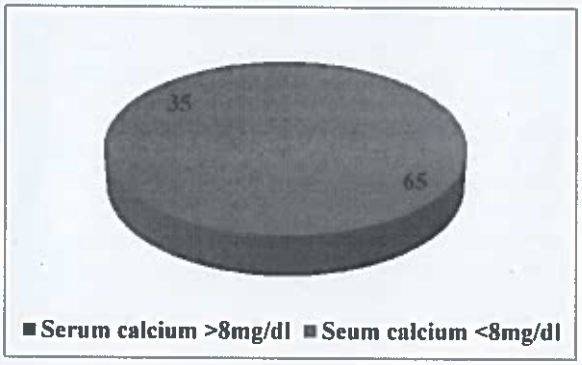

Figure 1: Incidence of hypocalcemia in term neonates after phototherapy.

Table 4: Descriptive data of symptoms among hypocalcemic cases post phototherapy.

Variable	N=35/100
Symptomatic (jitterriness)	1/100 (2.86%)
Asymptomatic	34/100 (97.14%)

Out of 35 subjects who had hypocalcemia, only one subject (2.86%) was symptomatic and developed jitteriness. Rest of the subjects (97.14%) were asymptomatic (Table 4). Also, incidence of hypocalcemia was more in neonates who received phototherapy for 48 hours (77.1%) as compared to neonates who received phototherapy for 24 hours (22.9%) (Table 5, Figure 2).

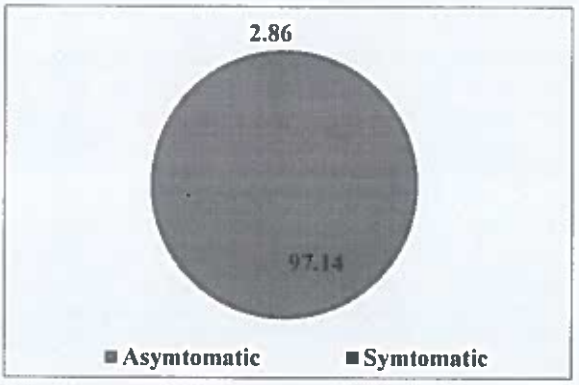

Figure 2: Incidence of symptomatic hypocalcemia.

Table 5: Incidence of hypocalcemia based on the duration of phototherapy.

	Hypocalcemia	Percentage
24 hours	8	22.9%
48 hours	27	77.1%
Total	35	100%

DISCUSSION

Phototherapy is an appropriate and commonly used measure to reduce indirect bilirubin level in newborns. Romagnoli et al was the first to suggest the association of hypocalcemia in newborn following phototherapy.[3]

The mechanism of hypocalcemic effect of phototherapy was reported by inhibition of pineal gland via transcranial illumination, resulting in decline of melatonin secretion which blocks the effect of cortisol on bone calcium. Cortisol has a direct hypocalcemic effect and increases bone uptake of calcium and induces hypocalcemia.[4]

In this study, there was a significant decrease in serum calcium levels after 48 hours of phototherapy ($p<0.001$). The mean serum calcium in this study after phototherapy was 8.53±0.77mg/dl. This was in correlation with studies done by Bahbah et al (8.58±0.76) and Singh et al (8.42±1.19).[5,6]

In an Iranian study, 7.5% neonates developed hypocalcemia after receiving phototherapy.[7] In our study, hypocalcemia was observed in 35.0% of neonates after phototherapy. Shrivastva et al, also observed hypocalcemic effect of phototherapy in 30.0% of term neonates.[8] Sethi et al, observed hypocalcemia in 75% of term neonates after phototherapy.[9]

None of the hypocalcemic neonates were clinically symptomatic in studies by Tehrani et al and Reddy et al.[7,10] In our study, symptomatic hypocalcemia was

observed in 2.86% of neonates which was similar to studies by Yadav et al and Sethi et al who also observed symptomatic hypocalcemia in term neoantes.[11,9] Bahbah et al. observed jitteriness in 14% and convulsions represented 10% of hypocalcemic cases.[5]

In a study by Reddy et al. the incidence of hypocalcemia was 18.8% when duration of phototherapy was >48 hours as compared to duration <48 hours (10.9%).[10] Out of total 35 cases of hypocalcemia in our study, incidence of hypocalcemia was more in neonates who received phototherapy for 48 hours (77.1%) as compared to neonates who received phototherapy for 24 hours (22.9%).

CONCLUSION

Phototherapy induced hypocalcemia is a significant problem. Careful estimation of calcium status should be done before starting and during phototherapy for neonatal jaundice and close monitoring of neonates for signs of hypocalcemia should be done. Calcium supplementation can be considered as prophylaxis in neonates undergoing phototherapy.

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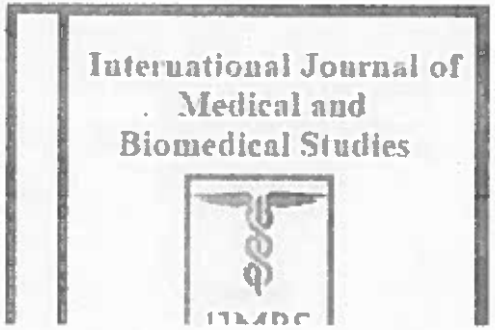

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Original Research Article

IJMBS

ROLE OF GLUTEN FREE DIET IN CELIAC DISEASE WITH CHILDREN SUFFERING FROM SEVERE ACUTE MALNUTRITION.

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Abstract

Background: Diagnosis of celiac disease in children suffering from severe acute malnutrition without duodenal biopsy or HLA typing is a dilemma. The objective of this study was to study the response to gluten free diet in sero-positive Celiac Disease children suffering from severe acute malnutrition in age group 1-5 years. **Methods:** This prospective, observational, hospital-based study was conducted at MTC of tertiary care medical college hospital of southern Rajasthan from Feb. 2019 to Jan. 2020. Total 220 children with SAM were enrolled and screened for celiac disease on the basis of tissue tTg-IgA/IgG serology. Seropositive cases were kept on gluten free diet for short period of time and observed for the resolution of symptoms and improvement in growth, monitored by anthropometry on discharge and follow up visit. **Results:** Mean weight gain (gm/kg/day) on follow up was 3.87±3.49 in seropositive and 1.88±3.79 in seronegative cases (P-value<0.05). Mean weight gain was 6.43±3.28gm/kg/day in only tTg-IgA positive and 3.04±2.95 gm/kg/day in only tTg-IgG positive cases (P-value-<0.05). The mean weight gain in strictly gluten free adherent sero-positive cases was 4.89±2.97 gm/kg/day while in gluten free non-adherent patients it was -0.49±1.70 (P-value <0.001). Mean weight gain in probable (tTg-Ig-A <10 times ULN) and presumptive (tTg-IgA >10 times ULN) Celiac disease were 3.44±3.73 and 5.44±3.78, respectively without statically significant difference (P-value >0.05).**Conclusions:** In situations where facility of duodenal biopsy and or HLA DQ2/DQ8 typing is not available, resolution of symptoms and improvement in growth on gluten free diet confirms the diagnosis of celiac disease.

Keywords: Celiac disease, Gluten free diet, Tissue trans-glutaminase, Severe acute malnutrition.

Introduction

Celiac disease is emerging as a public health problem in India. Almost 6-8 million Indians are estimated to have celiac disease.[1] A massive increase in the number of patients with celiac disease is expected now and in the subsequent decade in India because of increasing awareness and availability of diagnostic facilities. Celiac disease is a common cause of malabsorption in the children and adults. It is characterized by an enteropathy and lifelong intolerance to gluten initiated by ingestion of gliadin related prolamines from cereals such as wheat, barley and rye in genetically susceptible individual.[2] As per NFHS-4 (2015-16) severe acute malnutrition afflicts nearly 7.5% of children below 60 months of age in India.[3] Several studies had reported high prevalence of celiac disease in north India particularly Punjab and Rajasthan in general population and children.[4-7] The clinical features of severe acute malnutrition (SAM) often overlap with the common manifestations of celiac disease such as diarrhea, failure to thrive, vomiting, abdominal distension, anemia, weight loss and irritability.[8,9] The diagnosis of celiac disease is based on clinical features, celiac serology followed by confirmation by duodenal biopsy and or HLA DQ2/DQ8 typing.[10] Facility of upper GI endoscopy and duodenal biopsy or HLA typing is available at very few centres and are expensive and most of the time not possible.This study was designed to diagnose the celiac disease in SAM children of 1-5 years of age group on the basis of celiac serology and observe the response to gluten free diet in celiac seropositive patients.

METHODS

The present study was an observational hospital based prospective study, carried out at malnutrition treatment center (MTC) at ananta institute of medical science & research center Rajsamand, Rajasthan. The study was conducted from February 2019 to January 2020. Prior approval was sought from institutional ethical committee of medical college. After written informed consent from both the parents total 220 children of either gender admitted in MTC, fulfilling the inclusion criteria, were enrolled for the study. Diagnosis of severe acute malnutrition was based on WHO criteria for severe acute malnutrition.

Inclusion criteria

- All the SAM children (meeting the WHO criteria for SAM) of age 1 to 5 years admitted in MTC and who are exposed to gluten containing diet.

- Parents given informed and written consent to enroll in the study.

Exclusion criteria

- Seriously sick SAM children admitted in PICU.
- Patients with secondary malnutrition-known c/o chronic medical or surgical disorders leading to malnutrition-congenital heart diseases with CHF, chronic renal failure, hepatic cholestasis, thyrotoxicosis, isolated childhood diabetes mellitus, HIV, childhood tuberculosis, cerebral palsy, genetic/ chromosomal syndromes, inborn errors of metabolism (IEM), malignancies, surgical resection of intestine etc
- Patients with known celiac serology
- Patients who were not exposed to gluten containing diet
- Parents not given for consent.

Celiac disease sero-positivity was accessed by screening for tissue transglutaminase IgA (tTg-IgA) and IgG (tTg- IgG) antibodies by enzyme linked immuno-sorbent assay (ELISA) method (Aeskulisat tTg-A/tTg-G new generation antigen-based kit by Aesku. Diagnostics Gmbh and Co. Kg). As per manufacturer manual of the kit, cut off value for sero-positivity for tTg-IgA/IgG was>18U/ml. Celiac Disease status was labeled according to titer of tTg-IgA and tTg-IgG as shown in Table 1.All the celiac disease seropositive patients were kept on strict gluten free diet after proper counselling. After admission anthropometric measurements and symptomatic improvement were recorded on discharge and on follow up visit.

Statistical analysis

All the collected data were managed and analysed with standard software (SPSS version 20). P-value of <0.05 was considered significant.

Table 1: Celiac disease status according to titer of tTg-IgA and tTg-IgG.

Celiac disease status	tTg-IgA Titre (Unit/ml)*	tTg-IgG Titre (Unit/ml)*
No celiac disease	≤18	≤18
Probable celiac disease (<10 times of ULN)	>18 - up to 180	>18
Presumptive celiac disease (10 times of ULN)	>180	

* Normal Range for tTg-IgA and tTg-IgG: 12-18 unit/ml (as per manufacturer manual of the kit); ULN- Upper limit of normal.[11]

Results:

Table 2: Gender wise distribution of cases.

Gender	No.	Percentage
Male	130	59.09
Female	90	40.91
Total	220	100.00

Out of total 220 enrolled cases 130 (59.09%) were male and 90 (40.91%) were female. The male to female ratio was 1.44:1 (Table 2).

Table 3: Mean weight gain at follow-up.

Sero-positivity status	Weight gain (gm/kg/day) at follow-up	
	Mean	SD
Seronegative	1.88	±3.79
Seropositive	3.87	±3.49

P-value>0.05

Seropositive celiac disease (either tTg-IgA or IgG or both IgA and IgG) was positive in 60 (27.28%) cases out of 220 enrolled cases of severe acute malnutrition. Mean weight gain (gm/kg/day) on follow up was (3.87±3.49) in seropositive group and in seronegative was 1.88±3.79. This difference was statistically significant (P- value<0.05) (Table 3).

Table 4: Mean weight gain at follow-up according to tTg-IgA titre levels.

Levels of tTg- IgA titre (U/ml)	Mean weight gain (gm/kg/day) at follow-up	
	Mean	SD
>18 up to 180	3.44	3.73
>180	5.79	3.78

P-value >0.05

Mean weight gain (gm/kg/day) on follow up in both tTg-IgA positive cases was statically insignificant (P-value>0.05) (Table 4).

Table 5: Mean weight gain at follow-up in only tTg- IgA v/s only tTg -IgG seropositive cases.

Seropositivity status	Mean weight gain(gm/kg/day)	
	Mean	SD
Only tTg-IgA positive (n=8)	6.43	3.28
Only tTg-IgG positive (n=7)	3.04	2.95

P-value <0.05

Mean weight gain (6.43±3.28) was more in only tTg-IgA positive compared to tTg-IgG positive group (3.04±2.95). This difference was statically significance (P-value-<0.05) (Table 5).

Table 6: Follow up status in cases.

Follow-up status	Seronegative group (n=80)	%	Seropositive group (n=30)	%
Follow-up	60	37.50	42	70
Follow-up failure	100	42.50	18	30

After discharge follow-up was 70% (42 out of 60) in seropositive group and 37.5% (60 out of 160) in seronegative group (Table 6).

Table 7: Gluten free diet adherence status and mean weight gain in seropositive cases on follow-up.

Gluten free diet adherence status	No.	%	Mean weight gain (gm/kg/d)	SD	P- value
Strictly Followed Gluten free diet	34	80.95	4.89	±2.97	<0.001 (HS)
Not Followed Gluten free diet	8	19.05	-0.49	±1.70	

Most of the seropositive patients 34 (80.95%) were adhered to gluten free diet as per counselling at discharge. While 8 (19.05%) were not adhered to gluten free diet (Table 7).

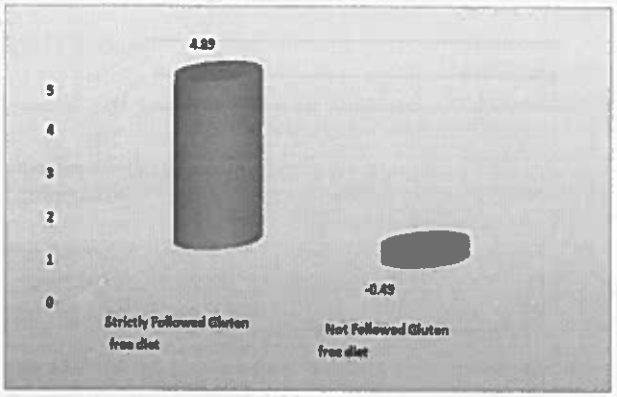

Figure 1: Mean weight gain (gm/kg/day) in gluten free diet adherent and non-adherent cases.

Mean weight gain (gm/kg/day) in strictly gluten free adherent sero-positive cases was 4.89±2.97 while in gluten free non-adherent patients it was -0.49±1.70. This difference of mean weight gain in gluten free adherent and non-adherent was statistically highly significant (P- value <0.001) (Table 6 and Figure1).

Discussion

Celiac disease and severe acute malnutrition in children share common clinical features. Confirmatory diagnosis of celiac disease is based on serology followed by duodenal biopsy or HLA DQ2/DQ8 typing.In situations where availability of Pediatric Gastroenterologist and facility of upper GI endoscopy for duodenal biopsy in small sick children (less than 5 years) is not possible or available and HLA typing is also not available/feasible then gluten free diet may be tried in celiac positive serology patients and observed for improvement in anthropometry and resolution of symptoms.In present study, authors kept the celiac seropositive patients suffering from SAM on gluten free diet and observed the response. On follow up the mean weight gain (gm/kg/day) in sero- positive cases was more in comparison to seronegative cases (P-value <0.05). This shows good response to gluten free diet in sero-positive cases and confirms the diagnosis of celiac disease in these cases.The mean weight gain on follow up was more in presumptive celiac disease sero-positive cases (5.79±3.78 gm/kg/day) in comparison to probable celiac disease sero-positive cases (3.44±3.73gm/kg/day). Although the mean weight gain was more in presumptive celiac Disease sero-positive cases but the difference of weight gain between probable and presumptive celiac sero- positive cases was statistically not significant (P- value>0.05). This suggests that response to gluten free diet is similar in tTg-IgA titre <10 and >10 times of ULN cases.So, we should not wait for to rise the tTg antibody titres>10 times of ULN and start the gluten free diet at lower level if clinical features are also suggestive of celiac disease and observe the response to gluten free diet.Mean weight gain in only tTg-IgA seropositive cases was more (6.43±3.28gm/kg/day) in comparison to only tTg- IgG sero-positive cases which was statistically significant (P-value <0.05). Comparatively lower weight gain in only tTG-IgG sero-positive cases may be because of underlying IgA deficiency leading to recurrent gastrointestinal infections and another reason may be more damage to intestinal epithelium requiring more time to regenerate and slow response to gluten free diet.In present study most of patients (93%) discharged successfully but follow-up was 70% (42 out of 60) in seropositive group and rest 30 % of seropositive cases could not be followed and follow up failure was reported for these cases. This showed that more emphasis should be given on follow up counseling in addition to dietary counseling at the time of discharge.On follow up visit after discharge authors observed that most of the sero-positive patients were well adhered to gluten free diet as per dietary counselling at the time of discharge.The mean weight gain was more in strictly adhered to gluten free diet as compared to non-adhered to gluten free diet (P-value <0.001). This is suggestive of importance of adherence to gluten free diet in Celiac disease.Other study conducted by Bhadada S et al, in short stature children age 10-15 years were screened for Celiac disease and observed that all patients showed good response in growth velocity (cm/year) to a gluten-free diet, but no other study was conducted so far to see the response to gluten free diet in celiac disease in children suffering from severe acute malnourished children in age group 1-5 years.[13]

Conclusion

Gluten free diet may be started empirically in sero- positive patients for short period of time assuming presumptive celiac disease and observed for resolution of signs/symptoms and improvement in growth.If there is rapid resolution of signs/symptoms and significant improvement in growth, confirmed celiac disease may be considered and gluten free diet continued for life long. There is no need for duodenal biopsy or HLA DQ2/DQ8 typing in these patients.If sero-positive patients with good adherence to gluten free diet do not show neither resolution of symptoms nor improvement in growth, then gluten free diet may be stopped and evaluated further to find the etiology.

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Original Research Article

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ASSOCIATION OF CELIAC DISEASES WITH SEVERE ACUTE MALNUTRITION CHILDREN, AT TERTIARY CARE CENTRE: - A PROSPECTIVE STUDY

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Abstract

Introduction: Celiac disease (CD) may be an underlying cause of malnutrition.

Aim: The objective of this study was to find out the seroprevalence of CD in children suffering from severe acute malnutrition (SAM) in age group of 1–5 years.

Materials and Methods: This was a prospective, observational, hospital-based study carried out at Malnutrition Treatment Centre attached with the ananta institute of medical science & research center Rajsamand, Rajasthan, from February 2019 to January 2020. A total of 220 children with SAM were enrolled and screened for CD on the basis of celiac serology (tissue transglutaminase [tTg]-immunoglobulin A/G [IgA/IgG]).

Results: Celiac serology was positivity in 60 (27.28%) cases; out of total 60 seropositive cases, 28 (46.66%) cases were seropositive for both tTg-IgA and IgG, while only tTg-IgA and only tTg-IgG were positive in 18 (30%) and 14 (23.33%) cases, respectively. Mean serotiter of serum tTg-IgA and IgG in seropositive cases was 134.01±198.74 and 49.05±25.74 unit/ml.

Conclusions: High seroprevalence of CD in SAM should be taken as alert as CD may be an underlying cause and responsible for malnutrition. These children should be screened by celiac serology (tTg-IgA/IgG) to rule out CD.

Key words: *Celiac disease, Seroprevalence, Severe acute malnutrition*

Introduction

Celiac disease (CD) is defined as a permanent intolerance to ingested gluten (the protein components of wheat, barley, and rye). The intolerance to gluten results in immune-mediated damage to the mucosa of the small intestine characteristically inducing villous atrophy and crypt hyperplasia that resolves with the removal of gluten from the diet [1]. CD is one of the most common lifelong disorders in countries populated by individuals of European origin, affecting approximately 1% of the general population worldwide [2].The exact incidence of CD in India is not known, but the disease is estimated to constitute 26% of all cases of malabsorption syndrome or 4–5% of all chronic diarrheas. In PGI, Chandigarh, 20–40 new patients are seen every year and CD constitutes 7% of indoor admissions and about 5% of the patients attending pediatric gastroenterology clinic [3]. Indian Council of Medical Research task force commissioned community- based study completed recently at three sites in India, the pooled prevalence of CD and potential CD, respectively, were 8.53/1000 and 3.70/1000 in northern (Haryana), 4.66/1000 and 3.92/1000 in northeastern (Assam), and 0.11/1000 and 1.22/1000 in the southern (Tamil Nadu) study sites [4]. This is clearly an area for further inquiry and evidence generation.Diagnosis of CD is based on the combination of clinical features with a high index of suspicion, celiac serology, duodenal biopsy, and/or human leukocyte antigen (HLA)-DQ2/DQ8 typing [5]. The clinical features of severe acute malnutrition (SAM) often overlap with the common manifestations of CD such as diarrhea, failure to thrive, vomiting, abdominal distension, anemia, and weight loss [6,7]. As per the National Family Health Survey-4 (2015–2016), SAM affects nearly 7.5% of children

<60 months of age in India [8]. Several studies had reported a high prevalence of CD in North India particularly, Punjab and Rajasthan, in general population and children [9-12].Considering the high prevalence of CD among the children, it could be a major contributor or comorbid condition in children with SAM. There is very little information currently available regarding the prevalence of CD among children with SAM. The treatment of SAM in the rehabilitation phase involves cereal- based diet, which may have high gluten content. If SAM child has an underlying undetected CD, then the response to cereal based diet will be poor due to gluten content. This study was planned to find out the seroprevalence of CD in children with SAM. The objective of the study was to make the early

screening of CD in SAM children so that gluten-free diet may be started early.

Materials and Methods

The present study was an observational hospital-based prospective study, carried out at Malnutrition Treatment Center (MTC) attached with the ananta institute of medical science & research center Rajsamand, Rajasthan, from February 2019 to January 2020. Written approval from the Institutional Ethical Committee was obtained before the study. After written and informed consent from the parents, total 220 children of either gender who were admitted in MTC and fulfilling the inclusion criteria, were enrolled for the study. Inclusion criteria of this study were all the SAM children(meeting the WHO criteria for SAM) of age 1–5 years admitted in MTC and exposed to gluten containing diet and whom parents willing to enroll their child in the study. Exclusion criteria were: seriously sick SAM, children admitted in pediatric intensive units. Patients with secondary malnutrition – known c/o chronic medical or surgical disorders leading to malnutrition – congenital heart diseases with congestive heart failure, chronic renal failure, hepatic cholestasis, thyrotoxicosis, isolated childhood diabetes mellitus, HIV, childhood tuberculosis, cerebral palsy, genetic/chromosomal syndromes, inborn errors of metabolism, malignancies, surgical resection of intestine, etc., and the patients, who were not exposed to gluten-containing diet. CD seropositivity was accessed by screening for tissue transglutaminase-immunoglobulin IgA (tTg-IgA) and IgG (tTg-IgG) antibodies by enzyme-linked immunosorbent assay method(Aeskulisa tTg-A/tTg-g new generation antigen-based kit). As per manufacturer manual of the kit cutoff value for seropositivity for tTg-IgA/IgG was >18 U/ml (normal range for tTg-IgA and tTg-IgG: 12-18 unit/ml as per manufacturer manual of thekit)(13). All the collected data regarding positivity or negativity of celiac serology were entered and managed in an Excel sheet and analyzed with standard software (SPSS Version 20). P<0.05 was considered significant.

Results:

A total of 220 enrolled cases of SAM, serology for CD (either tTg-IgA or IgG or both IgA and IgG) was positive in 60 (27.28%) cases.A total of 60 seropositive cases, 28 (46.66%) cases were seropositive for both tTg-IgA and IgG, while only tTg-IgA and only tTg-IgG were positive in 18 (30%) and 14 (23.33%) cases, respectively (Table 1).

Table 1: Seropositivity status of cases

Seropositivity Status*	No (%)
Seronegative (Serum tTg-IgA and IgG negative)	160 (72 72)
tTg-IgA Positive	18 (30)
tTg-IgG Positive	14 (23 33)
Both tTg-IgG and IgA positive	28 (46 66)
Total seropositive	60 (100)
Total cases	220 (100)

***Cutoff values: tTg-IgA/tTg-IgG>18 U/ml (as per manufacturer manual of the kit) [13], tTg: Tissue transglutaminase, IgG: Immunoglobulin G, IgA: Immunoglobulin A**

Mean serotiter of serum tTg-IgA and IgG in seropositive cases was 134.01±198.74 (range – 21.04–800) and 49.05±25.74 (range – 22.20–109) unit/ml. Out of 46 tTg-IgA celiac seropositive cases, tTg-IgA titer of <10 times of upper limit of normal (ULN) was present in 34 (73.91%) cases while titer of>10 times of ULN was present in 12 (26.08%) cases (Table 2).

Table 2: CD seropositivity according to tTg-IgA titer (n=23)

tTg-IgA seropositivity	Titer (unit/ml)	No (%)
<10 times of ULN	>18 upto 180	34 (73 91)
>10 times of ULN)	>180	12 (26 08)

***Cutoff value for tTg-IgA: >18 U/ml (as per manufacturer manual for the kit) [13]; ULN-Upper limit of normal, CD: Celiac disease, Tg: Tissue transglutaminase, IgA: Immunoglobulin A**

CD seropositivity was more in males (60%, 36 in 60) as compared to females (40%, 24 in 60), and this difference in seropositivity was statistically insignificant (p>0.05). Celiac seropositivity was maximum (24/60, 40%) in age group of 4–5 years followed by 1–2 years age group (18/60, 30%) (Table 3).

Table 3: Gender and age-wise distribution of seropositivity

Anthropometric measures	Seronegative (n=80) (%)	Seropositive (n=30) (%)
Gender		
Male	94 (58 75)	36 (60)
Female	66 (41 25)	24 (40)
Age		
1–2	98 (61 25)	18 (30)
2–3	30 (18 75)	12 (20)
3–4	10 (6 25)	6 (10)
4–5	22 (13 75)	24 (40)
Total	160 (100)	60 (100)

Discussion:

CD is a common disorder in children with variable presentation wherein, underweight or malnutrition is a common presentation. Clinical manifestation of CD and SAM, in children, overlaps each other. CD may be an underlying cause responsible for malnutrition in these children. Till date, very few studies were conducted to find out the prevalence of CD in children suffering from SAM in the age group of 1–5 years age group [6,7]. We planned and conducted this study to find out and evaluate the seroprevalence of CD in children suffering from SAM. The status of seropositivity in enrolled cases according to the positivity of serology (tTg–IgA/tTg-IgG) was evaluated. Out of total 220 enrolled cases, 60 (27.28%) were seropositive (tTg-IgA/IgG/both IgA and IgG positive) for CD. Out of these 60 seropositive cases, only Ttg -IgA was positive in 18 (8.18%) cases and only Ttg-IgG was positive in 14 (6.63%) cases while both tTg-IgA and IgG were positive in 28 (12.70%) cases. Overall, the seroprevalence of CD was 27.28%. The cases in whom only tTg-IgG were positive (14 cases) may have underlying IgA deficiency, and these case may be missed if accessed for tTg-IgA only.The prevalence reported by Kumar *et al.* [6] was 13.1% (seropositive and biopsy confirmed) among the SAM children. Seroprevalence for CD reported by Beniwal *et al.* [7] was 15.38% while, the prevalence of biopsy-confirmed CD was 14.42% among the SAM children. The

prevalence of CD was more in our study as compared to other reported studies. The reason for this may be that our study is based on celiac serology only as we were not able to perform a duodenal biopsy or HLA typing for confirmation either due non-availability or feasibility at our institute. Other reason may be a high prevalence of SAM in our region having underlying CD presenting as SAM in children. This needs further research.In our study, the mean serotiter of serum tTg-IgA and IgG in seropositive cases was 134.01±198.74 and 43±24.43 unit/ml. We evaluated the CD seropositivity status according to serum tTg-IgA titers. In our study, serum tTg-IgA titer <10 times of ULN was present in 34 (73.91%) cases and serum tTg-IgA titer >10 times of ULN was present in 12 (26.08%) cases. More cases were having tTg-IgA titers of <10 times of ULN due to a low titer of tTg-IgA in these cases. It is well known fact that titer of tTg antibodies depends on the quantity and duration of gluten in the ingested diet.We compared various parameters in CD seronegative and seropositive cases. Seropositivity was more in males as compared to females. Similarly, male preponderance in seropositivity was reported by Kumar *et al.* [6] and Sharma *et al.* [14]. This suggests gender biases in society as more male children are brought for admission as compared to females. CD seropositivity was maximum in the 4–5 years age groups, suggesting the cumulative effect of gluten in the ingested diet with age. In our study, we observed high seroprevalence of CD in children suffering from SAM.The study has a few limitations, for example, only hospitalized SAM patients were included in this study. Children suffering with SAM at the community level also should be included for true seroprevalence of CD in SAM. We were not able to estimate serum IgA level to rule out serum IgA deficiency and presumed all tTg-IgA negative but tTg-IgG positive cases as IgA deficient. Our study was purely based on celiac serology for the prevalence of CD. We were not able to do upper gastrointestinal endoscopy for duodenal biopsy or HLA typing due to non-availability/feasibility at our center or expanse involved in these investigations.

Conclusions

We found high seroprevalence of CD in children of 1–5 years age, suffering from SAM which is much higher than the prevalence reported in the general population. We should have a high index of suspicion in children suffering from SAM. It is recommended that early screening and diagnosis of CD in these children by celiac serology should be done where the facility of duodenal biopsy/HLA typing not available/possible followed by gluten-free diet challenge in celiac seropositive cases.

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Original Research Article

Maternal Risk Factors associated with Neonatal Sepsis-A Cross Sectional Study

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Abstract

Introduction: Neonatal sepsis can be defined as a clinical condition which is characterized by signs and symptoms of infection in an infant 28 days of life or younger. This is manifested by systemic signs of infection and/ or isolation of a bacterial or other pathogen from the bloodstream. Sepsis is still one of the major causes of morbidity and mortality globally in neonates, despite of recent advances in healthcare units. The incidence of neonatal sepsis by bacteremia in asymptomatic infants is low. In neonatal sepsis we can include septicemia, pneumonia, meningitis, osteomyelitis, and arthritis and urinary tract infections. The burden for neonatal sepsis was 2,202 (95% CI: 1,099–4,360) per 100,000 live births, with mortality between 11% and 19% and more than 40% of under-five deaths occur in the neonatal period, resulting in 3.1 million new-born deaths each year globally.**Material and methods:** The total number neonates admitted in the hospital in given study period was 447, of which 198 were diagnosed for neonatal sepsis by the physician based on the signs and symptoms during admission. The data was collected in three parts: sociodemographic characteristics: maternal information; and part neonatal information for neonatal sepsis. Data was collected in the excel sheet and questionnaires were reviewed and organized by investigators.**Results:** Of the 198 neonates, 162 (81.8%) infants were in the age range of 0 to 7 days while 36 (18.2%) were aged between 8 and 28 days. Statistically significant difference was observed between early onset and late onset sepsis patients. Out of 198 cases 107 (54%) were male while 91(46%) were female. In early onset sepsis cases maternal UTI, Meconium stained amniotic fluid, Multipara and Premature rupture of membrane was seen in 24(14.8%), 21(13.0%), 19(11.7%) and 32 (19.8%) cases respectively. In late onset sepsis cases maternal UTI, Meconium stained amniotic fluid, Multipara and Premature rupture of membrane was seen in 1(2.8%), 2 (5.6%), 4(11.1%) and 2 (5.6%) cases respectively. Maternal risk factors were identified in 104(64.2%) of early onset sepsis cases while maternal risk factors in late onset sepsis cases were 10(27.8%). Culture positivity was observed in 28 (17.3%) cases of early neonatal sepsis while it was 4 (11.1%) in late onset sepsis.**Conclusion:** There was male preponderance in early as well as late onset neonatal sepsis. Maternal risk identification may help in the early identification and timely empirical antibiotic therapy. The prediction and/ or diagnosis of neonatal sepsis should be bases on culture-independent diagnostics and risk factor-based scoring systems.

Keywords: Neonatal,sepsis,antibiotic,therapy

Introduction

Among term and preterm infants neonatal sepsis is one of the leading causes of morbidity and mortality[1]. Also it contributes significantly to mortality and morbidity among very-low-birth-weight (VLBW, weight less than1500 gm) infants in Neonatal Intensive Care Units (NICU)[2]. Mortality in the neonatal period each year account for 41% (3.6 million) of all deaths in children under 5 years and most of these deaths occur in low income countries and about one million of these deaths are attributable to infectious causes including neonatal sepsis, meningitis, and pneumonia [3]. Neonatal sepsis can be defined as a clinical condition which is characterized by signs and symptoms of infection in an infant 28 days of life or younger. This is manifested by systemic signs of infection and/ or isolation of a bacterial or other pathogen from the bloodstream[4].Sepsis is still one of the major causes of morbidity and mortality globally in neonates, despite of recent advances in healthcare units. The burden for neonatal sepsis was 2,202 (95% CI: 1,099–4,360) per 100,000 live births, with mortality between 11% and 19% and more than 40% of under-five deaths occur in the neonatal

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period, resulting in 3.1 million new-born deaths each year globally[5,6]. In neonatal sepsis we can include septicemia, pneumonia, meningitis, osteomyelitis, arthritis and urinary tract infections[7]. Clinical features are generally non-specific and are inefficient for identifying neonates with early-onset sepsis (EOS)[8]. The incidence of neonatal sepsis by bacteremia in asymptomatic infants is low[9]. Full term infants are more likely to react to a bacterial infection with fever while preterm newborns were more likely to react with hypothermia, because of transitional difficulty with temperature control especially in the first two days[10,11]. Respiratory distress with tachypnea, nasal flaring, grunting and retraction of respiratory muscles can be the manifestation of sepsis with or without pneumonia and this can be confused with transient tachypnea of newborn initially. Neonatal sepsis can be complicated by metastatic foci of infection, disseminated intravascular coagulation, congestive heart failure and shock[12]. Based on the timing of the infection neonatal sepsis has been classified into early-onset sepsis (EOS) and late-onset sepsis (LOS)[13]

Material and methods

The present study was conducted at Ananta Institute of Medical Sciences and Research Centre Rajsamand, Rajasthan. This study was carried out using institution based cross section study in the department of pediatrics. The total number neonates admitted in the hospital in given study period was 447, of which 198 were diagnosed for neonatal sepsis by the physician based on the signs and symptoms during admission. The data was collected in three parts: sociodemographic characteristics; maternal information; and part neonatal information for neonatal sepsis. Data was collected in the excel sheet and questionnaires were reviewed and organized by investigators. The data were entered after defining variables and analyzed using SPSS v. 20.0 statistical software. Statistical significance was shown if p value less than 0.05 for multivariable and 0.25 for bivariate logistic regressions. Finally, the result is presented using tables and texts.

Results

Among 447 neonates admitted 198 (44.3%) were diagnosed for neonatal sepsis by the physician based on the signs and symptoms during admission. Of the 198 neonates, 162 (81.8%) infants were in the age range of 0 to 7 days while 36 (18.2%) were aged between 8 and 28 days. Statistically significant difference was observed between early onset and late onset sepsis patients.

Table 1: Onset of neonatal sepsis

Age	Number [% (n=198)]	P value
0 to 7 days	162(81.8%)	P < 0.0001
8 to 28 days	36(18.2%)	
Total	198	

Table 2: Male to female ratio

Gender	Early onset sepsis	late onset sepsis	Total
Male	86(80.4%)	21(19.6%)	107
Female	76(83.6%)	15(16.4%)	91
Total	162(81.8%)	36(18.2%)	198

Out of 198 cases 107 (54%) were male while 91(46%) were female. Of the 107 males 86(80.4%) were of early onset sepsis while 21(19.6%) were late onset sepsis. Of the 91 females 76(83.6%) were early onset sepsis while 15(16.4%) were diagnosed as late onset sepsis.

Table 3: Maternal risk factors

Risk factors	Early onset sepsis (n= 162)	%	Late onset sepsis (n=36)	%
Foul smelling liquor	8	4.9%	1	2.8%
Maternal UTI	24	14.8%	1	2.8%
Meconium stained amniotic fluid	21	13.0%	2	5.6%
Multipara	19	11.7%	4	11.1%
Premature rupture of membrane	32	19.8%	2	5.6%
Total	104	64.2%	10	27.8%

UTI: Urinary tract infection

Maternal risk factors were identified in 104(64.2%) of early onset sepsis cases while maternal risk factors in late onset sepsis cases were 10(27.8%). Maternal risk factor foul smelling liquor in early onset sepsis and in late onset sepsis was 8 (4.9%) and 1 (2.8%) respectively. In early onset sepsis cases maternal UTI, Meconium stained amniotic fluid, Multipara and Premature

rupture of membrane was seen in 24(14.8%), 21(13.0%), 19(11.7%) and 32 (19.8%) cases respectively. In late onset sepsis cases maternal UTI, Meconium stained amniotic fluid, Multipara and Premature rupture of membrane was seen in 1(2.8%), 2(5.6%), 4(11.1%) and 2 (5.6%) cases respectively.

Table 4: Culture positive cases

Type	Culture positive	Percentage
Early onset sepsis	28	17.3%
Late onset sepsis	4	11.1%

Culture positivity was seen in 28 (17.3%) cases of early neonatal sepsis while it was 4 (11.1%) in late onset sepsis.

Discussion

Globally, there are three million annual neonatal sepsis cases (2202/ 1,00,000 live births) while India has the highest incidence of clinical sepsis (17,000/ 1,00,000 live births). The case fatality rate of sepsis among neonates is between 25% to 65% in India[15]. The application of a risk-factor based approach for guidance of the management decisions has been debated with relation to its cost-effectiveness. It has, however, been shown to be one of the highly effective approaches for reducing neonatal early-onset sepsis (EOS)-based mortality in High Income Countries. So it is adviced in resource-limited settings with a high neonatal mortality rate, such as in India, a combination of risk factors and clinical signs should guide the intrapartum and neonatal management[16]..In our study maternal risk factors were identified in 104(64.2%) of early onset sepsis cases while maternal risk factors in late onset sepsis cases were 10(27.8%). In studies it was evident that the maternal risk factors are important in early onset sepsis particularly of Group B Streptococcal aetiology[17]. Such evidence can help to design risk-factor based eligibility criteria for intervention studies on neonatal sepsis [18]. Also it has been suggested that maternal factors such as premature delivery and premature rupture of membrane have also been implicated as significant risk factors in a meta-analysis on neonatal early onset sepsis[14].In our study 107 (54%) were male while 91(46%) were female. Of the 107 males 86(80.4%) were of early onset sepsis while 21(19.6%) were late onset sepsis. Of the 91 females 76(83.6%) were early onset sepsis while 15(16.4%) were diagnosed as late onset sepsis. Higher incidences of sepsis in male were shown in other studies possibly based on the male disadvantage hypothesis[19,20]. It was found that 28 (17.3%) cases of early neonatal sepsis while it was 4 (11.1%) in late onset sepsis were culture positive. In other studies culture positive cases ranges from 25% to 45%[20]. But the disadvantage of culture is it takes around 48 hours to give the positive report and has risk of false-positive or low-yield results after antenatal antibiotic exposure[21].

Conclusion

There was male preponderance in early as well as late onset neonatal sepsis. Maternal risk identification may help in the early identification and timely empirical antibiotic therapy so that mortality and morbidity can be reduced. The prediction and/ or diagnosis of neonatal sepsis should be bases on culture- independent diagnostics and risk factor-based scoring systems.

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"Clinical Profile And Comparison Of Narrow Versus Broad Spectrum Antibiotic Therapy For Community Acquired Pneumonia In Children Hospitalized At Tertiary Care Centre"

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ABSTRACT:

Background: Pneumonia is the leading cause of morbidity and mortality in under 5 year age children. Objective: To compare the effectiveness of treatment for Community Acquired Pneumonia (CAP) in children with narrow versus broad spectrum antibiotic therapy. Methods: A prospective randomized controlled trial was conducted in Pediatric ward of tertiary care medical college hospital of southern Rajasthan from July 2017 to June 2018. Total 184 children of age group of 2 months to 18 years, admitted with a clinical diagnosis of CAP were enrolled for the study. Results:A total 184 children were enrolled.Maximum no. of cases (93) admitted with CAP were among 2 months to 12 months of age group. All 6 parameters in our study (i.e. total duration of fever, O_2requirement, respiratory distress, length of stay, change of antibiotic and readmission) were compared between both the groups suggesting that Ampicillin having similar effect on children hospitalized with CAP when compared with Ceftriaxone.Throat swab culture in children with CAP was positive in 55% of cases. Most common organism grown on throat swab of affected children was Streptococcus pneumoniae (30%) followed by H.influenzae (15%).Conclusion:CAP is a major health problem in children below 5 years. Most common organism for CAP in children is still S.pneumoniae. In our study narrow spectrum antibiotic coverage for CAP was associated with similar outcomes when compared with broad spectrum agent. So we highlights in our study to promote the use of narrow spectrum antibiotics in children hospitalized with CAP.

Keywords: Community Acquired Pneumonia, Ampicillin, Ceftriaxone, S.pneumoniae.

Introduction

Pneumonia is defined as "An acute inflammation of the pulmonary parenchyma that can be caused by various infective and noninfective origin".[1]On the basis of source of infection it has been classified ascommunity acquired, health care associated, ventilator associated and hospital acquired pneumonia.Pneumonia affects 156 million children under age of 5 years every year across the globe, and is the leading cause of morbidity and mortality in this age group.[2] More than 2 million annual deaths are estimated to occur because of pneumonia in under 5 children and almost all of them are occurring in developing world.[3]India carries the largest burden of the disease and death because of pneumonia, approximately for 43 million cases and 0.4 million deaths annually.[4]Childhood pneumonia is an important cause of morbidity and mortality worldwide. More than 2 million children younger than five years of age die from pneumonia every year, accounting for almost one-fifth of overall childhood mortality. [5]The respiratory rate thresholds for acute lower respiratory tract infection according to the WHO are a respiratory rate of > 60/minute for children less than 2 months of age, > 50/minute for children aged 2 to 12 months, and >40 /minute for children aged 1 to 5 years (WHO,1990). This easily detected diagnostic sign of pneumonia is helpful in the developing world where radiographic facilities are rarely available, trained staff are lacking, and pneumonia mortality is high.The short distance between upper respiratory tract and alveoli, the small diameter of the airways, profuse mucus production, and the immaturity of the immune defence predisposes children to pneumonia. In addition, the nasopharyngeal colonization of pneumonia causing bacteria is common in young children.[6,7,8]Although most cases of pneumonia are caused by microorganisms, noninfectious causes include aspiration (of food or gastric acid, foreign body, hydrocarbons), hypersensitivity reactions or drug induced pneumonitis.[9]

Community-acquired pneumonia (CAP) is an acute lower respiratory tract infection (LRTI) acquired from the community with fever, cough, dyspnea, tachypnea and pleural chest pain as typical symptoms. Diagnosis is confirmed with new opacity in chest radiograph.[10,11,12]. Appropriate antibiotic prescribing is associated with favorable level of antimicrobial resistance and clinical outcome. In October 2011, Pediatrics Infectious Disease Society (PIDS) and Infectious Disease Society of America (IDSA) published guidelines for the management of CAP in children.[13]In prospective, microbiology-based studies, the leading bacterial cause is S. Pneumoniae, being identified in 30–50% of pneumonia cases.[14] The second most common organism isolated in most studies is **H. influenzae** type b (Hib; 10–30% of cases), followed by S. aureus and K. pneumoniae.Some of Indian studies had also reported as S. Pneumoniae and H.Influenzae being the most common causes of CAP in children of age group 2months to 5 years of age.[15,16]. Narrow spectrum beta lactams effectively target S. Pneumoniae. New guidelines recommend Penicillin or Ampicillin/Amoxicillin as first line therapy for the most children hospitalized with CAP.[13]

Material and method

A prospective randomized controlled study was carried out in Pediatric ward of tertiary care hospital of southern Rajasthan attached with medical college.

Study period: Jan.2019 to Dec. 2019

Study population: Total 184 children of age group of 2 months to 18 years were admitted with a clinical diagnosis of CAP were enrolled for the study.

INCLUSION CRITERIA:

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1. Children only whose parents have given consent to participate in the study will be included in this study.
2. Children of age group 2 months to 18 years of age hospitalized with diagnosis of CAP.
3. Evidence of respiratory illness (cough/increased work of breathing).
4. Chest radiograph showing Pneumonia (e.g. Infiltrates or consolidation)
5. Patients who received a minimum of 2 days antibiotic therapy during hospitalization

EXCLUSION CRITERIA:

1. Children whose parents refused for participation in the study.
2. Children with severe pneumonia who required ICU admission within 48 hours of hospitalization.
3. Children with some congenital/chronic respiratory illness. (e.g. Cystic fibrosis, asthma ,lung malformation)
4. Complicated pneumonia (defined as imaging study indicating moderate to large pleural effusion, lung abscess , necrosis or bronchopulmonary fistula)
5. Children who got hospitalized within last 30 days due to any illness
6. Children who received staphylococcal coverage / macrolide monotherapy within last 7 day

Prior written informed consentwas obtained from the parents or available relatives of each child. Confidentiality of data was ensured.Cases were enrolled within 6 hours of admission.All the enrolled children included in the study were divided into 2 groups: Patient with odd no. of sequences named as group A and patient with even no. as group B.Basic information of the child, detailed clinical history and treatment history was obtained followed by general physical and systemic examination done. All the informations were recorded on structured proforma.Routine investigations includingHemoglobin, TLC, DLC and Chest x-ray were done in all the patients at time of admission. Sample for blood culture was collected in every patient before starting antibiotic. Similarly throat swab sample was also taken for culture of organism.

Pneumonia was diagnosed as per WHO ARI control program. Respiratory rate was counted for one full minute when the child was calm, sleeping or feeding. Fast breathing was defined as respiratory rate above the limit as defined by WHO[17]. The presence of subcostal indrawing, suprasternal indrawing and intercostal indrawing was assessed. Positive findings were noted on basis of symptoms and clinical examination.

Microbiology: Processing of 368 samples (184 blood culture + 184 throat swab culture)was done in Microbiology Department of the institute. All the samples were collected with aseptic precautions by using standard sterile techniques and transported to the laboratory as soon as possible maintaining optimum transportation conditions.

The following procedures were carried out in the laboratory –

1. Gram's staining
2. Bacteriological culture
3. Biochemical reactions
4. Antibiotic sensitivity testing

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Direct gram stained smear of the samples observed under microscope to detect the presence and type of bacteria and to correlate it with the growth obtained on culture plate.Primary inoculation was done on the Thio-glycolate broth, Mac Conkey media and Blood agar. Colony characteristics were observed.

Antimicrobial susceptibility testing: The isolates tested by the disc diffusion method (modified Kirby-Bauer method) on Muller Hinton agar (Hi-Media) following the zone size criteria which is recommended by the CLSI .

After initial workup selection of antibiotic was decided according group. Group A patients received narrow spectrum antibiotic therapy in form of injection Ampicillin intravenously at dose of 50mg/kg/dose every 6 hourly while group B received broad spectrum antibiotic therapy in form of injection Ceftriaxone intravenously at dose of 50mg/kg/day divided in two doses. Patients were discharged once the symptoms relieved and need of intravenous therapy was not there with further advice to complete 7 to 10 days of therapy with oral antibiotic therapy.

Effect of narrow versus broad spectrum antibiotic therapy compared in both the groups based upon following parameters in each group:

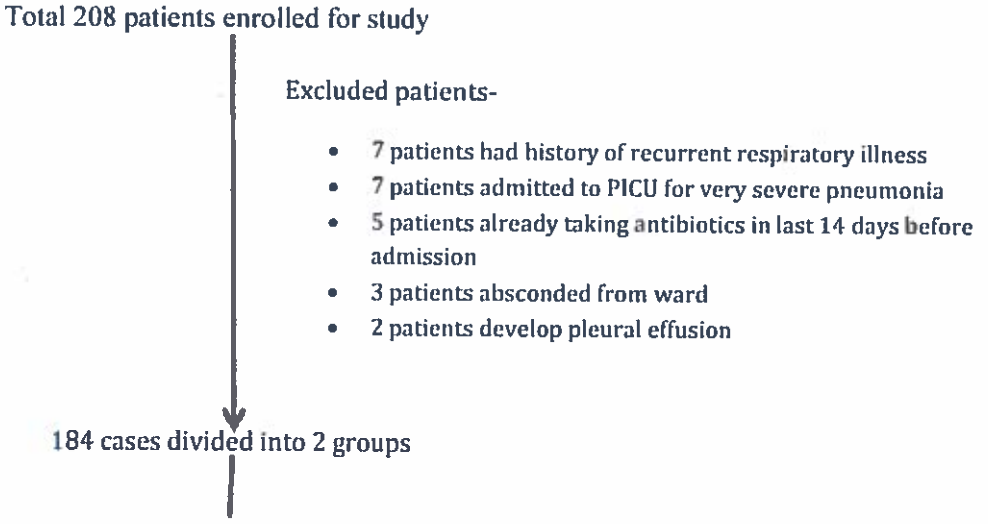
1. Duration of fever (Temp. >38 ^{0}c).
2. Duration of supplemental oxygen required (hours).
3. Hospital length of stay (LOS) measured in hours.
4. Signs of respiratory distress.
5. Readmission within 15 days of discharge from hospital.
6. Required changing of antibiotics.

STATISTICAL ANALYSIS :

Data analysis was done by SPSS software (20.0 trial version) and appropriate statistical tests were used to find out the final results.

Results

Total 208 children of age group 2months to 18 years were admitted with diagnosis of CAP in children ward of the hospital, out of them 24 children were excluded and final 184 children categorized into two groups (92 each).



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Maximum no. of cases admitted with CAP were among 2 months to 12 months of age group(93) followed by 1- 2year (26) and 2-3(28) year of life. Patients older than 5 year were only 9.8% (18)of total patients with CAP(Table 1). All patients admitted for CAP were having tachypnoea and chest indrawing *(100%)* at admission. But fever *(94.6%)* and cough *(92.4%)* was not consistent finding in all children.

Outcome measures for both groups were compared in form of total duration of fever, O_2 requirement and signs of respiratory distress (in form of tachypnoea, grunting, chest retractions). All outcomes were measured in duration of hours from the time of hospitalization.Table 2 depicts thattotal duration of fever in Ampicillin group was 18.4 hours which was almost similar to Ceftriaxone group (18.9 hours). Difference among these was statistically not significant (p 0.636).Similarly duration of O_2 required in both groups was also similar (Ampicillin: 14.6 vs. Ceftriaxone: 17.7 hours). p value 0.58 suggests that this difference was also not significant.Signs of respiratory distress in Ampicillin group were lasted for a mean of 36.0 hours which was quite similar to Ceftriaxone group (mean 37.9 hrs). p value 0.392 is suggesting of this difference not significant.

Out of 92 patients received Ampicillin, 8 patients (8.7%) required change of antibiotic during their hospitalization, while Ceftriaxone group required change of antibiotic in 5(5.4%) patients(Table 3). (p=0.388) suggesting of difference between both groups in this parameter to be not significant.We compared the total length of stay in hospital for I.V. antibiotics in both group (Table 4). Patients in Ampicillin group had lesser stay in hospital as compared to Ceftriaxone group (77.2 vs 80.6 hrs, p =0.149). The difference was not significant so both drugs were similar in this outcome also.Out of 92 patients in each group only 2 patients in each group required readmission with 15 days after discharge from hospital(Table 5). So all 6 parameters in our study (i.e. total duration of fever, O_2, respiratory distress, LOS, change of antibiotic and readmission) were compared between both groups and they were statistically not significant suggesting that Ampicillin having similar effect on children hospitalized with CAP when compared with Ceftriaxone.

In our study we sent blood and throat swab samples for culture and sensitivity of organism in every patient. Out of 184 patients only 13 (7%) patients have shown growth of some organism in their blood sample obtained from venipuncture (Table 6).Throat swab culture in children with CAP were positive in more number of cases 96 (55%) as compared to blood culture of same patients (positive in 7%). It is suggestive of that throat swab culture is a better mode for detection of causative organism responsible for pneumonia in children. Table 6 depicts thatmost common organism grown on throat swab of affected children was Streptococcus pneumonia (30%) followed by H.influenzae (15%). These two are the most common organism responsible for CAP in children between age group 2 months to 5 years of age.We found that out of those 96throat swab culture positive cases 17 were resistant to Ampicillin (9.2%) and 15 Patients (8.2%) were resistant to Ceftriaxone. It suggest that sensitivity pattern for organisms causing CAP in local population is similar in both narrow (Ampicillin) and broad (Ceftriaxone) spectrum groups (Table 7). Most common organisms for CAP in children (S.pneumoniae, H.influenzae) are having similar sensitivity and resistance pattern for

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both group of antibiotics.52% of S. pneumoniae positive case were from age group 2-12months while only 1 case was >5 year age. Similarly H.influenzae was also common in infantile age (39%).

Discussion: According to our study majority of children admitted with CAP were among infantile age group. 50% of cases were of age group 2months to 12 months and only 9.8% of cases were older than 5 year of age.Williams BG et al[5]Bryce J et al[2]and Wardlaw T et al[18] observed in their studies that childhood pneumonia is an important cause of morbidity and mortality worldwide.

In our study all children were having respiratory distress in form of tachypnoea at time of admission as we used WHO criteria for defining Pneumonia.Palafox and colleagues found that the presence of tachypnea was the single most sensitive and specific clinical indicator of pneumonia, with 74 % sensitivity and 67 %specificity among children less than 5 years of age.[19]Duration of fever in Ampicillin group (18.4 hrs) was similar to Ceftriaxone group (18.9hrs) (p value 0.636).Williams DJ et al [20] in their retrospective cohort study observed that duration of fever in patients receiving narrow spectrum antibiotic was similar to braod spectrum group when they studied among 43 children hospitals.

Total duration O_2 supplementation required was less in narrow spectrum group (Ampicillin 14.6 hrs vs Ceftriaxone 17.7 hrs), but this difference is statistically not significant (p value 0.058).Marry N Queen [4] also observed that children receiving narrow spectrum antibiotics were having less duration of oxygenation (mean 15.6 hrs) as compare to children who received broad spectrum antibiotics (mean 21.8 hrs). This difference was also not significant (p value 0.18). Out of 92 patients received Ampicillin, 8 patients (8.7%) required change of antibiotic during their hospitalization, while Ceftriaxone group required change of antibiotic in 5(5.4%) patients. (p=0.388) suggesting of difference between both groups in this parameter to be not significant.We compared the total length of stay in hospital for I.V. antibiotics in both group (Table 4). Patients in Ampicillin group had lesser stay in hospital as compared to Ceftriaxone group (77.2 vs 80.6 hrs, p =0.149).Williams DJ et al [20] compared the LOS in both groups in terms of total days and they found it similar (3-4 days for both narrow & broad spectrum groups) while Marry N Queen [4] mentioned it in total hours. Though it was shorter in narrow spectrum groups (43 hrs vs 52.3 hrs, p=0.04). Out of 92 patients in only 2 patients in each group required readmission with 15 days after discharge from hospital. Williams DJ et al [20] compared the readmission within 14 days while Marry N Queen [4] compared readmission within 7 days of discharge from hospital. In both studies difference between both groups was not significant.

So all 6 parameters in our study (i.e. total duration of fever, O_2, respiratory distress, LOS, change of antibiotic and readmission) were compared between both groups and they were statistically not significant suggesting that Ampicillin having similar effect on children hospitalized with CAP when compared with Ceftriaxone.In our studythroat swab culture in children with CAP were positive in more number of cases (55%) as compared to blood culture of same patients (7%). It is suggestive of that throat swab culture is a better mode for detection of causative organism responsible for pneumonia in children.Das et al [21] also demonstrated the same difference while comparing results of blood culture and OPS and BAL samples from children with CAP. Only 4 samples were positive in blood culture out of 180, while 131 children showed growth of organism in their OPS and BAL samples. The difference was significant.

Most common organism grown on throat swab of affected children was Streptococcus pneumoniae (30%) followed by H.influenzae (15%). These two are the most common organism responsible for CAP in children between age group 2 months to 5 years of age.Various other studies like Nantanda R et al [22] Hortal M et al [23] and Gratten M et al [24] have found S.pneumoniae & H.influenzae to be the most common isolate from respiratory samples of children with CAP. S.aureus and K.pneumoniae

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were detected as leading cause of pneumonia by Johnson et al[25]. Das et al [21] also found S.pneumoniae and H.influemzae as the leading cause of CAP in children under 5 year.There were total 96 patients in whom throat swab culture was positive. We found that out of those 96 cases 17 were resistant to Ampicillin (9.2%) and 15 Patients (8.2%) were resistant to Ceftriaxone. It suggest that sensitivity pattern for most common organisms causing CAP in local population is similar in both narrow (Ampicillin) and broad (Ceftriaxone) spectrum groups of antibiotics.

Conclusion: We can summarize results of our study as CAP is a major health problem in childrenbelow 12 months. In the modern era of antibiotic resistance we should avoid overuse of broad spectrum antibiotics. Most common organism for CAP in children is still S.pneuminae and its sensitivity to narrow spectrum antibiotics like Ampicillin is good in local population also. So misconception about PIDS and IDSA guideline that this has to be followed in developed countries is not true. Narrow spectrum antibiotic coverage for CAP associated with similar outcomes when compared with broad spectrum agents. There was no difference in total duration of fever, O_2 requirement, respiratory distress, length of stay in hospital, change of antibiotic and readmission rates. So we highlights in our study to promote the use of narrow spectrum antibiotics in children hospitalized with CAP.There exist many reasons to preferentially use penicillins as first line antibiotic therapy for CAP. First penicillins provide appropriate coverage for the most prominent pathogen, S.pneumoniae. Second treatment of patients with non-central nervous system penicillin-resistant pneumococcal infections with penicillins has not been associated with treatment failures. Finally the use of broad spectrum antibiotics has been shown to increase the risk of developing subsequent infections with resistant organisms.

TABLE 1: Distribution of cases according age group

Age	Total cases N (%)
2mo-12mnths	93 (50.5)
1-2 Years	26 (14.1)
2-3 Years	28 (15.2)
3-4 Years	15 8.2)
4-5 years	4(2.2)
5-18 years	18(9.8)
Total	184 (100)

Table 2: Comparison of Ampicillin and Ceftriaxone group.

	Drug	N	Mean	Std. Deviation	T value	P value
Duration of fever (in	AMP	92	18.4239	7.78027		

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hours)	CEFT	92	18.9022	5.76473	0.474	0.636
Duration of O2adm.(in hours)	AMPI	92	14.6739	10.77044	1.910	0.058
	CEFT	92	17.7500	11.06983		
Signs of Resp.Distress (in hours)	AMPI	92	36.0652	13.86418	0.859	0.392
	CEFT	92	37.9348	15.62318		

TABLE 3: Distribution of **CHANGE/ADD** Antibiotic according to Antibiotic Drug Given

		DRUG		Total	Chi Sq	P value
		AMPI	CEFT			
CHANGE/ADD Antibiotics	NO	84	87	171		
		91.3%	94.6%	92.9%		
	YES	**8**	**5**	**13**	0.745	0.388
		8.7%	5.4%	7.1%		
Total		92	92	184		
		100.0%	100.0%	100.0%		

TABLE 4: Distribution of Length of stay (in hours) according to Antibiotic Drug Given

	DRUG	N	Mean	Std. Deviation	T value	P value
Length of stay (hours)	AMPI	92	77.2717	15.58536	1.450	0.149
	CEFT	92	80.6087	15.63242		

TABLE 5: Distribution of READMISSION according to Antibiotic Drug Given

		DRUG		Total	Chi sq	P value
		AMPI	CEFT			
READMISSION	NO	90	90	180		
		97.8%	97.8%	97.8%		
	YES	2	2	4	0.000	1.00
		2.2%	2.2%	2.2%		
Total		92	92	184		
		100.0%	100.0%	100.0%		

TABLE 6: Growth on Blood culture & Throat Swab culture in patients with CAP

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Organism on Blood culture	Frequency (%)	Organism on Throat Swab culture	Frequency (%)
NO GROWTH	171 (92.9)	NO GROWTH	84(45.7)
Strep.pneum.	9 (4.9)	Strep.pneumoniae	55(29.9)
commensal.	1 (0.5)	H. Influenzae	28(15.2)
Klebsiella	1 (0.5)	Chlamydia	1(0.5)
Pseudomonas	1 (0.5)	Citrobacter	2(1.1)
Staph. aureus	1 (0.5)	Commensal	4(2.2)
Total	184 (100)	Enterococcus	3(1.6)
		Klebsiella	3(1.6)
		Pseudomonas	2 (1.1)
		Staph.aureus	2 (1.1)
		Total	184(100)

TABLE 7: Distribution of sensitivity for Ampicillin &Ceftraixone.

Sensitivity for AMP	Frequency	Percent	**Sensitivity for CEFT.**	Frequency	Percent
NO GROWTH	88	47.8	NO GROWTH	88	47.8
Resistance	17	9.2	Resistance	15	8.2
Sensitive	79	42.9	Sensitive	81	44.0
Total	184	100.0	Total	184	100.0

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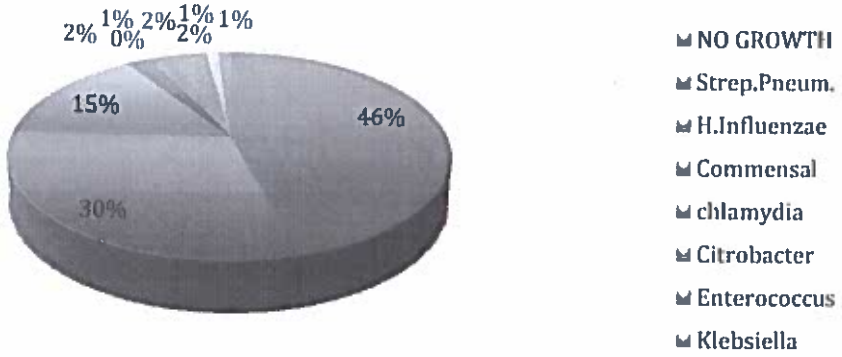
FIGURE 1: Distribution of cases according Throat Swab culture



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Original Research Article

Etiological, Clinical and Mortality Profile of Shock in Children at PICU of Southern Rajasthan Hospital.

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Abstract

Pediatric Intensive Care Unit (PICU) plays a very important role in the care of critically-ill children who are at risk for organ dysfunction. Worldwide the most common causes of morbidity and mortality in children is sepsis particularly in developing countries. Especially in children there is high rate of mortality in septic shock may be as high as 50%. In septic shock, outcome is worse when associated with co-morbidities. The clinical syndrome of shock, a clinical state characterized by inadequate tissue perfusion, is one of the most dramatic, dynamic and life-threatening problems faced by the physician in the critical care setting. Shock is defined as an acute syndrome in which the circulatory system is not able to supply adequate amount of nutrients and oxygen for vital organs. In children Shock accounts for more morbidity and mortality worldwide than any other disease, especially when shock is accompanied by need of mechanical ventilation.**Aim:** The main objective of this study is to know clinical profile and outcome of shock in children. Material and method: Children with the different age group between 1 to 15 years old age admitted with the clinical evidence of shock in the pediatric emergency. From all the patients' detailed clinical history were taken with the help of their relatives or parents. For the identification of shock in the patients, there must be present of at least one of the following parameters i.e., tachycardia and/or hypotension along with signs of systemic hypoperfusion. From all the patients laboratory investigation were done like blood culture, C-reactive protein, liver function tests, urine routine and culture, stool routine and culture, calcium, urine electrolytes, etc. were done.Result: Out of total patients 20, 17 and 13 were in age group 1-5 years, 5-10 years and 10-15 years respectively. In this study maximum male gender were predominate to female with the ratio 1.5:1 and the mean age were 5.8 ± 3.4 years. Congenital heart disease (54.2%) was the most common underlying etiology in cardiogenic shock followed by cardiomyopathy (24.5%) and heart rate abnormalities (21.3%). In hypovolemic shock, 87.9% patients were in compensated stage of septic shock.**Conclusion**: Especially in children Shock is a major cause of morbidity and mortality. Hypovolemic shock is the commonest form of shock in children which required mechanical ventilation. In septic shock severe pneumonia was the commonest illness. Hence, Diagnosis and management of shock in reimburse stage bring better forecast than in uncompensated shock irrespective of the age.

Keywords: PICU, Hypovolemia, Cardiogenic, Shock, Outcome

Introduction

Pediatric Intensive Care Unit (PICU) plays a very important role in the care of critically-ill children who are at risk for organ dysfunction[1]. Worldwide the most common causes of morbidity and mortality in children is sepsis particularly in developing countries [2]. According to World Health Organization (WHO), worldwide there are mainly four causes of death in children are severe Pneumonia (1.9 million deaths/ year), severe diarrhea (1.6 million/year), severe malaria (1.1 million/year), severe measles (5,50,000 deaths/ year). Therefore WHO used term severe when children develop acidosis or hypotension or both[3]. Especially in children there is high rate of mortality in septic shock may be as high as 50%.In septic shock, outcome is worse when associated with co-morbidities[4]. The clinical syndrome of shock, a clinical state characterized by inadequate tissue perfusion, is one of the most dramatic, dynamic and life-threatening problems faced by the physician in the critical care setting[5]. Shock is defined as an acute syndrome in which the circulatory system is not able to supply adequate amount of nutrients and oxygen for vital organs[6]. Because of inadequate production of ATP for the support and function of the cell then it revert to anaerobic metabolism, causing acute energy failure[7]which results in the cell being unable to maintain homeostasis, accumulation

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of intracellular sodium, accumulation of cytosolic calcium, disruption of ionic pumps, efflux of potassium and eventual cell death. More no of cell death results in multi-organ dysfunction. In children Shock accounts for more morbidity and mortality worldwide than any other disease, especially when shock is accompanied by need of mechanical ventilation[8,9]. The main objective of this study is to know clinical profile and outcome of shock in children.

Material and method

This is a prospective study carried out in pediatric intensive care unit (PICU) at Ananta institute of medical science & research centre Rajsamand, Rajasthan. Total 50 pediatric patients were included in this study during the period of 1 year. Children with the different age group between 1 to 15 years old age admitted with the clinical evidence of shock in the pediatric emergency.From all the patients' detailed clinical history were taken with the help of their relatives or parents. For the identification of shock in the patients, there must be present of at least one of the following parameters i.e.,tachycardia and/or hypo-tension along with signs of systemic hypo-perfusion[10]. According to the presence of hypo-tension Patients were classified into compensated or decompensated shock. With the presence of hypotension and cold extremities Cold septic shock was identified. On the basis of history and physical examination Shock was then classified functionally into hypovolemic, cardiogenic, septic and distributive [11,12]. From all the patients laboratory investigation were done like blood culture, C-reactive protein, liver function tests, urine routine and culture, stool routine and culture, calcium, urine electrolytes, etc. were done.

Result

In this study total 50 patients with shock admission in the hospital were included in the study period. Out of total patients 20, 17 and 13 were in age group 1-5 years, 5-10 years and 10- 15 years respectively. In this study maximum male gender were predominate to female with the ratio 1.5:1 and the mean age were 5.8 ± 3.4 years. Various types of shock with age wise distribution were shown in table no 1 below.

Table 1: Showing Age Wise Distribution with various types of Shock

Age(yrs)	1-5	5-10	10-15	Total
Total cases of shock	20	17	13	50
Hypovolemic shock	9	7	7	23
Septic shock	6	5	3	14
Cardiogenic shock	5	4	2	11
Distributive shock	0	1	1	2

Nearly 64% of cases were in compensated stage of shock, which was not significantly related to age. Dehydration following diarrhea and vomiting was most common underlying etiology in hypovolemic shock. Congenital heart disease (54.2%) was the most common underlying etiology in cardiogenic shock followed by cardiomyopathy (24.5%) and heart rate abnormalities (21.3%). In hypovolemic shock, 87.9% patients were in compensated stage of septic shock. As per the stage of shock and outcome is shown in table no: 2 below.

Table 2: Showing the various Stage and Outcome of types of Shock

Types of shock	Compensated stage	Decompensated	Survival (%)*
Hypovolemic	18	5	22(95.7)
Septic	5	9	6(42.9)
Cardiogenic	7	4	4(36.4)
Distributive	2	0	2(100)
Total	32	18	34(68)

*Survival is calculated after excluding patients who left against medical advice

Discussion

In worldwide shock is a major cause of morbidity and mortality in critically ill children. 4.6% is The frequency of shock noted in pediatric intensive care. Hypovolemic shock was the most commonly encountered shock followed by Septic shock. Many researches in developed countries showed that about 2% shock occurs in all hospitalized infants, children and adults. Depending on the etiology and clinical scenario mortality varies[13] in developing countries There is sparse data about the incidence of shock. Many studies in India have reported frequency of 4.3%, and 9% in another studied which corresponds to this study[14,15]. In this study children under 5years of age were majorities which are consistent with the previous studies[16]..Due to diarrhea and vomiting Hypovolemic shock was the most common type of shock in this study which is similar to the different studied of Perkin RM et al[17], Singhi S et al[18] and Chang P et al[19]. Cardiogenic shock during childhood represents a diagnostic and therapeutic challenge because of its multitude etiologies[20]. In cardiogenic shock cardiomyopathies,

congenital heart diseases and Heart rate abnormalities are the common causes. This is traditionalism to the fact that in compensated stage, vital organ perfusion is maintained by intrinsic mechanism with early detection and management of shock that increases rate of survival before hypotension develop[21,22]. High mortality was observed in septic shock in this study which is similar to the other studied of Pollack MM et al[23]. though the mortality rates have declined over the past several decades to less than 20% as studied showed by Kutko MC et al[24]. Management of shock in children requiring mechanical ventilation requires good infrastructure, trained staff and protocol-based management.

Conclusion

Especially in children Shock is a major cause of morbidity and mortality. Hypovolemic shock is the commonest form of shock in children which required mechanical ventilation. In septic shock severe pneumonia was the commonest illness. Therefore larger prospective study in developing countries is advisable. Hence, Diagnosis and management of shock in reimburse stage bring better forecast than in uncompensated shock irrespective of the age.

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"A Prospective Observational Study About Assessment Of Prevalence And Clinico-Etiological Parameters Of Disorder's Of The Thyroid Gland In Children, At A Southern Rajasthan Hospital"

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ABSTRACT

Introduction-Thyroid hormone abnormalities are commonest endocrine disorders in India and also the commonest preventable cause of mental retardation. Objectives-To determine the prevalence, clinical profile and etiology of thyroid dysfunction in children. Materials and Methods- A hospital based prospective observational study performed in newborns and children below 18 years fulfilling the inclusion criteria visiting the pediatric OPD and IPD in Ananta Institute of Medical Science & Research Centre Rajsamand, Rajasthan. If they had clinical suspicion of thyroid dysfunction. Patients having normal TSH levels defined by age wise cut offs were not evaluated further. Thyroid profile consisting of Free T4 , Total T4,TSH levels were done if there was suspicion of hypothyroidism and Free T3 and TSH if there was suspicion of hyperthyroidism. Other investigations like USG thyroid, thyroid 99^{m} technetium scan anti TPO and anti TG antibody levels were done to look for the etiological diagnosis. Appropriate treatment was started according to standard guidelines. Results- Out of 252, 35 children were found to have thyroid dysfunction, 34 were having hypothyroidism and 01 was having hyperthyroidism. Overall male to female ratio in our study was 1:4. Most common clinical presentation in hypothyroidism cases were constipation followed by short stature. Autoimmune hypothyroidism was the most common etiology. Prevalence of goiter in the study was 20%. 07 cases were congenital hypothyroidism. Treatment was started according to standard guidelines. Conclusion- Autoimmune thyroid diseases are now the major leading cause of thyroid disorders in childhood. There is high prevalence of thyroid dysfunction in children in and around the rajsamand.

Key words- Autoimmune thyroid diseases ,thyroid dysfunction , thyroid stimulating hormone.

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INTRODUCTION

Disorders of thyroid gland are commonest endocrine disorder in India.[1]In pediatric age group thyroid hormones are primarily concerned with maintenance of growth, metabolism and mental development[2,3] .Thyroid hormones deficiency in infancy leads to irreversible impairment of neuro-cognitive function and physical and mental retardation [3].It is a spectrum of disorders manifesting either as hypo or hyper functioning of the thyroid gland reflected in the circulating levels of Tri-iodothyronin (T3), Thyroxin (T4) and Thyroid stimulating hormone (TSH). The disorders of thyroid hormone can be due to diseases of the thyroid gland itself (primary), secondary to pituitary disorder (secondary) or due to hypothalamic diseases (tertiary)[4]. Congenital hypothyroidism is the most common preventable cause with worldwide incidence of 1:3000-4000. In India this ratio is 1:2500 - 2800 [2,3]. Hypothyroidism after the age of three years when most of the brain development is completed, their deficiencies leads to slow growth and delayed skeletal maturation [3].Autoimmune thyroid diseases are now major leading cause of thyroid disorders in childhood and now considered the most common cause of acquired hypothyroidism. They include Hashimoto thyroiditis and lymphocytic thyroiditis. Their clinical manifestations range from euthyroid goiter to hypo or hyperthyroid state [5,6].Hyperthyroidism is rare in children and if present it causes rapid linear growth and skeletal maturation due to increase metabolic activity [5,7].

AIMS AND OBJECTIVES

1. To Study the prevalence of thyroid disorders in children.
2. To study the etiology and clinical profile of thyroid disorders in children.

METHODOLOGY

SOURCE OF DATA -

A hospital based observational study was performed in newborns and children below 18 years fulfilling the inclusion criteria visiting the Paediatric outpatient department [OPD] and in patient department [IPD] in Ananta Institute of Medical Science & Research Centre Rajsamand Rajasthan, having clinical suspicion of thyroid dysfunction from January 2019 to December 2019(12 months).Patients having clinical features suggestive of thyroid disorders like constipation, short stature , lethargy, goiter, mental retardation, obesity, prolonged neonatal jaundice, palpitations etc were enrolled in the study. Thyroid profile consisting of TSH, free T4 and Total T4 is done if there is suspicion of hypothyroidism and in suspicion of hyperthyroidism thyroid profile consisting of TSH and free T3 is done. Patients having normal thyroid function test are not evaluated further in the study. Patients having abnormal thyroid function, which is defined as per the standard cut offs of free T3,totalT4 , freeT4 and TSH according to different age groups [38] are evaluated further in the study and taken as a positive case. Later detailed demographic data (age, sex, address) including family history of thyroid disorders, use of iodised salt, vital parameters, anthropometry , systemic examination , examination of the thyroid gland was performed. Further tests like complete blood count in cases is done. Anaemia is defined according to WHO guidelines [39]. Anaemia is graded as mild, moderate and severe depending upon the age and sex wise cut offs. USG thyroid was done in all the positive case and looked for presence of goiter. In case of suspicion of congenital hypothyroidism the patient is subjected to 99 ^{m} technetium scan.

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In cases of suspected autoimmune etiology tests like anti thyroid peroxidase antibodies (anti TPO) and anti thyroglobulin antibodies (anti TG) are performed in the patients. Normal reference values of anti TPO levels is < 35 IU/ml and anti TG antibody levels is < 20 IU / ml[49]. All the diagnosed patients are treated as per guidelines [31].

SELECTION CRITERIA OF THE PATIENTS:

Inclusion Criteria:

1. Newborns.
2. Children below 18 years of age.

Exclusion Criteria:

1. Patient on any medication altering the thyroid hormone status.
2. Patient in whom informed consent could not be obtained.

These 252 patients were selected from OPD and IPD having clinical suspicion of thyroid dysfunction visiting at Ananta Institute of Medical Science & Research Centre Rajsamand, Rajasthan. Of these 252, cases having abnormal thyroid function test were evaluated further.

DATA ANALYSIS AND INTERPRETATION –

Data was entered into Microsoft Excel (Windows 8; Version 2012) and analysis was done using the Statistical Package for Social Sciences (SPSS) for windows software. Descriptive statistics such as mean and standard deviation (SD) for continuous variables, frequencies and percentages were calculated for categorical variables were determined. Bar charts and pie charts were used for visual representation of the analyzed data.

RESULTS

Table 1: Distribution of Study Subjects according to the Age wise TSH Level (Prevalence)

Age wise TSH Levels	No.	Percent
Normal	217	86.1
Abnormal	35	13.9

Out of 252 patients screened, 217 (86.1%) patients had normal TSH levels and 35(13.9%) patients had abnormal TSH levels. In our study, Prevalence was 13.9%. Patients with abnormal TSH were evaluated further in the study.

Table2: Distribution of Study Subjects according to the Gender (N=70)

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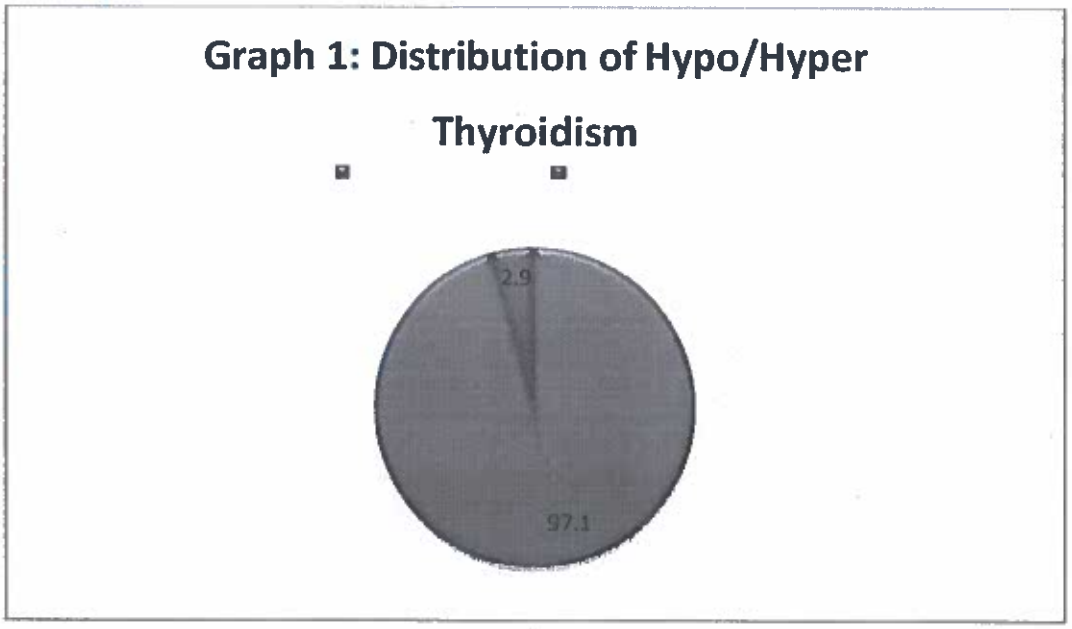
Gender	No.	Percent
Female	28	80
Male	07	20

Out of 35 cases 07 were male (20%), and 28 were female with (80%) with over all Male:Female ratio of 1:4.



Out of 35 cases, 34 cases (97.1%) were hypothyroidism and 01 cases (2.9%) was hyperthyroidism.

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Table 3: Distribution of Hypothyroidism Study Subjects according to Signs and Symptoms (N=34)

Chief Complaints	No.	Percent
Constipation	19	55.8
Short stature	17	50.0
Dry skin	16	47.0
Lethargy	15	44.1
Cold intolerance	13	38.2
Swelling in the neck	09	26.4
Goiter	07	20.5
Non-pitting edema	05	14.7
Fatigue	05	14.7
Developmental delay	04	11.7
Pallor	03	8.8
Abnormal weight gain	03	8.8
Polyuria	01	2.9
Umbilical hernia	01	2.9
Not gaining height	01	2.9
Delayed dentition	01	2.9
Not gaining weight	01	2.9
Bradycardia	01	2.9
Change in voice	01	2.9
Prolonged neonatal jaundice	01	2.9

Only 01 case belongs to hyperthyroidism that had increased frequency of stools, heat intolerance, hyperactivity, tachycardia, short stature, pallor & swelling of the neck.02 out of 35 cases had family history of thyroid disorders (5.7%) and 33 cases had no family history of thyroid diseases(94.2%). All the 02 were hypothyroid cases. Out of 35 cases, 07 cases had thyroid enlargement on examination (20%), 28 cases had no thyroid enlargement (80%). In our study out of 35 cases, 51.4% had height < 3rd percentile and 45.7% patients had weight < 3rd percentile.

Table 4: Distribution of Study Subjects according to the Haemoglobin (N=35)

HB (in g%)	No.	Percent(%)
Normal	11	31.4
Mild	13	37.1

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Moderate	08	22.8
Severe	03	08.5

Out of 35 cases, 24 cases had anaemia,13 cases with mild anaemia (31.4%), 08 cases with moderate anaemia (22.8%),03 cases with severe anaemia (8.5%), 11 cases were having normal haemoglobin levels (31.4%).Out of 35 cases, 07 cases had goiter (20%), 03 had hypoplastic features (8.5%) and 25 cases were having normal USG thyroid (7.4%).

Table 5: Distribution of Study Subjects according to Thyroid 99^{m} Technetium scan (N=07)

99^{m} technetium scan	**No.**	**Percent(%)**
Thyroid Dysgenesis	05	71.4
.-Aplasia	01	20
-Hypoplasia	03	60
-Ectopic	01	20
Dyshormonogenesis	02	28.5

Out of 07 cases with Congenital Hypothyroidism,05 cases (71.4%) are Thyroid Dysgenesis ,followed by Dyshormonogenesis in 02 cases (28.5%). In 05 cases of Thyroid Dysgenesis 03 are hypoplastic (60%) , 01 cases aplasia (20%) and 01 ectopic thyroid (20%).

Table 6: Distribution of Study Subjects according to the Diagnosis (N=35)

Diagnosis	**No.**	**Percent**
Autoimmune hypothyroidism	27	77.1
-with Goiter	07	25.9
-without Goiter	20	74.1
Hyperthyroidism	01	02.8
-without goiter	01	100.0
-with Goiter	00	0.0
Congenital Hypothyroidism	07	20
-with thyroid dysgenesis	05	71.4
-with dyshormonogenesis	02	28.6
Thyroid dysgenesis	05	
- *aplasia*	01	20
- *hypoplasia*	03	60
- *ectopia*	01	20

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Out of 35 cases , 27 (77.1%) are autoimmune hypothyroidism in which 20 (74.1%) cases had no goiter and 07 had goiter (25.9%), 07 (18.6%) are congenital hypothyroidism, 05 cases are Thyroid Dysgenesis (71.4%), 02 cases are Dyshormonogenesis(28.6%).Out of 35 cases, 01 cases (2.8%) are hyperthyroidism without goiter (100%). Out of 05 cases of thyroid dysgenesis, 03 cases are from Hypoplasia, 01case is belongs to aplasia & ecopia of thyroid gland

Table 7: Distribution of Study Subjects according to the Anti-Thyroid Antibodies (N=28)

Anti-Thyroid Antibodies	No.	Percent
Elevated anti-TPO	22	78.57
Elevated anti TG	24	85.71
Anti TPO positive Anti TG negative	03	10.71
Anti TG positive Anti TPO negative	05	17.85

Out of 28 cases of suspected autoimmune etiology, 22 (78.57%) cases had elevated anti TPO antibody levels, and 24 (85.71%) cases had elevated anti TG antibody levels. Out of 28 cases, 03 (10.71%) cases are positive for anti TPO antibodies but negative for anti TG antibodies where as 05(17.85%) cases are positive for anti TG antibodies but negative for anti TPO antibodies.

DISCUSSION

PREVALENCE: - Out of 252 patients tested having suspicion of thyroid dysfunction, 35 children had abnormal thyroid dysfunction, 34 were hypothyroid and 01 was hyper thyroid. Estimated Prevalence in our study is 13.88%. While results of Amitabh singh et al (2016) was 13% prevalence of thyroid disorders in children at a tertiary care hospital in western India.**MALE: FEMALE RATIO**-Thyroid disorders are well known to be more in female than male of all age groups[4]. In our study, out of 35 cases, 07 are Male (20%) and 28 are Female (80%). Overall Male: Female ratio was 1:4.In a Study done by Ian Hunter et al [40] on Prevalence and aetiology of hypothyroidism in the young noted that out of 140 cases 37 were male and 103 were female and the male to female ratio was 1:2.8.In a study done by kapil U et al [41] on Assessment of iodine deficiency in Ernakulam district, Kerala state noted that out of 1254 children between age group of 6-12 years for the prevalence of IDD in children, the male to female ratio was 1:2.9.In a study done by Meena desai[6] on Autoimmune Thyroid Disease In Childhood noted that out of 78 cases 58 were female and 20 male, the male to female ratio was 1:2.9.In a study done by R. K. Marawah et al[42] on Prevalence of thyroid diseases in children noted that out of 122 diagnosed, 14 children were male (11.47%) and 108 were female (83.52%) the male to female ratio was 1:7.7.**SIGNS AND SYMPTOMS** -In our study, out of 34 cases of hypothyroidism , the most common clinical presentation in patients is constipation (55.8%) followed by short stature (50%).In a study done by Desai MP et al [30] on disorders of thyroid gland in India noted that most common clinical presentation was constipation(87%) followed by lethargy (55%). In a study done by Amitabh Singh et al[43] on prevalence of thyroid disorders in children noted that out of 61 hypothyroid cases the most common clinical presentation was short stature (59%) followed by lethargy (49.2%).In a study done by Virmani A et al [32] on Profile of thyroid disorders in a referral centre in North India noted that the most common clinical presentation was short stature (44%).In our study, Only 01 case belongs to hyperthyroidism that had increased frequency of stools, heat intolerance, hyperactivity, tachycardia, short stature, pallor & swelling of

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the neck.In a study done by Amitabh Singh et al[43] on prevalence of thyroid disorders in children noted that out of 4 cases of hyperthyroidism , the most common clinical presentation was tachycardia (100%), followed by palpitations (75%).**FAMILY HISTORY:-**In our study out of 35 cases, 02 cases (5.7%) had family history of thyroid disorders .In a study done by Amitabh singh et[43] al on prevalence of thyroid disorders in children noted that 4 cases (6.5%) had family history of thyroid disorders.**GOITER:-**In our study out of 35 cases, 07 (20%) children with thyroid dysfunction had thyroid gland enlargement which was confirmed by ultrasound thyroid showing goiter.In a study done by Desai MP et al[30] on Disorders of thyroid gland in India reported prevalence of goiter in 38% children with thyroid hormone abnormalities. In a study done by R. Pradhan et al[44] on Assesment of iodine deficiency disorders in urban areas of Udaipur district Rajasthan ,India noted that the prevalence of goiter was 25%.Similarly in a study done by Shah NA et al[33]on Evaluation of thyroid diseases by hormonal analysis in Paediatric age group noted that out of 16 cases, 3 cases had prevalence of goiter (5%).**ANEMIA**:-Anaemia is known to be associated with hypothyroidism[45]. The common type of anaemia found in hypothyroidism is anaemia of chronic disease [46].In our study out of 35 cases, prevalence of anaemia was found to be 24 (68.5%).In a study done by Amitabh singh et al[43] on prevalence of thyroid diseases in children noted that the prevalence anaemia was (31.1%).While the available literature suggest the prevalence to be higher (20 -60 %)[47].**THYROID 99^{m} TECHNETIUM SCAN** -In our study out of 35 cases, thyroid 99^{m} Technetium scan is done in 07 patients, out of which 05 (71.4%) are Thyroid Dysgenesis followed by Dyshormonogenesis in 02 cases (28.5%). Out of 05 cases of thyroid dysgenesis 03(60%) have thyroid hypoplasia , 01 (20%) have aplasia and 01 (20%) case of ectopic thyroid .Where as in study done by Amitabh singh et al[43] on prevalence of thyroid disorders in children noted that thyroid scintigraphy was done in 35 patients and most common finding was dyshormonogenisis (46 %). **DIAGNOSIS:-**In our study out of 35 cases with thyroid dysfunction, 34 cases (97.1%) were hypothyroidism and 01 cases (2.8%) were hyperthyroidism.In a study done by Desai MP et al[30] on Disorders of thyroid gland in India noted that out of 800 cases 79% were having hypothyroidism and 2% were having hyperthyroidism.In a study done by Shah NA et al[33]on Evaluation of thyroid diseases by hormonal analysis in paediatric age group noted that out of 16 cases 6 cases were having hypothyroidism(37.5%) and 1 case had hyperthyroidism(6.25%).In a study done by Amitabh Singh et al[43] on prevalence of thyroid disorders in children noted that Out of 65 cases , 61 cases were having hypothyroidism (93.8%) and 4 cases were having hyperthyroidism (6.1%).In a study done by Meena P Desai and Swati karandhikar[6] on Autoimmune thyroid disease of childhood noted that Out of 77 cases, 60 children (77%), had hypothyroidism and 8 cases (10%) had thyrotoxicosis.In our study, out of 34 cases of hypothyroidism, 27 cases were autoimmune hypothyroidism (77.1%), and 07 cases were congenital hypothyroidism (19.5%).In a study done by Meena P et al[6] on Autoimmune thyroid disease in childhood noted that 40% cases were autoimmune hypothyroidism and 46% cases were congenital hypothyroidism. **ANTI THYROID ANTIBODIES-** In our study of 35 cases, 28 cases suspected of having autoimmune etiology are subjected to anti TPO and anti TG levels, 22 cases (78.57%) had elevated anti TPO antibodies and 24 cases (85.71%) had elevated anti TG antibodies. In a study done by Meena Desai et al[6] on Autoimmune thyroid disease in childhood noted that out of 96 cases, 66 cases (68.7%) were having anti thyroid antibodies positive. Anti TPO antibodies positivity were more common than anti TG antibodies. Out of 57 cases, 6 (10.52%) cases are positive for anti TPO antibodies but negative anti TG antibodies where as 11(19.29%) cases are positive for anti TG antibodies but negative for anti TPO antibodies. In study done Meena P et al[6] anti thyroid antibody levels of 1:100 were considered significant and taken as positive case. **TREATMENT**-All the cases of hypothyroidism were treated with tablet levothyroxine and hyperthyroidism cases with Carbimazole according to standard guidelines[31]. Iron, calcium and vitamin D3 supplementation was given to the patients. Review of literature reveal that in India less than 10% cases of congenital hypothyroidism are diagnosed by the age of 3 months and only about

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50% by the age of 2 years [34,48].lack of awareness amongst the primary health care practitioners and family physicians was one of the important reasons for delayed diagnosis [34].

CONCLUSION

Thyroid hormones estimation is very useful in diagnosis of various thyroid disorders in children with clinical suspicion of thyroid dysfunction. Thyroid hormones are unique in view of their role in fetal development and early neonatal brain development and also having actions on growth and developmental during the first two decades of life. Congenital hypothyroidism is one of the major preventable thyroid diseases if diagnosed early. Hence screening of all newborns and children should be mandatory as early diagnosis and treatment helps in prevention of mental retardation and other complications of thyroid disorders. Other thyroid diseases commonly seen in pediatrics age group are autoimmune thyroiditis, goiter and rarely hyperthyroidism. Autoimmune thyroid disorders are now emerged as a leading cause of thyroid disorders in pediatric age group. Many cases have been encountered in our study where in patients with autoimmune thyroid disorders are having anti TPO antibodies negative but anti TG antibodies positive. Out of 252 patients having clinical suspicion of thyroid dysfunction, 35 cases had thyroid function abnormalities and after subjecting these 35 patients for further tests based on the suspected etiology we found out 34 cases as hypothyroidism and 01 case as hyperthyroidis

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"A PROSPECTIVE OBSERVATIONAL STUDY ABOUT ASSESSMENT OF PREVALENCE AND CLINICO-ETIOLOGICAL PARAMETERS OF DISORDER'S OF THE THYROID GLAND IN CHILDREN, AT A SOUTHERN RAJASTHAN HOSPITAL"

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Original Research Article

Clinico-etiological Profile of Hospital Acquired Diarrhea in children below 15 years admitted at tertiary care centre- A Cross Sectional Study.

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Abstract

Introduction: Hospital-acquired diarrhea (HAD), among hospitalized children is responsible for increased costs and prolonged hospital stay and also important cause of morbidity and mortality. Especially in children Hospital-acquired diarrhea an important hazard in developed and developing countries occurring about 2–32% of admitted in pediatric wards. Children under the age of three years in developing countries experience on an average of three time of diarrhea every year. On each and every episode of diarrhea, it contributes deprivation to significant nutrition which is necessary for child growth. Patients in the hospital stay may face the additional risk of acquiring infections due to contact with other patients, contaminated hospital surfaces or healthcare workers and in low-income hospitals infection control is often less meticulous which could be higher risk. **Aim:** The main objective is to study the etiology and prevalence of hospital acquired diarrhea in children. **Material and methods:** In this study total 100 patients were included with the age between 1 to 15 years old who were admitted to the pediatric ward for reasons other than diarrhea and stayed for more than 3 days. Detail history from all the patients were noted including laboratory investigation. From each and every patient stool sample were collected in disposable clean containers and send to microbiology laboratory for processed. Several diagnostic laboratory tests were done for the detection of viral, bacterial, parasitic and fungal agents. Enzyme linked Immunosorbent assay (ELISA) were done for the detection of Clostridium difficile toxins and latex agglutination test were done for detection of human rotavirus antigen. **Results:** In this study total 100 hospitalized children between the ages 1 to 15 years old were examined. Out of these 82 children (82%) were diagnosed as hospital acquired diarrhea. out of total 100 patients majority mere male children(63%) and followed by female(37%) children. Out of total 100 children, children with the age group 1-4 years showed maximum (38%) of hospital acquired diarrhea followed by 4-8 years (29%), 8-12 years(18%) and 12-16 years(15%) respectively. **Conclusions:** This study also revealed a high prevalence of hospital acquired diarrhea our area and the infectious causes were more than the non-infectious causes, with bacterial predominance among the infectious agents. Therefore this study recommends routine general stool examination, stool culture/sensitivity for detection for microbial infection and Cl. difficile detection by ELISA methods for all patients with hospital acquired diarrhea to identify the causative agent. Hence, healthcare strategy and campaign should be focused on specific hospital staff and community area must be available.

Keywords: Children, Hospital acquired diarrhea, Enteropathogenic Escherichia coli.

Introduction

Hospital-acquired diarrhea (HAD), among hospitalized children is responsible for increased costs and prolonged hospital stay and also important cause of morbidity and mortality[1]. Especially in children Hospital- acquired diarrhea an important hazard in developed and developing countries occurring about 2–32% of admitted in pediatric wards[2,3]. Especially in the cases of children diarrheal disease is the most common disease which causes mortality and morbidity in worldwide mainly in developing countries. According to WHO about 525,000 children under five years worldwide die due to diarrheal diseases each year with 1.7 billion cases of diarrheal disease every year[4]. Children under the age of three years in developing countries experience on an average of three time of diarrhea every year. On each and every episode of diarrhea, it contributes deprivation to significant nutrition which is necessary for child growth[5]. In developed countries, long term uses of broad spectrum antibiotics may disturb normal colonic flora followed by colonization of Clostridium difficile and this may be the common cause of new onset of diarrhea among

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hospitalized patients[6]. Patients in the hospital stay may face the additional risk of acquiring infections due to contact with other patients, contaminated hospital surfaces or healthcare workers and in low-income hospitals infection control is often less meticulous which could be higher risk[7,8] .Research from developed and developing countries suggest that age, length of hospitalization, immune status, nutritional status, and exposure to gastrointestinal procedures such as endoscopy and nasogastric intubation are host-related risk factors for hospital-acquired diarrhea[9,10]. For the control and spread of Hospital-acquired diarrhea from contaminated food is and main concern in hospitals and nursing homes. Due to untrained staff using unsafe practices for the storage, preparation and handling of food frequently. Furthermore quality of drinking water with limited resources is often unsafe controlling outbreaks of waterborne infectious diarrhea are continuing problem[11].The main objective is to study the etiology and prevalence of hospital acquired diarrhea in children.

Material and methods

This is a cross sectional study carried out at Ananta institute of medical science & research centre Rajsamand, Rajasthan in the department of pediatric with the collaboration of department of microbiology. In this study total 100 patients were included with the age between 1 to 15 years old who were admitted to the pediatric ward between march 2019 to February 2020 for reasons other than diarrhea and stayed for more than 3 days. For the diagnosis of the hospital acquired diarrhea in the hospitalized patients, the Centers for Disease Control and Prevention (CDC)[12] definition of hospital diarrhea was used, as in a hospitalized patient acute onset of diarrhea with a period of at least 3 days of hospitalization prior to the onset of diarrhea. Detail history from all the patients were noted including laboratory investigation. From each and every patient stool sample were collected in disposable clean containers and send to microbiology laboratory for processed. Several diagnostic laboratory tests were done for the detection of viral, bacterial, parasitic and fungal agents. Enzyme linked immunosorbent assay (ELISA) were done for the detection of Clostridium difficile toxins and latex agglutination test were done for detection of human rotavirus antigen

Results

In this study total 100 hospitalized children between the ages 1 to 15 years old were examined. Out of these 82 children (82%) were diagnosed as hospital acquired diarrhea. out of total 100 patients majority mere male children (63%) and followed by female(37%) children as shown in table no 1 below.

Table 1: showing the total no of children according to their gender

	No of Cases	Percentage(%)
Male	63	63
Female	37	37
Total	100	100

Out of total 100 children, children with the age group 1-4 years showed maximum (38%) of hospital acquired diarrhea followed by 4-8 years(29%), 8-12 years(18%) and 12-16 years(15%) respectively as shown in table no 2 below.

Table 2: showing age groups distribution of children with hospital acquired diarrhea

Age group	No of Cases	Percentage (%)
1-4	38	38
4-8	29	29
8-12	18	18
12-16	15	15
Total	100	100

Among all the patients, in 82% of the patients showed various causative agents as variety of microbial causative agents were isolated and identified and remaining 18% was no obvious causative agent detected. Out of the total single infectious agent causing 63.2% and 15.9% had mixed infections of bacterial–bacterial, bacterial–parasitic or bacterial–viral. Enteropathogenic Escherichia coli (EPEC) was most commonly isolated microbial agent 23.2% cases followed by parasitic infection 20.8% and rotavirus in 17.1% respectively. In about two- thirds of isolates, 3 organism's isolates were found. Remaining organism was found in low frequency as shown in table no 3 below.

Patients with the age group 1-4 years of age were most affected by hospital acquired diarrhea followed by age group 4-8 years. In both the age group EPEC was most predominant which is followed by Rota virus. The opportunistic microorganisms like Pseudomonas aeruginosa, Proteus mirabilis, Klebsiella oxytoca were detected in age group 1-4 years, and they represented 15% of the total isolates. In this study out of total hospital acquired diarrhea bacterial infection 58.6% were most common which is followed by parasitic infection 20.8%, viral 17.1% and fungal infection 3.7% respectively.

Table 3: Age distribution of infectious agents in stool samples of children with nosocomial diarrhea diagnosed

Infectious agent	Isolates by age group					
	1-4	4-8	8-12	12-16	total	%
Enteropathogenic Escherichia coli	5	8	4	2	19	23.2
Clostridium difficile	4	3	3	1	11	13.4
Salmonella enteritidis	0	1	2	1	4	4.9
Klebsiella oxytoca	1	0	1	0	2	2.4
Pseudomonas aeruginosa	2	3	1	0	6	7.3
Proteus mirabilis	1	1	1	0	3	3.7
Shigella flexneri	1	1	0	1	3	3.7
Entamoeba histolytica	4	2	2	1	9	11.0
Cryptosporidium parvum	2	1	1	0	4	4.9
Giardia lamblia	0	1	2	1	4	4.9
Candida albicans	2	1	0	0	3	3.7
Rotavirus	6	4	3	1	14	17.1
Total	28	26	20	8	82	100.0

Discussion

Hospital acquired diarrhea is an acute diarrhea defined by the place of infection and the time of onset after 72 hours. in order to exclude microorganisms the 3-day cut-off period is used which may be acquired from the community and stay dormant in the body without clinical evidence[13]. A study reported from northern Brazil a higher prevalence of hospital acquired diarrhea among children was about 40% which showed less than this study as it shows higher prevalence whereas in south India showed prevalence to be 20% among hospitalized children with age less that 36 months[14,15]. This difference in prevalence may be related to different factor such as hygiene practices. sanitation level of the hospitals and type of microorganisms endemic in the area. While admit in the hospital and stay for longer period in hospital with limited routine infection control that may increase the possibility of exposure to potential pathogens at hospital settings which might cause new onset of diarrhea. Moreover, in hospital many care givers had diarrhea while caring for ill patients and that also pose one of the risk factor to patients[16,17]. In this study showed that a high prevalence of cases were in children with the age below 5 years and this prevalence were agree with other studies from Iraq[18] and also from Saudi Arabia[19]. In India there are many studies which showed that the incidence of diarrhea among children in high in the age between 4 months and 2 years[20]. Many studies showed that gastrointestinal system is most frequent site as in the other general pediatric service[21]. In this study EPEC were most common isolated organism and rotavirus were most common viral agent causing infectious diarrhea in children which is also similar to the studied of Jindal et al[22]as it showed 21.4% of cases of infectious diarrhea were due to EPEC. A studied from Turkey by Oguz F et al[23] showed Cl. Difficile as 20.7% which is similar to this study. In this study period there was no clinical evidence of cholerae due to Vibrio cholerae and diarrhea with food poisoning due to Staphylococcus aureus was found. Other bacteria like Campylobacter jejuna and Yersinia enterocolitica were also not found that are sometimes involve in hospital acquired diarrhea among children.

Conclusion

In children diarrhea is very important issue in developing countries like India. This study also revealed a high prevalence of hospital acquired diarrhea our area and the infectious causes were more than the non-infectious causes, with bacterial predominance among the infectious agents. Therefore this study recommends routine general stool examination, stool culture/sensitivity for detection for microbial infection and Cl. difficile detection by ELISA methods for all patients with hospital acquired diarrhea to identify the causative agent. Hence, healthcare strategy and campaign should be focused on specific hospital staff and community area must be available.

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Section Medicine

Original Article

Serum Magnesium Levels in Type II Diabetes Mellitus and Its Association with the Microvascular Complications

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ABSTRACT

Background: Hypomagnesemia has been associated with type 2 diabetic mellitus and is known to be a risk factor for microvascular complications. This study aimed to evaluate serum magnesium levels in patients with type 2 DM and correlate them with microvascular complications.

Materials & Methods: A hospital based cross-sectional study was conducted on150 patients with type 2 diabetes mellitus were admitted in the Mahatma Gandhi Hospital, Bhilwara, Rajasthan, India. Serum magnesium levels were assessed in all the diabetic patients and they were also tested for presence of microvascular complications.

Results: In the present study majority of the patients (71.33%) were males and male to female ratio was 2.48:1. The commonest age group was > 60 years (50%) and the mean age was 60.38 ± 10.81 years. The duration of diabetes in 45.33% of the patients was between 6 to 10 years and mean duration was 7.43 ± 4.11 years. Hypomagnesemia was associated with microvascular complications including diabetic retinopathy, diabetic nephropathy and diabetic neuropathy (p<0.050). Also, association was found between serum magnesium levels glycaemic control cnd duration of diabetes (p<0.050).

Conclusion: Hypomagnesemia is widely prevalent in patients with type 2 diabetes mellitus and a major risk factor for the development microvascular complications that is, diabetic retinopathy, nephropathy and neuropathy.

Key words: Hypomagnesemia, Diabetic nephropathy, Diabetic neuropathy, Diabetic retinopathy, Microvascular complications, Type 2 diabetes mellitus

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INTRODUCTION

The prevalence of diabetes is rapidly rising all over the globe at an alarming rate.[1] It is important to note that the rise in prevalence is seen in all six inhabited continents of the globe.[2] Over the past 30 years, the status of diabetes has changed from being considered as a mild disorder of the elderly to one of the major causes of morbidity and mortality affecting the youth and middle aged people.

The epidemic of diabetes is most pronounced in India as the World Health Organization (WHO) reports show that 32 million people had diabetes in the year 2000.[2] The International Diabetes Federation (IDF) estimates the total number of diabetic subjects to be around 40.9 million in India and this is further set to rise to 69.9 million by the year 2025.[3] Diabetes mellitus leads to impaired metabolism of carbohydrates, proteins, fats, water and electrolytes. The persistence of these metabolic disturbances lead to permanent and irreversible functional and structural changes in the cells of the body which in turn lead to the development of "diabetic complications", characteristically affecting, the cardiovascular system, eye, kidney and nervous system mainly.[4]

Micronutrients have been investigated as potential, preventive and therapeutic agents for type 2 diabetes mellitus and their complications.[5] In particular, diabetes has shown to be associated with abnormalities in the metabolism of zinc, chromium, copper, magnesium and manganese.[6] Out of these magnesium has been investigated as a clinically

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significant electrolyte, for a long term global policy to lower the burden of diabetes mellitus, with new findings and researches.[7] Studies have shown that magnesium levels are lower in patients with diabetes compared with nondiabetic controls.[8] The reported incidence of hypomagnesemia in patients with type 2 DM varies between 13.5 to as high as 47.7%.[9]

Magnesium is the fourth most abundant cation in the human body and the second most abundant intracellular cation.[10] It plays an important role in the carbohydrate metabolism. It serves as a cofactor for all enzymatic reactions that require kinases.[11] Magnesium depletion has a negative impact on glucose homeostasis and insulin sensitivity in patients with type 2 diabetes as well as on the evolution of complications such as retinopathy, arterial atherosclerosis and nephropathy. Moreover, a low serum magnesium level is strong, independent predictor of development of microvascular complications in type 2 DM.[12]

Although, serum magnesium levels are known to be low in type 2 DM, the entity of hypomagnesemia very often remains under-diagnosed and under-evaluated due to its usual asymptomatic presentation. Also, to date, there are very few studies which have evaluated the association of serum magnesium levels with the microvascular complications especially in India. Hence, this study was planned to evaluate the serum magnesium levels in patients with type 2 DM and to correlate them with the microvascular complications.

METHODS

A hospital based cross-sectional study was conducted on 150 patients with type 2 diabetes mellitus were admitted in the Mahatma Gandhi Hospital, Bhilwara, Rajasthan, India.

Inclusion Criteria

- Patients with type 2 diabetes mellitus.
- Age more than 18 years.

Exclusion Criteria: The following patients were excluded from the study.

- Non-diabetic kidney disease
- Chronic diarrhea
- Thyroid dysfunction
- Sepsis
- Chronic alcoholics
- Pregnancy and lactation

Patients were interviewed to obtain the demographic characteristics such as age and sex, presenting complaints, diabetic history and history of other comorbid conditions. These patients were subjected to clinical examination and the findings including vitals and systemic examination findings were noted. Patients were evaluated for the features of diabetic peripheral neuropathy.

RESULTS

In this study the commonest age group for type 2 DM was more than 60 years which comprised of 50% of the patients. The mean age was 60.38 ± 10.81 years and median age was 60.5 years (Range 36-89 years). The male to female ratio was 2.48:1. The mean duration of diabetes was 7.43 ± 4.11 years.

In the present study most common presentation of complications was tingling and numbness i.e symptoms suggestive of neuropathy (28%) (Table 2).

In the present study hypomagnesemia (< 1.8 mg/dL) is seen in 58.54% of the patients with microvascular complications compared to 20.59% of the patients. This difference was statistically significant (p<0.001) (Table 3). The mean serum magnesium levels in patients with and without microvascular complications. The mean serum magnesium levels were significantly low among the patients who had complications (p<0.050) (Table 4).

Table 1: Age & gender wise distribution of cases

Age distribution (years)	Number	Percentage
18-30 years	0	0%
31-45 years	18	12%
46-60 years	57	38%
>60 yrs	75	50%
Total	150	100%
Gender		
Male	107	71.33%
Female	43	28.77%
Male: Female	2.48:1	
Duration of diabetes	7.43 ± 4.11 years	

Table 2: Clinical presentation

Clinical presentation	Number	Percentage
Tingling	42	28%
Numbness	42	28%
Nocturnal pain	6	4%
Blurring of vision	4	2.67%
Dysuria	3	2%
Puffiness of face	1	0.67%
Sensory ataxia	1	0.67%

Table 3: Association of serum magnesium level with Microvascular complication

Microvascular complications	Serum Magnesium (mg/dl)				Total	
	<1.8		1.8-2.5			
	No.	%	No.	%	No.	%
Present	48	58.54	34	41.46	82	100%
Absent	14	20.59	54	79.41	68	100%
Total	62	41.33	88	58.67	150	100%

Table 4: Comparison of mean serum magnesium levels with complications

Diabetic Complications	Serum Magnesium (mg/dl)				P-value
	Complication		Non-complication		
	No.	Mean ± SD	No.	Mean ± SD	
Overall Complications	82	1.70±0.31	68	1.92±0.25	<0.001
Diabetic Retinopathy	48	1.65±0.30	102	1.86±0.28	<0.001
Diabetic Nephropathy	54	1.70±0.27	96	1.85±0.31	0.002
Diabetic Neuropathy	48	1.62±0.31	102	1.91±0.24	<0.001

DISCUSSION

Magnesium is the fourth most abundant cation in the human body and the second most abundant intracellular cation. The low serum magnesium levels in diabetics may contribute to the evolution of diabetic complications such as retinopathy, abnormal platelet function, cardiovascular disease and hypertension via reduction in the rate of inositol transport and

subsequent intracellular depletion. Patients with severe diabetic retinopathy have lower magnesium levels than do diabetic patients with minimal retinal changes, which suggests that hypomagnesaemia may be a risk factor in development of diabetic retinopathy.[13]

It is reported that, the prevalence of diabetes higher in men than women.[14-20] The same was true in the present study as males (71.33%) outnumbered females (28.67%) with male to female ratio 2.48:1. These findings suggest higher prevalence of diabetes among males in this study which was consistent with the previous literature.[14-20]

Unlike in the West, where older persons are most affected, diabetes in Asian countries is disproportionately high in young to middle-aged adults.[14-20] However, in this study nearly half of the study population (50%) presented with age > 60 years. The next common age group was 46 to 60 (38%) followed by 31 to 45 years (12%). The findings show that diabetes mellitus was widely prevalent among elderly. The higher prevalence of diabetes among aged can be explained by the rise in the segment of geriatric population.[21]

In the present study 45.33% of the patients reported duration of diabetes between 6 to 10 years and mean duration was 7.43 ± 4.11 years. The mean duration of diabetes mellitus observed in the present study was comparable with a study by Badyal A. et al.[22] from Mullana, Ambala (Haryana) who reported duration of T2DM ranging from one month to eleven years with a mean duration of 9.91±5.06 years.

In the present study more than one fourth of the study population (42 patients) presented with tingling and numbness (28% each). The next common presentation was nocturnal pain (4%), blurring of vision (2.67%) and dysuria (2%). However, few patients (0.67% each) also presented with puffiness of face and sensory ataxia.

The reasons for the high prevalence of magnesium deficiency in diabetes are not clear, but may include increased urinary loss, due to osmotic diuresis, lower dietary intake, rampant use of loop and thiazides diuretics promoting magnesium wasting, diabetic autonomic neuropathies, impaired absorption of magnesium compared to healthy individuals. Sometimes frequent use of antibiotics and antifungals such as aminoglycosides and amphotericin in patients with diabetes may also contribute to renal magnesium wasting. Recently a specific tubular defect in magnesium reabsorption in thick ascending loop of Henle is postulated. This defect results in reduction in tubular reabsorption of magnesium and consequently hypomagnesemia. The reason for this tubular defect in diabetics in unclear. Insulin treatment has been shown to correct renal magnesium loss in diabetics.[23]

In the present study, the overall microvascular complications were significantly high in patients with hypomagnesemia that is, 58.54% of the patients with hypomagnesemia (<1.8mg/dL) had microvascular complications compared to 41.46% of the patients with normo-magnesemia (p<0.001). Further, the frequency of diabetic nephropathy (53.7%) diabetic neuropathy (79.17%) and diabetic retinopathy (64.58%) was significantly high among the patients with hypomagnesemia (p<0.050). The mean serum magnesium levels were significantly low (1.70 ± 0.31 mg/dL) in patients who presented with microvascular complications compared to diabetic patients without having microvascular complications (1.92 ± 0.25 mg/dL) (p<0.001) and similar trend was noted in patients with the individual complications.

This study reveals a strong association between hypomagnesemia and microvascular complications. Hence it could be suggested that routine surveillance for hypomagnesemia is done in patients of type 2 diabetes mellitus.

This study had certain limitations. As the study focused on incidence of hypomagnesemia and microvascular complications, other confounding variables such as demographic characteristics, clinical profile and biochemical profile could not be ascertained to the effect of hypomagnesemia on microvascular complications. Hence, further studies considering these confounding variables will focus higher accuracy of relationship between hypomagnesemia and microvascular complications in T_2DM.

CONCLUSION

Hypomagnesemia is widely prevalent (41.33%) among patients with type 2 diabetes mellitus and lower serum magnesium were seen in patients with poor control and longer duration of diabetes. Low serum magnesium is one of the additional risk factors for the development of microvascular complications in type 2 diabetes mellitus.

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Pharmacoeco-economic study: A cost variation analysis of AKT drugs available in Indian market

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Abstract

Introduction: The cost of drug play important role in practice of medicine and disease outcome. In Indian market numerous brand available of generic drug. Tuberculosis is curable disease but if proper treatment not taken by patients then lead to development of drug resistance or pulmonary disability. AKT drugs used for the management of tuberculosis.

Objective: To compare and analysed cost variation in AKT drugs with different brand name for same dosage form & same active compound.

Materials and Methods: The price of the drug with same formulation and same strength (Dosage) was review from Indian drug review issue 3, 2017 (IDR) & CIMS (Apr- Jul 2017). Percentage of cost price variation and Cost ratio is analysed.

Result: High percentage of cost variation among first line AKT drugs seen with Ethambutol (474.51%) followed by Isoniazid (432.60%). Least percentage of cost variation seen with streptomycin (1.01%) followed by rifampicin (1.33%). Maximum cost ratio of first line drugs seen with Ethambutol (5.74). Among 2nd line AKT drug Maximum and least percentage of cost variation are seen with levofloxacin 500 mg tablet formulations (1550.84%) and Ofloxacin 400 mg sustained Releases - tablet (1.57%) respectively. Higher percentage of cost variation seen with more manufacture company/ no. of brand.

Conclusion: The wide percentage of cost variation is seen with AKT drugs available in Indian market. Regulation of drug price by concerned agencies and by government is needed. Rational drug prescription with low cost is important for treatment adherence and disease outcome.

Keywords: Pharmacoeconomics, Cost variation, Cost ratio, AKT drugs.

Introduction

Pharmacoeconomics identifies, measure and compare the cost and consequences of drug therapy to healthcare system and play important role in practices of medicine.[1,2] Cost of drugs is important factor for the good patient's compliances with treatment. In Indian market AKT drugs (antitubercular) drugs available are available with brand name.

Tuberculosis is cause by mycobacterium tuberculosis and it is treatable and curable disease. Globally, the best estimate is that 10.0 million people (range, 9.0–11.1 million) developed TB disease in 2017. Drug-resistant TB continues to be a public health crisis. The best estimate is that, worldwide in 2017, 558 000 people (range, 483 000–639 000) developed TB that was resistant to rifampicin (RR-TB), the most effective first line drug, and of these, 82% had multidrug-resistant TB (MDR-TB). TB is one of the top 10 causes of death and the leading cause from a single infectious agent.[3,4] AKT drugs /*is also known as antitubercular drugs use for the treatment of tuberculosis. Antitubercular drug divided into first line drugs and second line drug according to clinical utility. Tuberculosis patient divided into newly diagnosed and previously treated patient. First line drugs having high therapeutic efficacy and low toxicity used for newly diagnosed and previously treated patients. Second line drugs have a either low antitubercular efficacy or higher toxicity or both used for drug resistant tuberculosis. So, 2nd line drugs are reserve drugs.[5] treatment failure have higher morbidity and mortality compared with those who are cured as well as high rates of multidrug-resistant TB have been found among treatment failure cases especially in developing countries.[6] Obstructive ventilatory disorder is the commonly found disorder in patients with pulmonary TB.[7]

This study was planned to compare cost of various AKT drugs with same active compound (drug) and evaluate the difference in cost of various brand of same active compound (drug) with same formulations.

Materials and Methods

For this study price of the drug was review from Indian drug review issue 3, 2017 (IDR) & CIMS (Apr- Jul 2017). Difference between maximum and minimum price of the same drug (same generic name) manufactured by different company was calculated from these percentage of price variation was calculated. By using following formula percentage of price variation was calculated.[2]

$$\text{Percentage of cost variation} = \frac{\text{Price of the most expensive brand} - \text{Price of least expensive brand}}{\text{Price of least expensive}} \text{X } 100$$

Cost ratio was calculated by the ratio of the most expensive brand to least expensive brand of the same drug.[2] Cost ration and percentage of variation was calculated by entered data in Microsoft excel 2013. Permission was taken from institutional ethical committee of the American international institute of the medical sciences. Udaipur, Rajasthan.

Inclusion Criteria

1. All single molecules, Fixed drug combinations of AKT drugs manufactured by more than one company

Exclusion Criteria

1. Drug formulation manufactured by only one company.
2. Drug formulations with no price information.

In present study cost of first line drug Isoniazid, Rifampicin, Pyrazinamide, Ethambutol, Streptomycin (total number of drugs five) and second line drugs ofloxacin, levofloxacin, ciprofloxacin, moxifloxacin, ethionamide, cyclosporine, amikacin, capriomycin, prothioemide (total number of drugs nine) were analysed.

Five fixed drug combinations of first line drugs with different formulation were analysed. Second line drug like terizidone, para- aminosalicyclic acid (PAS), rifabutin, thiacetazone, cyclosporine were not match with our inclusion criteria so not included in analysis.

Result

Table 1: Cost variation analysis of the 1st line AKT drugs

Drug	Strength	Formulation	MC	Minimum Price (INR)	Maximum price (INR)	Cost variation (%)	Cost ratio
Isoniazid	300 mg	Tab	2	2.76	14.7	432.60	5.32
Rifampicin	150 mg	Cap	2	17.74	21.78	22.77	1.22
	300 mg	Cap	4	30.13	47.02	56.05	1.56
	450 mg	Cap	6	44.31	68.93	55.56	1.55
		Tab	2	47.02	47.65	1.33	1.01
	600 mg	Cap	4	54.26	68.93	27.03	1.27
Pyrazinamide	500mg	Tab	5	35.3	52.54	48.83	1.48
	750 mg	Tab	7	26.76	86.87	224.62	3.24
	1000 mg	Tab	5	35.42	105.5	197.85	2.97
Ethambutol	200 mg	Tab	4	3.92	11.11	183.41	2.83
	400mg	Tab	6	7.18	41.25	474.51	5.74
	800mg	Tab	9	13.69	57.75	321.84	4.21
	1000 mg	Tab	2	55.68	72	29.31	1.29
	600 mg	Tab	3	25.05	39.84	59.04	1.59
Streptomycin	0.75 g	Inj	2	8.17	8.25	0.97	1.00
	1 g	Inj	2	9.83	9.93	1.01	1.01

MC: Manufacture Company, Tab: tablet, Cap: capsule, Inj: injection

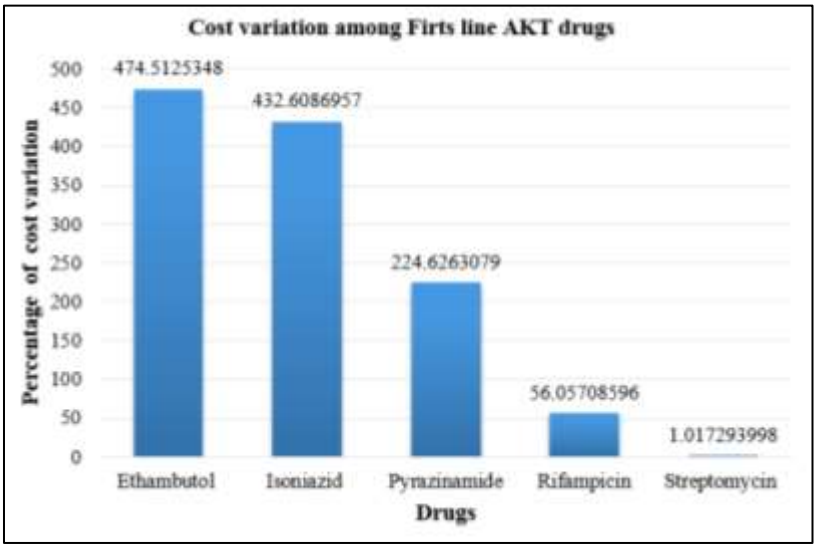

Fig. 1: Percentage of cost variation among first line drugs

The cost variation of first line AKT drug are shown in Table 1 & figure 1. There is wide variation in price of Anti tubercular drugs. More manufacture company more price variation seen. Among first line drugs maximum percentage cost variation seen with Ethambutol (474.51%) followed by Isoniazide (432.60 %). Least percentage cost variation seen with streptomycin (1.01 %) followed by rifampicin (1.33%). Maximum cost ratio of first line drugs seen with Ethambutol (5.74) followed by Isoniazid (5.32).

Table 2: Cost variation analysis of first generation fluroquinolone (2nd line AKT drugs)

Drug	Strength	Formulation	MC	Minimum Price (INR	Maximum price (INR)	Cost variation (%)	Cost ratio
Ofloxacin	100 mg	Tab	5	24.9	37	48.59	1.48
		DIS- tab	15	19.5	36	84.61	1.84
		FC- tab	2	16	34.65	116.56	2.16
	200 mg	Tablet	90	28	310	1007.14	11.07
		FC- tab	4	28.5	87.5	207.01	3.07
	400 Mg	Tablet	47	59.26	531.4	796.72	8.96
		FC- tab	4	53.26	112	110.28	2.10
		SR- tab	2	94	95.48	1.57	1.01
	50 mg/5 ml	Suspension	26	19.5	48	146.15	2.46
	100mg/5ml	Suspension	4	31	78.5	153.22	2.53
Ciprofloxacin	100 mg	Tab	2	13.95	20.33	45.73	1.45
		FC- tab	2	22.19	23.35	5.22	1.05
	250 mg	Tab	47	17.01	49.46	190.77	2.90
		FC- tab	4	30.66	59.8	95.04	1.95
	500 mg	Tab	59	34	156	358.82	4.58
		FC-tab	6	58	99.5	71.55	1.71
	750 mg	Tab	3	55	101.6	84.72	1.84
		FC tab	2	129.95	139.75	7.54	1.07
	1000 mg	Tab	2	79.35	150	89.03	1.89
	2mg/ml	Inf	5	18.37	51.1	178.17	2.78

MC: Manufacture Company, Tab: tablet, DIS-tab: Dispersible tablet tablet, FC-Tab: Film coated tablet, Inf: Infusion

Table 3: Cost variation analysis of second generation fluroquinolone (2nd line AKT drugs)

Drug	Strength	Formulation	MC	Minimum Price (INR	Maximum price (INR)	Cost variation (%)	Cost ratio
Levofloxacin	250 mg	Tab	35	29.5	74	150.84	2.50
		FC- tab	7	30.04	102	239.54	3.39
	500mg	Tab	81	59	974	1550.84	16.50
		FC- tab	8	45	174	286.66	3.86
	750 mg	Tab	27	37.5	136	262.66	3.62
		FC -tab	7	73.02	123.5	69.13	1.69
	125/5 ml 30 ml	Suspension	2	32	54	68.75	1.68
	500 mg/m100 ml	Inf	11	35	279	697.14	7.97
Moxifloxacin	400 mg	Tab	2	750.2	800	6.63	1.06

MC: Manufacture Company, Tab: tablet, FC-Tab: Film coated tablet, Inf: Infusion

Fluroquinolones are 2nd line AKT drugs. They are divided into first generation and second generation drugs. Ofloxacin and Ciprofloxacin are first generation fluroquinolones and levofloxacin and moxifloxacin are second generation fluroquinolones. The cost variation among fluroquinolones are shown in Table 2 and Table 3. Fluroqulinolones have different type of formulation available in market. Maximum percentage of cost variation is seen with levofloxacin 500 mg tablet formulations (1550.84%) followed by Ofloxacin 200 mg tablet formulation (1007.74%). While least percentage of cost variation seen with the Ofloxacin 400 mg sustained Releases - tablet (1.57%). Maximum cost ratio seen with levofloxacin 16.50 and minimum seen with Ofloxacin (1.01). The cost variation of Second line AKT drugs other than fluroquinolones are shown in table 4. Maximum price variation seen with amikacin (119.71%) and least cost variation seen with prothonemide so among all 2nd line AKT

drug maximum price variation seen with levofloxacin and least cost variation seen with ofloxacin.

Table 4: Cost variation analysis of other 2nd line AKT drugs

Drug	Strength	Formulation	MC	Minimum Price (INR	Maximum price (INR)	Cost variation (%)	Cost ratio
Amikacin	100 g/2ml	inj	22	15	29	93.33	1.93
	250mg/2ml	inj	21	24.9	95	281.52	3.81
	500 mg/ml	inj	22	38.55	84.7	119.7147	2.19
Prothionemide	250 mg	tab	2	99.9	126.2	26.32633	1.26
Capriomycin	1g	inj	2	236.1	428	81.27912	1.81

MC: Manufacture Company, Tab: tablet, Inj: injection

Table 5: Cost variation among fixed dose combination

Drug	Strength	Formulation	MC	Minimum Price (INR	Maximum-price (INR)	Cost variation (%)	Cost ratio
Rifampicin(R) + Isoniazid(H)	R(450),H(300))	FC tab	2	52.35	52.58	0.43	1.00
		Tab	8	51.5	67.74	31.53	1.31
	R(600),H(300))	Tab	4	50.2	77.83	55.03	1.55
	R(100),H(100))	Tab(p)	2	12.12	14.76	21.78	1.21
	R(100),H(100))	FC tab	2	18.53	29.94	61.57	1.61
Rifampicin (R) +Isoniazid (H) + Ethambutol (E)	R (150), H(75), E(275)	Tab	3	28.73	34.73	20.88	1.20
		Fc tab	2	30.78	39.9	29.62	1.29
Rifampicin(R) +Isoniazid(H) +Pyrazinamide (Z)	R (225), H(150), Z (75O)	Tab	2	49.4	51.76	4.77	1.04
	R(120), H(80), Z (250)	Tab	2	29.9	30.09	0.63	1.00
Rifampicin (R) +Isoniazid(H)+ Ethambutol (E) +Pyrazinamide (Z)	R(150), H(75), Z(400) E(275)	Tab	4	29.23	47.08	61.06	1.61
		FC tab	2	45.96	49.9	8.57	1.08
	R(450), H(100) Z(750), E(800)	Tab	2	44.45	48.02	8.0314	1.08

MC: Manufacture Company, Tab: tablet, FC-Tab: Film coated tablet,

Fixed drug combination available with different formulations and different dosage form, among them FDCs which match our criteria they are analysed. The cost variation analysis is given in table 5. Maximum cost variation seen with isoniazid and ethambutol combinations (1984.69 %). Least cost variation seen with isoniazid and rifampicin(R 450+ H 300) combination (0.43%).

Discussion

According to global tuberculosis report 2018, Tuberculosis is one of the top 10 causes of death and the leading cause from a single infectious agent & the proportion of people with TB who died from the disease was 16% in 2017.[3] According to various population-based studies there are numbers of risk factors associated with mortality following diagnosis of tuberculosis one of them is drug resistance.[8] MDR-TB is associated with an increased risk of death during treatment.[9] One of the reason for development of drug resistant TB is patient do not complete a full course of treatment.[10] So, patient adherence to the treatment is import for cure of the disease and to stop drug resistant TB.

In this Pharmacoeconomic studies result shows wide variation in the pricing of AKT drugs. First line drug which is mainly used for the treatment of TB shows wide variation in cost. High percentage cost variation seen with drug have more brand. Cost of the drug is one of the important factor for the compliance of the patients or adherence to treatment because the patient feels that the cost of therapy is a financial burden, then the compliance with therapy will be compromised.[11] Cost of the prescription rise more during last several decades. In USA for single prescription average price was $55 in 2004. The average charge over prescription was over $80, with generic product being under $40 per prescription and brand name product over $140. Reason for this rise in cost is occasioned by new technology, marketing cost and stockholder expectations.[12] This may directly affect the adherence of the treatment which affect the success of treatment. Poor adherence to the treatment decreases optimum clinical benefits and therefore reduces the overall

effectiveness of health systems.[13] According study conducted by Indrajt Hazarika around half of the patient attended privet facility for tuberculosis although AKT drugs are available free of cost under RNTCP program in government sector. Thus Role of privet sector is also important for the control of tuberculosis.[14] Pharmaceutical are not affected as all cost incurred in developing a drug/ formulations is ultimately passed on poor patients who have no choice and have to accept the drug.[15] The patients are mainly depend upon the clinician for the treatment so, whatever is prescribed they have to use it. Thus the rational prescription by clinician is important, they should prescribed low cost drug to the patients.[2] If clinician do not prescribed the higher cost formulation of drug the drug automatic out of market. So, Clinicians has greater responsibility to promote or to discourage the drug on the basis of scientific justification and rationality without influence any of pharmaceutical companies.[15]

The DPCO (Drug price control order) list of price controlled drug includes rifampicin and streptomycin from first line AKT drugs.[16] Rifampicin having low cost variation about 1% to 56% among all first line AKT drugs. Cost ratio helps to know how many times the most expensive formulation is costlier then the least expensive formulation of the same drugs.[2] In present study cost ratio of rifampicin is ranges from 1.01 to 1.56 according to different formulations and dosage of the drug which suggest lower cost ratio then other first line drugs because rifampicin is controlled drug. Ofloxacin having both high and lest price variation, reason for this may be no. of brand available as in result shows more number of brand high cost variation.[2] High cost variation seen with 200 mg tablet which is manufactured by around 90 pharmaceutical companies & least percentage of cost variation seen with 400 mg SR which is manufactured by only 2 pharmaceutical companies. The DPCO fixed the price of the drug so, once medicine included as controlled drug under DPCO, drug cannot be sold at a price higher than that fixed by the government (DPCO).[17] Thus, first line drugs used for tuberculosis treatment should be include under DPCO as controlled drug.

This study provide cost variation among AKT drugs so, advantages of the study is to cross cut out of pocket expenditure of patients on AKT drugs and that will lead to more compliance for treatment and reduce economical burden among patients.

Conclusion

The wide percentage of cost variation is seen with AKT drugs available in Indian market. High no. of brand or manufacture companies for single drug then high cost variation is seen. So, regulation of drug price by concerned agencies and by government is needed. The cost of drug is plays important role for the treatment adherence. Thus, low cost of prescription more treatment adherence. Clinician should aware about the different drug formulation with high cost variation which are available in Indian market. Privet sector also play important role in economics by rational prescribing with low cost.

Conflict of Interest: None.

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MANAGEMENT OF PARACETAMOL INDUCED HEPATOTOXICITY BY THE MEDICINAL PLANTS : A SYSTEMIC REVIEW

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Abstract
The acetaminophen induced liver toxicity is known to a substantial health problem concerning the patients with liver problems and further leads to liver transplantation. In present the therapies used for the treat APAP induced hepatotoxicity is the management with the drug named N-acetyl-cysteine (NAC) which is a sulphydryl constituent and an approved medication used to replenish the cellular glutathione storage in the liver cells. Various efforts are going on to develop innovative treatments for APAP induced liver toxicity, mainly focused on the faster recovery of liver patients and without any harmful effects. From the early 1990's the study on various herbal plants extracts, different phytochemicals and their influence on the APAP induced liver toxicity have been going on. The phytochemicals observed in the plant extracts are known to diminish the necrosis and also have a protective nature contrary to acetaminophen induced hepatotoxicity by the restoration of cellule antioxidant defensive mechanism. This further limits the oxidative stress and consequently protects the mitochondria from inflammation and impairment. On this basis, this review have summarized the herbal plant extracts which exhibit hepatoprotective properties, mechanisms etc which will help to guide and advance the existing status of herbal medicines against liver toxicity.

Keywords: Hepatotoxicity, Acetaminophen induced liver toxicity, liver transplantation, APAP, liver toxicity

Introduction

Acetaminophen (APAP) is known to be a habitually used drug for its antipyretic and analgesic properties (Lee, 2013). It is a known drug which is incorporated in the list of important medications of the WHO (World health organization) and is also an extensively used drug in the environment. APAP is advised to be highly effectual and safe analgesic as well as antipyretic medicine which should be administered in an accurate manner because of its reluctant consequences (Herndon et al., 2014). In the United States, Acetaminophen is commonly known by its brand name, Tylenol which is a derivative of *N*-acetyl-*p*-aminophenol (Nourjah et al., 2006). It is nontoxic and efficacious at recommended doses, while excessive dose may contribute to liver toxicity and subsequently leads to acute liver failure (ALF). Actually, paracetamol induced liver toxicity remains the furthermost common cause of ALF in numerous nations (Lee, 2013). About 40 years, due to the APAP toxicity there have been a 46% acute liver failure (ALF) in the US (Ostapowicz et al., 2002) alone whereas, other countries like the Great Britain and Europe have publicised a percentage level of 40 and 70% respectively (Bernal et al., 2010; Stravitz et al., 2019; Ganger et al., 2018).
Despite the evidence on the high involvement of APAP in liver failure, the mechanism of action is yet unclear. With respect to drug induced hepatotoxicity, excessive attempts had been taken in order to recognize the mechanism of its lethal consequence. A common

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Comparative Study of two Arbs on Memory and Psychomotor Functions in Mild to Moderate Hypertension

Medical Science

KEYWORDS : Telmisartan, Olmesartan, cognitive functions, psychomotor functions

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ABSTRACT

In this study we evaluated the effects of two ARBs, Telmisartan and Olmesartan on memory and psychomotor functions in Indian population. Material and Methods : A Prospective, comparative, randomized, before-after, open-label study was conducted at a tertiary care hospital of Ajmer. Memory functions were evaluated with PGI Memory Scale, while psychomotor functions were evaluated with Six Letter Cancellation test and Digit Letter Substitution test. Total 101 patients (SBP≥ 140 mm hg; DBP ≥ 90 mm Hg), Group I (n=52) received Telmisartan 40 mg OD and group II (n=49) received Olmesartan 20 mg OD for 16 weeks. Wilcoxon Signed Rank test and Mann Whitney U test were used. Statistical significance was considered at P<0.05. Results : A improvement in scores of memory and psychomotor functions were observed in both the groups. A statistically significant improvement (p<0.05) was shown in 3 subtests out of 10 subtests of cognitive fuctions in telmisartan as compare to Olmesartan. Both the drugs showed significant improvement in psychomotor function tests (P<0.05). Conclusion : Telmisartan showed more improvement as compare to Olmesartan.

Introduction:

Hypertension is the most important factor that negatively affects the modalities of cerebral aging[1] and is associated with cognitive compromise in aging individuals[2]. Studies have demonstrated that hypertensives exhibit reduced cerebral blood flow and metabolism (utilization of glucose to obtain energy), particularly in certain brain regions[3].Neurochemical transmission within the brain and basic cellular functions are also affected by hypertension[4].

Experimental studies suggest that treatments targeting RAS such as Angiotensin converting enzyme inhibitors(ACEIs) and Angiotensin receptor blockers (ARBs) may have beneficial effect on cognitive decline and dementia[5]. Angiotensin receptor blockers (ARBs) may have greater neuroprotective effect than ACEIs through prevention of vascular damage induced by β-amyloid[6]. They potentially and selectively inhibit effects of angiotensin II , including angiotesin II induced contraction of vascular smooth muscles, rapid and slow pressor response ,vasopressin release, increase in sympathetic tone, enhancement of nor- adrenergic neurotransmission, changes of renal function etc.[7] In this study to compare the effects of two ARBs, Telmisartan and Olmesartan on memory and Psychomotor functions in mild to moderate hypertensive patients in Indian population.

Material and Methods:

Patient selection

Patients of 20 to 70 years with both sexes male and female who were newly diagnosed as per JNC VIII[8](SBP ≥ 140 mmHg and/or DBP ≥ 90 mmHg) or were not on any antihypertensive for at least one month, having ability to understand, read, write, and communicate in Hindi with primary knowledge of English.

Exclusion criteria for the cases were patients age less than 20 and more than 70, patients known to have psychological and behavioral disorders or any other CNS disorder that could interfere with the memory and psychomotor functions and patients on any other medications (e.g. sedatives, antipsychotics, antidepressants, antihistaminic) that are known to affect memory and psychomotor functions, patients who were unwilling and did not have ability to understand, read, write, and communicate in Hindi with primary knowledge of English, Patients who have history of significant hepatic, renal, gastrointestinal, pulmonary, musculoskeletal, endocrine, neuropsychiatric, hematologic cardiovascular disease other than hypertension, Pregnant women, lactating women and any adverse drug reaction came during the study period due to drug therapy then patients supposed to be excluded from the study .

Methodology

After institutional ethical approval, a prospective, non-randomized, Observational, before-after, open label study was conducted. After sample size calculation 45 patients in each group provided 80% power, considering withdrawl during study, we enrolled 52 patients in each group. Those who met with the inclusion and exclusion criteria were enrolled in the study. Written informed consent was obtained from the patient. 3 patients were failed to come for followup so, Group I (n=52) received Telmisartan 40 mg OD , group II (n=49) received Olmesartan 20 mg OD for 16 weeks. Patient selection, treatment or drug, dose and route were solely decided by physicians from Dept. of medicine, J.L.N. Medical College and asso. hospitals.The baseline information was collected on the day zero i.e. before starting of the drug treatment. The patients were then evaluated with the help of PGI memory scale and psychomotor function tests on day zero and after 4 months. The systolic and diastolic blood pressure was recorded by the auscultatory method with the help of sphygmomanometer every fortnightly. All the cognitive functions tests were conducted in Hindi and English language. They were conducted in particular sequence and this sequence was maintained for every subject.

Tests for memory

The PGI memory scale (PGIMS)[9] was employed to assess memory function of patients. PGI memory scale consists of ten sub-tests. The subjects were explained about the test and were relaxed. The tests were done as per the instructions of PGI memory scale and scoring according to scale was done simultaneously in the following order:

Remote memory, Recent memory, Mental Balance, Attention and concentration, Delayed Recall, Immediate Recall, Verbal retention for similar pair, Verbal retention for dissimilar pairs ,Visual retention, Recognition Psychomotor function tests: [10,11]

Six Letter Cancellation Test (SLCT) and Digit Letter Substitution Test (DLST)

Statistical analysis G*Power 3.0.10 was used to calculate the sample size. Power analysis indicated that a sample size of Total 90 patients (45 per group) would give 80% power to detect differences between groups, at an α level of <0.05 and with 95% confidence interval.Statistical significance was set at P < 0.05.Data obtained in the various tests were analyzed using Graph Pad Prism 5 softwere. Analysis of distribution of data was done using the Komolgorov--Smirnov test and Wilcoxan signed rank test was used to compare cognitive and psychomotor functions at baseline and after 4 months in each group. Mann whitney U test was used to compare the pre- and post-treatment scores of memory and psychomotor functions in between groups.

Table 1: age and sex distribtution of patients in Telmisartan and Olmesartan group

	Male	Female
20-29	0	0
30-39	3	2
40-49	4	15
50-59	12	17
60 and above	25	23
Total	44	57
	43.56%	56.44%

TABLE:2 Effect of Telmisartan on Cognitive and Psychomotor Functions

Parameter	Pre- treatment values	Post-treatment values	Mean of Differences	P-value	
Remote memory	5.58±0.572	5.59±0.63	0.019±0.64	> 0.05	NS
Recent memory	4.52±0.58	4.56±0.50	0.038±0.59	> 0.05	NS
Mental Balance	5.96±0.86	7.52±1.11	1.56±1.14	<0.05	S
Attention and concentration	8.58±1.39	10.08±1.94	1.5±1.83	< 0.05	S
Delayed Recall	6±1.29	6.48±1.11	0.48±1.12	< 0.05	S
Immediate Recall	6.52±0.88	6.75±1.15	0.23±0.96	> 0.05	NS
Verbal Retention for Similar Pairs	4.38±0.63	4.59±0.49	0.21±0.82	> 0.05	NS
Verbal Retention for Dissimilar Pairs	6.88±1.54	7.12±1.35	0.23±1.14	>0.05	NS
Visual Retention	8±1.26	8.31±1.26	0.31±1.39	> 0.05	NS
Recognition	6.52±0.91	7.56±1.13	1.04±1.31	< 0.05	S
SLCT	34.77±5.85	36.37±5.06	1.59±3.94	<0.05	S
DLST	41.12±7.83	44.28±5.84	3.17±4.41	< 0.05	S

SLCT = Six Letter Cancellation Test
DLST = Digit Letter Substitution Test
S= Significant
NS= Not significant

TABLE:3 Effect of Olmesartan on Cognitive and Psychomotor Functions

Parameter	Pre- treatment values	Post-treatment values	Mean of Differences	P-value	
Remote memory	5.63±060	5.83±0.66	0.20±0.49	> 0.05	NS
Recent memory	4.61±0.49	4.65±0.48	0.04±0.61	>0.05	NS
Mental Balance	6.04±1.02	6.78±1.17	0.73±1.08	< 0.05	S
Attention and concentration	8.96±1.65	9.26±1.90	0.30±1.62	>0.05	NS
Delayed Recall	5.78±1.30	6.55±1.28	0.78±1.36	<0.05	S
Immediate Recall	6.65±1.18	7.06±1.34	0.40±1.31	>0.05	NS
Verbal Retention for Similar Pairs	4.42±0.58	4.59±0.53	0.16±0.87	>0.05	NS
Verbal Retention for Dissimilar Pairs	7.10±1.62	7.56±1.83	0.44±1.64	> 0.05	NS
Visual Retention	7.89±1.71	8±1.90	0.10±1.37	>0.05	NS
Recognition	6.51±1.19	6.95±1.27	0.44±1.31	< 0.05	S
SLCT	33.90±5.45	35.24±4.77	1.35±2.74	< 0.05	S
DLST	40.53±7.62	41.86±7.44	1.32±2.50	<0.05	S

Table 4: Comparative study of Telmisartan and Olmesartanon cognitive and psychomotor functions

Parameter	Telmisartan	Olmesartan	p-value	
Remote memory	0.019±0.64	0.20±0.49	P > 0.05	NS
Recent memory	0.038±0.59	0.04±0.61	P >0.05	NS
Mental Balance	1.56±1.14	0.73±1.08	P < 0.05	S
Attention and concentration	1.5±1.83	0.30±1.62	P < 0.05	S
Delayed Recall	0.48±1.12	0.78±1.36	P > 0.05	NS
Immediate Recall	0.23±0.96	0.40±1.31	P >0.05	NS
Verbal Retention for Similar Pairs	0.21±0.82	0.16±0.87	P >0.05	NS
Verbal Retention for Dissimilar Pairs	0.23±1.14	0.44±1.64	P >0.05	NS
Visual Retention	0.31±1.39	0.10±1.37	P >0.05	NS
Recognition	1.04±1.31	0.44±1.31	P <0.05	S
SLCT	1.59±3.94	1.35±2.74	P >0.05	NS
DLST	3.17±4.41	1.32±2.50	P >0.05	NS

Results:

Table 1 shows the age and sex distribution of patients enrolled in Telmisartan and olmesartan group. Out of them 43.56% were male and 56.44% female. As shown in table 2, Telmisartan improved cognitive and psychomotor function tests. Out 10 , 4 sub-tests were improved significantly (P<0.05) in memory function tests and improvement in psychomotor functions (SLCT & DLST) also found significant. Effect of Olmesartan on above mentioned parameters were tabulated in table 3, it shows, 3 out of 10 subtest were improved after olmesartan administration.SLCT and DLST were also significantly improved .Table 4 shows comparative analysis of two ARBs on memory and psycho-

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motor function tests. A significant (P<0.05) change was observed in 3 out 10 subtests i.e mental balance, attention and concentration and recognition in Telmisartan group as compare to Olmesartan. Both the drugs showed significant improvement in psychomotor function tests (P < 0.05) but Telmisartan showed greater improvement as compare to Olmesartan, However, comparative results were not statistically significant.

Discussion:

Age and sex distribution shows (Table 1) that maximum hypertensive patients were of 60 and above in age and female (57) patients. In our study, an improvement in the scores of memory and psychomotor functions was observed in both the groups throughout the study period. Telmisartan significantly improved (P < 0.05) 4 out of 10 subtests and in comparison between two drugs, statistically significant improvement (P < 0.05) was seen in 3 out of 10 subtests of cognitive functions for telmisartan as compare to Olmesartan.Similarly , In a another study,[12] found that Telmisartan(40 mg) is associated with an improvement in cognitive functions, whereas Lisinopril (5 mg) could not provide any potential benefits to cognitive improvements after 12 weeks in metabolic syndrome patients. Swetha ES et al[13],also concluded that ARBs Losartan and Olmesartan at higher doses, Telmisartan at both lower and higher doses possess significant anti-anxiety property on elevated plus maze test. However other study, found that Pretreatment with a low dose of Olmesartan completely prevented beta-amyloid induced vascular dysregulation and partially attenuated the impairment of hippocampal synaptic plasticity in young Alzheimer's disease model transgenic mice (APP23 mice) with cerebrovascular dysfunction. Telmisartan is also reported to improve memory impairment of mice that had been intracerebroventricularly injected with Amyloid β [14] Additionally, Telmisartan partially induce PPARγ activity [15]. The PPARγ activation in the brain suppresses the inflammatory response in neuronal cells[16], endothelial cells[17], astrocytes, microglia[18]and also increases Amyloid-β clearance[19]. While,Olmesartan has low affinity towards PPARγ receptor [20].

Conclusion:

Long stayed hypertension is associated with cognitive decline. ARBs are claimed to have positive effect on cognitive performance. In present study, we observed that improvement in memory and psychomotor function tests was more with Telmisartan as compare to Olmesartan.

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Comparative Study of Telmisartan Alone And With Atorvastatin On Cognitive Functions In Mild To Moderate Hypertensive Patients

KEYWORDS: Telmisartan, Atorvastatin , cognitive functions.

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ABSTRACT *In this study we evaluated the effects of ARB, Telmisartan alone and with Atorvastatin on cognitive functions in hypertensives.* ***Material and Methods*** *: A Prospective, comparative, randomized, before-after, open-label study was conducted at a tertiary care hospital of Ajmer. Memory functions were evaluated with PGI Memory Scale, while psychomotor functions were evaluated with Six Letter Cancellation test and Digit Letter Substitution test. Patients (with SBP≥ 140 mm hg; DBP ≥ 90 mm Hg) devided into two groups, group I (n=52) received Telmisartan 40 mg OD and group II (n=51) received Telmisartan 40 mg OD with Atorvastatin 10 mg OD for 16 weeks. Wilcoxon Signed Rank test and Mann Whitney U test were used. Statistical significance was considered at P<0.05.* ***Results*** *: A improvement in scores of memory and psychomotor functions were observed in both the groups. A statistically significant difference (p<0.05) in both groups was shown in 2 subtests out of 10 subtests of memory functions. Both the groups showed significant improvement in psychomotor function tests (p<0.05).* ***Conclusion*** *:Telmisartan shows improvement in cognitive functions in both groups. Atorvastatin did not affect memory and psychomotor functions adversely.*

Introduction:
Studies have shown that hypertension is a risk factor for cognitive decline and dementia [1]. Angiotensin receptor blockers and Statins are frequently prescribed for cardiovascular diseases. Previous clinical studies have suggested that blockade of the RAS could prevent cognitive impairment associated with hypertension [2].Recent studies shows that angiotensin II inhibitors help to preserve cognitive functions in patients with Alzheimer's disease through a mechanism that is independent of the blood-pressure-lowering effect[3]. Relative stimulation of AT2 signaling during ARB treatment has been highlighted in terms of protection against brain damage[4]. Some ARBs like Telmisartan and Irbesartan have PPAR-γ agonistic activity[5],which is involved in prevention of brain damage by interrupting inflammatory process of brain cells[6].

Statins can also improve cognitive ability by inhibition of cholesterol synthesis[7], suppression of neurogenesis[8], increased cellular proliferation and differentiation in the dentate gyrus, also improved spatial learning[9]. But in 2014 FDA[10] released a alert that Atorvastatin can lead to cognitive impairment. The status of statins for cognitive function is still controvercial.

So, we planned to compare ARB Telmisartan alone and Telmisartan with Atorvastatin on memory and psychomotor function tests in mild to moderate hypertension.

Material and Methods:
Patient selection
Patients of 20 to 70 years with both sexes male and female who were newly diagnosed as per JNC VIII[11](SBP ≥ 140 mmHg and/or DBP ≥ 90 mmHg) or were not on any antihypertensive for at least one month, having ability to understand, read, write, and communicate in Hindi with primary knowledge of English.

Exclusion criteria for the cases were patients age less than 20 and more than 70, patients known to have psychological and behavioural disorders or any other CNS disorder that could interfere with the memory and psychomotor functions and patients on any other medications (e.g. sedatives, antipsychotics, antidepressants, antihistaminic) that are known to affect memory and psychomotor functions, patients who were unwilling and did not have ability to understand, read, write, and communicate in Hindi with primary knowledge of English, Patients who have history of significant hepatic, renal, gastrointestinal, pulmonary, musculoskeletal, endocrine, neuropsychiatric, hematologic cardiovascular disease other than hypertension, Pregnant women, lactating women and any adverse drug reaction came during the study period due to drug therapy then patients supposed to be excluded from the study .

Methodology: After institutional ethical approval, a prospective, non-randomized, Observational, before-after, open label study was conducted. After sample size calculation 45 patients in each group provided 80% power, considering withdrawal during study, we enrolled 52 patients in each group. Those who met with the inclusion and exclusion criteria were enrolled in the study. Written informed consent was obtained from the patient. One patient was failed to come for follow up so, group I (n=52) received Telmisartan 40 mg OD , group II (n=51) received Telmisartan 40 mg OD with Atorvastatin 10 mg OD for 16 weeks. Patient selection, treatment or drug, dose and route were solely decided by physicians from Dept. of medicine, J.L.N. Medical College and associated hospitals. The baseline information was collected on the day zero i.e. before starting of the drug treatment. The patients were then evaluated with the help of PGI memory scale and psychomotor function tests on day zero and after 4 months. The systolic and diastolic blood pressure was recorded by the auscultatory method with the help of sphygmomanometer every fortnightly. All the cognitive functions tests were conducted in Hindi and English language. They were conducted in particular sequence and this sequence was maintained for every subject.

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Tests for memory
The PGI memory scale (PGIMS)[12] was employed to assess memory function of patients. PGI memory scale consists of ten sub-tests. The subjects were explained about the test and were relaxed. The tests were done as per the instructions of PGI memory scale and scoring according to scale was done simultaneously in the following order:

Remote memory, Recent memory, Mental Balance, Attention and concentration, Delayed Recall, Immediate Recall, Verbal retention for similar pair, Verbal retention for dissimilar pairs ,Visual retention, Recognition

Psychomotor function tests: [13,14]
Six Letter Cancellation Test (SLCT) and Digit Letter Substitution Test (DLST)

Statistical analysis G*Power 3.0.10 was used to calculate the sample size. Statistical significance was set at $P < 0.05$.Data obtained in the various tests were analyzed using Graph Pad Prism 5 software. Analysis of distribution of data was done using the Komolgorov--Smirnov test and Wilcoxan signed rank test was used to compare cognitive and psychomotor functions at baseline and after 4 months in each group. Mann whitney U test was used to compare the pre- and post-treatment scores of memory and psychomotor functions in between groups.

Table 1: Age and sex distribution of patients:

	Male	Female
0-20	0	0
21-30	0	0
31-40	4	6
41-50	7	22
51-60	13	24
>60	14	13
Total	38(36.08%)	65(63.1%)

TABLE:2 Effect of Telmisartan on Cognitive and Psychomotor Functions

Parameter	Pre- treatment values	Post-treatment values	Mean of Differences	P-value	
Remote memory	5.58±0.572	5.59±0.63	0.019±0.64	> 0.05	NS
Recent memory	4.52±0.58	4.56±0.50	0.038±0.59	> 0.05	NS
Mental Balance	5.96±0.86	7.52±1.11	1.56±1.14	<0.05	S
Attention and concentration	8.58±1.39	10.08±1.94	1.5±1.83	< 0.05	S
Delayed Recall	6±1.29	6.48±1.11	0.48±1.12	< 0.05	S
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Verbal Retention for Dissimilar Pairs	6.88±1.54	7.12±1.35	0.23±1.14	>0.05	NS
Visual Retention	8±1.26	8.31±1.26	0.31±1.39	> 0.05	NS
Recognition	6.52±0.91	7.56±1.13	1.04±1.31	< 0.05	S
SLCT	34.77±5.85	36.37±5.06	1.59±3.94	<0.05	S
DLST	41.12±7.83	44.28±5.84	3.17±4.41	< 0.05	S

SLCT = Six Letter Cancellation Test

DLST = Digit Letter Substitution Test

S= Significant

NS= Not significant

TABLE:3 Effect of Telmisartan with Atorvastatin on Cognitive and Psychomotor Functions

Parameter	Pre- treatment values	Post-treatment values	Mean of Differences	t-value	P-value	
Remote Memory	5.53±0.73	5.74±0.72	0.22±0.78	1.899	>0.05	NS
Recent memory	4.43±0.54	4.65±0.522	0.21±0.73	2.047	<0.05	S
Mental Balance	5.96±1.02	7.35±1.23	1.39±1.15	5.429	< 0.05	S
Attention and concentration	8.82±1.60	10.25±2.31	1.43±2.17	4.098	< 0.05	S
Delayed Recall	5.98±1.25	7.20±1.61	1.22±1.53	4.539	< 0.05	S
Immediate Recall	6.62±0.96	6.86±1.13	0.24±1.08	1.440	>0.05	NS
Verbal Retention for Similar Pairs	4.49±0.50	4.67±0.48	0.17±0.65	1.877	>0.05	NS
Verbal Retention for Dissimilar Pairs	7.45±1.71	7.76±1.80	0.31±1.71	1.363	>0.05	NS
Visual Retention	8.35±1.39	8.71±1.48	0.35±1.60	1.694	>0.05	NS
Recognition	6.76±1.32	7.25±1.57	0.49±1.53	2.206	< 0.05	S
SLCT	33.71±5.74	37.14±5.13	3.43±6.83	3.052	< 0.05	S
DLST	42.29±6.74	45.39±5.32	3.10±7.10	2.827	< 0.05	S

Table 4: Comparative study of Telmisartan and Telmisartan with Atorvastatin on cognitive and psychomotor functions

Parameter	Telmisartan	Telmisartan with Atorvastatin	p-value	
Remote memory	0.019±0.64	0.22±0.78	> 0.05	NS
Recent memory	0.038±0.59	0.21±0.73	> 0.05	NS
Mental Balance	1.56±1.14	1.39±1.15	>0.05	NS
Attention and concentration	1.5±1.83	1.43±2.17	>0.05	NS
Delayed Recall	0.48±1.12	1.22±1.53	<0.05	S

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Immediate Recall	0.23±0.96	0.24±1.08	>0.05	NS
Verbal Retention for Similar Pairs	0.21±0.82	0.17±0.65	>0.05	NS
Verbal Retention for Dissimilar Pairs	0.23±1.14	0.31±1.71	>0.05	NS
Visual Retention	0.31±1.39	0.35±1.60	>0.05	NS
Recognition	1.04±1.31	0.49±1.53	<0.05	S
SLCT	1.59±3.94	3.43±6.83	>0.05	NS
DLST	3.17±4.41	3.10±7.10	>0.05	NS

RESULTS:

Table-1 shows the age and sex wise distribution of hypertensives , 63.1% were female. Table-2 shows 4 out 10 subtests were improved significantly ($p<0.05$) after Telmisartan administration and 5 out of 10 subtests were improved by Telmisartan with Atorvastatin ($p<0.05$;table-3). Comparative results revealed that improvement in Delayed recall was more with Telmisartan with Atorvastatin while subtest Recognition wasimproved more in Telmisartan alone group. Both SLCT and DLST were improved significantly in group I and II. But Interdrug comparison for groups was statistically not significant ($p>0.05$; table 4).

Discussion:

In present study 4 out of 10 subtests were improved after Telmisartan administration. After Telmisartan with Atorvastatin administration, 5 subtests were improved statistically. Interdrug comparison shows significant ($p<0.05$) difference in 2 subtests out of 10 memory function tests. Comparative analysis of psychomotor function tests reveals no statistical significant ($p<0.05$) differences between groups. Angiotensin receptor blockers (ARB) improve cognitive functions by several mechanism like, increased cerebral blood flow which was decreased by activation of renin angiotensin system activation[15].prevention of accumulation of amyloid β[16].increase release of acetylcholine for neurocommunication [17].Telmisartan is also reported to improve memory impairment of mice that had been intracerebroventricularly injected with Aβ[18].

Wincewicz D & Braszko JJ,[19] found that Telmisartan diminishes deleterious effects of chronic restraint stress on memory in a statistically significant manner ($p < 0.01$) in both, PA(Passive avoidance) situation and ORT (object recognition test). So, Telmisartan may constitute a new therapeutic option in a stress-related cognitive impairment. Other researcher[20] stated that Telmisartan provides effective neuroprotection against dopaminergic cell death through PPAR-γ activation. Telmisartan protects against cognitive decline via up-regulation of BDNF/TrkB (tropomyosin related kinase B) in the hippocampus of hypertensive rat , partly because of PPAR-gamma activation independent of blood pressure-lowering effect[21].

Statins also improves memory functions by several way apart from cholesterol lowering effect,statins have shown promise in enhancing neurogenesis. Both simvastatin and atorvastatin have been shown to enhance neurogenesis in the dentate gyrus following traumatic brain injury in rats which was associated with increased vascular endothelial growth factor (VEGF) and brain-derived neurotrophic factor (BDNF) expression , increased cellular proliferation and differentiation in the dentate gyrus and improved spatial learning[9] , reduced delayed neuronal death in the hippocampus [22].

Zhao L et al,[23] found that administration of Atorvastatin ameliorated the cognitive deficits, depressed the inflammatory responses, improved the (long term potentiation) LTP impairment. It also prevents Aβ25-35-induced neurotoxicity in cultured hippocampal neurons. In contrast, another study[24] found that statins use has been associated with more cognitive impairment. So the status of statins in cognitive function is still controvercial.

Conclusion:

Improvement in cognitive functions was observed throughout the study period. Telmisartan improves cognitive functions probably due to PPARγ activity, it significantly improved ($p < 0.05$) 4 out of 10 subtests and with Atorvastatin improvement was seen in 5 out of 10 subtests of PGI memory scale which were statistically significant ($p < 0.05$). Comparative analysis shows, both the treatment groups had almost similar effect on cognitive functions. Atorvastatin does not affect memory and psychomotor functions adversely.

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Original Article

A Study on Critical Review of Drug Promotional Literature Using the WHO Guidelines

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Abstract

Background: Drug promotion refers to all the informational and persuasive activities of the pharmaceuticals, which include the activities of medical representatives, drug package insert, provision of gift and samples, conducting or organize seminar, etc. However, promotion of drug by ethical way is important because it may influence the irrational drug prescriptions.

Objective: The objective of this study was to evaluate and analyze the drug promotional literature distributed by pharmaceutical companies to physicians using the World Health Organization (WHO) criteria for ethical medicinal drug promotion.

Materials and Methods: A total of 100 drug promotion literatures were evaluated collected from the various outpatient departments and evaluated according to the WHO criteria for drug promotion.

Results: Among 100 drug promotional literatures (DPLs), a total of 109 drugs were promoted. However, only 33% of DPLs gives side effect, precaution, contraindication, and warning and only 10% of DPLs gives drug interaction information. None of the DPLs fulfills all criteria of who drug promotion.

Conclusion: Information on the DPLs given only focus on the positive aspect of the drugs and not fulfill all the WHO criteria of drug promotion.

Key words: Drug promotional literature, Review, WHO

INTRODUCTION

According to the World Health Organization (WHO), drug promotion refers to "all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase, and/or use of medicinal drugs" (WHO 1988).[1] For the promotion of many new drugs, pharmaceutical companies are using drug promotional literatures (DPLs).[2] Many studies conducted previously concluded that increased promotion is usually associated with increased sales.[3]

All promotion making claims about drugs should be accurate, informative, up to date, and ethical. They should not contain misleading, false and biased statements (WHO 1988). Pharmaceutical companies promote their products as best and better to existing to which physician are familiar. However, many times due to inadequate, inaccurate, and false information from DPLs lead to irrational drug prescription and for physicians, many times DPLs are only source for updating their knowledge about the existing and novel drugs.[4,5]

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MATERIALS AND METHODS

An observational cross-sectional study conducted by the Department of Pharmacology at Ananta Institute of Medical Sciences and Research Centre from January 2019 to March 2019. DPLs were collected from the outpatient department (OPD) of a tertiary care center attached Ananta institute of medical sciences and Research Centre from January 2019 to February 2019. Printed DPLs promoting allopathic drugs were collected from OPDs of medicine, pediatrics, skin, psychiatry, ophthalmology, obstetrics and gynecology, otorhinolaryngology, and orthopedics. 100 drug promotional literature included in the study according

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to exclusion criteria. DPLs were evaluated using the WHO criteria by the following parameters:

1. The names of the active ingredients using either international non-proprietary names or approved generic names of the drugs.
2. The brand names.
3. Amount of active ingredients per dose.
4. Other ingredients known to cause problems, i.e., adjuvant.
5. Approved therapeutic uses.
6. Dosage form or dosage schedule.
7. Safety information including side effects and major adverse drug reactions, precautions, contraindications, and warnings and major drug interactions.
8. Name and address of manufacturer or distributor.
9. References to scientific literature appropriate.

Exclusion criteria: DPLs promoting.

- Drugs other than allopathic drugs,
- Medicinal devices.
- Equipment.

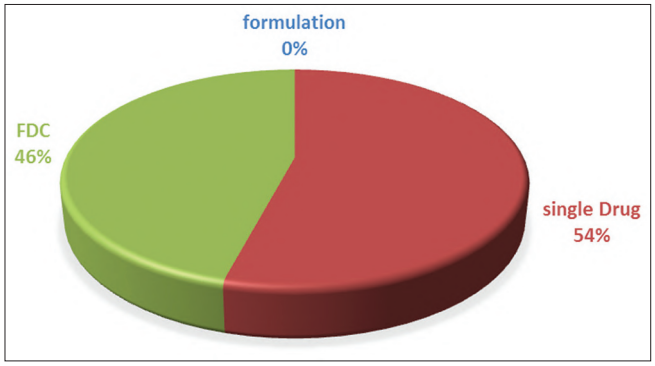

Figure 1: Distribution according to drug formulation

RESULTS

A total of 100 DPLs evaluated. A total of 109 drugs were promoted from 100 DPLs. Among them, 59 (54%) were prompted as single drug formulations and 50 (46%) promoted as fixed drug combinations [Figure 1].

Majority of drug promoted in collected DPLs were from drug act on endocrine system 36 (33%) followed by cardiovascular system 20 (18%). There were only 3% DPLs of drugs acting on kidney and 4% of respiratory system [Figure 2].

Of 100 DPLs, 63 (63%) DPLs promoted one active compound formulation and 37 (37%) DPLs promoted >1 active compound formulation [Figure 3].

None of the DPLs fulfilled all the WHO criteria. Active ingredient generic name, brand name, and dosage detail were presented in all DPLs (100%). Only 33 (33%) DPLs showed side effect and 33 (33%) showed precaution, contraindication, and warning. Few of total collected DPLs showed drug interactions 11 (11%) [Table 1].

Of 100 DPLs, 30 DPLs had not shown any references for their claim and 70 DPLs showed their references. Among 70 DPLs which provide references for their claim where consider from various National and International Journals. Some of the DPLs also had given more than 1 references. Journal references about 40% were before 2010 [Figure 4].

For attractive presentation of DPLs, companies are using picture on drug promotional literature. Of 100 DPLs, 23 (23%) DPLs not given any picture, but majority of 77 (77%) were given the picture on DPL. Among these

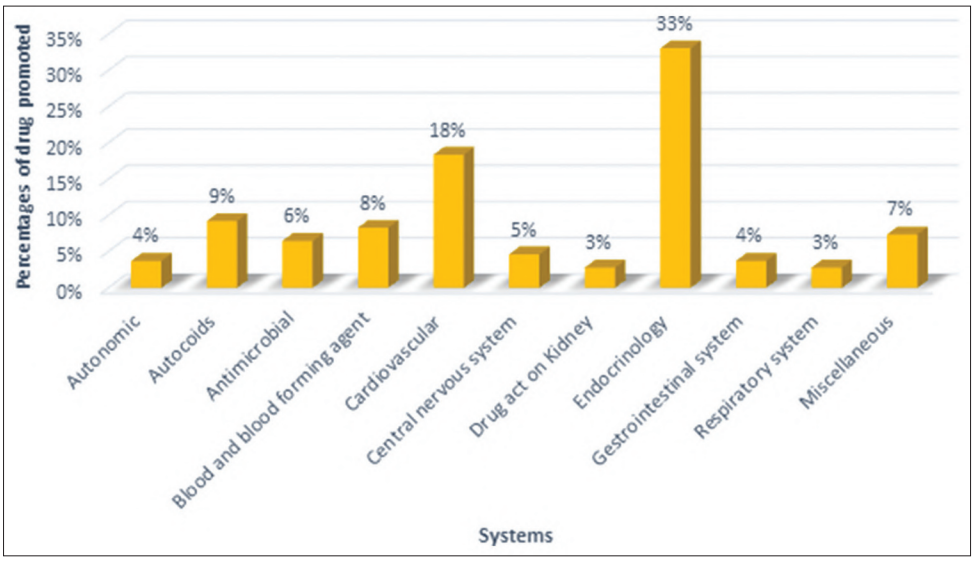

Figure 2: System-wise classification of drugs promoted in drug promotional literatures

77 literature, majority of picture were not relevant to disease and promoted drug 59 (77%). Only 18 (23%) DPLs presented with disease or drug-related picture.

DISCUSSION

The pharmaceutical industries have the right to promote its products, but it should do in ethical manner and promotional claims need to be reliable, truthful, informative, balanced, and up to date. However, while promoting their products, pharmaceutical industries do not adhere to these ethical principles it may influence irrational use of drugs.[6]

Table 1: WHO criteria for drug promotional literature

WHO criteria for drug promotional literature	Information available in DPL *n*=100 (%)
Active ingredient-generic name of drug	100 (100)
The brand names	100 (100)
Amount of active ingredients per dose	100 (100)
Other ingredients known to cause problems, i.e., adjuvant	5 (5)
Approved therapeutic uses	89 (89)
Dosage form or dosage schedule	100 (100)
Side effects	33 (33)
Drug interaction	11 (11)
Precautions, contraindications, and warnings	33 (33)
Name of manufacturer or distributor	93 (93)
Address of manufacturer or distributor	42 (42)
References to scientific literature appropriate	70 (70)

WHO: World Health Organization, DPLs: Drug promotional literatures

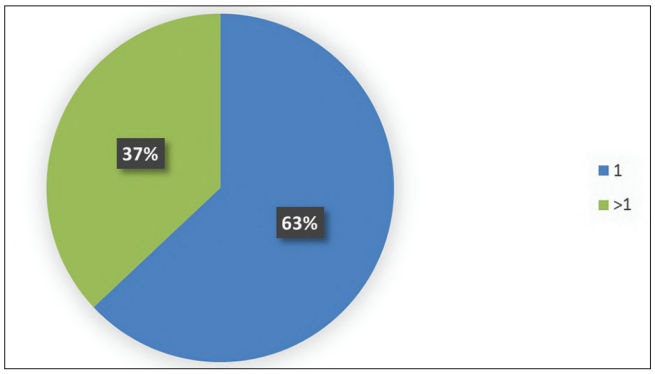

Figure 3: Distribution according to the number of drugs promoted in drug promotional literatures

In the present study, 100 DPLs evaluated. A total of 109 drugs were promoted from 100 DPLs. Of 109 drugs, 59 (54%) were prompted as single drug formulations and 50 (46%) promoted as fixed drug combinations which are similar finding as the study conducted by Jadav *et al.*, of 224 drug promoted, 54% were single component and 46% FDCs.[4]

In the present study, drug promoted from collected DPLs, majority of drug promoted in from drug act on endocrine system 36 (33%). In other studies, chemotherapy agents and cardiovascular drugs are promoted more which was different from the present study.[2,7]

In our studies show that none of the DPLs fulfill the WHO criteria which is similar finding as other studies.[2,7,8,9] Active ingredient that is generic name, brand name, and dosage detail were presented in all DPLs (100%), but other prescription information such as side effect precaution, contraindication, and warning were presented only on 33% of DPLs, drug interaction presented only in 11% of DPLs. This information is very important for rational use of drug but not available in majority of the DPLs. The study conducted by Sonwane *et al.* same shows that side effect, major drug interaction, precaution, contraindication, and warning were mentioned in only 31% which is also match with other studies.[8]

Of 100 DPLs, among 70 DPLs, majority of reference are from journal articles (93%), but among them 40% of references from before 2010. Hence, recent data about product are not given. Moreover, catchy words such as "best one" and "the only" are not available in given references. DPLs are colorful and attractive, but the picture provided on it majority were not related with disease and promoted drug.

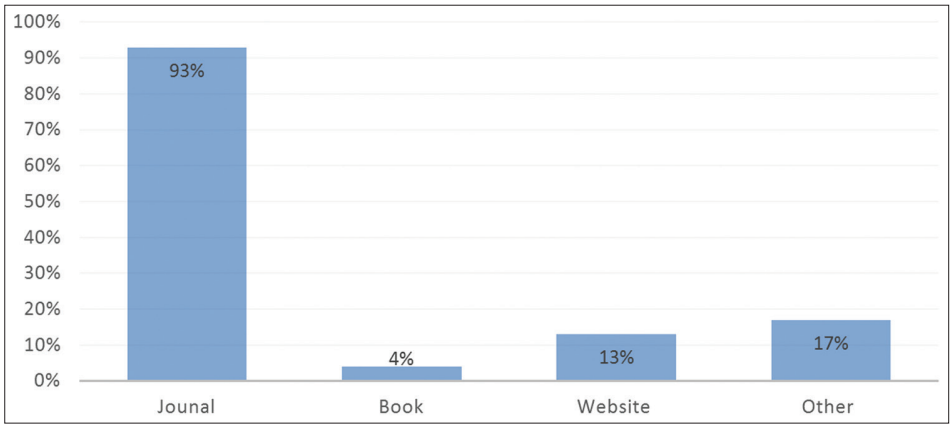

Figure 4: References given in drug promotional literatures

CONCLUSION

None of the Drug promotional literatures fulfilled all criteria of WHO for drug promotion. Promotion mainly focuses on the positive aspect of drug not the negative aspect such as side effects, contraindications, and drug interaction.

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RESEARCH ARTICLE

Impact of Educational Training and Workshop on knowledge, attitude, and practice of pharmacovigilance in nursing staff of tertiary care hospital, Rajasthan

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ABSTRACT

Background: Pharmacovigilance program of India plays an important role for monitoring of adverse drug reaction (ADR) in patients. However, due to lack of knowledge about pharmacovigilance among health-care professionals, underreporting of ADR observed. **Aims and Objectives:** This study aims to involve, inspire, and encourage the nursing staff to report error – free adverse drug event that meets both the needs and legitimate expectations. **Materials and Methods:** A predesigned questionnaires based cross-sectional study conducted by the Department of Pharmacology among nursing staff working at tertiary care hospital. Participants were given pre-test and post-test with ADR form filling before and after educational Interventional lecture, respectively. For data analysis, Chi-square with yet correction was applied. **Results:** A total of 30 nursing staff participants involved in questionnaires based study. An overall knowledge about pharmacovigilance ranging from 10% to 53% which was lower rang except knowledge about what is ADR was 83% in pre-test. Positive attitude toward pharmacovigilance also low ranges from 23% to 53%. Only 12% of participants were report the ADR. Majority of participant had obtained average score in ADR form filling. After educational intervention, improvement seen in knowledge, positive attitude and majority of participants fall under good score for ADR form filling. **Conclusion:** Improvement in knowledge and attitude was seen after educational intervention for pharmacovigilance among nurses.

KEY WORDS: Pharmacovigilance; Knowledge; Attitude; Practice; Nurses

INTRODUCTION

Pharmacovigilance, according to the World Health Organization, is defined as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems."[1] Pharmacovigilance Programme of India (PvPI) initiated nationwide in July 2010 by Central Drugs Standard Control Organization. IPC Ghaziabad is the national coordinating center for monitoring adverse drug reaction (ADR) in the country to safeguard public health. Majority of the health-care professional are not aware about this development. Hence many times, they are not reporting or late reporting of ADR.[2]

Early reporting and rapid dissemination of information regarding ADRs are two important tasks in pharmacovigilance. Voluntary reporting of ADRs by health-care professional can make the above task easy. Reason for underreporting is lack of training and awareness of this issue like where to report and whom to report as is shown by the poor knowledge of the health-care professionals, especially the nursing staff. Motivation and training of health-care professional toward pharmacovigilance will improve ADR reporting.[3,4]

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MATERIALS AND METHODS

A questionnaire-based cross-sectional study conducted by the Department of Pharmacology in nursing staff working at Ananta Institute of Medical Sciences and Research Center, Rajsamand, Rajasthan. A total of 30 nursing staffs were involved. Questionnaires were pre-designed. Initially, pre-knowledge, attitude, and practice (KAP) questionnaires were given to all nursing staff after that a one hour interventional lecture was given which includes detail about ADRs and PvPI. After completion of interventional lecture, a workshop for how to fill-up ADR form conducted. Initially, in workshop, one ADR patient case was given and then nursing staff fills the ADR form. After that, they taught about how to fill-up the ADR form. After completion of interventional lecture and workshop, post-KAP questionnaire and ADR form were given to participants. Pre-test and post-test data were analyzed using Chi-square test with yet correction from website *quantpsy.org.* ADR filling form analysis was done using Microsoft Excel 2013.

RESULTS

The KAP study on pharmacovigilance before and after interventional lecture and workshop was done on the nursing staff of this institute. In this present study, a total 30 nurses were participated and fill-up pre- and post-test questionnaires and ADR reporting form.

Assessment of Knowledge toward Pharmacovigilance Pre- and Post-test – Educational Intervention

Knowledge about the pharmacovigilance assessed using questionnaires listed in Table 1. Out of 30 participants, only 16 (53%) heard about the pharmacovigilance. Only 8 (27%) participants know what is pharmacovigilance? (Correct definition of pharmacovigilance). Majority of participants 25 (83%) know about the ADR. Only 15 (50%) know who can report the ADRs. Among all participants, only 3 (10%) know about the location of national coordinator center of PvPI and only 8 (30%) know about the regulatory body of PvPI in India. About 12 (40%) participants know about the pharmacovigilance committee in this institute. After educational interventional lecture the knowledge of participants significantly increased and that was statistically significant ($P < 0.5$) [Table 1].

Assessment of Attitude toward Pharmacovigilance

Attitude toward pharmacovigilance is assessed by questionnaires listed in Table 2. Out of 30 participants, 13 (43%) believe that ADR reporting is professional obligation. Only 8 (27%) participants believe in necessity of ADR reporting, but after educational interventional lecture, majority of participants 29 (97%) believe in necessity of ADR reporting. About half of the participants 16 (53%) think that ADR reporting increase patient safety. Only 7 (23%) participants say that ADR monitoring center

Table 1: Knowledge about pharmacovigilance pre- and post-test analysis

Knowledge questions	Correct response		*P*-value
	Pre-test *n*=30, *n* (%)	Post-test *n*=30, *n* (%)	
Have you ever heard about the name pharmacovigilance program of India?	16 (53)	30 (100)	<0.5
What is pharmacovigilance?	8 (27)	27 (90)	<0.5
In general, what is ADR?	25 (83)	26 (87)	<0.5
Health-care professional responsible for reporting ADR in a hospital is/are?	15 (50)	29 (97)	<0.5
PvPI monitoring center (National Coordination Center) located at	3 (10)	26 (87)	<0.5
Name the regulatory body of PvPI in India	9 (30)	25 (83)	<0.5
Is any pharmacovigilance committee in your hospital/college?	12 (40)	29 (97)	<0.5

ADR: Adverse drug reaction, PvPI: Pharmacovigilance Programme of India

Table 2: Attitude toward pharmacovigilance questionnaires based pre- and post-test analysis

Attitude questions	Positive response (yes)		*P*-value
	Pre-test *n*=30, *n* (%)	Post-test *n*=30, *n* (%)	
Do you think ADR reporting is a professional obligation?	13 (43)	22 (73)	<0.5
Do you think ADR reporting is necessary?	8 (27)	29 (97)	<0.5
Do you think ADR reporting will increase patient safety?	16 (53)	27 (90)	<0.5
What is your opinion about establishing ADR monitoring center in every hospital? Should in every hospital Not required in hospital	7 (23)	24 (80)	<0.5
Do you think pharmacovigilance should be taught in detail to health-care professionals?	12 (40)	25 (83)	< 0.5

ADR: Adverse drug reaction

Table 3: Analysis of practice for pharmacovigilance

Practice questions	Pre-test (%)
Have you ever seen ADR during clinical posting?	26 (86)
Have you ever-reported ADR?	4 (12)
What is reason for not reporting?	12 (40)
(a) Not aware about the presence of ADR monitoring center	18 (60)
(b) Did not know how to report ADR	

ADR: Adverse drug reaction

Table 4: ADR form filling analysis

ADR reporting form score	Pre-test (%)	Post-test (%)
Poor score	5 (25)	1 (5)
Average score	16 (80)	5 (25)
Good score	7 (35)	14 (70)
Excellent score	2 (10)	10 (50)

ADR: Adverse drug reaction

requires in every hospital. About 12 (40%) participants think that pharmacovigilance should be taught in detail to health-care professionals. Change in positive attitude toward pharmacovigilance seen after educational interventional lecture which was statistically significant ($P < 0.5$).

Assessment of Practice of Pharmacovigilance

Practice of pharmacovigilance assessed by questionnaires listed in Table 3. Out of 30 participants majority of participants 25 (83%) had seen ADRs, but only 5 (17%) participants report ADRs. Among all participants, majority of participants 18 (60%) give a reason for not reporting ADR was they were not knowing how to report an ADR.

ADR Reporting Form Filling

ADR reporting form filling was done by participant before and after workshop. Analysis of ADR form filling was done by total scoring from 20 marks. If obtained marks were between 1 and 5, then it categorized poor scoring, 5–10 marks then average score, and 10–15 score then good score, and between 15 and 20 marks then excellent score. Detail of analysis is given in Table 4. During pre-test, majoring of participants fall under average score 16 (80%) after workshop for ADR form filling majority of participants fall under good score 14 (70%) [Table 4].

DISCUSSION

Lack of knowledge about the pharmacovigilance is one of the factors responsible for the underreporting of ADR.[5,6] Voluntary ADR reporting by health-care professional play a key role for success of pharmacovigilance.[7] Nursing practices mainly come under administration of the drug. The administration of medications to the patients is one of the most common routine procedures in the practice of nursing professionals. In this, the nurse assumes the important responsibility that aims to ensure patient safety through the safe and accurate administration of prescribed medication.[8]

Nurses having an important role in pharmacovigilance activities, particularly identifying ADR in patients and they are available round the clock with indoor patients. However, lack of knowledge about the pharmacovigilance and lack of external motivation by the institute to report ADR influence the underreporting by nursing professionals.[8,9] This study was planned for improvement in knowledge and attitude and practice for pharmacovigilance by nursing staff that will improve patient safety.

The present study shows that half of the participants have knowledge about who can report ADR, only 27% of participants know about what is pharmacovigilance and only 30% know about the regulatory body of PvPI in India, after educational interventional lecture, improvement in knowledge is seen 90% and 85%, respectively. A study conducted by Goel shows that only 30.6% of participants know about pharmacovigilance, 25% of participate know about regulatory body of pharmacovigilance program and after educational intervention improvement in 99% and 86%, respectively, seen which is comparable to our study.[10]

The present study shows that of 30 participants, 43% believe that ADR reporting is professional obligation. However, positive response improves to 73% after educational intervention. Only 27% of participants give positive attitude toward the necessity of ADR reporting, but after educational intervention, majority of participants (97%) give positive attitude for the same. A study by Goel shows comparable results for the same about 29.6% before and after educational intervention 97.9%, respectively.[10] About half of the participants (53%) think that ADR reporting increases patient safety which was change to positive attitude for 90% of participants for the same.

The present study seen that majority of participants (83%) seen ADR in clinical posting, but only few participant reports the ADR (12%), the result of the study conducted by Vural *et al*. shows that only 8% of nurses report the ADR which is comparable to our study.[11] Majority of participates give a reason for not reporting ADR was do not know how to report ADR.

The present study shows significant improvement in knowledge and attitude in post-test after educational intervention and also shows improvement in ADR form filling. KAP studies for pharmacovigilance concluded that nurses having lack of knowledge and poor practice regarding the pharmacovigilance so need of regular interventions like workshop about pharmacovigilance needed.[12,13]

CONCLUSION

Improvement in knowledge and attitude after educational intervention of pharmacovigilance was seen among nurses. This indicated ADR training workshop, detail of pharmacovigilance during undergraduate course will be useful to improve KAP among nursing professionals which is helpful for patient safety through pharmacovigilance program.

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RESEARCH ARTICLE

A correlative study of serum uric acid and serum malondialdehyde level in early essential hypertension

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ABSTRACT

Background: Hypertension (HT) posing a major public health challenge to the universe in socioeconomic and epidemiological transition. Hyperuricemia in HT is coupled with augmented cardiovascular morbidity and mortality. It also predates the development of HT and suggests that it is not simply a consequence of HT *per se*. Increased urate level along with greater production of oxygen-free radical and augmented oxidative stress may contribute to progression of HT. **Aims and Objectives:** This study aims to assess the correlation between serum uric acid (SUA), serum malondialdehyde (S. MDA) level, and blood pressure in early essential HT. **Materials and Methods:** In this cross-sectional study, after applying inclusion and exclusion criteria, 200 subjects were divided into three groups: 50 subjects as control group, 75 in prehypertensive group, and 75 in hypertensive group. SUA and S. MDA level were estimated in all subjects. Data were analyzed by appropriate statistical methods. **Results:** A significant and positive correlation was observed between SUA and S. MDA level in HT group. Both parameters were correlated positively and significantly with systolic blood pressure (SBP), but not with diastolic blood pressure (DBP) in hypertensive individuals. **Conclusion:** An elevated SUA level is predictive for the evolution of both HT and coronary artery disease. Hyperuricemia plays a role in the formation of free radicals and oxidative stress through increased lipid oxidation. Furthermore, positive correlation with SBP further established its potential role in the etiopathogenesis of essential HT.

KEY WORDS: Essential Hypertension; Hyperuricemia; Serum Malondialdehyde Level; Lipid Peroxidation; Oxidative Stress

INTRODUCTION

Essential hypertension (HT) is being increasingly documented as a part of a complex multifaceted disorder worldwide due to its high incidence and associated risks of renal and cardiovascular disease (CVD), for instance, stroke, myocardial infarction, and heart failure. The effective union between HT and hyperuricemia has been documented for more than a century. Studies from the 1950s and 1960s demonstrated the incidence of hyperuricemia in hypertensive cases to be between 20 and 40%.[1] Later on, it was found that an increasing level of serum urate is an autonomous risk factor of HT.[2]

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Raised serum uric acid (SUA) level is also associated with increased cardiovascular morbidity and mortality rate.[3] Its level is thoroughly controlled by the balance among uric acid production and excretion.[4] Urate is freely filtered in the glomerulus, reabsorbed, secreted, and then again reabsorbed in the proximal tubule. Essential HT may also be linked with hyperuricemia with normal renal functions.[5] Hyperuricemia (>5.5 mg/dl [330 μmol/L]) was detected in almost 90% of teenagers with primary HT, whereas uric acid levels were

significantly lower in controls and youth with any white coat or secondary HT.[6] The finding that uric acid levels were not lifted in secondary HT also cuts down the probability that the hyperuricemia resultants from HT.

There are abundant reports that oxidative stress is amplified in patients with HT. Further, the extreme production of reactive oxygen species (ROS) due to raised urate level, out stripping antioxidant defense mechanisms, has been involved in pathophysiological conditions that influence on the cardiovascular system.[7] Moreover, ROS react with membrane lipids to yield lipid hydroperoxide, a destructive process known as lipid peroxidation. Lipid hydroperoxide decomposes to build various products containing malondialdehyde. In the present study, serum malondialdehyde (S. MDA) was used as a biochemical marker for the assessment of lipid peroxidation.

The significance of both SUA and S. MDA level in the development of essential HT has not been thoroughly investigated, especially in Southern Rajasthan. Hence, this study has been designed to study the correlation between SUA, S. MDA level, and blood pressure among newly diagnosed essential HT.

MATERIALS AND METHODS

This cross-sectional case–control study was conducted among 200 subjects in the Department of Physiology, Geetanjali Medical College and Hospital (GMCH), Udaipur. All the subjects were chosen randomly from medicine outpatient department, family members or attendants of established hypertensive patients, individual's comings to hospital for health checkup, and healthy volunteers such as clinical and non-clinical staff of a tertiary care hospital. This study was ethically approved by the institutional ethical committee of GMCH, Udaipur (Ref. No. GU/UCE/EC/2013/299 dated15/05/2013).

Inclusion Criteria

All the sex-matched subjects, aged between 20 and 50 years old were broadly divided into three groups:

- 50 participants with normal blood pressure (systolic blood pressure [SBP] = 90–119 mmHg and diastolic blood pressure [DBP] = 60–79 mmHg) were taken as control group
- 75 cases of prehypertension (preHT) (SBP = 120–139 mmHg and DBP = 80–89 mmHg) were taken as preHT group
- 75 cases of newly diagnosed cases of essential HT (SBP = 140–159 mmHg and DBP = 90–99 mmHg) were taken as HT group.

Exclusion Criteria

The subjects suffering with gout, diabetes mellitus, gestational HT, and/or secondary HT caused by renal disorders, metabolic disorders, fluid volume disturbances, endocrinal disorders, etc., were excluded from the study groups. Smokers, alcohol consumers, and patients on medication for HT were also excluded from the study. After diagnosis, a written informed voluntary consent was taken from all the participants after explaining their participation in the study in their local language. All the data from three groups were collected in the detailed pro forma along with required physical examination. For biochemical analysis, blood sample (5 ml) was drawn after an overnight fasting (12 h) by venous puncture and serum was separated by centrifugation at 3000 rpm for 10 min. SUA level and S. MDA were estimated using commercially available reagents or kits.[8,9]

Statistical Analysis

The data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 16. Significance testing of difference for mean of three groups was done by analysis of variance test (ANOVA). $P < 0.05$ was used to establish statistical significance. The correlation between different parameters was assessed by Pearson coefficient of correlation test.

RESULTS

Figures 1 and 2 showing that the difference in mean of SUA level and S. MDA level between control, preHT, and HT group was highly significant ($P < 0.0001$). Table 1 shows that SUA level was significantly and positively correlated with SBP

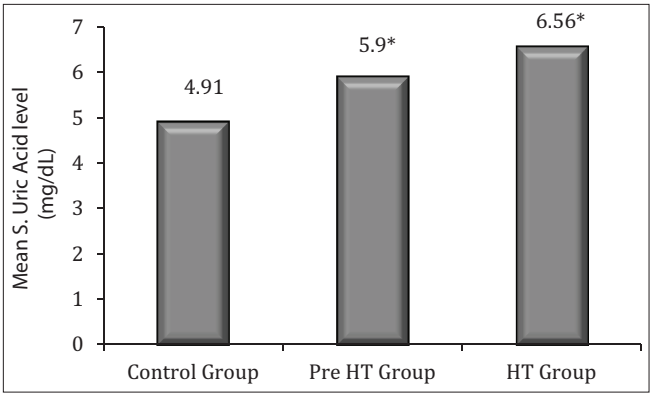

Figure 1: Comparison of mean serum uric acid level among different groups (*significant with $P < 0.001$)

Table 1: Correlation of serum uric acid levels with various parameters

Parameters	Control group		Hypertension group	
	r value	*P* value	*r* value	*P* value
SBP	−0.234	NS	+0.478	<0.001
DBP	−0.230	NS	+0.202	NS
S. MDA	+0.236	NS	+0.574	<0.001

S. MDA: Serum malondialdehyde, SBP: Systolic blood pressure, DBP: Diastolic blood pressure

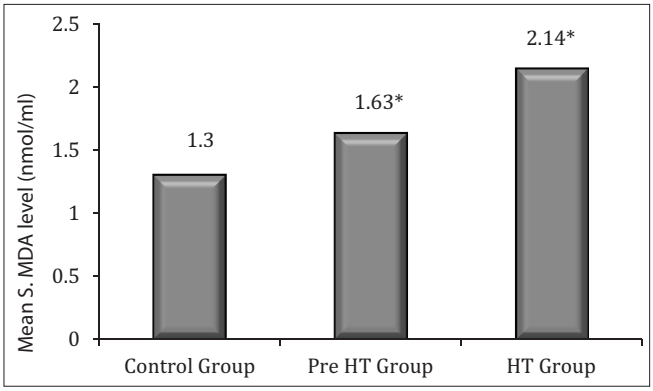

Figure 2: Comparison of mean serum malondialdehyde level among different groups (*significant with $P < 0.001$)

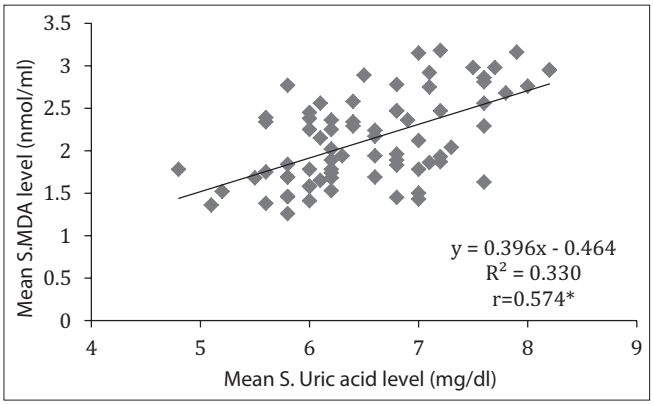

Figure 3: Correlation between serum uric acid levels and serum malondialdehyde levels (*significant with $P < 0.001$)

(r = +0.478, $P < 0.001$) and S. MDA (r = +0.574, $P < 0.001$), whereas no significant correlation was found with DBP ($P > 0.05$). Figures 3-5 showed that S. MDA was significantly and positively correlated with SBP (r = +0.486, $P < 0.001$) and SUA (r = +0.574, $P < 0.001$), whereas no significant correlation was found between S. MDA and DBP ($P > 0.05$).

DISCUSSION

In this study, we found that the mean of SUA level and S. MDA level in hypertensive group was significantly higher as compared to prehypertensive and controls ($P < 0.001$). The increased trend in mean SUA level was observed from control to prehypertensive and prehypertensive to hypertensive cases [Figures 1 and 2]. Results also showed that SUA and S. MDA were significantly and positively correlated with each other and SBP ($P < 0.001$), whereas no significant correlation was observed with DBP ($P > 0.05$) for the same.

Masuo *et al*. assessed the linear relationship of SUA and SBP and showed an average raise of 23 mmHg per 1 mg/dl increase in SUA within non-obese young men.[10] Another study on 125 children (age group 6–18 years) with essential HT proved the association of SUA with SBP (r = 0.80) and DBP (r = 0.66).[6] In support to our study, Acharya and Mishra found that S. MDA level was significantly and positively correlated

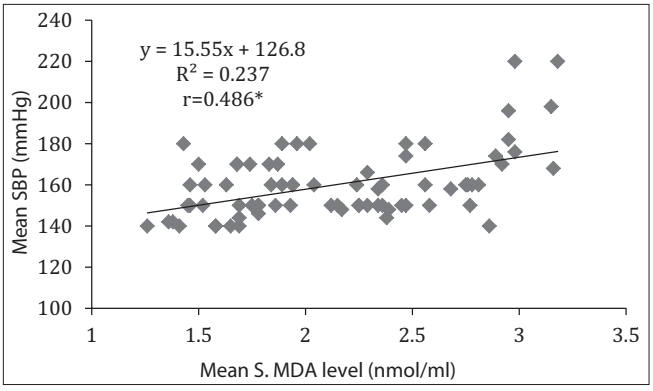

Figure 4: Correlation between serum malondialdehyde levels and systolic blood pressure (*significant with $P < 0.001$)

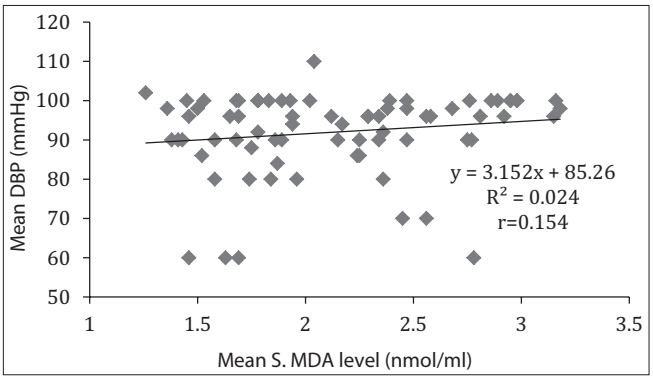

Figure 5: Correlation between serum malondialdehyde levels and diastolic blood pressure (*significant with $P < 0.001$)

with SBP (r = +0.364, $P < 0.01$) and SUA level (r = +0.289, $P < 0.05$). They found no significant correlation between S. MDA and DBP.[11] Amirkhizi *et al*. assessed the oxidative stress marker related to atherosclerosis in prehypertensive women. Regarding MDA level, they attained that MDA was positively correlated with both SBP (r = +0.24, $P < 0.001$) and DBP (r = +0.18, $P < 0.001$).[12] Ouppatham *et al*. examined the relationship of hyperuricemia and blood pressure in the Thai army population and observed a significant and positive correlation between both SUA levels and SBP (r = 0.186, $P < 0.001$) and same with DBP (r = 0.255, $P < 0.001$).[13] However, Teng *et al*. described a contrary result, wherein uric acid was associated with the risk of HT in the elderly.[14]

Hyperuricemia is commonly experienced with essential HT, even untreated HT. Studies in animal models proposed that hyperuricemia may be predominantly important in early HT[15] and likewise studies in humans illustrated that the strongest relationship of hyperuricemia is with premature HT such as discovered in adolescents.[6] Contrary to these findings, a number of studies have recommended that the association between elevated SUA and cardiovascular risk does not carry on after rectifying for other risk factors.

Experimental studies provide a credible physiologic mechanism by which increases in SUA might cause HT. Uric acid enters vascular smooth muscle cells, where it stimulates

mitogen-activated protein kinases, cyclooxygenase-2, and platelet-derived growth factor to stimulate vascular smooth muscle proliferation and preglomerular arteriolopathy.[15,16] Increased SUA further causes an increase in juxtaglomerular renin production and a decrease in macula densa neuronal nitric oxide (NO) synthase expression, leading to renal vasoconstriction and probably increasing blood pressure.[17] If renal vasoconstriction persistent, it may impart to arteriosclerosis and the exploitation of salt-sensitive HT, even if the hyperuricemia is rectified.

In addition, SUA plays a role in the formation of free radicals and may elucidate the link between hyperuricemia and HT.[18] Augmented intracellular uric acid may accelerate oxidative stress directly by raising NADPH oxidase linked ROS or generated by stimulation of xanthine oxidase during the generation of uric acid as well. Oxidative stress may contribute to the generation and/or development of HT through a number of probable mechanisms included (a) curbing of the vasodilator NO by ROS such as superoxide, (b) production of vasoconstrictor lipid peroxidation products, (c) diminution of tetra hydrobiopterin (BH4), an important NO synthase cofactor, (d) structural and functional changes within the vasculature.[19]

Experimentally, by means of which, hyperuricemia results in HT are by way of oxidative stress, endothelial dysfunction, and activation of the renin angiotensin system. The net effect is to provoke renal and systemic vasoconstriction and the progression of HT. Increase in SUA has been demonstrated as an earlier marker of HT, which occurs even before the modification in serum creatinine.[18]

Limitations

As the present study is hospital-based case–control study, so to establish these results to the population of Southern Rajasthan, large sample size should be taken.

CONCLUSION

From the above discussion, it can be concluded that increased serum MDA in hypertensive indicates an association between increased oxidative stress and HT. SUA through lipid peroxidation might be processing toward the etiopathogenesis of essential HT even in its former stages, and its serum level may be a modifiable factor for progression of the disease. Measuring these biomarkers in clinical practice may identify high-risk individuals. Further, the maintenance of the oxidative balance and SUA in hypertensive patients would be helpful in preventing the CVD and other diseases associated with HT.

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STUDY OF SERUM LIPID PROFILE IN REPRODUCTIVE AND POST MENOPAUSAL WOMEN.

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Conflict of interest: No conflict of interest.

Abstract

According to WHO estimates, 16.7 million people around the globe die of cardiovascular disease each year. Economic transition, urbanization, industrialization and globalization bring about life style changes that promote heart disease. High blood pressure, high cholesterol and obesity are likely to become more prevalent in developing countries. Increased energy intake and sedentary lifestyle are also responsible for heart disease. The presence of one or more cardiovascular risk factors like high levels of TC, LDL, TG, glucose, insulin, BMI and a decreased HDL have been found to increase the progression of prehypertension to hypertension. Prehypertension increases the risk of MI and CAD. The present study was undertaken to know serum lipid profile changes in reproductive and postmenopausal women. Total 60 Subjects of age group 20-45years (reproductive), 46-60years (postmenopausal) female volunteered for our study. During the study period, BMI, Lipid profile, parameters were recorded in all the subjects. In BMI, TC, LDL, VLDL, TG, is gradually increased, HDL is gradually decreased from reproductive age women to post menopausal women. Dyslipidemia occurs due to multifactorial reasons like physical activity, life style, diet, smoking, alcohol consumption, ethnicity and genetic makeup. Post-menopausal women are at increased risk of developing cardiovascular disease due to change in the lipid pattern and loss of cardioprotective effect of estrogen. Predicting the factors affecting the lipid profile in post-menopausal women, adopting strategies to control these mechanisms by modifying the relative risk factors during menopausal transition may improve the cardiovascular risk profile in these women.

Keyword: Lipid profile, Menopause, Reproductive age group.

Introduction:

Menopause is the cessation of menstrual cycle in women. It represents a transitional phase in the natural biological woman's age, a natural event that marks the end of the reproductive years of women in terms of the menstrual cycle permanently stopped and the resulting stop ovarian function in females [1]. Most of the women at this stage suffer from a variety of symptoms due to hormonal changes and these symptoms are possible to be severe and frequent, some women have more severe symptoms and others do not suffer from any symptoms at all [2]. Menopause is an oestrogen deficient state characterised by permanent amenorrhoea lasting for a period of 1 year due to the cessation of ovarian functions.[3] There is considerable variation in the level of estrogen in postmenopausal women occurs during the early postmenopausal years because of continued secretion of estradiol from the ovary and conversion of androstenedione to estrone in fat tissue.[4] In young women, where oestrogen production is high, serum lipids are normal but after menopause, lipid levels are increased resulting in increased incidence of coronary heart diseases. This shows the possible relationship among oestrogen, normal lipid profile and atherosclerosis and the relative immunity to coronary artery diseases (CAD).[5] Natural menopause confers a 3 fold increase in CAD risk and postmenopausal women account for > 30% of the female population at risk for CAD in India.[6,7]. Circulating Serum Cholesterol, Low Cholesterol (LDL-C) and Serum Triglycerides are major

risk factors of this disease. The incidence of cardiovascular disease after menopause may partly be due to changes in the plasma lipid level that occurs following menopause.(8,9) The modification of profile may be important both in the prevention and control of coronary heart disease(10) . Estrogen leads to the increased risk of cardiovascular diseases after menopause, as evidenced by reduction in the cardiovascular diseases after hormone replacement therapy. Estrogen replacement therapy, through an effect on the blood vessel wall and on serum lipids, also appears to stabilize existing atherosclerotic plaques. Antithrombotic therapy, exercise and smoking cessation also contribute to reduced risk of cardiovascular disease in older women(11). In order to contribute to the better understanding of lipid profile status in postmenopausal women, the present study was conducted to estimate the serum levels of total cholesterol (TC), triglyceride (TG),high density lipoprotein cholesterol (HDL-C), low density lipoprotein cholesterol (LDL-C), very low density lipoprotein cholesterol (VLDL-C), and atherogenic index and compare it with premenopausal women.

Material and Methods:

The present study was undertaken to know serum lipid profile changes in reproductive and postmenopausal women. Healthy subjects with no evidence of metabolic or endocrinal abnormalities, hypertension or coronary heart disease were selected randomly for reproductive and post menopausal age group consisting of 30 subjects in each group .Total 60 Subjects of age group 20-45years (reproductive), 46-60 years (postmenopausal) female volunteered for our study. During the study period, anthropometric, biochemical dietary intake and physical activity and parameters were recorded in all the subjects.

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Study groups includes

Group-1: 30 Reproductive age women

Group-2: 30 Postmenopausal women

Inclusion Criteria:

Suitable subjects, who accept to take part in this research,

Subjects with no history of any chronic disorder,

Reproductive age women with a history of regular menstrual cycle.

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The following subjects are excluded from the study:

Smokers, Alcoholics,Obese individuals those who are on exogenous hormone replacement therapy or lipid lowering drugs

Subjects with the following chronic disorders are also excluded:

- Cardiovascular disease and hypertension,

- Diabetes mellitus, •

- Hepatic, thyroid, renal, and gall bladder diseases

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Venous blood samples (5 ml) were collected from 60 subjects after an overnight fast for determination serum lipid profile. The serum was separated within 2 hours of blood collection using a centrifuge at 1000 rpm for about 20 minutes at room temperature. Estimation of Total cholesterol (TC) ,Triglycerides(TG) and (High densitylipoprotein)HDL was carried out using enzymatic method. Low density lipoprotein (LDL), VLDL were also estimated. BMI was calculated (measured as weight in kilograms divided by square of height in meters). Lipid profile was compared in 2 groups. The data collected in this study was analyzed statistically by computing the descriptive statistics viz .mean, standard deviation, The 'P' value ≤ 0.05 was considered as statistically significant.

Results:

Table 1: Shows the mean, standard deviation, for age difference in 2 age groups.

Age	Reproductive age group (20-45 years) n=30	Post menopausal age group (46-60) n=30
Mean	33.24	54.33
Standard Deviation	6.90	2.27

Table 2: shows values of Lipid profile parameters in Reproductive age group and Post menopausal age group

Parameters	Post menopausal age group (46-60 years) n=30		Reproductive age group (20-45 years) n=30		P value
	Mean	SD	Mean	SD	
BMI	25.74	2.88	23.11	2.64	0.0005095
TC mg%	206.53	59.84	170.3	36.34	0.0063077
HDL mg%	43.13	6.49	55.33	41.27	0.1151860
LDL mg%	124.43	70.24	102.63	27.48	0.1188853
VLDL mg%	35.6	10.65	25.5	6.94	< 0.00001
TG mg%	162.76	68.01	129	33.98	0.0180973

In both groups from reproductive to post menopausal women BMI, TC, LDL, VLDL, TG, is gradually increased. HDL is gradually decreased from reproductive to post menopausal women, it is statistically significant.

Discussion

In the present study there was a significant difference in BMI, TC, LDL, HDL, VLDL ,TG, Diet, physical activity with significant p value of <0.05 Estrogen has a beneficial effect on lipid metabolism .Estrogen reduces the degradation of HDL by inhibiting the enzymatic action of lipoprotein lipase. So in the presence of estrogen there will be more amount of HDL in the reproductive women. Ovaries are the only source for estrogen in the women and these ovaries become inactivated and the source of estrogen is reduced in the postmenopausal women. So the postmenopausal women have more degradation of HDL when compare to reproductive women so the HDL levels are decreased in the post menopausal women. Post menopausal women had higher had higher TC, and lower HDL levels. **Goswami K and Bandyopadhyay A** showed that HDL cholesterol was significantly decreased in post menopausal women and significant rise in TC and LDL –cholesterol[12]. **Gandhi BM** showed Triglycerides in plasma increased with age [13]. **Bonithon-kopp** concluded that total cholesterol and LDL cholesterol significantly increased in postmenopausal women[14]. **Nerbrand et al, smiti nanda et al** suggested that loss of endogenous sex steroids contribute substantially to increased atherogenic lipid profile[15]. **Bhagya et al** concluded that total cholesterol increases significantly with age and the significant rise in LDL is mainly due to hormonal levels in post menopausal women[16]. Our study group being otherwise normal subjects .Assessing the presence of major CVD risk factors in women of particular importance, since it would allow us to promptly identify persons at high risk for development of clinical CVD later in life. We concluded the presence of normal lipid profiles and Cardio protective HDL is normally higher in prepubertal females. Lower levels of HDL increases CVD risk. This can be attributed mainly to sedentary life style, stress and dietary habits this is seen in post menopausal women.

Conclusion:

From our study it is evident that the mean values of total Cholesterol, LDL were higher and HDL was lower in menopausal women due to estrogen deficiency when compared with reproductive age group women. Dyslipidemia occurs due to multifactorial reasons like physical activity, life style, diet, smoking, alcohol consumption, ethnicity and genetic makeup. So further extensive studies with importance to the duration following menopause need to be done to understand the underlying mechanism

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STUDY OF SERUM LIPID PROFILE IN REPRODUCTIVE AND POST MENOPAUSAL WOMEN.

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Menopause is the cessation of menstrual cycle in women. It represents a transitional phase in the natural biological woman's age, a natural event that marks the end of the reproductive years of women in terms of the menstrual cycle permanently stopped and the resulting stop ovarian function in females [1]. Most of the women at this stage suffer from a variety of symptoms due to hormonal changes and these symptoms are possible to be severe and frequent, some women have more severe symptoms and others do not suffer from any symptoms at all [2]. Menopause is an oestrogen deficient state characterised by permanent amenorrhoea lasting for a period of 1 year due to the cessation of ovarian functions.[3] There is considerable variation in the level of estrogen in postmenopausal women occurs during the early postmenopausal years because of continued secretion of estradiol from the ovary and conversion of androstenedione to estrone in fat tissue.[4] In young women, where oestrogen production is high, serum lipids are normal but after menopause, lipid levels are increased resulting in increased incidence of coronary heart diseases. This shows the possible relationship among oestrogen, normal lipid profile and atherosclerosis and the relative immunity to coronary artery diseases (CAD).[5] Natural menopause confers a 3 fold increase in CAD risk and postmenopausal women account for > 30% of the female population at risk for CAD in India.[6,7]. Circulating Serum Cholesterol, Low Cholesterol (LDL-C) and Serum Triglycerides are major

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Original research article

Study of Lipid profile, Liver enzymes and Haematological parameters in alcoholic individuals.

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Abstract

Context: Alcohol consumption has been steadily increasing all over world, especially in India. Alcohol can cause physical, mental and social effects which is determined by quantity and pattern of alcohol drinking.

Aim: Present study was conducted to observe alterations in the biochemical and haematological parameters in heavy alcohol consumers.

Subjects and Method: 40 young males of 20-40 years age with history of daily alcohol consumption for past one to five years duration were included in study .Estimation of the biochemical and haematological parameters were carried out in study and control subjects**.**

Statistical Analysis: Analysis of the haematological and biochemical parameters data of the study subjects and controls was done by using student t test

Results: Lipid profile parameters were not altered in study subjects .Liver enzymes AST and ALT were significantly elevated in alcoholic subjects. Hemoglobin and platelets was lower in alcoholic subjects. Mean corpuscular volume was significantly higher in alcoholics.

Conclusion: These alterations of liver enzymes and haematological parameters in alcoholics can be used as early indicator of alcohol abuse and person can be motivated to stop alcohol consumption.

Key words: Alcoholics, Lipid profile, Liver enzymes, Hemoglobin

Introduction

Alcohol is not often thought as a drug largely because its use is common for both religious and social purposes in most parts of world. However , it is a drug and of all the drugs , alcohol is the only drug whose self induced intoxication is socially acceptable. Compulsive drinking in excess has become modern society's one of the most serious problems [1] . Alcohol has been widely consumed through ages because of its perceived benefits as a social lubricant and for relaxation , mood alteration and sensory pleasure . But long term consumption of large amount is harmful leading to addiction and fatal or non fatal injuries . Alcoholism is a worldwide social and medical problem . Over the past 30-40 years , alcohol consumption has increased in quantity and frequency [2] . The age at which people start drinking has also declined. Consumption of alcohol in young people has created concern as alcoholism may run a greater risk of alcoholic problems in later life [3] .All organs can be damaged due to direct effects of alcohol, especially the digestive and nervous systems . At the level of

digestive system , alcohol causes gastrointestinal problems , cirrhosis of liver , pancreatitis and cancer of mouth , pharynx and oesophagus . At level of nervous system it causes problems with reflexes , vision , equilibrium of the body , lesions of nerves [4] . Alcohol has numerous adverse effects on various types of blood cells and their functions [5]. Other effects include loss of appetite, vitamin deficiency , infection , sexual impotence and menstrual irregularities. The diagnosis occurs when the adverse effects are already obvious and recognizable[6]. Effective and low cost methods are now available for identification and treatment of alcohol addiction at an early stage . They include various haematological and biochemical parameters. Some of the commonly studies parameters are Aspartate amino transferase (AST), Alanine amino transferase (ALT) , Alkaline Phosphatase, and haemoglobin (Hb%) , Mean corpuscular volume (MCV) , Mean corpuscular Haemoglobin (MCH) . Combination of one or more of these markers has been reported to give better sensitivity and diagnostic accuracy characterizing the early events leading to alcoholic disease at later stage. Earlier studies have shown the once the alcohol consumption is stopped at earlier stage, the alteration are reversed, thus altering the pathway of morbidity and mortality and ensure a disease free life to the individual.

The present study was done to identify the alteration in serum lipid profile, liver enzymes (AST, ALT) and haematological parameters like haemoglobin (Hb%) Mean corpuscular volume (MCV) , Mean corpuscular Haemoglobin (MCH) , platelet counts in asymptomatic young alcoholic individuals of 20-40 years age group, which were considered as a heavy drinkers with history of consumption of alcohol for one to five years.

Material and methods:

This case control study was conducted in November 2019 to February 2020 . The study was done by obtaining blood and serum samples from study and control subjects . The samples were drawn in morning under aseptic precautions after over night fast . The study group consisted of 40 subjects and 40 control subjects . They were selected on the basis of following inclusion and exclusion criteria.

Inclusion criteria:

Male subjects aged 20-40 years with history of heavy alcohol consumption for duration of one to five years .

Exclusion criteria :

Person with following disorders were not included in study.

- Hypertension
- Diabetes mellitus
- Malignant condition
- Cardiovascular and respiratory disorders
- Individual on medication
- Smokers

Collection of blood samples , which is invasive procedure and need overnight fasting was explained to the subjects in detail. Subjects unconditionally gave consent to participate in study. The study complied with the Declaration of Helsinki and protocol was approved by the institution review board.

Method of collection of data.

- A questionnaire was given to the subjects and controls to elicit the details of alcohol consumption , history of past or present illness [7] .

- The average number of alcohol drinks consumed per mouth was asked .Daily consumption of six or more drinks (> 90 ml daily) was defined as heavy drinker [8] .
- Height and weight was recorded . Body mass index was calculated.
- Vital parameters like pulse rate , Blood pressure was recorded .Detail examination of cardiovascular , Respiratory system , Abdomen and Central nervous system was done.
- Under aseptic precautions 4 ml of blood was drawn from anterior cubital vein .2ml was taken in EDTA bulb for estimation of Haematological parameters and 2 ml was taken in a plain bulb for estimation of lipid profile and liver enzymes in blood .
- Serum lipid profile and liver enzymes were estimated by using Biochemistry Analyzer.
- Haematological parameters were measured by using Automated hematology Analyzer.
- Following parameters were studied .

1) Lipid profile - Total cholesterol (TC) ,High density lipoprotein cholesterol (HDL-C) ,low density lipoprotein cholesterol (LDL-C) , Very low density lipoprotein cholesterol (VLDL-C), and Triglycerides TL.
2) Liver enzymes - Aspartate amino transferase (AST) , Alanine amino transferase (ALT) , Alkaline Phosphatase .
3) Haematological parameters like haemoglobin (Hb %) , Mean corpuscular volume (MCV) , Mean corpuscular Haemoglobin (MCH) , platelet counts

Statistical Analysis :

Analysis of the haematological and biochemical parameters data of the study subjects and controls was done by using student t test [9,10] . p value was calculated , $p < 0.05$ was considered significant and $p < 0.01$ was considered highly significant , > 0.05 was considered not significant .

Results :

The results obtained were expressed as Mean ± Standard deviation . p value was calculated

Anthropometric data

The table 1 shows anthropometric data of the study subjects and controls . There was no significant difference in Age , Weight , Height , BMI between study and control groups.

Table 1 : Anthropometric data of control and study subjects .

Anthropometric Parameters	Control subjects Mean ± SD (n = 40)	Study subjects Mean ± SD n = 40	P value	Significance
Age (Years)	30.8 ± 2.8	31.48 ± 3.22	> 0.05	Not Significant
Weight (Kg)	60 ± 7.23	63.36 ± 4.24	> 0.05	Not Significant
Height (Cm)	165.3 ± 7.2	163.4 ± 5.82	> 0.05	Not Significant
BMI (Kg/ m^2)	22.82 ± 2.54	23.24 ± 2.24	> 0.05	Not Significant

Vital data

Resting pulse rate :

The Mean ± SD of pulse rate at rest in control was 76.24 ± 3.26 beats / minute and in study subject was 72 ± 4.32 beats / minute .There was no significant difference in the resting pulse rate between the two groups.

Blood Pressure :

The Mean ± SD systolic blood pressure at rest in controls was 122.24 ± 4.26 mm Hg and 124.42 ± 6.18 mm Hg in study subjects .

The Mean ± SD diastolic blood pressure was 78.62 ± 4.24 mm Hg in control and 76.34 ±3.82 mm Hg in study subjects.
There was no significant difference in Blood Pressure between study and control group.

Lipid Profile :

The lipid profile data of study and controls are shown in Table 2.

Table 2: Lipid profile data of control and study subjects .

Parameters of Lipid Profile (mg/dl)	Control subjects Mean ± SD (n = 40)	Study subjects Mean ± SD (n = 40)	P value	Significance
Total cholesterol	210 ± 36.24	218.18 ± 32.46	> 0.05	Not Significant
HDL-cholesterol	42.46 ± 6.48	40.24 ± 8.21	> 0.05	Not Significant
LDL-cholesterol	140.18 ± 32.78	138.24 ± 30.68	> 0.05	Not Significant
VLDL-cholesterol	26.82 ± 10.26	27.76 ± 11.34	> 0.05	Not Significant
Triglycerides	148.72 ± 48.26	150.36 ± 44.34	> 0.05	Not Significant

There was no significant difference between the serum lipid profile parameters between study and control subjects.

Liver enzymes :

The data of liver enzymes of study and controls are shown in table 3.

Table 3: Liver Enzymes data of control and study subjects

Liver enzymes (IU/L)	Control subjects Mean ± SD (n = 40)	Study subjects Mean ± SD (n = 40)	P value	Significance
AST	21.38 ± 6.72	34.42 ± 7.26	<0.01	Highly Significant
ALT	16.84 ± 8.03	25.76 ± 9.34	<0.05	Significant
Alkaline Phosphatase	62.76 ± 11.42	60.82 ± 9.34	>0.05	Not Significant

AST levels were more in alcoholic subjects as compared to control subjects and this difference was statistically highly significant .
ALT levels were significantly higher in alcoholic subjects as compared to control group subjects.
There was no significant difference in alkaline phosphatase levels between the two groups.

Haematological parameters :

Table 4: Haematological parameters of study and controls .

Haematological parameters	Control subjects Mean ± SD (n = 40)	Study subjects Mean ± SD (n = 40)	P value	Significance
Haemoglobin (gm/ dl)	13.64 ± 1.24	11.34 ± 1.05	<0.05	Significant
Mean corpuscular volume(fL)	84.76 ± 5.37	92.84 ± 6.24	<0.01	Highly Significant
Mean corpuscular aemoglobin(pg)	31.86 ± 1.24	32.241.18	>0.05	Not Significant
Platelet count (lac /mm^3)	2.75 ± 0.67	2.01 ± 0.48	<0.01	Highly Significant

Haemoglobin was lower in study subjects .There was significant difference in haemoglobin levels in study and control group subjects .The Mean corpuscular volume of the study subjects was significantly higher as compared to controls. There was no significant difference in Mean corpuscular Haemoglobin values between two groups. Platelet count was lower in the study subjects as compared to control subjects and this difference was highly significant.

Discussion :

This study was conducted to find the effects of alcohol abuse in young adults of 20-40 years age group with history of heavy consumption of alcohol for duration of one to five years .The effects of alcohol intake on serum lipids and lipoprotein depends on the dose and mode of alcohol intake , individual susceptibility , genetic variables and dietary factors .In heavy drinkers the synthesis of VLDL is stimulated .Even short term use of alcohol stimulate lipoprotein lipase activity in adipose tissue and consequently the concentration of VLDL in plasma stays normal or is even subnormal . There is increased transport rate of VLDL particles as a result of high lipoprotein lipase activity results in upregulation of HDL receptors [11].

In our study , lipid profile parameters like Total cholesterol , HDL cholesterol LDL cholesterol and triglycerides were studied .We observed that there was no significant alteration in the lipid profile parameters between control and study subjects. This findings correlates with the previous study done by T. Oduaola et al in which there was no association between alcohol intake with total cholesterol levels [12]. Similar observation were also found in a study conducted by Marita Passilta et al in which there was no difference in HDL-C and LDL-C concentration between controls and in those with highest alcohol intake [13]. However , Vaswani . M et al in their study found values of Total cholesterol , HDL-C , VLDL-C , Triglycerides except LDL-C were higher in alcohol dependents as compared to non dependent subjects . Similarly study by John .B Whitfield et al , showed that the triglycerides levels were increased with increasing alcohol intake . Studies by J.B Ruidavets et al and Hans Hoffmeister et al , found that blood levels of HDL- C increased with increasing alcohol intake [14,15] . The above studies were conducted in people with history of longer duration of alcohol consumption of greater than 5 years , which may be reason for the alteration in lipid profile in these subjects . Our results showed no alteration in lipid profile as our subjects were exposed to shorter duration of one to five years . In our study we studied the liver enzymes like SGOT , SGPT , and alkaline phosphatase .We observed that the liver enzymes SGOT , SGPT were significantly higher in study subjects as compared to controls . Alkaline phosphatase did not alter in both groups. Osaretin Albert Taiwo Ebuehi et all in a study found the activities of SGOT , SGPT Alkaline phosphatase of heavy drinkers were higher as compared to moderate drinkers and non drinkers [16] .An association between liver disease and heavy alcohol consumption was recognised more than 200 years ago [17] . The liver is particularly susceptible to alcohol related injuries .Since liver is the major site of alcohol metabolism .Alcohol is broken down in liver and free radicals are generated .Liver injury is caused by direct toxicity of free radicals [18]. When hepatocytes are damaged , they leak enzymes in to blood .Hence level of liver enzymes in plasma is important indicator of liver dysfunction .

Various haematological parameters like Haemoglobin content , Mean corpuscular volume , Mean corpuscular haemoglobin and Platelets were studied in our study. Haemoglobin was lower in alcoholic subjects as compared to controls subjects and this difference was statistically significant. Anemia was found in a study conducted by Subir Kumar Das et al , Latvala J et al and Louis.W Sullivan et al [19,20,21] . A number of clinical observation in man have suggested that alcohol may act as a haematological toxin in body. In our study MCV was higher in study subjects as compared to controls and this was statistically highly

significant. Platelets count was lower in study subjects as compared to controls and this difference was statistically highly significant. A study conducted by John Lindenbaum et al , showed a marked decrease in platelet count in alcoholics [22]. David Savage et al found an increase of MCV and lower platelet counts much more commonly associated with heavy alcoholic intake [23] .

The adverse effects of alcohol on Haemopoietic system are both direct and indirect . Direct effect of alcohol consumption include toxic effects on bone marrow and blood cell precursors. The indirect effect include nutritional deficiencies like folic acid and other vitamin resulting in macrocyte of red blood cells .Alcohol intake can interfere with a late stage of platelet production by suppressing the maturing megakaryocytes . Alcohol also shorts the life span of existing platelets .

Conclusion :

The present study concludes that consumption of alcohol for duration of one to five years may not alter the levels of lipid parameters in body .Liver enzymes were increased in heavy drinkers as compared to non alcoholics . Anaemia is commonly observed in alcoholics. There alteration can be considered as early indicater of alcoholism . These changes are found to be reversible once alcohol consumption is stopped as observed by many researchers .Therefore awareness should be created among public regarding major health problem associated with alcohol intake .This will help to lesser the damage and better recovery of alcoholic individuals .

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Original Article

Physiology Section

Hyperuricaemia – A Potential Indicator to Diagnose the Risk of Essential Hypertension

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ABSTRACT

Introduction: Hypertension has turned out to be the major cause of morbidity among the life style diseases. Studies in human and animal models have documented an independent association of hyperuricaemia with early hypertension. Hyperuricaemia is a modifiable and treatable risk factor, which might reduce the incidence of Essential Hypertension (EHT).

Aim: Hence, the present study was designed to find out the association between hyperuricaemia and EHT in the population of Southern Rajasthan as there is a dearth of literature on Indian scenario especially in Rajasthan.

Materials and Methods: A cross-sectional, case control study was carried out in the Department of Physiology among 125 subjects; aged 20-50 years of both sexes, which were chosen randomly from Medicine OPD and healthy volunteers. The subjects were broadly divided into two groups (A & B); group A comprised of newly diagnosed cases of EHT (n=75) and group B had healthy normotensive controls (n=50). S. Uric Acid (SUA), Serum creatinine and fasting blood glucose levels were estimated by using the respective kit methods on semi auto-analyser in both groups. S. creatinine and fasting blood glucose levels were estimated to exclude renal disorder and diabetes mellitus respectively. The data was analysed by student t-test, chi-square test and Odds Ratio.

Results: The mean SUA level in group A was significantly higher than group B (6.56 ± 0.76, 4.91 ± 0.97 mg/dl, $p<0.001$ respectively). 37.33% of patients had hyperuricaemia in group A as compared to 14% in group B ($p<0.01$, OR=3.66) indicating that a hyperuricaemic individual has 3.66 times more risk of developing EHT as compared to the one with lower value of SUA.

Conclusion: The mean SUA level and the frequency of hyperuricaemia was significantly higher in newly diagnosed cases of EHT as compared to healthy controls. Hence, SUA could be useful as a potential indicator for early risk detection of development of EHT.

Keywords: Primary hypertension, Preclinical hyperuricaemia, Serum uric acid, Southern Rajasthan

INTRODUCTION

Hypertension has emerged as a major public health problem in developing as well as developed countries. It is very common among the population, affecting 1 in 3 adults worldwide [1] which translates to nearly one billion in absolute numbers in the year 2000 and this is expected to grow to more than 1.5 billion by 2025 [2]. Increasing prevalence of hypertension is a documented public health problem in India as it predisposes to cardiovascular diseases [3,4]. A recent study by Sachdev, among tribal population of Rajasthan has shown 16% to 30% prevalence of hypertension among different tribes [5]. In 1870, Frederick Mohamed was the first to note the association of Serum uric acid (SUA) and Essential Hypertension (EHT) [6] and a recent re-evaluation of the Framingham Heart Study data has also suggested that a higher SUA level is associated with increased risk of hypertension [7]. Further, studies have even shown that hyperuricaemia is more commonly associated with primary EHT than in secondary hypertension, at least in adolescents [8]. Traditional modifiable risk factors have been extensively evaluated but there is a pressing need to identify additional treatable risk factors that are easily measured and highly prevalent in general population. Hyperuricaemia could be such potentially modifiable & treatable risk factor, which might reduce the incidence of EHT.

AIM

Hence, the present study was designed to establish the association between the SUA and risk of development of EHT in the population of Southern Rajasthan as there is dearth of literature for Indian scenarios especially in Rajasthan.

MATERIALS AND METHODS

The present study is a part of a bigger project carried out in the Department of Physiology of a tertiary care hospital. This cross-sectional, case control study included 125 subjects, chosen randomly from Medicine OPD and healthy volunteers like clinical and nonclinical staff of a hospital and individuals comings to hospital for health checkup during August 2013 to July 2014.

On the basis of a pilot study in our hospital, we calculated the incidence of new cases of hypertension to be 35%. We also found out the percentage of healthy controls, after meeting all the inclusion and exclusion criteria, to be around 22%. The sample obtained, was proportionally divided into cases and controls in the ratio of approximately 3:2.

All the age matched (20-50 years) and sex matched subjects were broadly divided into two groups (A&B); group A comprised of newly diagnosed cases of EHT (n=75) whereas group B had healthy normotensive controls (n=50). The subjects with gout, diabetes mellitus, gestational hypertension and/or secondary hypertension caused by renal disorders, metabolic disorders, fluid volume disturbances, endocrinal disorders etc. were excluded from both the groups. Smokers, alcohol consumers and patient using medication for hypertension were also excluded from both the groups.

After obtaining the ethical clearance from the institutional ethical committee, the data from both the groups were collected in a detailed proforma along with requisite physical examination. The biochemical parameters; SUA, Serum creatinine and fasting blood glucose levels, were estimated in both groups, for which 3 ml of blood was drawn after an overnight fast (12 h) by venous puncture. After clotting of blood, serum was separated by centrifugation at 3000 rpm for 10 minutes and used for biochemical analysis. The SUA level was measured on semi auto-analyser by Modified Trinder method [9]. Serum creatinine and fasting blood glucose levels, were estimated by Jaffe's Method [10] and enzymatic method, using Glucose Oxidase (GOD) and Peroxidase [11] respectively.

Serum creatinine and fasting blood glucose levels, were estimated to exclude renal disorder and diabetes mellitus respectively.

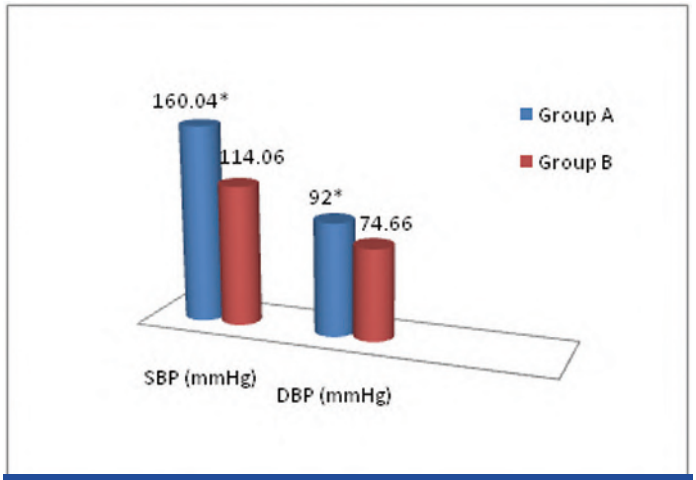
STATISTICAL ANALYSIS

The data was analysed by using Statistical Package for the Social Sciences (SPSS) Version 16.0. Association between EHT and hyperuricaemia was tested by Chi-square test and Odds ratio. Comparison of mean SUA level between group A and group B was tested by Student t-test.

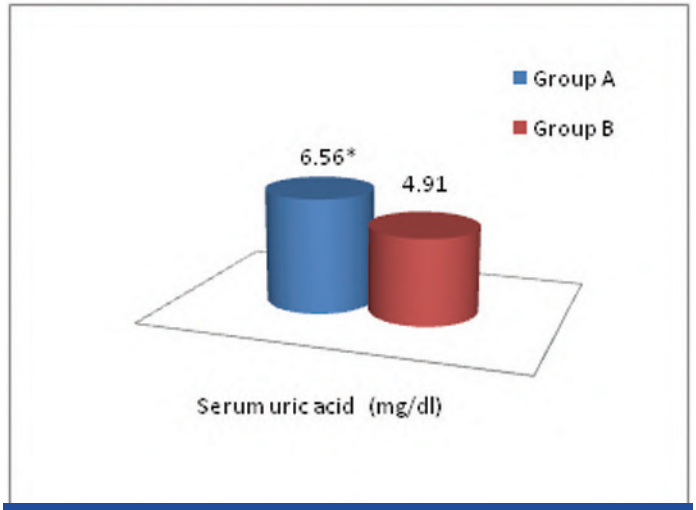
RESULTS

The mean age of group A and B were 40.25 ± 7.71 and 37.46 ± 8.09 years respectively (p<0.001). The mean systolic BP was 160.04 ± 16.77 mmHg and 114.06 ± 5.79 mmHg and the mean diastolic BP was 92.0 ± 10.15 mmHg and 74.66 ± 6.23 mmHg in group A and B respectively. The difference in mean systolic and diastolic BP was statistically significant (p<0.0001) between the two groups [Table/Fig-1].

In addition, we found that the mean SUA level was 6.56 ± 0.76 mg/dl and 4.91 ± 0.97 mg/dl in group A & B respectively, which was significantly higher in group A as compared to group B (p<0.001) [Table/Fig-2]. [Table/Fig-3] shows distribution of the study subjects according to hyperuricaemia in group A and group B.



[Table/Fig-1]: Mean systolic & diastolic blood pressure in both the groups.
* p<0.0001



[Table/Fig-2]: Comparison of SUA level between group A and B.
* p<0.001

Particulars	Total no. of subject	Subject with Hyperuricaemia	Percentage	Odds Ratio	p-value
Group A	75	28	37.33%	3.66	<0.01
Group B	50	7	14%		

[Table/Fig-3]: Distribution of the study subjects according to hyperuricaemia in group A and group B.
Odds Ratio (OR) = 3.66, p-value <0.01, p value reached from Chi-square test

Hyperuricaemia is defined as plasma uric acid level greater than 6.8 mg/dl at physiological temperature (37°C) and neutral pH [12].

DISCUSSION

As we know that a number of factors could affect blood pressure but they cannot completely explain the cause of EHT, which hints towards some unidentified risk factors associated with it. Since 1870, high SUA, a kind of purine metabolite, has been linked with EHT but of late it has just become diagnostic indicator of gout and renal functions, losing its significance in the pathogenesis of hypertension, cardiovascular and cerebrovascular diseases. From past centuries, a large number of epidemiological and clinical trials [7,8,13-15] have confirmed that the increased level of SUA is closely related to hypertension and other cardiovascular and cerebrovascular diseases but the lost significance of this indicator has led to surgence of the present study.

This study reflects the preclinical hyperuricaemia, as a potential risk factor for the development of EHT. An increasing trend was observed in mean serum uric acid level from control to hypertensive cases (p<0.001). These results were in concordance with several other studies which have also quoted significant increase in SUA level in essential hypertensive cases [16-19].

Further, the number of individuals with hyperuricaemia were significantly higher in group A than group B. This finding is in concurrence with other studies, which also reported 30.6% (OR= 2.13, p<0.05) and 28.8 % (OR=2.55, p<0.001) cases had hyperuricaemia with EHT respectively [16,17]. These results indicate a definite association between hyperuricaemia and EHT.

Hence, preclinical hyperuricaemia is a predictive tool for early detection of risk of development of hypertension. Several mechanisms have been suggested on the role of hyperuricaemia in the induction of systemic hypertension. Elevated SUA level lowers the endothelial nitric oxide level, by reducing nitric oxide synthase in the macula densa of the kidney with activation of renin-angiotensin system and mediates renal vasoconstriction that leads to uric acid mediated hypertension [13,20]. Persistent renal vasoconstriction may contribute to arteriosclerosis and the development of salt sensitive hypertension, even if hyperuricaemia is corrected [21]. This mechanism was demonstrated in animal studies by Mazzali et al., in which rats developed high blood pressure in about 3 to 5 weeks after raised SUA level; was induced by the administration of oxonic acid which is an inhibitor of uricase [22]. Animal and human studies have repeatedly shown an independent association of hyperuricaemia with early hypertension [8,14,19] and hypertension is a well documented preliminary risk factor for the development of coronary artery disease (CAD). In one small study, the use of allopurinol, a xanthine oxidase (XO) inhibitor, resulted in reduction of BP in adolescents with newly diagnosed hypertension with hyperuricaemia [23]. In another small study, UA lowering therapy with either allopurinol or probenecid, a uricosuric agent, significantly reduced BP in prehypertensive obese adolescent with hyperuricaemia irrespective of UA lowering mechanism [15]. Although, several international authorities such as the Joint National Committee on prevention, detection, evaluation and treatment of high blood pressure and the American Heart Association have not recognized elevated SUA as an important risk factor for CAD, but studies in humans with asymptomatic hyperuricaemia have demonstrated its association with EHT, CAD, obesity, kidney disease and metabolic syndrome [13].

The preclinical asymptomatic rise in SUA, though largely ignored, is a potential risk indicator for EHT. Hence, this study recommends the screening of SUA to detect the risk of developing EHT in future.

LIMITATIONS

First, this was a cross-sectional study and so did not permit us to make any inference on the causal relationship between uric acid and hypertension. Secondly, the limited sample size also limited the power of the analysis. A further study designed as a prospective randomized follow up study with a larger sample size would be required to substantiate the results of the present study.

CONCLUSION

The mean SUA levels and the frequency of hyperuricaemia were significantly higher in newly diagnosed cases of EHT as compared to normotensive healthy controls. Though the SUA level was within the normal reference range, it was significantly elevated in newly diagnosed cases of EHT. In clinical practice, measurement of SUA level may help to detect the risk of development of EHT. Moreover, further studies can be carried out to evaluate the SUA as a modifiable risk factor, to lower the incidence of EHT per se.

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Significance of Dietary Pattern in Oxidative Stress among Newly Diagnosed Essential Hypertension

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Abstract

Background: Hypertension is a significant global public health problem and it is associated with increased oxidative stress. Oxidative stress is disequilibrium between tissue oxidants (free radicals or reactive oxygen species ROS) and antioxidants and may be an integrative mechanism in the progress of cardiovascular diseases (CVD).

Aims & Objectives: To study the impact of dietary pattern on oxidative stress markers in newly diagnosed essential hypertension.

Material and Method: The study was conducted on 75 cases of essential hypertension (HT), 75 prehypertensives (preHT) and 50 control subjects for 15 months. After screening, serum uric acid (SUA) and serum malondialdehyde (S.MDA) level were investigated in both vegetarians (V) and nonvegetarians (NV) in all groups.

Findings: The difference in mean ± SD of SUA and S. MDA level between control, preHT and HT group were found to be highly significant ($p<0.0001$). SUA and S. MDA level was higher in NV as compared to vegetarians in all groups but significant results were found in case of SUA ($p<0.001$).

Conclusion: Long-term vegetarians have improved antioxidant status and coronary heart disease risk profile than do apparently healthy omnivores.

Keywords: *Hypertension, prehypertension, oxidative stress, serum uric acid, serum malondialdehyde, vegetarians, nonvegetarians, systolic blood pressure (SBP), diastolic blood pressure (DBP) .*

Introduction

Hypertension is one of the most important public health challenge world-wide because of its high incidence and associated risks of cardiovascular disease for instance stroke, myocardial infarction and heart failure. Although it has frequently been indicated that the causes of essential hypertension are not known, this is only partially true. Essential hypertension is a heterogeneous disorder, with different patients having different causal factors that lead to high blood pressure. Vascular oxidative stress has been shown in genetic and experimental models of hypertension.[1] In search for a causative factor for essential hypertension, uric acid and lipid peroxidation due to increased oxidative stress are considered.

Although serum uric acid is regarded to be an antioxidant within its normal physiological conditions, it might be accountable for production of free radicals directly or indirectly in hypertensive. Hyperuricaemia (plasma uric acid level more than 6.8 mg/dl at

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physiological temperature (37°C) and neutral pH)[2] has been found to be associated with subsequent morbidity and mortality in the general population among patients with congestive heart failure, diabetics and hypertensive patients. Moreover, hyperuricaemia has also been linked to multiple proatherogenic processes, including increased oxidative stress. In recent years, oxidative stress due to ROS is implicated in the pathogenesis of ample variety of diseases like cancer, cataract, diabetes mellitus, rheumatoid arthritis, atherosclerosis, hypertension.[3] In addition the reasons for augmented rate of hypertension include life style changes, sugar rich diet, high fat processed foods and sedentary behavior.[4]

Rapid changes in diets and lifestyles that have took place with urbanization, industrialization and economic advancement have intensified over the past decade. Because of these changes, chronic diseases like hypertension are becoming increasingly significant cause of impairment and premature death.

Material & Method

A hospital based case control study was conducted among 200 subjects of age group between 20–50 years, irrespective of sex in the department of Physiology, Geetanjali medical college & hospital (GMCH), Udaipur.

Inclusion criteria: All the subjects were chosen randomly and following groups were made according to JNC7 criteria

Control group: 75 normotensive subjects

PreHT group: 75 cases of prehypertension

HT group: 75 cases of newly diagnosed cases of essential hypertension with SBP= 140-159 mmHg, DBP= 90-99 mmHg.

Exclusion criteria:

Patients with secondary hypertension, gout, diabetes mellitus, gestational hypertension, and patients taking antihypertensive, smokers and alcohol consumers were excluded from the study.

After obtaining ethical approval (Ref. No. GU/UCE/EC/2013/299 dated 15/05/2013), a written voluntary informed consent was obtained from all the subjects. Then all the subjects were screened as per the detailed history, routine physical examination and appropriate tests. After screening, blood sample (5 ml) was drawn in to a plain vial after an overnight fast (12 hrs) by antecubital venous puncture from all the subjects. Then serum was separated by a centrifugation at 3000rpm for 10 minutes. After that serum sample was used for following biochemical analysis.

Serum Uric Acid: By Modified Trinder Method.[5]

Serum Malondialdehyde (MDA): Thiobarbituric acid (TBA) assay method.[6]

Statistical Analysis: The data were analyzed by using Statistical Package for the Social Sciences (SPSS) Version 16.0. Difference between the groups was analyzed by Analysis of variance test (ANOVA). Diet wise comparison of oxidative stress parameters were tested by Student t-test with p value <0.05 is considered as statistically significant.

Findings

Table: 1 Characteristics of study population among different groups (Mean ±SD)

Variables	Control	Pre HT Group	HT Group	Anova P Value
Age (Yrs.)	37.46 ± **8.09**	35.84 ± **6.5**	40.25 ± 7.71	<0.001
Veg./ Nonveg.	68/32	51/49	40/60	-
SBP (mmHg)	114.06 ± **16.77**	134.00 ± **5.1**	160.04 ± **11.49**	<0.0001
DBP (mmHg)	74.66 ± **6.23**	86.45 ± **2.93**	92.00 ± **10.15**	<0.0001

The difference in mean ± SD of SBP & DBP between three groups were highly significant (p<0.0001).

Table: 2 Diet wise variation of SBP among different groups (Mean ± SD)

	Control			PreHT			HT		
Diet	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**
Non Veg	114.62 ± 6.37		16	134.38 ± 5.01		37	161.82 ± 12.52		45
Veg	112.88 ± 5.84		34	133.63 ± 5.24		38	157.37 ± 9.33		30
T value	0.92			0.63			1.76		
P value	NS			NS			NS		

Table: 3 Diet wise variation of DBP among different groups (Mean ± SD)

	Control			PreHT			HT		
Diet	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**
Nonveg	75.21 ± 6.75		16	87.27 ± 2.83		37	92.44 ± 11.17		45
Veg	73.50 ± 5.99		34	86.63 ± 3.05		38	91.33 ± 9.68		30
T value	0.87			0.94			0.46		
P value	NS			NS			NS		

The table no. 2 & 3 showed that mean ± SD value of both SBP and DBP were higher in NV as compared to V among all three groups but the results were not significant (p>0.05)

Table: 4 Comparison of SUA and S. MDA level among different groups (Mean ± SD)

Variables	Control	Pre HT Group	HT Group	Anova P Value
S. Uric acid (mg/dL)	4.91 ± 0.97	5.90 ± 0.97	6.56 ± 0.76	<0.0001
S. MDA (nmol/mL)	1.30 ± 0.20	1.63 ± 0.28	2.14 ± 0.42	<0.0001

The difference in mean ± SD of SUA and S. MDA level between control, preHT and HT group were found to be highly significant (p<0.0001).

Table: 5 Diet wise variation of SUA level among different groups (Mean ± SD)

Diet	**Control**			**Pre HT group**			**HT Group**		
	Mean	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**
Non veg	5.65 ± 0.77		16	6.55 ± 0.80		37	6.77 ± 0.59		45
Veg.	4.56 ± 0.69		34	5.24 ± 0.53		38	6.19 ± 0.56		30
T value	4.82			8.34			4.25		
P value	<0.0001			<0.0001			<0.001		

Mean ± SD of SUA was significantly higher in NV as compared to vegetarians in all groups (p<0.001).

Table: 6 Diet wise variation of S. MDA level among different groups (Mean ±SD)

Diet	Control			Pre HT group			HT Group		
	Mean	SD	N	Mean	SD	N	Mean	SD	N
Non veg	1.33 ± 0.19		16	1.68 ± 0.27		37	2.20 ± 0.43		45
Veg.	1.28 ± 0.21		34	1.57 ± 0.27		38	2.04 ± 0.39		30
T value	0.84			1.76			1.67		
P value	NS			NS			NS		

Mean ± SD of S.MDA level was higher in NV as compared to V among HT, preHT and control group but this difference was not statistically significant ($p>0.05$).

Discussion

There is a close relationship between the diet and chronic degenerative diseases such as obesity, hypercholesterolemia and hypertension. Our study showed that NV had higher mean SBP and DBP than V in HT, preHT and control group but the results were not significant ($p>0.05$). Our results were similar to the study of Nande PJ et al.[7] but they found significant results in case of DBP ($0.01<p<0.05$). These findings are steady with the results of the DASH (Dietary Approaches to Stopping Hypertension) trial, that a dietary pattern plenteous in fruits, vegetables, low fat dairy products and with abbreviated total and saturated fat can be efficient in the suppression of hypertension.[8] Diet represents a significant role in the primary suppression of hypertension. It is a conception that the non vegetarian diet comprises cholesterol and saturated fatty acids and these are the root cause of problems like coronary heart diseases and hypertension. Vegetarian diets are normally ample in carbohydrates, n-6 fatty acids and dietary fiber and are more helpful in preventing, treating or reversing heart disease. Lifestyle adjustments in diet are playing important role in determining the outcome for people with hypertension.[9]

In the present study serum uric acid level was found to be significantly high in NV as compared to vegetarians among HT, preHT and control group ($p<0.001$). Choi HK et al.[10] also noticed that SUA level enhanced with increasing total meat or sea food intake and diminished with increasing dairy intake. Similarly Schmidt JA et al.[11] found that vagan had the highest concentration followed by meat eaters and vegetarians. This might be due to their lack of ingestion of dairy foodstuffs, which are believed to lower UA concentrations.[12].

In humans yield of UA relies on purine uptake[13] and a purine-ample diet (such as veal, bacon, kid meat, mutton, turkey, pork, duck, goose, etc) would be responsible for rising only 1 to 2 mg/dL of uric acid[14] whereas diary foodstuff intake has a reciprocal relation with uric acid.[15,10] Since dairy products are low in purine content and it may perform its urate-lowering effect by increasing the elimination of uric acid and its precursor xanthine.[12]

The results of our study also presented that the oxidative stress marker, serum MDA level was high in NV compared to V among HT, preHT and control group but this difference was not statistically significant ($p>0.05$). This is in accordance with the findings of Somannavari MS & Kodliwadmath MV[16] but they found that the difference was significant. Whereas Szeto et al.[17]shown that there was no significant change of MDA level between V and NV. The increased oxidative stress and associated oxidative damage are mediators of renovascular injury in cardiovascular pathologies.[18] Dierckx et al.[19] concluded that serum MDA level (a marker of lipid peroxidation) was significantly increased in NV, as their diet is good resource of iron and copper and these transitional metals in the diet have important role in the initiation and progression of lipid peroxidation. Further these findings were confirmed by Sagare SM et al.[20] This may be due to higher and habitual consumption of fruit and vegetables, dark and whole grain products, grain sprouts, plant oils and oil seeds plentiful in trace elements like zinc, copper and selenium, mono and polyunsaturated fatty acids, antioxidant vitamins, fibers, complex carbohydrates and flavonoids by vegetarians.

The diminished risk of diseases found among vegetarians suggests that biological processes are molded by diet.[21] Therefore, much attention is currently focused on the beneficial effect of vegetarian versus non-vegetarian diet.[22,23] Efficient lifestyle modification may reduce blood pressure as much as a single antihypertensive drug. Combinations of two or more lifestyle alterations can accomplish even better results.[24]

Conclusion

The present study indicates that vegetarian nutrition provides sufficient antioxidants which efficaciously prevent the free radical generation and thus responsible for better antioxidant status and decreased oxidative stress. Maintenance of the oxidative balance in hypertensive patients would be helpful in preventing the CVD and other diseases associated with hypertension. Therefore, our study emphasizes the monitoring of the blood pressure, oxidative stress parameters (SUA and serum MDA level) at regular interval for therapeutic interventions. Moreover, the progress of disease could be prevented by giving proper education to the patient about healthy lifestyle and also advising them to practice yoga, aerobics, walk etc.

Conflict of Interest: None

Source of Funding: Self

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Significance of Dietary Pattern in Oxidative Stress among Newly Diagnosed Essential Hypertension

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Abstract

Background: Hypertension is a significant global public health problem and it is associated with increased oxidative stress. Oxidative stress is disequilibrium between tissue oxidants (free radicals or reactive oxygen species ROS) and antioxidants and may be an integrative mechanism in the progress of cardiovascular diseases (CVD).

Aims & Objectives: To study the impact of dietary pattern on oxidative stress markers in newly diagnosed essential hypertension.

Material and Method: The study was conducted on 75 cases of essential hypertension (HT), 75 prehypertensives (preHT) and 50 control subjects for 15 months. After screening, serum uric acid (SUA) and serum malondialdehyde (S.MDA) level were investigated in both vegetarians (V) and nonvegetarians (NV) in all groups.

Findings: The difference in mean ± SD of SUA and S. MDA level between control, preHT and HT group were found to be highly significant ($p<0.0001$). SUA and S. MDA level was higher in NV as compared to vegetarians in all groups but significant results were found in case of SUA ($p<0.001$).

Conclusion: Long-term vegetarians have improved antioxidant status and coronary heart disease risk profile than do apparently healthy omnivores.

Keywords: *Hypertension, prehypertension, oxidative stress, serum uric acid, serum malondialdehyde, vegetarians, nonvegetarians, systolic blood pressure (SBP), diastolic blood pressure (DBP) .*

Introduction

Hypertension is one of the most important public health challenge world-wide because of its high incidence and associated risks of cardiovascular disease for instance stroke, myocardial infarction and heart failure. Although it has frequently been indicated that the causes of essential hypertension are not known, this is only partially true. Essential hypertension is a heterogeneous disorder, with different patients having different causal factors that lead to high blood pressure. Vascular oxidative stress has been shown in genetic and experimental models of hypertension.[1] In search for a causative factor for essential hypertension, uric acid and lipid peroxidation due to increased oxidative stress are considered.

Although serum uric acid is regarded to be an antioxidant within its normal physiological conditions, it might be accountable for production of free radicals directly or indirectly in hypertensive. Hyperuricaemia (plasma uric acid level more than 6.8 mg/dl at

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physiological temperature (37°C) and neutral pH)[2] has been found to be associated with subsequent morbidity and mortality in the general population among patients with congestive heart failure, diabetics and hypertensive patients. Moreover, hyperuricaemia has also been linked to multiple proatherogenic processes, including increased oxidative stress. In recent years, oxidative stress due to ROS is implicated in the pathogenesis of ample variety of diseases like cancer, cataract, diabetes mellitus, rheumatoid arthritis, atherosclerosis, hypertension.[3] In addition the reasons for augmented rate of hypertension include life style changes, sugar rich diet, high fat processed foods and sedentary behavior.[4]

Rapid changes in diets and lifestyles that have took place with urbanization, industrialization and economic advancement have intensified over the past decade. Because of these changes, chronic diseases like hypertension are becoming increasingly significant cause of impairment and premature death.

Material & Method

A hospital based case control study was conducted among 200 subjects of age group between 20–50 years, irrespective of sex in the department of Physiology, Geetanjali medical college & hospital (GMCH), Udaipur.

Inclusion criteria: All the subjects were chosen randomly and following groups were made according to JNC7 criteria

Control group: 75 normotensive subjects

PreHT group: 75 cases of prehypertension

HT group: 75 cases of newly diagnosed cases of essential hypertension with SBP= 140-159 mmHg, DBP= 90-99 mmHg.

Exclusion criteria:

Patients with secondary hypertension, gout, diabetes mellitus, gestational hypertension, and patients taking antihypertensive, smokers and alcohol consumers were excluded from the study.

After obtaining ethical approval (Ref. No. GU/UCE/EC/2013/299 dated 15/05/2013), a written voluntary informed consent was obtained from all the subjects. Then all the subjects were screened as per the detailed history, routine physical examination and appropriate tests. After screening, blood sample (5 ml) was drawn in to a plain vial after an overnight fast (12 hrs) by antecubital venous puncture from all the subjects. Then serum was separated by a centrifugation at 3000rpm for 10 minutes. After that serum sample was used for following biochemical analysis.

Serum Uric Acid: By Modified Trinder Method.[5]

Serum Malondialdehyde (MDA): Thiobarbituric acid (TBA) assay method.[6]

Statistical Analysis: The data were analyzed by using Statistical Package for the Social Sciences (SPSS) Version 16.0. Difference between the groups was analyzed by Analysis of variance test (ANOVA). Diet wise comparison of oxidative stress parameters were tested by Student t-test with p value <0.05 is considered as statistically significant.

Findings

Table: 1 Characteristics of study population among different groups (Mean ±SD)

Variables	Control	Pre HT Group	HT Group	Anova P Value
Age (Yrs.)	37.46 ± **8.09**	35.84 ± **6.5**	40.25 ± 7.71	<0.001
Veg./ Nonveg.	68/32	51/49	40/60	-
SBP (mmHg)	114.06 ± **16.77**	134.00 ± **5.1**	160.04 ± **11.49**	<0.0001
DBP (mmHg)	74.66 ± **6.23**	86.45 ± **2.93**	92.00 ± **10.15**	<0.0001

The difference in mean ± SD of SBP & DBP between three groups were highly significant (p<0.0001).

Table: 2 Diet wise variation of SBP among different groups (Mean ± SD)

	Control			PreHT			HT		
Diet	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**
Non Veg	114.62 ± 6.37		16	134.38 ± 5.01		37	161.82 ± 12.52		45
Veg	112.88 ± 5.84		34	133.63 ± 5.24		38	157.37 ± 9.33		30
T value	0.92			0.63			1.76		
P value	NS			NS			NS		

Table: 3 Diet wise variation of DBP among different groups (Mean ± SD)

	Control			PreHT			HT		
Diet	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**
Nonveg	75.21 ± 6.75		16	87.27 ± 2.83		37	92.44 ± 11.17		45
Veg	73.50 ± 5.99		34	86.63 ± 3.05		38	91.33 ± 9.68		30
T value	0.87			0.94			0.46		
P value	NS			NS			NS		

The table no. 2 & 3 showed that mean ± SD value of both SBP and DBP were higher in NV as compared to V among all three groups but the results were not significant (p>0.05)

Table: 4 Comparison of SUA and S. MDA level among different groups (Mean ± SD)

Variables	Control	Pre HT Group	HT Group	Anova P Value
S. Uric acid (mg/dL)	4.91 ± 0.97	5.90 ± 0.97	6.56 ± 0.76	<0.0001
S. MDA (nmol/mL)	1.30 ± 0.20	1.63 ± 0.28	2.14 ± 0.42	<0.0001

The difference in mean ± SD of SUA and S. MDA level between control, preHT and HT group were found to be highly significant (p<0.0001).

Table: 5 Diet wise variation of SUA level among different groups (Mean ± SD)

Diet	**Control**			**Pre HT group**			**HT Group**		
	Mean	**SD**	**N**	**Mean**	**SD**	**N**	**Mean**	**SD**	**N**
Non veg	5.65 ± 0.77		16	6.55 ± 0.80		37	6.77 ± 0.59		45
Veg.	4.56 ± 0.69		34	5.24 ± 0.53		38	6.19 ± 0.56		30
T value	4.82			8.34			4.25		
P value	<0.0001			<0.0001			<0.001		

Mean ± SD of SUA was significantly higher in NV as compared to vegetarians in all groups (p<0.001).

Table: 6 Diet wise variation of S. MDA level among different groups (Mean ±SD)

Diet	Control			Pre HT group			HT Group		
	Mean	SD	N	Mean	SD	N	Mean	SD	N
Non veg	1.33 ± 0.19		16	1.68 ± 0.27		37	2.20 ± 0.43		45
Veg.	1.28 ± 0.21		34	1.57 ± 0.27		38	2.04 ± 0.39		30
T value	0.84			1.76			1.67		
P value	NS			NS			NS		

Mean ± SD of S.MDA level was higher in NV as compared to V among HT, preHT and control group but this difference was not statistically significant ($p>0.05$).

Discussion

There is a close relationship between the diet and chronic degenerative diseases such as obesity, hypercholesterolemia and hypertension. Our study showed that NV had higher mean SBP and DBP than V in HT, preHT and control group but the results were not significant ($p>0.05$). Our results were similar to the study of Nande PJ et al.[7] but they found significant results in case of DBP ($0.01<p<0.05$). These findings are steady with the results of the DASH (Dietary Approaches to Stopping Hypertension) trial, that a dietary pattern plenteous in fruits, vegetables, low fat dairy products and with abbreviated total and saturated fat can be efficient in the suppression of hypertension.[8] Diet represents a significant role in the primary suppression of hypertension. It is a conception that the non vegetarian diet comprises cholesterol and saturated fatty acids and these are the root cause of problems like coronary heart diseases and hypertension. Vegetarian diets are normally ample in carbohydrates, n-6 fatty acids and dietary fiber and are more helpful in preventing, treating or reversing heart disease. Lifestyle adjustments in diet are playing important role in determining the outcome for people with hypertension.[9]

In the present study serum uric acid level was found to be significantly high in NV as compared to vegetarians among HT, preHT and control group ($p<0.001$). Choi HK et al.[10] also noticed that SUA level enhanced with increasing total meat or sea food intake and diminished with increasing dairy intake. Similarly Schmidt JA et al.[11] found that vagan had the highest concentration followed by meat eaters and vegetarians. This might be due to their lack of ingestion of dairy foodstuffs, which are believed to lower UA concentrations.[12].

In humans yield of UA relies on purine uptake[13] and a purine-ample diet (such as veal, bacon, kid meat, mutton, turkey, pork, duck, goose, etc) would be responsible for rising only 1 to 2 mg/dL of uric acid[14] whereas diary foodstuff intake has a reciprocal relation with uric acid.[15,10] Since dairy products are low in purine content and it may perform its urate-lowering effect by increasing the elimination of uric acid and its precursor xanthine.[12]

The results of our study also presented that the oxidative stress marker, serum MDA level was high in NV compared to V among HT, preHT and control group but this difference was not statistically significant ($p>0.05$). This is in accordance with the findings of Somannavari MS & Kodliwadmath MV[16] but they found that the difference was significant. Whereas Szeto et al.[17]shown that there was no significant change of MDA level between V and NV. The increased oxidative stress and associated oxidative damage are mediators of renovascular injury in cardiovascular pathologies.[18] Dierckx et al.[19] concluded that serum MDA level (a marker of lipid peroxidation) was significantly increased in NV, as their diet is good resource of iron and copper and these transitional metals in the diet have important role in the initiation and progression of lipid peroxidation. Further these findings were confirmed by Sagare SM et al.[20] This may be due to higher and habitual consumption of fruit and vegetables, dark and whole grain products, grain sprouts, plant oils and oil seeds plentiful in trace elements like zinc, copper and selenium, mono and polyunsaturated fatty acids, antioxidant vitamins, fibers, complex carbohydrates and flavonoids by vegetarians.

The diminished risk of diseases found among vegetarians suggests that biological processes are molded by diet.[21] Therefore, much attention is currently focused on the beneficial effect of vegetarian versus non-vegetarian diet.[22,23] Efficient lifestyle modification may reduce blood pressure as much as a single antihypertensive drug. Combinations of two or more lifestyle alterations can accomplish even better results.[24]

Conclusion

The present study indicates that vegetarian nutrition provides sufficient antioxidants which efficaciously prevent the free radical generation and thus responsible for better antioxidant status and decreased oxidative stress. Maintenance of the oxidative balance in hypertensive patients would be helpful in preventing the CVD and other diseases associated with hypertension. Therefore, our study emphasizes the monitoring of the blood pressure, oxidative stress parameters (SUA and serum MDA level) at regular interval for therapeutic interventions. Moreover, the progress of disease could be prevented by giving proper education to the patient about healthy lifestyle and also advising them to practice yoga, aerobics, walk etc.

Conflict of Interest: None

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Knowledge, Attitude and Practice for Prevention and Treatment of Swine Flu in Population of Udaipur City

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Abstract

Background: Swine flu has become a very common seasonal respiratory disease having larger number of morbidities and mortalities. It has created panic situation among general public and health care workers just because of lack of awareness regarding the same.

Aims & Objectives: This study was carried out to reach general public of every class for their perception for this pandemic disease. Knowledge regarding measures for prevention and treatments available if it occurs was the objective of this study. Also to find out myths prevalent in them and to create awareness in proper direction was the objective of this study.

Material and Method: This study was carried out on 500 people chosen randomly from different places of Udaipur having different class and strata. Study was done by making pre-formed questionnaires. Data was analyzed by using SPSS.

Findings: Major part of study population gain information from news papers and TV channels. 76% of study population had heard about swine flu by different resources. Myths are prevalent in 37% of populations regarding causes and mode of occurring of swine flu. Only 23% of study population knows importance of hand-washing as measure for preventing swine flu.

Conclusion: Though large campaign carried out by government and media, people needs to be made aware for every aspects of swine flu through ground level awareness programmes.

Keywords: *Swine flu, knowledge, attitude, practice.*

Introduction

Swine influenza is an acute respiratory disease occurs due to different strains of influenza virus type A which is named globally as H1N1.[1] Initially virus outbreak was prevalent only in pigs but due to regular contacts between pigs and human, some strains had spread from pigs to human. In 21st century first outbreak of this H1N1 flu occurred in Maxico city in the month of March 2009, after that it spread within a very limited time to all over the world.[1] After that outbreak, World health organization (WHO) had declared it as pandemic as it had approached in more than two continents.[2] It was given a name 'swine flu' as during 2009 pandemic, the strain of H1N1 influenza showed very similar genes to the influenza virus affecting North American swine.[3,4]

Considering amongst the largest populist country, India is on 3rd rank according to the number of cases and total number of deaths because of swine flu.[5] Due to increasing numbers of morbidities and mortalities in subsequent years, swine flu is considered as global threat amongst emerging diseases. According to data of Ministry of health and family welfare, government of India, 6,804 cases and 542 deaths from swine flu has been registered up to October 2018.[6] Rajasthan reported 191 deaths from swine flu amongst 1912 cases with

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second most after Maharashtra in the year of 2018.[6]

Material & Method

This is a cross-sectional study carried out on general public of Udaipur city. For knowledge, attitude and practice study, sample size should be atleast 200.[7] In this study total 500 participants were included so as to achieve larger representation of population. Study was carried out during October-December 2018.

Study was approved by institutional ethical committee. Inclusion criteria for participants were minimum 15 years of age with at least primary education achieved. To make this study more representative of population, participants were selected from different parts of city having different economic status, different educational level and different occupations like some professional persons working as company executives, lawyer, bankers, and also some shopkeepers, street vendors, students, housewife etc. Random sampling was done for selection. Informed consent was taken from participants. None of the participant refused as they were assured for complete anonymous study.

Participants were approached personally for interview. Pre formed questionnaires were used which includes their demographic profile (sex, age, education, occupation), knowledge regarding swine flu (how it occurs, mode of spreading, signs and symptoms), attitude towards disease and practice they follow for prevention and treatment of disease.

Findings

In the present study 346 participants were male and 154 were female. Educational levels of participants were from primary to professional level with different job profile.

Table-1: Knowledge on symptoms of swine flu

Symptoms	No.	Percentage
Fever	390	89.1
Running nose	85	19.4
Cough	375	85.6
Headache	128	29.2
Body ache	143	32.6
Vomiting	76	17.3
Diarrhea	74	16.8

Amongst 500 participants, 438 (87.6%) had previously heard about swine flu so further interview was carried out for these 438 participants only. 190 (43.3%) knew that swine flu is caused by virus. The most common symptoms of swine flu like running nose was known to 85 participants (19.4%), fever to 390 (89.1%) and cough to 375 (85.6%) participants. (Table-1)

Table-2: How to prevent swine flu?

Preventive measures	No.	Percentage
Face mask	323	73.7
Frequent hand wash	157	35.8
Avoid crowded place	193	44.1
By home remedies	146	33.3
By homeopathic drugs	82	18.7
Avoiding animal contacts	107	24.4

Regarding preventive measures, use of mask or handkerchief was known to 323 (73.7%), frequent hand washing and personal hygiene 157 (35.8%) while 193 (44.1%) participants believe that avoid crowded place for prevention. (Table-2)

Table-3: How swine flu spread?

Mode of spread	No.	Percentage
Contact of patient	316	72.1
Non-vegetarian food	34	7.7
Bite of bugs	26	5.9
Blood contact of patient	43	9.8
Through water	21	4.7

Myths or misconception regarding swine flu are by eating non-vegetarian food 34 (7.7%), bite of some bugs 26 (5.9%), blood contact of infected patient 43 (9.8%), while majority of participants 316 (72.1%) were aware that swine flu spread by close contact with affected person and by inhalation through respiratory route when patient cough or sneeze. (Table-3)

Table-4: Sources of information

Sources	No.	Percentage
Television	196	44.7
News paper	180	41.1
Internet	88	20.1
Doctors	32	7.3
Social media	71	16.2
Hoardings and banners	60	13.6
Programmes by health department	19	4.3

Participants have different sources of information with telemedia is the highest 196 (44.7%). (Table-4)

Knowledge regarding vaccine available for swine flu was known to 171 (39.1%) participants and treatment availability was known to 236 (53.8%) but only 29 (6.6%) participants have heard the name of drug Tamiflu.

Discussion

Knowledge regarding infectious disease among community people is the benchmark of incidence and prevalence of that disease. Right attitude and practice towards the disease make them less vulnerable and ultimately it decides well being of any community. This study is based on knowledge, attitude and practice for prevention and treatment of swine flu (H1N1) amongst urban community of Udaipur city which may help local authorities related to health sectors for planning and implementing programme for awareness regarding swine flu. Some misconceptions must be removed from general public like swine flu is always deadly disease and no any treatment available.

In this study 87.6% participants have heard about swine flu which is lower than study done by Chaudhary V et al[8] and Rathi S et al[9] while it is higher than study done by Singh S et al[10] which may be due to different educational level of participants and awareness programmes by local authorities at different places. Study population represents all aspects of community with wide variety of demographic profiles. Male participants are more in numbers which is similar to study done by Singh S et al[10] while in study of Latiff et al[11] female participants are more.

Knowledge on clinical features of swine flu amongst participants of this study is found to be similar to study done by Farhat et al[12] with fever is known to be the most common symptoms while another common symptom of running nose is not much known amongst participants.

Prevention is always considered as more important tool than treatment. In this study 73.7% participants consider use of face mask as the best method for prevention but another much important measure of frequent hand washing is known only to 35.8% which is contrast to study done by Rubin et al.[13] This is because lack of interest and lazy attitude towards disease and awareness programmes run by authorities.

Myths also prevalent amongst participants like eating of non vegetarian food specially pork, bite of mosquito or other bugs or by taking contaminated food or water which contradict to study done by Shilpa K et al[14] in Karnataka having very low 2.4% prevalence of myths . This may be due to failure of health workers and authorities in making ground level efforts for spreading awareness regarding actual cause and mode of disease.

Telemedia and newspapers are major source of information as better availability of these resources in urban population similar to findings of other studies.[5,12,15] Health education is very important measure for increase well being of community by reducing prevalence of disease. Mass media including social media is considered best in current scenario to approach every individual of society.

Conclusion

If *knowledge* regarding swine flu is increased, it definitely changes *attitude* of community towards disease and *practice* of preventive measures to be taken. These are three pillars of health system as it directly affects health programmes implemented by government. Focal points regarding swine flu like running nose as important symptoms, frequent hand washing as important practice and removing all myths for disease are key areas to be considered and mass media can help during epidemic of swine flu for creating awareness of these key areas instead of creating panics and blaming health authorities. Also role of health workers and concerned authorities is important as early detection and timely notification of disease can help to break chain of spreading of

disease. This study conclude that there is either lack of knowledge or incomplete knowledge regarding swine flu in general public which is to be rectified by paying immediate attention

Conflict of Interest: None

Source of Funding: None

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Effect of Treadmill Exercise on Blood Glucose Control in Type-2 Diabetes Mellitus Patients

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Abstract

Background: Diabetes mellitus type 2 is because of resistance to insulin resulting in inability to utilize glucose. In addition to medicines and diet control, regular exercise helps in increase in utilization of glucose.

Aims & Objectives: To study efficacy of exercise especially treadmill walking on controlling blood glucose homeostasis in diabetes mellitus.

Material and Method: The study was conducted on 40 clinically confirmed cases of type-2 diabetes mellitus male patients who were divided in study group and control group with 20 patients in each group. Study was conducted for period of 8 weeks. Diet plan was formed by expert during this period and subjects were instructed to follow it strictly. Fasting blood glucose and postprandial blood glucose was measured before and after exercise programme.

Findings: There is significant decrease in fasting blood glucose and Postprandial blood glucose level in study group as compared to control group with inter-group difference was significant ($P<0.05$).

Conclusion: Treadmill exercise is very useful for blood glucose control in addition to diet control and medicines.

Keywords: *Type-2 diabetes mellitus, Treadmill exercise, Fasting blood glucose, Postprandial blood glucose, Glycemic control.*

Introduction

Diabetes mellitus (DM) refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. The two broad categories of DM are designated type 1 and type 2. Both types of diabetes are preceded by a phase of abnormal glucose homeostasis as the pathogenic processes progress. Type 1 DM is the result of complete or near-total insulin deficiency. Type 2 DM is a heterogeneous group of disorders characterized by variable degrees of insulin resistance, impaired insulin secretion, and increased glucose production.[1]

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The prevalence of diabetes is going to double globally from 171 million in 2000 to 366 million in 2030 with maximum increase in India. By 2030, around 79.4 million people will be affected by diabetes according to prediction made by Wild et al.[2]

In addition to medication and diet control, exercise is also helpful in increasing insulin sensitivity. American diabetes association recommends moderate aerobic physical activity of 150 minutes/week.[3] Walking is considered to be the best exercise as it involves larger muscles of lower limb as well as muscular work of upper limb. Treadmill machine which is electronically driven or manual simulates all the features of natural walking.

Material & Method

In our study we used treadmill (Phillips, Novafit turbo) machine, oscilloscope for measuring heart rate and respiratory rate, Sphygmomanometer for measuring

blood pressure, weighing scale. Permission from institutional ethical committee was taken.

From diabetes OPD 40 male patients of age group 45-55 years who were clinically and biochemically confirmed cases of diabetes included in study after obtaining informed consent. Patients with known case of cardiac, respiratory, renal and musculoskeletal disorders were excluded from programme. Those who were willing to do exercise were included in study group and who were not willing to do exercise were included in control group.

Whole programme was conducted for period of 8 weeks. At the beginning of study, fasting blood sugar (FBS) and postprandial blood sugar (PPBS) was measured for all subjects. Additionally weight, height and body mass index was measured. Subjects were examined for any muscular weakness in lower limb. Regular diet may vary in different subjects so diet plan was formed for whole day by advice of dietician and they were explained to follow it strictly during the whole exercise programme so as to avoid effects of diet on blood glucose level.

Treadmill machine (Phillips, Novafit turbo) used for the study can measure speed in form of RPM, total distance travelled in kilometers and calories used during exercise. All subjects in study group were first given demonstration of treadmill machine to make them familiarize. Programme was conducted for total 40 minutes which include 5 minutes of warm up, 30 minutes of treadmill walking followed by 5 minutes of rest. All subjects were instructed to report immediately if they feel breathlessness, headache, dizziness or any other symptoms which are indicative for stopping exercise. Blood pressure, heart rate and respiratory rate were taken in supine at the beginning of exercise.

First warm up was done in the form of active limb movements and muscle stretching. Then oscilloscope was attached for monitoring of heart rate, respiratory rate and blood pressure. Subjects were instructed to walk on treadmill for 30 minutes. Speed of treadmill machine was set to 3.5 km/hour with fixed inclination. All the subjects were constantly monitored for development of any symptoms and any noticeable change in parameters. At the end of thirty minutes, parameters were measured immediately and then they are instructed to take rest for five minutes. Vital parameters were also taken during recovery period of five minutes. This completed session was conducted for five days in a week for total 8 weeks. At the end of 8 weeks FBS and PPBS was taken again for both groups. Statistical analysis was done using student's t test with p value < 0.05 is considered as statistically significant.

Findings

All the subjects in study group completed exercise programme without any event. Pre and post exercise blood glucose levels are compared in both study and control group.

In study group, FBS and PPBS level before exercise was in the range of 150-196 mg% and 180-212 mg% respectively. After exercise programme range of FBS and PPBS was 130-162 mg% and 156-170 mg% respectively.

In control group, FBS and PPBS level before exercise was in the range of 154-202 mg% and 184-210 mg% respectively. After 8 weeks of observation range of FBS and PPBS was 150-188 mg% and 168-200 mg% respectively.

Difference between FBS and PPBS before and after programme in both the group was compared (Table-1). Mean decrease in FBS in study group was 38.6 mg% while in control group it was 26.8 mg% with intergroup difference is statistically significant ($p<0.05$). In study group decrease in PPBS was 42.8mg% as compared to control group having difference of 30.4 mg%. So inter group difference in PPBS is statistically significant (p value <0.05). Also subjects in study group reported of feeling of well being with loss of average two kilograms weight.

Table-1 Comparison between study and control group for change in FBS and PPBS after programme

Difference	Study group (mean±SD) Control group (mean±SD) n=10
FBS1-FBS2	38 ± 8.275 26 ± 8.910*
PPBS1-PPBS2	42 ± 6.784 30 ± 8.623*
FBS1- Fasting blood glucose before exercise FBS2- Fasting blood glucose after exercise PPBS1- Postprandial blood glucose before exercise PPBS2- Postprandial blood glucose after exercise *p<0.05, student t-test	

Discussion

Diabetes Mellitus is a clinical syndrome comprising a heterogeneous group of metabolic diseases that are characterized by chronic hyperglycemia and disturbances in carbohydrate, fat and protein metabolism secondary to defects in insulin secretion, insulin action or both.[4] Comprehensive management of diabetes includes drugs, insulin, lifestyle changes comprising of diet control, exercise and education.[5] In this study, efficacy of treadmill exercise on control of blood glucose was studied in addition to diet control and medication. Exercise improves insulin sensitivity and therefore has a positive effect on blood glucose control. In addition it also has positive effects on lipid profile and blood pressure and it is important part of weight management programme. For inactive person it is better to start with at least 5 minutes daily and then gradually increase 5 minutes to up to at least 30 minutes of daily walking.[6] Only problem with diet and exercise is that it requires strong motivation and self confidence. So for the patient's perspective oral drugs for diabetes is the best management.

At the beginning of exercise, muscle utilizes stored glycogen as fuel consumption. But it is available only for short period only. If activity is continued, glycogenolysis becomes source of glucose and then after few minutes gluconeogenesis starts in liver. After depletion of glycogen store in liver, stored fat in adipose tissue converted into fatty acids which are used as fuel by muscle.[7]

Wahren et al. reported that working muscles are more sensitive to insulin as compared to resting muscle, which increase utilization of glucose. Also during exercise blood flow to working muscle increase which increase size of capillaries and number of insulin receptors which ultimately balance sensitivity of insulin.[8]

Shivananda nayak et al. reported that after six weeks of treadmill exercise, glucose utilization is increased in muscle which has positive effects on glucose homeostasis with significant fall in fasting and postprandial blood glucose level.[9]

Exercise programme is also affected by some factors like type of exercise, duration of exercise, intensity and frequency of exercise. According to American college of sports medicine, exercise with low intensity but long duration gives better result as compared to high intensity short duration exercise. Duration of exercise should be gradually increased over days. Exercise programme should be restricted to five days per week. Intensity can be controlled by counting target heart rate with formula of subtracting your age from 220. In this study it was found that endurance exercise helps in control of blood glucose level. It works by increasing insulin sensitivity in exercising muscle. As compared to resting condition, numbers of insulin receptors are more in working muscle which ultimately helps to utilize glucose despite low production by pancreas as in diabetes mellitus.

Conclusion

Well planned exercise programme which is strictly followed can improve glycemic control and also helps to reduce weight. In addition to mental well being it reduces cardiovascular risk factors in patients of diabetes mellitus.

Conflict of Interest: None

Source of Funding: Institution

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Table-4: Sources of information

Sources	No.	Percentage
Television	196	44.7
News paper	180	41.1
Internet	88	20.1
Doctors	32	7.3
Social media	71	16.2
Hoardings and banners	60	13.6
Programmes by health department	19	4.3

Participants have different sources of information with telemedia is the highest 196 (44.7%). (Table-4)

Knowledge regarding vaccine available for swine flu was known to 171 (39.1%) participants and treatment availability was known to 236 (53.8%) but only 29 (6.6%) participants have heard the name of drug Tamiflu.

Discussion

Knowledge regarding infectious disease among community people is the benchmark of incidence and prevalence of that disease. Right attitude and practice towards the disease make them less vulnerable and ultimately it decides well being of any community. This study is based on knowledge, attitude and practice for prevention and treatment of swine flu (H1N1) amongst urban community of Udaipur city which may help local authorities related to health sectors for planning and implementing programme for awareness regarding swine flu. Some misconceptions must be removed from general public like swine flu is always deadly disease and no any treatment available.

In this study 87.6% participants have heard about swine flu which is lower than study done by Chaudhary V et al[8] and Rathi S et al[9] while it is higher than study done by Singh S et al[10] which may be due to different educational level of participants and awareness programmes by local authorities at different places. Study population represents all aspects of community with wide variety of demographic profiles. Male participants are more in numbers which is similar to study done by Singh S et al[10] while in study of Latiff et al[11] female participants are more.

Knowledge on clinical features of swine flu amongst participants of this study is found to be similar to study done by Farhat et al[12] with fever is known to be the most common symptoms while another common symptom of running nose is not much known amongst participants.

Prevention is always considered as more important tool than treatment. In this study 73.7% participants consider use of face mask as the best method for prevention but another much important measure of frequent hand washing is known only to 35.8% which is contrast to study done by Rubin et al.[13] This is because lack of interest and lazy attitude towards disease and awareness programmes run by authorities.

Myths also prevalent amongst participants like eating of non vegetarian food specially pork, bite of mosquito or other bugs or by taking contaminated food or water which contradict to study done by Shilpa K et al[14] in Karnataka having very low 2.4% prevalence of myths . This may be due to failure of health workers and authorities in making ground level efforts for spreading awareness regarding actual cause and mode of disease.

Telemedia and newspapers are major source of information as better availability of these resources in urban population similar to findings of other studies.[5,12,15] Health education is very important measure for increase well being of community by reducing prevalence of disease. Mass media including social media is considered best in current scenario to approach every individual of society.

Conclusion

If *knowledge* regarding swine flu is increased, it definitely changes *attitude* of community towards disease and *practice* of preventive measures to be taken. These are three pillars of health system as it directly affects health programmes implemented by government. Focal points regarding swine flu like running nose as important symptoms, frequent hand washing as important practice and removing all myths for disease are key areas to be considered and mass media can help during epidemic of swine flu for creating awareness of these key areas instead of creating panics and blaming health authorities. Also role of health workers and concerned authorities is important as early detection and timely notification of disease can help to break chain of spreading of

disease. This study conclude that there is either lack of knowledge or incomplete knowledge regarding swine flu in general public which is to be rectified by paying immediate attention

Conflict of Interest: None

Source of Funding: None

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Knowledge, Attitude and Practice for Prevention and Treatment of Swine Flu in Population of Udaipur City

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Abstract

Background: Swine flu has become a very common seasonal respiratory disease having larger number of morbidities and mortalities. It has created panic situation among general public and health care workers just because of lack of awareness regarding the same.

Aims & Objectives: This study was carried out to reach general public of every class for their perception for this pandemic disease. Knowledge regarding measures for prevention and treatments available if it occurs was the objective of this study. Also to find out myths prevalent in them and to create awareness in proper direction was the objective of this study.

Material and Method: This study was carried out on 500 people chosen randomly from different places of Udaipur having different class and strata. Study was done by making pre-formed questionnaires. Data was analyzed by using SPSS.

Findings: Major part of study population gain information from news papers and TV channels. 76% of study population had heard about swine flu by different resources. Myths are prevalent in 37% of populations regarding causes and mode of occurring of swine flu. Only 23% of study population knows importance of hand-washing as measure for preventing swine flu.

Conclusion: Though large campaign carried out by government and media, people needs to be made aware for every aspects of swine flu through ground level awareness programmes.

Keywords: *Swine flu, knowledge, attitude, practice.*

Introduction

Swine influenza is an acute respiratory disease occurs due to different strains of influenza virus type A which is named globally as H1N1.[1] Initially virus outbreak was prevalent only in pigs but due to regular contacts between pigs and human, some strains had spread from pigs to human. In 21st century first outbreak of this H1N1 flu occurred in Maxico city in the month of March 2009, after that it spread within a very limited time to all over the world.[1] After that outbreak, World health organization (WHO) had declared it as pandemic as it had approached in more than two continents.[2] It was given a name 'swine flu' as during 2009 pandemic, the strain of H1N1 influenza showed very similar genes to the influenza virus affecting North American swine.[3,4]

Considering amongst the largest populist country, India is on 3rd rank according to the number of cases and total number of deaths because of swine flu.[5] Due to increasing numbers of morbidities and mortalities in subsequent years, swine flu is considered as global threat amongst emerging diseases. According to data of Ministry of health and family welfare, government of India, 6,804 cases and 542 deaths from swine flu has been registered up to October 2018.[6] Rajasthan reported 191 deaths from swine flu amongst 1912 cases with

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second most after Maharashtra in the year of 2018.[6]

Material & Method

This is a cross-sectional study carried out on general public of Udaipur city. For knowledge, attitude and practice study, sample size should be atleast 200.[7] In this study total 500 participants were included so as to achieve larger representation of population. Study was carried out during October-December 2018.

Study was approved by institutional ethical committee. Inclusion criteria for participants were minimum 15 years of age with at least primary education achieved. To make this study more representative of population, participants were selected from different parts of city having different economic status, different educational level and different occupations like some professional persons working as company executives, lawyer, bankers, and also some shopkeepers, street vendors, students, housewife etc. Random sampling was done for selection. Informed consent was taken from participants. None of the participant refused as they were assured for complete anonymous study.

Participants were approached personally for interview. Pre formed questionnaires were used which includes their demographic profile (sex, age, education, occupation), knowledge regarding swine flu (how it occurs, mode of spreading, signs and symptoms), attitude towards disease and practice they follow for prevention and treatment of disease.

Findings

In the present study 346 participants were male and 154 were female. Educational levels of participants were from primary to professional level with different job profile.

Table-1: Knowledge on symptoms of swine flu

Symptoms	No.	Percentage
Fever	390	89.1
Running nose	85	19.4
Cough	375	85.6
Headache	128	29.2
Body ache	143	32.6
Vomiting	76	17.3
Diarrhea	74	16.8

Amongst 500 participants, 438 (87.6%) had previously heard about swine flu so further interview was carried out for these 438 participants only. 190 (43.3%) knew that swine flu is caused by virus. The most common symptoms of swine flu like running nose was known to 85 participants (19.4%), fever to 390 (89.1%) and cough to 375 (85.6%) participants. (Table-1)

Table-2: How to prevent swine flu?

Preventive measures	No.	Percentage
Face mask	323	73.7
Frequent hand wash	157	35.8
Avoid crowded place	193	44.1
By home remedies	146	33.3
By homeopathic drugs	82	18.7
Avoiding animal contacts	107	24.4

Regarding preventive measures, use of mask or handkerchief was known to 323 (73.7%), frequent hand washing and personal hygiene 157 (35.8%) while 193 (44.1%) participants believe that avoid crowded place for prevention. (Table-2)

Table-3: How swine flu spread?

Mode of spread	No.	Percentage
Contact of patient	316	72.1
Non-vegetarian food	34	7.7
Bite of bugs	26	5.9
Blood contact of patient	43	9.8
Through water	21	4.7

Myths or misconception regarding swine flu are by eating non-vegetarian food 34 (7.7%), bite of some bugs 26 (5.9%), blood contact of infected patient 43 (9.8%), while majority of participants 316 (72.1%) were aware that swine flu spread by close contact with affected person and by inhalation through respiratory route when patient cough or sneeze. (Table-3)

Table-4: Sources of information

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disease. This study conclude that there is either lack of knowledge or incomplete knowledge regarding swine flu in general public which is to be rectified by paying immediate attention

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COMPARATIVE STUDY OF LIPID PROFILE AND FASTING BLOOD GLUCOSE AMONG VEGETARIANS AND NON VEGETARIANS

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Abstracts: **Background:** Cardiovascular diseases (CVD) one of the major chronic diseases and leading cause of death. One important risk factor for cardiovascular diseases is hyperlipidemia. Our diet determines development of hyperlipidemia to a great extent. **Objective:** Comparison of effect of vegetarian and non vegetarian diet on lipid profile and fasting blood glucose level. **Methods:** Present study was conducted among 100 males of lower middle socioeconomic class of bhuwana village who were divided into two groups based on their diet either vegetarian or non vegetarian. 55 and 45 subjects were included in each group respectively. A questionnaire containing detailed diet history was filled by each subject. Lipid profile and fasting blood sugar were recorded. Data were analysed by applying appropriate statistical test. **Results:** Mean value of total cholesterol, LDL among non vegetarian subjects were 210.60mg/dl, 127.56mg/dl respectively, which was higher than mean value of 171.94mg/dl, 104.46mg/dl respectively in vegetarian group ($P<0.05$). While mean serum triglyceride and HDL was found to be higher in vegetarian subjects which was 135.06mg/dl and 43.47mg/dl, as compared to non vegetarian subjects having mean value of 112.75mg/dl and 41.63mg/dl respectively ($P<0.05$). Fasting blood sugar of vegetarians was 96.48mg/dl while that of non vegetarians was 90.30mg/dl ($p>0.05$) **Conclusion:** Non vegetarian diet alters the lipid profile. Fasting blood glucose is normal in both groups.

Key Words:Fasting blood glucose, hyperlipidemia, lipid profile, non vegetarian, Vegetarian.

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Introduction

Cardiovascular diseases (CVD) one of the major chronic disease, which is the leading cause of death. In India, the death rate from CVD has increased at an alarming rate and is estimated currently as 52 per cent[1]. One of the major risk factors for cardiovascular diseases is hyperlipidemia. Cholesterol disorders or scientifically termed dyslipidemia refers to the clinical conditions produced by lipid aberrations, thus raising the cholesterol and triglyceride levels[2, 3]. Recent study says 80% of cholesterol is produced by liver while only 20% is contributed by dietary sources. [4]

There is great dispute whether vegetarian diet is better or non- vegetarian. The natural diet of man consists of fruits, nuts and grains, not meat. Then the question arises why do large numbers of people eat animal flesh? There is a variety of reasons for people having a non-vegetarian diet. Most people are concerned about their health and many people have the think that non-vegetarian foods being rich in protein and iron are the only source for getting all the nutrients that can make them strong, healthy and active. It is also well known fact that many essential amino acids are only available in animal proteins.

Vegetarian diet is that which excludes all food which is cooked from dead animals. Vegetarians do not eat meat or meat products, but may consume milk, dairy products. This diet, when appropriately planned and balanced, is healthful and provides health benefits, because it acts both in the prevention and in the treatment of diseases [5].Saturated fats, such as animal fats and cholesterol play an important role in person's health. Although some fats are necessary in a balanced diet for body maintenance, saturated fats can be hazardous to one's health, if taken in excess amounts. Diets high in saturated fats and cholesterol, increase cholesterol level in blood and produce atherosclerosis, which leads to heart

disease and stroke. Epidemiological studies on vegetarians show that appropriately planned vegetarian diets are healthy and nutritionally adequate[6]. Compared to omnivorous diets, vegetarian diets can provide several health benefits. Vegetarians have a lower prevalence of overweight and obesity also lower risk of IHD, diabetes and diverticular disease compared with non-vegetarians from a similar background, whereas the data are equivocal for stroke. [7] The long-term health of vegetarians appears to be generally good, and for some diseases and medical conditions it may be better than that of comparable omnivores. However, these positive health-related outcomes in vegetarians can be influenced by factors other than dietary practice.

The lipid profile is a blood test done to access the status of fat metabolism in the body and is important in heart diseases. High circulating serum cholesterol, low density lipoprotein- cholesterol (LDL-C) and serum triglycerides are major risk factors of this disease[8].

Aims and objectives:

- Impact of different composition of vegetarian as well as non vegetarian diet on lipid profile and blood glucose.
- To know effect of different composition of non vegetarian diet such as egg, fish, meat on lipid profile.

Material and Methods

Present cross sectional- observational type of study was conducted among 100 male individuals of 25-40 years residing at the bhuwana village. Reason behind selection of this age group was to exclude effect of normal ageing process on lipid profile as well as blood glucose level since effect of diet on these parameters is chronic. Prior approval from the institute ethical committee was taken. Out of 100, 55 subjects were strict vegetarian while 45 subjects eat different varieties of non vegetarian food that includes egg, meat (red +white) and fish. Frequency of eating non vegetarian food was at least 3 days in week. Socio economic class of all subjects was lower middle according to Kupuswamy classification.[9] As composition and quality of diet may change in different socio economic group, subjects were selected from same locality and socio economic class. All selected subjects were skilled workers who were engaged in mild-moderate type of physical activity (metabolic equivalent task-MET <6) and neither exposed to regular exercise nor regular fast food eater. Preferred method of cooking was fry with use of soyabean oil as it is cheaper and easily available in study area. The subjects were selected by simple random sampling. Subjects with family history of diabetes, hypertension or cardiovascular event, personal history of any chronic disease like diabetes, hypertension or any autoimmune disease, addiction of alcohol, tobacco, smoking, people taking steroidal drugs, people who were acutely ill were excluded from the study.

The data was collected by means of a personal interview and history taking. All the subjects were asked to fill a Performa containing details regarding demographic profile, medical, family, personal, diet history. In diet history whether they are vegetarian or non-vegetarian, type of food intake, food with addition of sugar/ 'gud' to 'dal' and vegetables, addition of oil in making dough, type of oil used in cooking, quantity of oil/ghee and sugar/ 'gud' consumed in the household per month per person, frequency of eating out, frequency and quantity of having sweets and fried food/ snacks/ junk food, frequency and quantity of fruit and vegetable intake, frequency and quantity of dairy products like cheese, paneer and milk made items were also considered.

After personal interview physical examination including height, weight, hip and waist circumference, blood pressure measurement was conducted.

Lipid profile of each subject measured in early morning after overnight fast by portable LipidPlus machine (JantPharmacal Corporation, Encino CA). Blood glucose level was recorded by glucometer (Accu-chek active glucometer). An informed consent of all the participants was taken prior to commencing the study.

We considered following normal range of values for the various parameters.

Lipid profile: Total cholesterol (TC) 150-200 mg/dl, Low Density Lipoprotein (LDL) fraction 80-150 mg/dl, High Density Lipoprotein (HDL) fraction 30-

60 mg/dl, Fasting Serum Triglyceride (TG) 75-150 mg/dl[10].

Blood pressure: systolic blood pressure (SBP) ≥140 mmHg and / or diastolic blood pressure (DBP) ≥90 mmHg taken as hypertensive. Rest all were taken as Non hypertensive (pre hypertensive and normotensive). (JNC 7 report on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure, U. S. Department of Health and Human Services) [11].

Body mass index (BMI): BMI ≥ 30 kg/m² were classified as being Obese and those with BMI ≥25 kg/m² but <30 kg/m² were identified as being Overweight (Global database on BMI, WHO 2005) [12].

Waist Hip Ratio (WHR): a WHR > 1.0 in males was taken as abnormal (Waist Circumference and Waist–Hip Ratio: Report of WHO Expert Consultation 2008) [13].

Fasting blood glucose: <100mg/dl- normal, 100-125mg/dl- prediabetes, >125-diabetes (American diabetes association) [14].

Statistical analysis:

The data was analyzed using Microsoft excel by applying unpaired t-test for quantitative data and using Epi Info 7 version 7.0-8.3. Significance level was taken as $p < 0.05$.

Result:

Table1: Baseline characteristics of Vegetarian and Non vegetarian subjects.

	Vegetarian (Mean ±SD)N=55	**Non vegetarian* (Mean ± SD)N=45**
Age(years)	35.41± 4.49	34.55±4.09
Weight (kg)	70.44±9.18	70.41±14.15
Height (m)	1.67±0.09	1.65±0.07**
BMI (kg/m²)	25.23±2.89	26.50±4.50
WHR	0.80±0.07	0.80±0.10
SBP (mm of Hg)	122.89±11.62	126.32±6.42
DBP(mm of Hg)	83.67±6.42	85.14±5.79
MBP(mm of Hg)	99.41±7.93	99.86±5.53
Pulse rate	80.98±11.60	77.39±6.46**
Average calorie intake (calorie per person/day	2159.35±87.74	2192.96±90.53
Total cooking oil consume (ml/person/ month)	681.36±58.26	688.40±59.21
Total sugar intake(mg/ person/mon th)	900.16±40.68	875.56±37.49**

*frequency of eating non vegetarian food at least 3days a week

** p<0.05

Table 2: Comparison of Lipid profile in Vegetarian and Non- vegetarian subjects

Lipid profile (mg/dl)	**Vegetarian (Mean±SD) N=55**	**Non-vegetarian* (Mean±SD) N=45**
TotalCholesterol	171.94±19.42	210.60±28.96**
LDL	104.46±13.50	127.56±19.25**
HDL	43.47±3.79	41.63±2.83**
S. Triglyceride	135.06±11.20	112.75±12.18**
LDL/HDL Ratio	2.49±0.48	3.14±0.58**
T.Chole./ HDL	4.05±0.70	5.13±0.80**

*frequency of eating Non vegetarian food at least 3days a week

**p<0.05

Table 3: Different food type preference among non vegetarian subjects (n=45)

Non-vegetarian food type*	Meat	Egg	Fish	Egg +fish	Egg +Meat	Fish +Meat	All three
No. of subjects	17	2	0	9	9	4	4

*frequency of eating non vegetarian food at least 3days a week

Table 4: Comparison of lipid profile among different pattern of non vegetarian food

Lipid profile (mg/dl)	Meat (red+white) (Mean±SD)	Egg (Mean± SD)	Egg +Fish (Mean± SD)	Egg+ Meat (Mean±SD)	Fish+ Meat (Mean±SD)	All three (Mean± SD)
TC	224.79±25.46*	200.15± 24.13	169.39± 18.56*	235.37±26.35	223.79±23.47	200.9±20.98
LDL	136.85±12.89*	127.56± 11.74	110.71± 10.36*	130.87±12.50	140.38±13.27	130.45± 12.36
HDL	40.28 ±3.26 *	41.50±3.68	43.20±3.17*	42.50 ±3.08	40.9± 3.04	41.30±3.74
TG	117.35±11.	118.17±	116.87±	108.67±10.	105.98±10.	120.34±
	36	12.49	11.78	89	42	10.39
LDL/ HDL	3.41± 0.36	3.19 ±0.26	2.60 ±0.46	3.05± 0.24	3.45± 0.78	3.21 ±0.21
TC/ HDL	5.61± 0.98	4.85 ±0.74	3.98 ±0.56	5.55± 1.12	5.45± 1.28	4.87 ±0.47

***p<0.05**

Table 5: Comparison of fasting blood sugar level in vegetarian and non vegetarian subjects

	Vegetarian (Mean±SD) N=55	Non-vegetarian* (Mean±SD)N=45
Fasting blood glucose(mg/dl)	96.48±8.24	90.30±9.45**

*frequency of eating non vegetarian food at least 3days a week

**P<0.05

Discussion: The present study is a cross sectional study of people aged 25-40 years residing in the bhuwana village. The aim of the study was to assess effect of vegetarian and non vegetarian diet on lipid profile and blood sugar level and to know which type of diet is better than another. As per table 1 both groups are comparable for most of the baseline characteristics (p>0.05) except height, pulse rate and average intake of sugar. All three parameters were higher among vegetarians as compared to non vegetarians (p<0.05). BMI of both the groups fall under overweight category. Blood pressure is comparable in both groups which are in contrast to result of Yokoyama et al[15] and Ophir et al[16] in which vegetarians exhibit lower BP than non vegetarians. Approximate total calorie intake per person and consumption of cooking oil /person/month were within normal range and groups do not show any significant difference. Soyabean oil is very popular for cooking in this part of India.

Average per capita sugar consumption among vegetarians is significantly high (table 1) as compare to non vegetarians however it is within normal range of 35mg/day as suggested by American diabetes association[17]. Excess sugar intake can cause cardiovascular disease. Jean welsh et al[18] found that people who consumed increased amount of added sugar had increased blood levels of harmful fats. LDL and TG were increased while HDL was decreased.In our study mean fasting blood glucose level among the study groups was within normal range.

Mean total cholesterol, LDL, LDL/HDL ratio, and total cholesterol/HDL in non vegetarian subjects are 210.60mg/dl, 127.56mg.dl, 3.14 and 5.13 respectively, which is higher than mean value of 171.94mg/dl, 104.46mg/dl, 2.49 and 4.05 respectively in vegetarian group ($p<0.05$)

While mean serum triglyceride and HDL is found to be higher in vegetarian subjects which is 135.06mg/dl and 43.47mg/dl, as compared to non vegetarian subjects having mean value of 112.75mg/dl and 41.63mg/dl respectively($p<0.05$).

Result of this study matches with study done by Alexander et al[19] and Li et al[20] indicated that meat-eaters had a significantly higher cluster of cardiovascular risk factors compared with vegetarians, including increased body mass index, waist to hip ratio, plasma total cholesterol, triacyglycerol, LDL levels, ratio of TC/HDL and LDL/HDL, though in our study serum triglyceride is found to be more in vegetarians. It is a well known fact that a high consumption of plant based foods such as fruit and vegetables, nuts and whole grains reduces risk of coronary artery disease and stroke. This vegetarian diet provides protection because of mono and polyunsaturated fatty acids, n-3 fatty acids, antioxidant vitamins, minerals, phytochemicals, fibre and plant protein[21, 22].

Among non vegetarian subjects, various pattern of consumption of non vegetarian food is seen (table 3). These are egg only, meat (red +white) only, egg and meat, fish and meat, egg and fish and all three. Significant difference ($P<0.05$) in blood lipid profile is seen in subjects consuming only meat with total cholesterol and LDL 224.79mg/dl and 136.85mg/dl respectively as compared to consumers of fish and egg with total cholesterol and LDL are 169.39mg/dl and 101.71mg/dl respectively (table 4). Also HDL is higher in fish and egg eaters with 43.20mg/dl as compared to only meat eaters 40.28mg/dl. Research worldwide has indicated that eating fish regularly- one or two servings weekly is beneficial. Fish is low in fat; high in protein and an excellent source of omega 3 fatty acids which reduces incidence of heart disease[23]. We couldn't find an exclusive fish eater since study area is far away from costal line, it was difficult to define lipid profile among exclusive fish eaters. Higher values also found in consumers of egg only with total cholesterol and LDL is 200.15mg/dl and 127.56mg/dl respectively.

Conclusion

Total cholesterol and low density lipoprotein found higher among non vegetarians while high density lipoprotein and triglycerides elevated among vegetarians. Non vegetarian subjects should limit the intake of meat. Fasting blood glucose and blood pressure were within normal range.

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RESEARCH ARTICLE

A correlative study of serum uric acid and serum malondialdehyde level in early essential hypertension

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ABSTRACT

Background: Hypertension (HT) posing a major public health challenge to the universe in socioeconomic and epidemiological transition. Hyperuricemia in HT is coupled with augmented cardiovascular morbidity and mortality. It also predates the development of HT and suggests that it is not simply a consequence of HT *per se*. Increased urate level along with greater production of oxygen-free radical and augmented oxidative stress may contribute to progression of HT. **Aims and Objectives:** This study aims to assess the correlation between serum uric acid (SUA), serum malondialdehyde (S. MDA) level, and blood pressure in early essential HT. **Materials and Methods:** In this cross-sectional study, after applying inclusion and exclusion criteria, 200 subjects were divided into three groups: 50 subjects as control group, 75 in prehypertensive group, and 75 in hypertensive group. SUA and S. MDA level were estimated in all subjects. Data were analyzed by appropriate statistical methods. **Results:** A significant and positive correlation was observed between SUA and S. MDA level in HT group. Both parameters were correlated positively and significantly with systolic blood pressure (SBP), but not with diastolic blood pressure (DBP) in hypertensive individuals. **Conclusion:** An elevated SUA level is predictive for the evolution of both HT and coronary artery disease. Hyperuricemia plays a role in the formation of free radicals and oxidative stress through increased lipid oxidation. Furthermore, positive correlation with SBP further established its potential role in the etiopathogenesis of essential HT.

KEY WORDS: Essential Hypertension; Hyperuricemia; Serum Malondialdehyde Level; Lipid Peroxidation; Oxidative Stress

INTRODUCTION

Essential hypertension (HT) is being increasingly documented as a part of a complex multifaceted disorder worldwide due to its high incidence and associated risks of renal and cardiovascular disease (CVD), for instance, stroke, myocardial infarction, and heart failure. The effective union between HT and hyperuricemia has been documented for more than a century. Studies from the 1950s and 1960s demonstrated the incidence of hyperuricemia in hypertensive cases to be between 20 and 40%.[1] Later on, it was found that an increasing level of serum urate is an autonomous risk factor of HT.[2]

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Raised serum uric acid (SUA) level is also associated with increased cardiovascular morbidity and mortality rate.[3] Its level is thoroughly controlled by the balance among uric acid production and excretion.[4] Urate is freely filtered in the glomerulus, reabsorbed, secreted, and then again reabsorbed in the proximal tubule. Essential HT may also be linked with hyperuricemia with normal renal functions.[5] Hyperuricemia (>5.5 mg/dl [330 μmol/L]) was detected in almost 90% of teenagers with primary HT, whereas uric acid levels were

significantly lower in controls and youth with any white coat or secondary HT.[6] The finding that uric acid levels were not lifted in secondary HT also cuts down the probability that the hyperuricemia resultants from HT.

There are abundant reports that oxidative stress is amplified in patients with HT. Further, the extreme production of reactive oxygen species (ROS) due to raised urate level, out stripping antioxidant defense mechanisms, has been involved in pathophysiological conditions that influence on the cardiovascular system.[7] Moreover, ROS react with membrane lipids to yield lipid hydroperoxide, a destructive process known as lipid peroxidation. Lipid hydroperoxide decomposes to build various products containing malondialdehyde. In the present study, serum malondialdehyde (S. MDA) was used as a biochemical marker for the assessment of lipid peroxidation.

The significance of both SUA and S. MDA level in the development of essential HT has not been thoroughly investigated, especially in Southern Rajasthan. Hence, this study has been designed to study the correlation between SUA, S. MDA level, and blood pressure among newly diagnosed essential HT.

MATERIALS AND METHODS

This cross-sectional case–control study was conducted among 200 subjects in the Department of Physiology, Geetanjali Medical College and Hospital (GMCH), Udaipur. All the subjects were chosen randomly from medicine outpatient department, family members or attendants of established hypertensive patients, individual's comings to hospital for health checkup, and healthy volunteers such as clinical and non-clinical staff of a tertiary care hospital. This study was ethically approved by the institutional ethical committee of GMCH, Udaipur (Ref. No. GU/UCE/EC/2013/299 dated15/05/2013).

Inclusion Criteria

All the sex-matched subjects, aged between 20 and 50 years old were broadly divided into three groups:

- 50 participants with normal blood pressure (systolic blood pressure [SBP] = 90–119 mmHg and diastolic blood pressure [DBP] = 60–79 mmHg) were taken as control group
- 75 cases of prehypertension (preHT) (SBP = 120–139 mmHg and DBP = 80–89 mmHg) were taken as preHT group
- 75 cases of newly diagnosed cases of essential HT (SBP = 140–159 mmHg and DBP = 90–99 mmHg) were taken as HT group.

Exclusion Criteria

The subjects suffering with gout, diabetes mellitus, gestational HT, and/or secondary HT caused by renal disorders, metabolic disorders, fluid volume disturbances, endocrinal disorders, etc., were excluded from the study groups. Smokers, alcohol consumers, and patients on medication for HT were also excluded from the study. After diagnosis, a written informed voluntary consent was taken from all the participants after explaining their participation in the study in their local language. All the data from three groups were collected in the detailed pro forma along with required physical examination. For biochemical analysis, blood sample (5 ml) was drawn after an overnight fasting (12 h) by venous puncture and serum was separated by centrifugation at 3000 rpm for 10 min. SUA level and S. MDA were estimated using commercially available reagents or kits.[8,9]

Statistical Analysis

The data were analyzed using the Statistical Package for the Social Sciences (SPSS) version 16. Significance testing of difference for mean of three groups was done by analysis of variance test (ANOVA). $P < 0.05$ was used to establish statistical significance. The correlation between different parameters was assessed by Pearson coefficient of correlation test.

RESULTS

Figures 1 and 2 showing that the difference in mean of SUA level and S. MDA level between control, preHT, and HT group was highly significant ($P < 0.0001$). Table 1 shows that SUA level was significantly and positively correlated with SBP

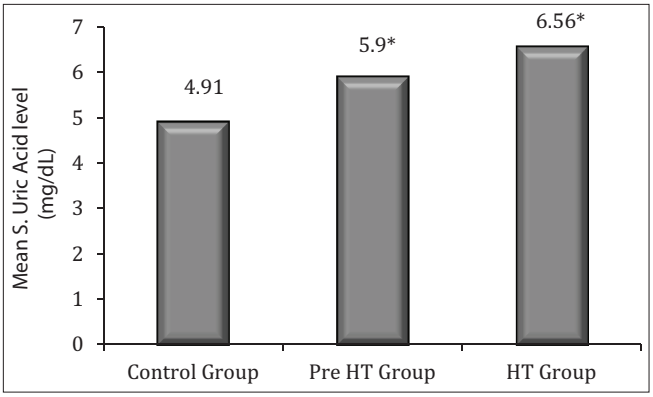

Figure 1: Comparison of mean serum uric acid level among different groups (*significant with $P < 0.001$)

Table 1: Correlation of serum uric acid levels with various parameters

Parameters	Control group		Hypertension group	
	r value	*P* value	*r* value	*P* value
SBP	−0.234	NS	+0.478	<0.001
DBP	−0.230	NS	+0.202	NS
S. MDA	+0.236	NS	+0.574	<0.001

S. MDA: Serum malondialdehyde, SBP: Systolic blood pressure, DBP: Diastolic blood pressure

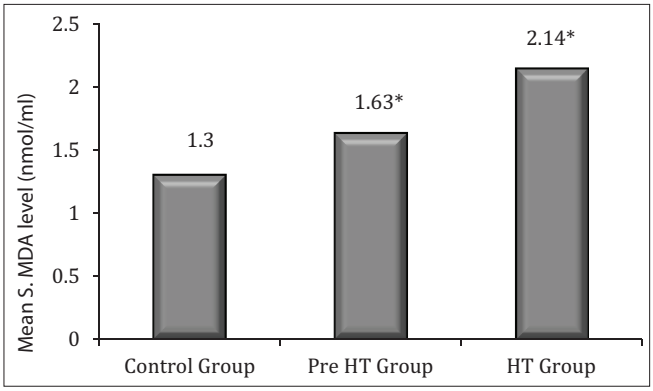

Figure 2: Comparison of mean serum malondialdehyde level among different groups (*significant with $P < 0.001$)

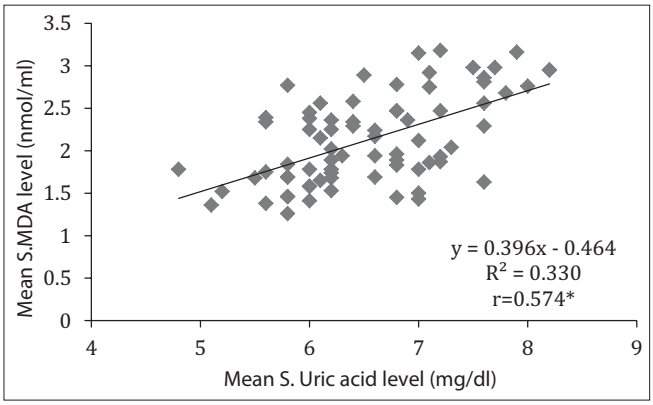

Figure 3: Correlation between serum uric acid levels and serum malondialdehyde levels (*significant with $P < 0.001$)

(r = +0.478, $P < 0.001$) and S. MDA (r = +0.574, $P < 0.001$), whereas no significant correlation was found with DBP ($P > 0.05$). Figures 3-5 showed that S. MDA was significantly and positively correlated with SBP (r = +0.486, $P < 0.001$) and SUA (r = +0.574, $P < 0.001$), whereas no significant correlation was found between S. MDA and DBP ($P > 0.05$).

DISCUSSION

In this study, we found that the mean of SUA level and S. MDA level in hypertensive group was significantly higher as compared to prehypertensive and controls ($P < 0.001$). The increased trend in mean SUA level was observed from control to prehypertensive and prehypertensive to hypertensive cases [Figures 1 and 2]. Results also showed that SUA and S. MDA were significantly and positively correlated with each other and SBP ($P < 0.001$), whereas no significant correlation was observed with DBP ($P > 0.05$) for the same.

Masuo *et al*. assessed the linear relationship of SUA and SBP and showed an average raise of 23 mmHg per 1 mg/dl increase in SUA within non-obese young men.[10] Another study on 125 children (age group 6–18 years) with essential HT proved the association of SUA with SBP (r = 0.80) and DBP (r = 0.66).[6] In support to our study, Acharya and Mishra found that S. MDA level was significantly and positively correlated

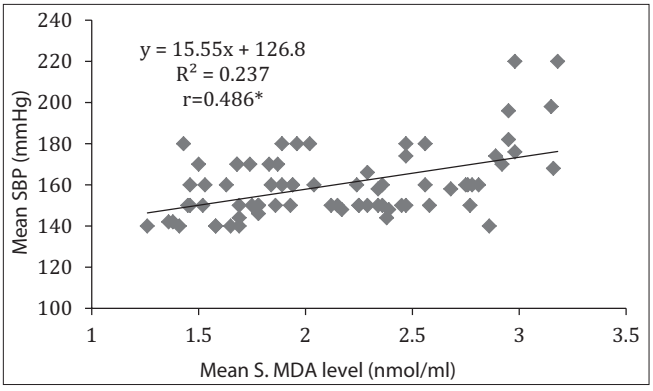

Figure 4: Correlation between serum malondialdehyde levels and systolic blood pressure (*significant with $P < 0.001$)

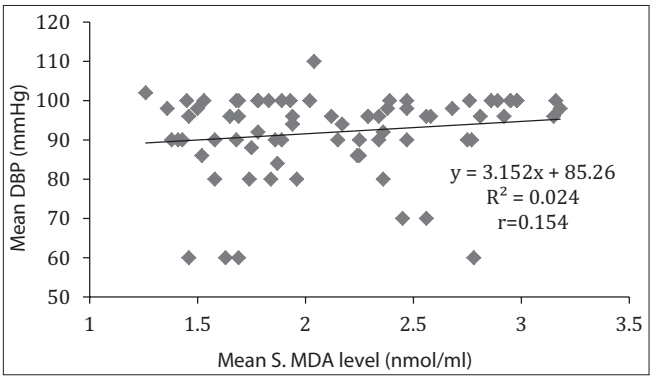

Figure 5: Correlation between serum malondialdehyde levels and diastolic blood pressure (*significant with $P < 0.001$)

with SBP (r = +0.364, $P < 0.01$) and SUA level (r = +0.289, $P < 0.05$). They found no significant correlation between S. MDA and DBP.[11] Amirkhizi *et al*. assessed the oxidative stress marker related to atherosclerosis in prehypertensive women. Regarding MDA level, they attained that MDA was positively correlated with both SBP (r = +0.24, $P < 0.001$) and DBP (r = +0.18, $P < 0.001$).[12] Ouppatham *et al*. examined the relationship of hyperuricemia and blood pressure in the Thai army population and observed a significant and positive correlation between both SUA levels and SBP (r = 0.186, $P < 0.001$) and same with DBP (r = 0.255, $P < 0.001$).[13] However, Teng *et al*. described a contrary result, wherein uric acid was associated with the risk of HT in the elderly.[14]

Hyperuricemia is commonly experienced with essential HT, even untreated HT. Studies in animal models proposed that hyperuricemia may be predominantly important in early HT[15] and likewise studies in humans illustrated that the strongest relationship of hyperuricemia is with premature HT such as discovered in adolescents.[6] Contrary to these findings, a number of studies have recommended that the association between elevated SUA and cardiovascular risk does not carry on after rectifying for other risk factors.

Experimental studies provide a credible physiologic mechanism by which increases in SUA might cause HT. Uric acid enters vascular smooth muscle cells, where it stimulates

mitogen-activated protein kinases, cyclooxygenase-2, and platelet-derived growth factor to stimulate vascular smooth muscle proliferation and preglomerular arteriolopathy.[15,16] Increased SUA further causes an increase in juxtaglomerular renin production and a decrease in macula densa neuronal nitric oxide (NO) synthase expression, leading to renal vasoconstriction and probably increasing blood pressure.[17] If renal vasoconstriction persistent, it may impart to arteriosclerosis and the exploitation of salt-sensitive HT, even if the hyperuricemia is rectified.

In addition, SUA plays a role in the formation of free radicals and may elucidate the link between hyperuricemia and HT.[18] Augmented intracellular uric acid may accelerate oxidative stress directly by raising NADPH oxidase linked ROS or generated by stimulation of xanthine oxidase during the generation of uric acid as well. Oxidative stress may contribute to the generation and/or development of HT through a number of probable mechanisms included (a) curbing of the vasodilator NO by ROS such as superoxide, (b) production of vasoconstrictor lipid peroxidation products, (c) diminution of tetra hydrobiopterin (BH4), an important NO synthase cofactor, (d) structural and functional changes within the vasculature.[19]

Experimentally, by means of which, hyperuricemia results in HT are by way of oxidative stress, endothelial dysfunction, and activation of the renin angiotensin system. The net effect is to provoke renal and systemic vasoconstriction and the progression of HT. Increase in SUA has been demonstrated as an earlier marker of HT, which occurs even before the modification in serum creatinine.[18]

Limitations

As the present study is hospital-based case–control study, so to establish these results to the population of Southern Rajasthan, large sample size should be taken.

CONCLUSION

From the above discussion, it can be concluded that increased serum MDA in hypertensive indicates an association between increased oxidative stress and HT. SUA through lipid peroxidation might be processing toward the etiopathogenesis of essential HT even in its former stages, and its serum level may be a modifiable factor for progression of the disease. Measuring these biomarkers in clinical practice may identify high-risk individuals. Further, the maintenance of the oxidative balance and SUA in hypertensive patients would be helpful in preventing the CVD and other diseases associated with HT.

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Effect of Treadmill Exercise on Blood Glucose Control in Type-2 Diabetes Mellitus Patients

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Abstract

Background: Diabetes mellitus type 2 is because of resistance to insulin resulting in inability to utilize glucose. In addition to medicines and diet control, regular exercise helps in increase in utilization of glucose.

Aims & Objectives: To study efficacy of exercise especially treadmill walking on controlling blood glucose homeostasis in diabetes mellitus.

Material and Method: The study was conducted on 40 clinically confirmed cases of type-2 diabetes mellitus male patients who were divided in study group and control group with 20 patients in each group. Study was conducted for period of 8 weeks. Diet plan was formed by expert during this period and subjects were instructed to follow it strictly. Fasting blood glucose and postprandial blood glucose was measured before and after exercise programme.

Findings: There is significant decrease in fasting blood glucose and Postprandial blood glucose level in study group as compared to control group with inter-group difference was significant ($P<0.05$).

Conclusion: Treadmill exercise is very useful for blood glucose control in addition to diet control and medicines.

Keywords: *Type-2 diabetes mellitus, Treadmill exercise, Fasting blood glucose, Postprandial blood glucose, Glycemic control.*

Introduction

Diabetes mellitus (DM) refers to a group of common metabolic disorders that share the phenotype of hyperglycemia. The two broad categories of DM are designated type 1 and type 2. Both types of diabetes are preceded by a phase of abnormal glucose homeostasis as the pathogenic processes progress. Type 1 DM is the result of complete or near-total insulin deficiency. Type 2 DM is a heterogeneous group of disorders characterized by variable degrees of insulin resistance, impaired insulin secretion, and increased glucose production.[1]

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The prevalence of diabetes is going to double globally from 171 million in 2000 to 366 million in 2030 with maximum increase in India. By 2030, around 79.4 million people will be affected by diabetes according to prediction made by Wild et al.[2]

In addition to medication and diet control, exercise is also helpful in increasing insulin sensitivity. American diabetes association recommends moderate aerobic physical activity of 150 minutes/week.[3] Walking is considered to be the best exercise as it involves larger muscles of lower limb as well as muscular work of upper limb. Treadmill machine which is electronically driven or manual simulates all the features of natural walking.

Material & Method

In our study we used treadmill (Phillips, Novafit turbo) machine, oscilloscope for measuring heart rate and respiratory rate, Sphygmomanometer for measuring

blood pressure, weighing scale. Permission from institutional ethical committee was taken.

From diabetes OPD 40 male patients of age group 45-55 years who were clinically and biochemically confirmed cases of diabetes included in study after obtaining informed consent. Patients with known case of cardiac, respiratory, renal and musculoskeletal disorders were excluded from programme. Those who were willing to do exercise were included in study group and who were not willing to do exercise were included in control group.

Whole programme was conducted for period of 8 weeks. At the beginning of study, fasting blood sugar (FBS) and postprandial blood sugar (PPBS) was measured for all subjects. Additionally weight, height and body mass index was measured. Subjects were examined for any muscular weakness in lower limb. Regular diet may vary in different subjects so diet plan was formed for whole day by advice of dietician and they were explained to follow it strictly during the whole exercise programme so as to avoid effects of diet on blood glucose level.

Treadmill machine (Phillips, Novafit turbo) used for the study can measure speed in form of RPM, total distance travelled in kilometers and calories used during exercise. All subjects in study group were first given demonstration of treadmill machine to make them familiarize. Programme was conducted for total 40 minutes which include 5 minutes of warm up, 30 minutes of treadmill walking followed by 5 minutes of rest. All subjects were instructed to report immediately if they feel breathlessness, headache, dizziness or any other symptoms which are indicative for stopping exercise. Blood pressure, heart rate and respiratory rate were taken in supine at the beginning of exercise.

First warm up was done in the form of active limb movements and muscle stretching. Then oscilloscope was attached for monitoring of heart rate, respiratory rate and blood pressure. Subjects were instructed to walk on treadmill for 30 minutes. Speed of treadmill machine was set to 3.5 km/hour with fixed inclination. All the subjects were constantly monitored for development of any symptoms and any noticeable change in parameters. At the end of thirty minutes, parameters were measured immediately and then they are instructed to take rest for five minutes. Vital parameters were also taken during recovery period of five minutes. This completed session was conducted for five days in a week for total 8 weeks. At the end of 8 weeks FBS and PPBS was taken again for both groups. Statistical analysis was done using student's t test with p value < 0.05 is considered as statistically significant.

Findings

All the subjects in study group completed exercise programme without any event. Pre and post exercise blood glucose levels are compared in both study and control group.

In study group, FBS and PPBS level before exercise was in the range of 150-196 mg% and 180-212 mg% respectively. After exercise programme range of FBS and PPBS was 130-162 mg% and 156-170 mg% respectively.

In control group, FBS and PPBS level before exercise was in the range of 154-202 mg% and 184-210 mg% respectively. After 8 weeks of observation range of FBS and PPBS was 150-188 mg% and 168-200 mg% respectively.

Difference between FBS and PPBS before and after programme in both the group was compared (Table-1). Mean decrease in FBS in study group was 38.6 mg% while in control group it was 26.8 mg% with intergroup difference is statistically significant ($p<0.05$). In study group decrease in PPBS was 42.8mg% as compared to control group having difference of 30.4 mg%. So inter group difference in PPBS is statistically significant (p value <0.05). Also subjects in study group reported of feeling of well being with loss of average two kilograms weight.

Table-1 Comparison between study and control group for change in FBS and PPBS after programme

Difference	Study group (mean±SD) Control group (mean±SD) n=10
FBS1-FBS2	38 ± 8.275 26 ± 8.910*
PPBS1-PPBS2	42 ± 6.784 30 ± 8.623*
FBS1- Fasting blood glucose before exercise FBS2- Fasting blood glucose after exercise PPBS1- Postprandial blood glucose before exercise PPBS2- Postprandial blood glucose after exercise *p<0.05, student t-test	

Discussion

Diabetes Mellitus is a clinical syndrome comprising a heterogeneous group of metabolic diseases that are characterized by chronic hyperglycemia and disturbances in carbohydrate, fat and protein metabolism secondary to defects in insulin secretion, insulin action or both.[4] Comprehensive management of diabetes includes drugs, insulin, lifestyle changes comprising of diet control, exercise and education.[5] In this study, efficacy of treadmill exercise on control of blood glucose was studied in addition to diet control and medication. Exercise improves insulin sensitivity and therefore has a positive effect on blood glucose control. In addition it also has positive effects on lipid profile and blood pressure and it is important part of weight management programme. For inactive person it is better to start with at least 5 minutes daily and then gradually increase 5 minutes to up to at least 30 minutes of daily walking.[6] Only problem with diet and exercise is that it requires strong motivation and self confidence. So for the patient's perspective oral drugs for diabetes is the best management.

At the beginning of exercise, muscle utilizes stored glycogen as fuel consumption. But it is available only for short period only. If activity is continued, glycogenolysis becomes source of glucose and then after few minutes gluconeogenesis starts in liver. After depletion of glycogen store in liver, stored fat in adipose tissue converted into fatty acids which are used as fuel by muscle.[7]

Wahren et al. reported that working muscles are more sensitive to insulin as compared to resting muscle, which increase utilization of glucose. Also during exercise blood flow to working muscle increase which increase size of capillaries and number of insulin receptors which ultimately balance sensitivity of insulin.[8]

Shivananda nayak et al. reported that after six weeks of treadmill exercise, glucose utilization is increased in muscle which has positive effects on glucose homeostasis with significant fall in fasting and postprandial blood glucose level.[9]

Exercise programme is also affected by some factors like type of exercise, duration of exercise, intensity and frequency of exercise. According to American college of sports medicine, exercise with low intensity but long duration gives better result as compared to high intensity short duration exercise. Duration of exercise should be gradually increased over days. Exercise programme should be restricted to five days per week. Intensity can be controlled by counting target heart rate with formula of subtracting your age from 220. In this study it was found that endurance exercise helps in control of blood glucose level. It works by increasing insulin sensitivity in exercising muscle. As compared to resting condition, numbers of insulin receptors are more in working muscle which ultimately helps to utilize glucose despite low production by pancreas as in diabetes mellitus.

Conclusion

Well planned exercise programme which is strictly followed can improve glycemic control and also helps to reduce weight. In addition to mental well being it reduces cardiovascular risk factors in patients of diabetes mellitus.

Conflict of Interest: None

Source of Funding: Institution

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Original research article

Study of Lipid profile, Liver enzymes and Haematological parameters in alcoholic individuals.

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Abstract

Context: Alcohol consumption has been steadily increasing all over world, especially in India. Alcohol can cause physical, mental and social effects which is determined by quantity and pattern of alcohol drinking.

Aim: Present study was conducted to observe alterations in the biochemical and haematological parameters in heavy alcohol consumers.

Subjects and Method: 40 young males of 20-40 years age with history of daily alcohol consumption for past one to five years duration were included in study .Estimation of the biochemical and haematological parameters were carried out in study and control subjects**.**

Statistical Analysis: Analysis of the haematological and biochemical parameters data of the study subjects and controls was done by using student t test

Results: Lipid profile parameters were not altered in study subjects .Liver enzymes AST and ALT were significantly elevated in alcoholic subjects. Hemoglobin and platelets was lower in alcoholic subjects. Mean corpuscular volume was significantly higher in alcoholics.

Conclusion: These alterations of liver enzymes and haematological parameters in alcoholics can be used as early indicator of alcohol abuse and person can be motivated to stop alcohol consumption.

Key words: Alcoholics, Lipid profile, Liver enzymes, Hemoglobin

Introduction

Alcohol is not often thought as a drug largely because its use is common for both religious and social purposes in most parts of world. However , it is a drug and of all the drugs , alcohol is the only drug whose self induced intoxication is socially acceptable. Compulsive drinking in excess has become modern society's one of the most serious problems [1] . Alcohol has been widely consumed through ages because of its perceived benefits as a social lubricant and for relaxation , mood alteration and sensory pleasure . But long term consumption of large amount is harmful leading to addiction and fatal or non fatal injuries . Alcoholism is a worldwide social and medical problem . Over the past 30-40 years , alcohol consumption has increased in quantity and frequency [2] . The age at which people start drinking has also declined. Consumption of alcohol in young people has created concern as alcoholism may run a greater risk of alcoholic problems in later life [3] .All organs can be damaged due to direct effects of alcohol, especially the digestive and nervous systems . At the level of

digestive system , alcohol causes gastrointestinal problems , cirrhosis of liver , pancreatitis and cancer of mouth , pharynx and oesophagus . At level of nervous system it causes problems with reflexes , vision , equilibrium of the body , lesions of nerves [4] . Alcohol has numerous adverse effects on various types of blood cells and their functions [5]. Other effects include loss of appetite, vitamin deficiency , infection , sexual impotence and menstrual irregularities. The diagnosis occurs when the adverse effects are already obvious and recognizable[6]. Effective and low cost methods are now available for identification and treatment of alcohol addiction at an early stage . They include various haematological and biochemical parameters. Some of the commonly studies parameters are Aspartate amino transferase (AST), Alanine amino transferase (ALT) , Alkaline Phosphatase, and haemoglobin (Hb%) , Mean corpuscular volume (MCV) , Mean corpuscular Haemoglobin (MCH) . Combination of one or more of these markers has been reported to give better sensitivity and diagnostic accuracy characterizing the early events leading to alcoholic disease at later stage. Earlier studies have shown the once the alcohol consumption is stopped at earlier stage, the alteration are reversed, thus altering the pathway of morbidity and mortality and ensure a disease free life to the individual.

The present study was done to identify the alteration in serum lipid profile, liver enzymes (AST, ALT) and haematological parameters like haemoglobin (Hb%) Mean corpuscular volume (MCV) , Mean corpuscular Haemoglobin (MCH) , platelet counts in asymptomatic young alcoholic individuals of 20-40 years age group, which were considered as a heavy drinkers with history of consumption of alcohol for one to five years.

Material and methods:

This case control study was conducted in November 2019 to February 2020 . The study was done by obtaining blood and serum samples from study and control subjects . The samples were drawn in morning under aseptic precautions after over night fast . The study group consisted of 40 subjects and 40 control subjects . They were selected on the basis of following inclusion and exclusion criteria.

Inclusion criteria:

Male subjects aged 20-40 years with history of heavy alcohol consumption for duration of one to five years .

Exclusion criteria :

Person with following disorders were not included in study.

- Hypertension
- Diabetes mellitus
- Malignant condition
- Cardiovascular and respiratory disorders
- Individual on medication
- Smokers

Collection of blood samples , which is invasive procedure and need overnight fasting was explained to the subjects in detail. Subjects unconditionally gave consent to participate in study. The study complied with the Declaration of Helsinki and protocol was approved by the institution review board.

Method of collection of data.

- A questionnaire was given to the subjects and controls to elicit the details of alcohol consumption , history of past or present illness [7] .

- The average number of alcohol drinks consumed per mouth was asked .Daily consumption of six or more drinks (> 90 ml daily) was defined as heavy drinker [8] .
- Height and weight was recorded . Body mass index was calculated.
- Vital parameters like pulse rate , Blood pressure was recorded .Detail examination of cardiovascular , Respiratory system , Abdomen and Central nervous system was done.
- Under aseptic precautions 4 ml of blood was drawn from anterior cubital vein .2ml was taken in EDTA bulb for estimation of Haematological parameters and 2 ml was taken in a plain bulb for estimation of lipid profile and liver enzymes in blood .
- Serum lipid profile and liver enzymes were estimated by using Biochemistry Analyzer.
- Haematological parameters were measured by using Automated hematology Analyzer.
- Following parameters were studied .

1) Lipid profile - Total cholesterol (TC) ,High density lipoprotein cholesterol (HDL-C) ,low density lipoprotein cholesterol (LDL-C) , Very low density lipoprotein cholesterol (VLDL-C), and Triglycerides TL.
2) Liver enzymes - Aspartate amino transferase (AST) , Alanine amino transferase (ALT) , Alkaline Phosphatase .
3) Haematological parameters like haemoglobin (Hb %) , Mean corpuscular volume (MCV) , Mean corpuscular Haemoglobin (MCH) , platelet counts

Statistical Analysis :

Analysis of the haematological and biochemical parameters data of the study subjects and controls was done by using student t test [9,10] . p value was calculated , $p < 0.05$ was considered significant and $p < 0.01$ was considered highly significant , > 0.05 was considered not significant .

Results :

The results obtained were expressed as Mean ± Standard deviation . p value was calculated

Anthropometric data

The table 1 shows anthropometric data of the study subjects and controls . There was no significant difference in Age , Weight , Height , BMI between study and control groups.

Table 1 : Anthropometric data of control and study subjects .

Anthropometric Parameters	Control subjects Mean ± SD (n = 40)	Study subjects Mean ± SD n = 40	P value	Significance
Age (Years)	30.8 ± 2.8	31.48 ± 3.22	> 0.05	Not Significant
Weight (Kg)	60 ± 7.23	63.36 ± 4.24	> 0.05	Not Significant
Height (Cm)	165.3 ± 7.2	163.4 ± 5.82	> 0.05	Not Significant
BMI (Kg/ m^2)	22.82 ± 2.54	23.24 ± 2.24	> 0.05	Not Significant

Vital data

Resting pulse rate :

The Mean ± SD of pulse rate at rest in control was 76.24 ± 3.26 beats / minute and in study subject was 72 ± 4.32 beats / minute .There was no significant difference in the resting pulse rate between the two groups.

Blood Pressure :

The Mean ± SD systolic blood pressure at rest in controls was 122.24 ± 4.26 mm Hg and 124.42 ± 6.18 mm Hg in study subjects .

The Mean ± SD diastolic blood pressure was 78.62 ± 4.24 mm Hg in control and 76.34 ±3.82 mm Hg in study subjects.
There was no significant difference in Blood Pressure between study and control group.

Lipid Profile :

The lipid profile data of study and controls are shown in Table 2.

Table 2: Lipid profile data of control and study subjects .

Parameters of Lipid Profile (mg/dl)	Control subjects Mean ± SD (n = 40)	Study subjects Mean ± SD (n = 40)	P value	Significance
Total cholesterol	210 ± 36.24	218.18 ± 32.46	> 0.05	Not Significant
HDL-cholesterol	42.46 ± 6.48	40.24 ± 8.21	> 0.05	Not Significant
LDL-cholesterol	140.18 ± 32.78	138.24 ± 30.68	> 0.05	Not Significant
VLDL-cholesterol	26.82 ± 10.26	27.76 ± 11.34	> 0.05	Not Significant
Triglycerides	148.72 ± 48.26	150.36 ± 44.34	> 0.05	Not Significant

There was no significant difference between the serum lipid profile parameters between study and control subjects.

Liver enzymes :

The data of liver enzymes of study and controls are shown in table 3.

Table 3: Liver Enzymes data of control and study subjects

Liver enzymes (IU/L)	Control subjects Mean ± SD (n = 40)	Study subjects Mean ± SD (n = 40)	P value	Significance
AST	21.38 ± 6.72	34.42 ± 7.26	<0.01	Highly Significant
ALT	16.84 ± 8.03	25.76 ± 9.34	<0.05	Significant
Alkaline Phosphatase	62.76 ± 11.42	60.82 ± 9.34	>0.05	Not Significant

AST levels were more in alcoholic subjects as compared to control subjects and this difference was statistically highly significant .
ALT levels were significantly higher in alcoholic subjects as compared to control group subjects.
There was no significant difference in alkaline phosphatase levels between the two groups.

Haematological parameters :

Table 4: Haematological parameters of study and controls .

Haematological parameters	Control subjects Mean ± SD (n = 40)	Study subjects Mean ± SD (n = 40)	P value	Significance
Haemoglobin (gm/ dl)	13.64 ± 1.24	11.34 ± 1.05	<0.05	Significant
Mean corpuscular volume(fL)	84.76 ± 5.37	92.84 ± 6.24	<0.01	Highly Significant
Mean corpuscular aemoglobin(pg)	31.86 ± 1.24	32.241.18	>0.05	Not Significant
Platelet count (lac /mm^3)	2.75 ± 0.67	2.01 ± 0.48	<0.01	Highly Significant

Haemoglobin was lower in study subjects .There was significant difference in haemoglobin levels in study and control group subjects .The Mean corpuscular volume of the study subjects was significantly higher as compared to controls. There was no significant difference in Mean corpuscular Haemoglobin values between two groups. Platelet count was lower in the study subjects as compared to control subjects and this difference was highly significant.

Discussion :

This study was conducted to find the effects of alcohol abuse in young adults of 20-40 years age group with history of heavy consumption of alcohol for duration of one to five years .The effects of alcohol intake on serum lipids and lipoprotein depends on the dose and mode of alcohol intake , individual susceptibility , genetic variables and dietary factors .In heavy drinkers the synthesis of VLDL is stimulated .Even short term use of alcohol stimulate lipoprotein lipase activity in adipose tissue and consequently the concentration of VLDL in plasma stays normal or is even subnormal . There is increased transport rate of VLDL particles as a result of high lipoprotein lipase activity results in upregulation of HDL receptors [11].

In our study , lipid profile parameters like Total cholesterol , HDL cholesterol LDL cholesterol and triglycerides were studied .We observed that there was no significant alteration in the lipid profile parameters between control and study subjects. This findings correlates with the previous study done by T. Oduaola et al in which there was no association between alcohol intake with total cholesterol levels [12]. Similar observation were also found in a study conducted by Marita Passilta et al in which there was no difference in HDL-C and LDL-C concentration between controls and in those with highest alcohol intake [13]. However , Vaswani . M et al in their study found values of Total cholesterol , HDL-C , VLDL-C , Triglycerides except LDL-C were higher in alcohol dependents as compared to non dependent subjects . Similarly study by John .B Whitfield et al , showed that the triglycerides levels were increased with increasing alcohol intake . Studies by J.B Ruidavets et al and Hans Hoffmeister et al , found that blood levels of HDL- C increased with increasing alcohol intake [14,15] . The above studies were conducted in people with history of longer duration of alcohol consumption of greater than 5 years , which may be reason for the alteration in lipid profile in these subjects . Our results showed no alteration in lipid profile as our subjects were exposed to shorter duration of one to five years . In our study we studied the liver enzymes like SGOT , SGPT , and alkaline phosphatase .We observed that the liver enzymes SGOT , SGPT were significantly higher in study subjects as compared to controls . Alkaline phosphatase did not alter in both groups. Osaretin Albert Taiwo Ebuehi et all in a study found the activities of SGOT , SGPT Alkaline phosphatase of heavy drinkers were higher as compared to moderate drinkers and non drinkers [16] .An association between liver disease and heavy alcohol consumption was recognised more than 200 years ago [17] . The liver is particularly susceptible to alcohol related injuries .Since liver is the major site of alcohol metabolism .Alcohol is broken down in liver and free radicals are generated .Liver injury is caused by direct toxicity of free radicals [18]. When hepatocytes are damaged , they leak enzymes in to blood .Hence level of liver enzymes in plasma is important indicator of liver dysfunction .

Various haematological parameters like Haemoglobin content , Mean corpuscular volume , Mean corpuscular haemoglobin and Platelets were studied in our study. Haemoglobin was lower in alcoholic subjects as compared to controls subjects and this difference was statistically significant. Anemia was found in a study conducted by Subir Kumar Das et al , Latvala J et al and Louis.W Sullivan et al [19,20,21] . A number of clinical observation in man have suggested that alcohol may act as a haematological toxin in body. In our study MCV was higher in study subjects as compared to controls and this was statistically highly

significant. Platelets count was lower in study subjects as compared to controls and this difference was statistically highly significant. A study conducted by John Lindenbaum et al , showed a marked decrease in platelet count in alcoholics [22]. David Savage et al found an increase of MCV and lower platelet counts much more commonly associated with heavy alcoholic intake [23] .

The adverse effects of alcohol on Haemopoietic system are both direct and indirect . Direct effect of alcohol consumption include toxic effects on bone marrow and blood cell precursors. The indirect effect include nutritional deficiencies like folic acid and other vitamin resulting in macrocyte of red blood cells .Alcohol intake can interfere with a late stage of platelet production by suppressing the maturing megakaryocytes . Alcohol also shorts the life span of existing platelets .

Conclusion :

The present study concludes that consumption of alcohol for duration of one to five years may not alter the levels of lipid parameters in body .Liver enzymes were increased in heavy drinkers as compared to non alcoholics . Anaemia is commonly observed in alcoholics. There alteration can be considered as early indicater of alcoholism . These changes are found to be reversible once alcohol consumption is stopped as observed by many researchers .Therefore awareness should be created among public regarding major health problem associated with alcohol intake .This will help to lesser the damage and better recovery of alcoholic individuals .

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Section Physiology

Original Article

Change in Basal Cardiac and Respiratory Parameters after Regular Practice of Bhramari Pranayama and Yoganidra in Young Medical Students

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ABSTRACT

Background: *Chronic obstructive pulmonary disease (COPD) patients are prone to exacerbation that account for significant morbidity and mortality. According to physio-pathologic and clinical-functional viewpoints, bronchiectasis and COPD have some common characteristics, it has been observed that bronchiectasis was present in up to 50% of patients with moderate to severe COPD . This observation suggests that COPD is a risk factor for bronchiectasis. Previous studies support the beneficial effect of Bhramari pranayama and Yoganidra individually in hypertension and other diseases. This is a study to evaluate effect of combination of pranayama and meditation on basal cardiac and respiratory parameters in young healthy individuals.*

Aim*: The aim of this study was to investigate the effect of regular practice of Bhramari pranayama and Yoganidra for 3 months on the basal cardiac and respiratory parameters of young healthy medical students.*

Methods: *Total 94 young medical students were selected who performed Bhramari Pranayama and Yoganidra for a duration of 3 months. Basal values of pulse, blood pressure and respiratory rate were recorded on each student before and after yoga.*

Results: *In our study mean pulse rate before yoga was 76.39 ± 4.34 per min. and after yoga it reduced to 74.56 ± 3.55 per min ($p < 0.001$) .The basal systolic blood pressure before yoga was systolic 117.12 ± 4.470 mm Hg and diastolic 74.18 ± 3.884 mm Hg .After 3 months of yoga systolic reduced to 114.18 ± 4.103 mm Hg and diastolic blood pressure fell to 71.37 ± 2.570 mm Hg ($p < 0.001$). Before yoga the mean respiratory rate was 19.25 ± 1.756 per minute which reduced to 18.16 ± 1.37 per minute ($p < 0.001$).*

Conclusions*: Bhramari Pranayama and Yoganidra significantly reduced pulse, blood pressure and respiratory rate.*

Keywords: *Bhramari Pranayama, Yoganidra, Pulse, Blood pressure, Respiratory Rate*

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INTRODUCTION

Yoga has been scientifically proven to be beneficial in a number of diseases till date. In modern times sedentary lifestyle and stress has increased the incidence of diseases like hypertension, diabetes etc.

Two specific techniques i.e. pranayama and Yoganidra have been individually shown to have beneficial effects on the cardiovascular and respiratory parameters.

Pranayamic breathing has been shown to contribute to a physiological response characterized by the presence of decreased oxygen consumption, decreased heart rate, and decreased blood pressure, as well as increased theta wave amplitude in EEG recordings, increased parasympathetic activity accompanied by the experience of alertness and re-invigoration.[1]

Training in yogic respiratory exercises, selectively increases the respiratory sensation, perhaps through its persistent conditioning of the breathing pattern.[2]

Also meditation & relaxation techniques like Yoganidra can also be beneficial in preventing hypertension.[3]

The practice of a combination of yoga with meditation has been shown in some studies to have profound effect on cardiac and respiratory parameters.[4] But there are very few

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studies which have evaluated this combination.

Our study aimed at studying effect of a combination of a pranayama and a meditation technique viz. Bhramari Pranayama and Yoganidra on basal cardiac and respiratory parameters.

METHODS

This study was done at Department of Physiology, SSMC Rewa (Madhya Pradesh), India. 94 medical students in the age group of 17-27 years participated in the study after obtaining clearance from an ethical committee of the institute and after taking written informed consent. They did Bhramari Pranayama and Yoganidra under guidance for 3 months. Those excluded from the study were anyone having respiratory or cardiac diseases or those on medical treatment. Pulse, respiratory rate and blood pressure was measured. Statistical analysis was done by MS Excel 2010 software.

RESULTS

This study was done at Department of Physiology, SSMC Rewa (Madhya Pradesh), India. 94 medical students in the age group of 17-27 years participated in the study after obtaining clearance from an ethical committee of the institute and after taking written informed consent. They did Bhramari Pranayama and Yoganidra under guidance for 3 months. Those excluded from the study were anyone having respiratory or cardiac diseases or those on medical treatment. Pulse, respiratory rate and blood pressure was measured. Statistical analysis was done by MS Excel 2010 software.

Table : Showing comparison of Pulse & Respiratory Rate in the subjects before and after Yoga

S No	Parameters	Before Yoga		After Yoga		Difference of mean value	P value
		Mean Value	S. D.	Mean Value	S. D.		
1	**Pulse Rate** (per min.)	76.39	4.342	74.56	3.55	1.83	<0.001
2	**Respiratory Rate** (per min.)	19.25	1.756	18.16	1.37	1.09	<0.001
3	**Systolic blood pressure** (mmHg)	117.12	4.470	114.18	4.103	2.9375	<0.001
4	**Diastolic blood pressure** (mmHg)	74.18	3.884	71.37	2.570	2.8125	<0.001

Thus all the cardiac and respiratory parameters examined i.e. pulse, respiratory rate and blood pressure (systolic and diastolic) had reduced significantly with regards to the difference in their mean value before and after bhramari pranayama and Yoganidra ($p<0.001$).

DISCUSSION

It was found in our study that there was significant reduction in pulse, respiratory rate and both systolic and diastolic blood pressure after regular practice of Bhramari Pranayama and Yoganidra. It is explained increased effect of the parasympathetic system on the autonomic regulation of these parameters as illustrated in many studies.

K Upadhyay Dhungel et al reported a decrease in pulse rate after Nadisudhi Pranayama for 4 weeks in their study.[5] Varun Malhotra et al conducted a study on thirty two subjects and reported a drop in pulse rate from 71.19±6.3 to 65.88±5.6. The change being significant at $p<0.001$. Also the subjects felt joy, peace and calm at the end of the procedure.[6]

T Pramanik et al showed in their study that in both the sexes slow Bhramari pranayamic breathing (respiratory rate 3/min) for 5 minutes caused a slight fall in heart rate. In male subjects heart rate was decreased from 78 beats/min to 76 beats/min and in female volunteers the same was decreased from 82 beats/min to 79 beats/min.[7]

Pratima M. Bhutkar et al observed that resting blood pressure and pulse rate were reduced significantly after regular practice of suryanamaskar and the cause of decrease resting b.p. and pulse rate was attributed to increased vagal tone and decreased sympathetic activity.[8]

Shankarappa V et al showed that the pulmonary function test values improved after short term(6 weeks) pranayama practice.The reason given was strengthening of the respiratory muscles and improvement in the expiratory power and decreased resistance to the air flow in the lungs. Pranayama training causes an increase in the voluntary breath holding time. This may be due to acclimatization of the chemoreceptors to hypercapnoea.[9]

Upadhyay Dhungel K et al compared different cardio respiratory variables before and after four weeks of alternate nasal breathing exercises and showed a fall in systolic pressure and diastolic pressure.

Reduction in heart rate and blood pressure indicate a shift in the balancing components of autonomic nervous system towards the parasympathetic activity which was reported by Santha Joseph et al and Anand BK et al.[10]

Meditation by modifying the state of anxiety reduces stress induced sympathetic over activity thereby decreasing arterial tone and peripheral resistance, and resulting in decreased diastolic blood pressure and heart rate.[11]

The study done by us shows clearly the benefits of combination of Bhramari pranayama and meditation techniques like Yoganidra in regulating the basal cardiac and respiratory parameters which is vital in both prevention and treatment of lifestyle related diseases.

CONCLUSION

Regular practice of Bhramari Pranayama and Yoganidra is beneficial for the cardiovascular and respiratory system as it counters the ill effects of stress and sedentary lifestyle. The mortality and morbidity associated with these lifestyle diseases like hypertension can be reduced by adopting yogic practices.

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Section Human Physiology

Original Article

Effect of Gender on Reactivity to Cold Stress in Young Medical Students

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ABSTRACT

Background: *Previous studies have found contradictory results in reactivity pattern in males and females to cold pressor test . It is important to understand these differences and its subsequent relevance in the pathogenesis of cardiovascular diseases like hypertension and coronary artery disease.*
Aim: *The purpose of this study was to investigate the effect of gender on reactivity to cold pressor test in young healthy medical students.*
Methods: *94 young medical students in the age group of 17 to 27 years were subjected to cold pressor test and the systolic and diastolic blood pressure recorded before and after the test.*
Results: *The mean systolic rise of blood pressure was found to be 13.63 ± 9.71mm Hg in females as compared to 12.31 ± 5.79 mm Hg in males. The mean diastolic rise in blood pressure was 9.71 ± 4.58 mm Hg in females as compared to 8.84 ± 4.14 mm Hg in males. The difference of mean for both mean systolic and diastolic rise of blood pressure in male and female subjects was not found to be statistically significant (p value = >0.1). The percentage of female hyper-reactors (36%) was found to be more than male hyper-reactors (31%).*
Conclusions*: No statically significant difference was found in the reactivity to cold pressor test between males and females. The percentage of female hyper-reactors was more probably due to lower threshold to cold induced pain.*

Keywords: *Cold pressor test, gender, hypertension.*

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INTRODUCTION

Hypertension and coronary artery disease have emerged as a major epidemic reinforced by the modern sedentary lifestyle and stress. The hypothalamus mediates response to stress by activating the sympathetic nervous system to release epinephrine and nor- epinephrine, leading to intense vasoconstriction and increased systemic vascular resistance. ADH and aldosterone also contribute.[1,2]

The use of cold pressor test, given by Hines and Brown, in the prediction of hypertension is well established in a number of studies.[3,4,5]

But there are few studies on gender variations in response to cold pressor test. Estrogen is known to have both good (vasodilator, increases HDL) and bad effects (increased tendency for thrombosis) on cardiovascular system. But by and large it is said to protect the cardiovascular system especially against coronary artery disease in the reproductive period.

Previous studies gave contradictory results on different response in males and females to cold pressor test. Understanding the different response to cold stress in both genders will give us an idea about the difference in pathogenesis of hypertension and coronary artery disease in males and females. Our study aimed at finding the same.

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METHODS

Our study was done at Department of Physiology, SSMC Rewa (Madhya Pradesh), India. 94 medical students (Age 17-27 years) were taken as subjects in the study out of which 45 were males and 49 females. Due permission was taken from ethical committee of the institute and written informed consent taken from students. Blood pressure was measured before and after the cold pressor test. Statistics was done by MS Excel 2010 software.

RESULTS

The mean systolic rise of blood pressure on applying the cold stimulus was found to be 13.63 ± 9.71mm Hg in females as compared to 12.31 ± 5.79 mm Hg in males. The mean diastolic rise in blood pressure was 9.71 ± 4.58 mm Hg in females as compared to 8.84±4.14 mm Hg in males. The difference between mean for both mean systolic and diastolic rise of blood pressure in male and female subjects was found to be not statistically significant (p value = >0.1).

Table 1: showing comparison of cold pressor reactivity between male and female subjects

S No	Rise of BP after cold stress	Males (n=45)		Females (n=49)		Difference Of mean	P value
		Mean	S.D.	Mean	S.D.		
1	Systolic rise	12.311	5.799	13.633	9.714	1.322	>0.1
2	Diastolic rise	8.8444	4.145	9.714	4.583	0.8696	>0.1

A total of 32 students were found to be hyper-reactors out of which 18 were females and 14 were males.

Table 2: showing distribution of male & female subjects regarding reactivity to cold pressor test

Category	Number and percentage of Males (Total males = 45)	Number and percentage of Females (Total females = 49)	Number and percentage of Total Subjects (Total subjects = 94)
Hypo-reactors	31 (68%)	31 (63%)	62 (65.95%)
Hyper-reactors	14 (31%)	18 (36%)	32 (34%)

DISCUSSION

Our study found that there was no significant difference to reactivity to cold stress amongst males and females. These results were similar to Kilogaur et al who found that males and females showed similar pressor response but blood pressure in males take longer to return to baseline. The explanation given was that men respond with greater and more prolonged peripheral adjustments (e.g., rise in SVR), whereas females are more like "cardiac" responders, with greater increases in heart rate and an attenuated blood pressure response to CPT.[6]

We also found that there was greater percentage of female hyper-reactors as compared to males. This may be due to higher threshold of pain in men as found by several studies.[7-9]

Also, Pierre-Julien et al found that myocardial blood flow as measured by CMR coronary sinus flow quantification revealed a higher response of myocardial blood flow in response to cold pressor test in women than in men. The reason given was gender differences in endothelial-dependent vasodilatation.[10]

Mahalakshmamma V et al found a greater rise in systolic blood pressure in females as compared to males whereas Srivastav et al found greater pressor response in females as compared to males in both systolic and diastolic values. The probable reasons for this variation were given as presence of more estrogen in females which has vascular protective actions especially in young females.[11,12]

Mclean JK et al found reduced pressor response in females as compared to males and Rachel M et al also found similar results in addition to reduced dilatation of the common carotid artery in females as well. It was found that the the mechanisms involved did not include a parallel difference in heart rate or venous plasma nor epinephrine concentration.[13,14]

Thus, a lot of further research is warranted to understand this gender variation in response to cold stress as it gives us an idea about the different pathogenesis of disease like hypertension and coronary artery disease in both genders especially pertaining to vascular endothelial factors.

CONCLUSION

Although we did not find any significant difference in the reactivity to cold stress between males and females per say but further studies are necessary to understand the difference in response to cold pressor test in both the genders. The percentage of female hyper-reactors was more probably due to lower threshold to cold induced pain.

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RESEARCH ARTICLE

Study of oxidative stress in smokers by estimating serum superoxide dismutase

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ABSTRACT

Background: Consuming tobacco is a major addiction worldwide. Smoking tobacco in the form of cigarette or beedi is prevalent in both males and females. Smoke of cigarette and beedi contains more than 2000 different toxic materials. These toxic materials produce local as well as systemic tissue damage. The damage caused by this smoke is mostly due to the oxidative stress produced by the free radicals due to smoking. **Aims and Objectives:** The aim of the study is to find out the level of oxidative stress in smokers and compare it with the non-smoking subjects of the same age group. Furthermore, this study aims to find out relationship of pack-years of smoking with the oxidative stress in the smokers. **Materials and Methods:** A total of 30 smokers having a history of more than 10 pack-years of smoking and 30 non-smoker subject of the age group of 40–70 years of age with no major illness were selected for the study. The serum superoxide dismutase (SOD) enzyme level was measured. The estimated SOD level was compared in both the groups. **Results:** When both the groups were compared for the serum SOD level, it was found that the SOD level was significantly low in the smokers as compared to non-smokers. Furthermore, there was a significant negative correlation between the pack-years of the smoking and the serum SOD level. **Conclusion:** The result of the study shows that smoking enhances oxidative stress by decreasing the level of lifesaving antioxidant enzymes in the body. This decrease in levels of antioxidant enzymes makes the smokers prone to various diseases such as coronary artery disease, chronic obstructive pulmonary disease, and cancers.

KEY WORDS: Smoking; Superoxide Dismutase; Oxidative Stress; Pack-years

INTRODUCTION

Tobacco is one of the most common addictions prevalent worldwide. Tobacco can be consumed in various ways. A common way to consume tobacco is by smoking cigarettes and beedies. A research showed that there are nearly 1.1 billion smokers present across the world making smoking one of the major addictions in the world.[1] Cigarette smoke contains more than 10^{10} toxic chemicals such as nicotine, ozone, benzene, phenols, carbon monoxide, polyphenols, formaldehyde, acetaldehyde, acrolein, nitrogen oxides, ammonia, and hydrogen cyanide.[2,3]

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These toxic reagents produce free radicals which are reactive oxygen species and nitrogen species such as superoxide, hydroxyl, and peroxide radicals. These free radicals directly as well as by producing inflammatory responses cause oxidative stress to various tissues. This oxidative stress leads to complications such as chronic obstructive pulmonary disease (COPD) in respiratory system, coronary artery disease

(CAD) in cardiovascular system, lung cancer, oral cancer, and atherosclerosis by the involvement of vascular endothelium.[4] It has been seen that more the number of cigarettes smoked per day more will be chanced of complications.[1]

Body responds to oxidative stress produced by smoking by forming some scavenging antioxidant enzymes such as superoxide dismutase (SOD), glutathione peroxidase, and catalase. These enzymes inhibit the oxidation of DNA, proteins, and lipids and control the oxidative stress.[4]

The aim of the present study was to find out the oxidative stress of the smokers by measuring the serum SOD level and compare it with the normal non-smoking subjects and to find if there is any significant alteration in oxidative stress of the smokers.

Aims and Objectives

The aim of the study is to estimate the serum SOD level in non-smoker subjects and smokers of the same age group and compare the oxidative stress of both the groups and to correlate the oxidative stress of the smokers to the pack-years.

MATERIALS AND METHODS

The present study was carried out in the physiology department in assistance with the biochemistry department of a government medical institute. Permission of college ethical committee was taken before starting the study. Written consent was taken from all the subjects included the study.

Thirty non-smoker healthy subjects and 30 smokers of the age group of 40–70 years were selected from the outpatient department of the institute.

The smoker subjects of the age group of 40–70 years with a history of smoking of at least 10 pack-years (A pack-year means 20 cigarettes or 80 beedies smoked each day for 1 year)[5] without any major illnesses such as diabetes, hypertension, or cardiac disorders were selected for the study. Control subjects were non-smoker subjects of the age group of 40–70 years without any major illness were included in the study.

After selecting the subjects, the serum SOD levels were measured. For that, venous blood samples were taken from both the groups. For smokers, the blood sample was taken after 12 h of last smoke to delineate the effect of acute smoking.

Serum SOD levels were measured with the Marklund and Marklund modified by Nandi and Chatterjee.[6,7] Normal level of SOD in serum is 2.93–3.71 units/ml. The mean value of SOD and the standard deviation was calculated for both the groups. The means of both the groups were compared using an "unpaired *t*-test" and statistical significance was calculated. A correlation test was also applied to find out if there any correlation between the pack-year and serum SOD level.

Statistical calculations such as mean, *t*-test, and correlation were done using GraphPad Prism software (version 6.01) and Microsoft Excel software.

RESULTS

From Table 1, it was found that the mean level of serum SOD was less in smokers when compared with non-smokers. Statistically highly significant difference was found using "unpaired *t*-test" ($P < 0.001$). Table 2 shows that there is a statistically significant correlation between the pack-years of smoking and serum SOD level. Negative "*r*" value denotes that this correlation is negative, i.e., if the number of pack-years increases, then the value of the SOD level decreases.

DISCUSSION

In the present study, the serum levels of enzyme SOD in the 30 smokers with a history of more than 10 pack-years of smoking were measured and compared with 30 non-smokers. It was found that the level of SOD was low in smokers (Mean ± SD = 2.50 ± 0.45) as compared to non-smokers (Mean ± SD = 3.01 ± 0.23). This decrease in SOD was statistically significant. On correlating the pack-years to serum SOD level using Pearson's correlation, the "*r*" value was found to be −0.584 and $P = 0.0032$. Thus, a significant negative correlation was found between the pack-years and the serum SOD levels in smokers. This suggests that as the number of the pack-years increases, the serum SOD level decreases. This means that more oxidative stress is produced if the pack-years of smoking increase.

Smoking is known to cause an imbalance between the oxidant and antioxidants in the body. Various toxic harmful substances in the smoke such as nicotine lead to the generation of oxygen and nitrogen-induced free radicals. These radicals are neutralized by free radical scavenging antioxidant system of the body which includes SOD, glutathione peroxidase, and catalase.[4] These antioxidant enzymes, however, get exhausted over a period of time which produces oxidative stress in the body.

Similar study was performed by Gordana *et al*. in smokers with CAD. They measured SOD, glutathione peroxidase, and catalase level in the patients of CAD and found that

Table 1: Comparison of serum SOD level in smokers and non-smokers

Antioxidant enzyme	Smokers	Non-smokers	*P*-value
SOD level (U/ml)	2.50±0.45	3.01±0.23	<0.001*

**P*-value: Statistically highly significant, SOD: Superoxide dismutase

Table 2: Correlation between the duration pack-years of smoking and the serum SOD level in smokers

Pack-years	Serum SOD (U/ml)	Pearson's correlation coefficient (r value)	*P*-value
16.02±3.20	2.50±0.45	−0.5206	0.0032*

**P*-value: Statistically significant, SOD: Superoxide dismutase

the level of SOD is very low in the patients of CAD with a history of smoking in the past.[4] Gavali *et al*. in their study on COPD patients had similar finding that the serum SOD level decreases in patients of COPD with a history of smoking.[8]

van der Vaart *et al*. in their study on acute effects of smoking on oxidative stress concluded that even acute smoking may cause oxidative stress in the smokers.[9] Saha *et al*. in their study also confirmed that long duration of smoking causes more deleterious health hazards as compared to lesser duration of smoking. Further, they concluded that even passive smoking exposure is as dangerous as the primary smoking.[1] Barreiro *et al*., in their study, found that oxidative stress due to smoking may cause skeletal muscle dysfunction, especially diaphragm which may worsen the COPD condition in the smokers.[10] Lipid peroxidation by oxidative stress produces ethane, which can be seen in schizophrenia patients also, so smoking may cause behavioral changes as concluded in a study of Puri *et al*.[11] Smoking may also cause auditory disturbances by inducing hypoxia in the auditory nerve.[12] There are also evidences that smoking causes raised intraocular pressure,[13] lung cancer,[1] etc.

Thus, smoking is a major addiction as well as it is a major public health problem. It is associated with many health problems such as CAD, COPD, cancer, behavioral changes, and ocular and auditory complications. These health problems mostly occur due to oxidative stress produced by the smoking and imbalance of antioxidant enzymes in the body. Secondary smoking also poses same risks as primary smoking. Thus, it is important to conduct more studies with larger sample size and increases the community awareness against smoking.

CONCLUSION

Smoking is a major public health issue. It is associated with oxidative stress by forming the oxygen and nitrogen free radicals which reduces the scavenging antioxidant enzymes like SOD. This puts the smokers at risk of various diseases such as CAD, COPD, and cancer.

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A cross-sectional survey of stressors and coping strategies among the first-year medical students in Kerala

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Abstract

Introduction: Compared to the general population medical students have to face more stress, which, if not handled properly, may negatively affect the career of future doctors and community health drastically. To counter this stress, they need appropriate coping strategies. Studies on stress and coping strategies among medical students in India are very few to date and show wide demographic variations in their results.

Materials and Methods: We carried out a cross-sectional survey to find out stressors using a validated Medical Students' Stressor Questionnaire (MSSQ) and we used Brief COPE scale to assess the coping strategies adopted by the first-year medical students in Kerala. Descriptive statistics was used to compile and summarize data.

Result: Most common stress inducer was found to be 'academic related stressor' domain, in which we observed that 88% students had moderate to high level of stress. In this domain, more common stressors were 'examinations' and 'large amount of content to be learnt'. 'Planning' was ranked first with mean score (SD) of 5.72 (1.42), while 'substance use', 2.07 (0.45) was least adopted coping method by them.

Conclusion: Academic stressors were found to be the most common stressor domain in first-year medical students. Timely reduction of such stress using various measures is expected from the educators. Maximum students employed constructive coping strategy i.e. 'planning' but maladaptive 'self-distraction' coping was also seen in substantial number of students who can be helped by guiding them for proper coping methods.

Keywords: Brief COPE, Coping strategy, MSSQ, Stressor.

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Introduction

The World Health Organization (WHO) has estimated that stress-related disorders will be one of the leading causes of disability by the year 2020.[1] Medical education is one of the highly stressful curricula, wherein the medical students face different types of stressors. The sources of stressors can be academic, economical, personal, social, parental pressure, drive and desire etc. The stress levels were shown to vary in different studies carried out worldwide.[2] Studies on stress among Indian medical students report wide variations in the prevalence of stress (37.3–97%). This wide variation in prevalence may be due to demographic differences in the subjects or different investigating strategies.[3] Supe (1998) identified academic, physical, emotional, and social factors as the principal stressors in a cohort of medical students in Maharashtra, India.[4] Such stress has been suggested to adversely affect the student's health, professional life, and ultimately the health of the society.

Students need effective coping strategies in such a highly competitive educational field. Coping with these stressors needs motivation, guidance, individual and social support. Coping is considered as a stabilizing factor which support an individual to effectively face the stressful situation.[2] Various coping methods used by students to reduce level of stress include effective time management, social support, spiritual activities, and involvement in entertaining activities. Some of the coping strategies are emotion focused that involve taking responsibility, positive reframing, venting and self-blame. Identifying and modifying these strategies at the entry level of medical education will prove crucial for the psychosocial wellbeing of the future doctors.

Studies on stress and coping strategies among medical students in India are very few till date. The present study is an attempt to explore these stressors and coping strategies employed by medical students at the very beginning of their medical education in a medical college in Kerala, India.

Materials and Methods

A descriptive, cross-sectional survey was conducted in a private medical college in Kerala, India. Prior ethical permission was obtained from the Institutional Ethical Committee. The study

was carried out in eighty-nine undergraduate students of both genders, admitted in first year MBBS course. Before enrolment in the study, informed written consent was obtained from all the participants who were willing to take part in the survey. All the subjects were assured of anonymity of the data collected in the questionnaires. Subjects having history of any major illness or any history of recent incidence affecting the mental health were excluded from the study.

The nature of the study was explained to all participants before handing over the questionnaires to them in a physiology lecture class. Besides the questionnaires, basic data such as age and gender were recorded. Two questionnaires were given in printed form to each of the respondents.

The MSSQ (Medical Students' Stressor Questionnaire) which is a validated rating instrument developed in a medical school in Malaysia and also validated in Indian set up by Gupta et al (2015) to measure stress and its sources within the students.[5,6] It consists of 40 items addressing six domains of stressors as mentioned below:

1. Academic-related stressors, which include 'examination system', 'getting poor marks', 'large amount of content to be learnt', 'difficulty understanding the content', 'lack of time to do revision', 'learning context full of competition', and 'having difficulty to answer questions asked by teachers'.
2. Intrapersonal and interpersonal-related stressors include 'conflicts with other students', 'verbal or physical abuse by teachers', 'conflict with personnel'.
3. Teaching and learning-related stressors involve 'appropriateness of tasks given by teachers to students', 'teachers' competency to teach', 'feedback and recognition given by teachers'.
4. Social-related stressors, with items like 'Facing illness or death of patients' and 'discussing the problems of patients'. 'Not getting leisure time with family and friend'.
5. Drive and desire related stressors, like 'Unwillingness to study medicine', 'Parental wish to study medicine by you', 'wrongly choosing the course'.
6. Group activities related stressors including 'Participation in any group discussion and interaction'.

Participants had to respond to each item along a five point Likert scale (0-4) as per the increasing level of severity of stress. All items in the six stressor domains measure the overall stress of the medical student. Mean item scores for each domain was calculated and ranked. Also, the percentage of students facing stress in each domain was measured according to mild (0–1), moderate (1.01–2), high (2.01–3), and severe (3.01–4) degree of stress. Mild stress means no stress or insignificant stress. Moderate stress signifies reasonable stress. Severe and high indicate reasonably significant emotional disturbances with and without interference in daily activities respectively.

Coping strategies were assessed using the "Brief COPE scale", which is a validated and abbreviated version of the COPE Inventory.[7] It consists of 14 scales/categories each having 2 items, thus total 28 items. These items ask what you've been doing to cope with each one. The scales are: 'self-distraction', 'active coping', 'denial', 'substance use', 'use of emotional support', 'use of instrumental support', 'behavioural disengagement', 'venting', 'positive reframing', 'planning', 'humour', 'acceptance, 'religion' and 'self-blame'. The answer choices depend upon how frequently each of these items are applied by the student, that is, 'I haven't been doing this at all', 'I've been doing this a little bit', 'I've been doing this a medium amount', 'I've been doing this a lot' which are scored from 1 to 4, respectively.

Descriptive statistics was used to compile and summarize data. The ranks of stressors and coping strategies based on the mean (SD) score as rated by the medical students were calculated using Microsoft Excel 2016. Also, distribution of subjects according to the severity of stress in each stressor domain was done.

Result

Out of 100 students enrolled in first year MBBS, 94 were present for the scheduled lecture class on the day of this survey. A total of 89 students filled the questionnaires completely, including 28 male and 61 female students. The median age of the participants was 20 years.

None of the participants was found to have severe stress. As shown in table 1, academic related stressor ranked first among the other stressor domains, followed by group activities related stressor and social related stressor with the mean scores of 2.11, 1.57 and 1.38 respectively. Drive & desire related stressor domain had the least mean score of 0.69.

In academic related stressor domain, we observed that 88% students had moderate to high stress and 66% students had high degree of stress. Group Activities Related Stressor domain included 27% participants in high degree stress category as shown in table 2.

Table 1: Stressor domains ranked by their mean scores

Stressor domain	Mean (SD)
Academic Related Stressor	2.11 (0.72)
Group Activities Related Stressor	1.57 (0.82)
Social Related Stressor	1.38 (0.70)
Interpersonal & Intrapersonal Related Stressor	1.35 (0.82)
Teaching and Learning Related Stressor	1.31 (0.74)
Drive & Desire Related Stressor	0.69 (0.71)

Table 2: Distribution of subjects according to the severity of stress in each stressor domain (N=89)

Stressor domain	Mild stress N (%)	Moderate stress N (%)	High stress N (%)
Academic Related Stressor	8 (8.99)	22 (24.72)	59 (66.29)
Interpersonal & Intrapersonal Related Stressor	36 (40.45)	34 (38.20)	19 (21.35)
Teaching and Learning Related Stressor	37 (41.57)	39 (43.82)	13 (14.61)
Social Related Stressor	32 (35.96)	41 (46.07)	16 (17.98)
Drive & Desire Related Stressor	68 (76.40)	17 (19.10)	4 (4.49)
Group Activities Related Stressor	27 (30.34)	38 (42.70)	24 (26.97)

Planning was the most utilized coping method by the participating students, while substance use was least adopted by them in case of stressful situation (Table 3).

Table 3: Coping strategies ranked by their mean scores

Coping strategies	Mean (SD)
Planning	5.72 (1.42)
Self-distraction	5.60 (1.78)
Religion	5.51 (2.05)
Positive reframing	5.44 (1.74)
Acceptance	5.39 (1.60)
Active coping	5.38 (1.51)
Self-blame	5.21 (1.89)
Use of instrumental support	4.93 (1.83)
Use of emotional support	4.72 (1.69)
Venting	4.63 (1.55)
Humor	4.18 (2.04)
Behavioral disengagement	3.66 (1.51)
Denial	3.46 (1.60)
Substance use	2.07 (0.45)

Discussion

Medical education and career in India are very stressful and many researchers have concluded that, compared to general population medical students are more subjected to stress. Such stress has been making them prone to suicide, depression and drug abuse. Efficient coping strategies can buffer the impact of stressful situations on the mental and physical wellbeing of medical students and finally improve patients' lives and community health.[8]

Plenty of literature is available proving the presence of stress among medical students in different countries, but few studies have been done to reveal different stressors and the coping strategies, particularly in India. Considering this, an assessment was done in the present study using MSSQ to find out stressors and Brief COPE inventory was used to find out coping strategies among medical students in a medical college in Kerala.

The present survey revealed that maximum students were getting stressed due to the academic stressors, out of those, 66% had high stress. Out of the different factors included in academic domain of stressors, it was observed from their responses that, students were getting stressed more due to 'examinations', 'large amount of

content to be learnt', 'heavy workload', and 'learning context- full of competition'.

'Group activities related stressor was the next common stress inducing domain, wherein, 27% students had high stress. In this domain, students were having more stress in 'participation in class presentation' and 'feeling of incompetence'. Drive and desire related high stress was observed merely in 3% of the participants.

Similar result revealing academic stressors as the source of maximum stress was obtained by Gupta et al (2015) in India.[6] Saxena et al (2014) carried out a study in Dehradun, India and found that moderate to high academic stress was present among 79% of students.[9] Research by Yusoff et al (2011) in Malaysia and Sarkar et al (2015) in Chhattisgarh also found that academic related issues were the most common forms of stressors among the medical students.[8,10]

Contrary to the present study, Samira et al (2015) in Riyadh concluded that, high stress causing stressors were worrying about future, trouble with friends, room-mate conflict, hearing bad news, and low self-esteem.[2]

Regarding the coping strategies adopted by the students, we found maximum students adopted adaptive (constructive) coping strategies like 'planning' with mean score (SD) of 5.72 (1.42) more than maladaptive or avoidant strategies such as 'self-distraction', 5.60 (1.78). 'Substance use' was the least adopted coping method.

In a similar study by Shakthivel et al (2017) in Tamil Nadu, India, it was revealed that the most commonly employed coping mechanism was 'religion' followed by 'self-distraction'.[11] Results obtained by Samira et al (2015) showed 'self-blame' and 'self-criticism' as the common reactions to stress. Religious coping was frequently adopted as a coping measure, while use of alcohol or other drugs was found to be rare.[2] Sreeramareddy et al (2007) found positive reframing, planning as the coping strategies commonly used by students in their institution in Nepal.[12]

Such differences in the finding major stressors and coping mechanisms in different studies may be attributed to geographical, cultural, and social environment of the students and different rating scales used. Thus, it is crucial for the medical educators to assess the stressors and coping strategies of their students at the beginning of medical education and mentor them to use desirable coping strategies to reduce stress, which will ultimately help the society to have better doctors and better health.

Further research encompassing students from different semesters, correlation of stressors and coping strategies with cultural and demographical parameters is suggested to get in to the deeper insights of these stressors.

Conclusion

The first-year medical students in the present study setup showed to suffer maximally from the academic related stressors, particularly stress due to examinations and large amount of content to be learnt. This stress can be alleviated by mentoring and motivating them to improve their studying styles, plan the study time, maintain a healthy lifestyle, give plenty of time to revise and apply anxiety reduction techniques.

Maximum students employed constructive coping strategy i.e. 'planning' but maladaptive 'self-distraction' coping was also seen in substantial number of students. Such students can be helped by mentoring, establishing wellness clinics and organizing personality development programmes within the campus itself.

Acknowledgments

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Conflict of interest

Authors declare that there is no conflict of interest about publishing this research article.

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Impact of medium of instruction during school education on the academic performance of medical students: An observational study

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Abstract

Introduction: Many of the students admitted in Indian medical colleges have had school education in vernacular medium. There exists a general opinion that such students find it difficult to cope up with medical academics in English medium as they think in one language and study in another. This study was carried out to find whether such language barrier affects their professional performance.

Materials and Methods: This multi-centric retrospective observational study was carried out in 274 medical students from four government medical colleges in Marathwada region of Maharashtra, India. The medium of instruction during their school education was recorded from their 10th standard mark-sheets. The marks of final year MBBS were obtained from their academic record in academic section of the colleges. The data were analysed using one-way ANOVA.

Result: There was statistically no significant difference of professional performance among the medical students with different media of instruction in their school education (P=0.1149).

Conclusion: Medium of instruction of school education doesn't have any significant effect on professional performance of medical students.

Keywords: Medium of instruction, Mother tongue, Language barrier, Professional performance.

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Introduction

There are nearly 5,000 languages in use in the world today. Every advanced country has its own national language. India has more languages compared to any other country in the world. Hindi is the primary language spoken by 30% of Indian population. Marathi and Urdu are the major languages of communication and instruction in Marathwada region of Maharashtra. English though not a primary language but is ubiquitous to India, a former British colony. English is certainly very important in higher education and played a crucial role in developing India as an economic power.[1] English language as a medium of instruction plays the key role in medical students' learning in India. Therefore, it is the popular belief in the society that the students' academic achievement depends largely on their English language abilities.

But productive learning process does not rely only on the knowledge about English language, it also involves other factors like communication skills, supportive teachers, supportive home environment and motivation. Learners get actively involved in the learning process through discussion, reading, writing, and analysis, rather than passively getting instructions. To learn, students have to communicate and exchange the information among them, which needs fair understanding of language. Being a tool to communicate, language allows students to convey ideas, facts, concepts and feelings to each other, which may be better done through their mother tongue or vernacular medium of instruction.

Studies show that medical undergraduates undergo multiple stressors. Mandal et. al. (2012) found that, understanding the medium of instruction, was significantly related to performance in medical students.[2] There is much literature available on the effect of medium of school education and performance of the students in various professional courses unlike in medical profession in India. So, the present study is an attempt to assess whether mode of instruction during school education really affects professional performance and whether students from English-medium schools perform better in MBBS academics than those from vernacular medium schools.

Materials and Methods

The present study is a multicentric retrospective observational study. The number of participants involved was 274 out of 350 students of both genders, passed in MBBS from four government medical colleges in Marathwada

region of Maharashtra. The colleges included were Government Medical College, Aurangabad, SRTR Medical College, Ambajogai, Government Medical College, Latur and Dr. Shankarrao Chavan Government Medical College, Nanded.

Ethical approval was obtained from the Institutional Ethical Committee of Government Medical College, Aurangabad. Before enrolment in the study, informed written consent was obtained from all the students who were willing to take part in the survey. Permission of the Deans of all the institutions was sought. Students with diagnosed psychological disorder were excluded from the study. Basic data like age and sex was collected. The medium of instruction during their school education was recorded from their 10th standard mark-sheets. Quantitative assessment of professional performance was done using their final MBBS marks, obtained in both practical and theory. The marks of final year MBBS were recorded from the mark-sheets available with the students or their academic record available in the academic section of the colleges involved in this study. Comparison of marks obtained in final MBBS was done among students from different media of instruction during their school education using one-way ANOVA in statistical software GrapPad Prism (Version 6.01).

Result

The study included 274 (78.29%) students out of 350 students passed in the final year MBBS. Remaining students were unwilling to participate in the study. Out of total 274 participants, 158 were males and 116 were females. The median age of the participants was 19.42 years. Frequency distribution of students as per the medium of instruction of their school education before getting admitted to MBBS course is shown in table-1. Maximum number of participants (67.15%) have got their school education in native Marathi language followed by English (25.55%).

Table1: Distribution of subjects according to the medium of instruction during school education

Medium of Instruction	Frequency (%)
Marathi	184 (67.15%)
English	70 (25.55%)
Urdu	12 (4.38%)
Hindi	8 (2.91%)

In the current study, we found that students who learned in Hindi during their school education had achieved maximum mean percentage score (60.90%) while Urdu medium students got the least marks (57.66%) as indicated in Fig.1.

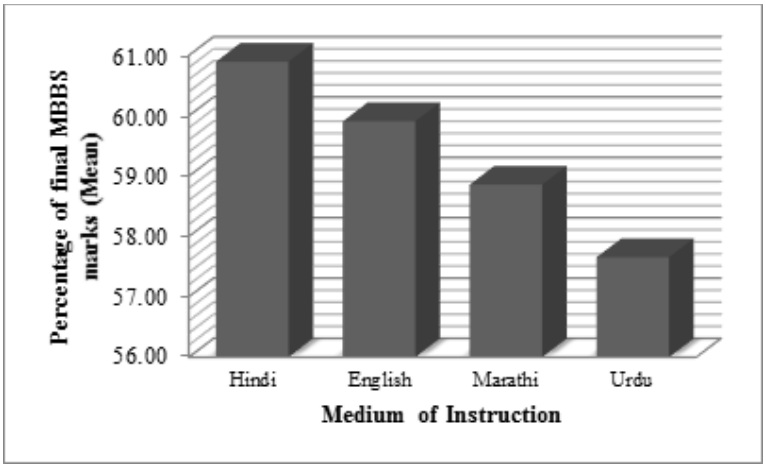

Fig. 1: Academic performance of medical students with different media of instruction during their school education

As shown in the table 2, when we compared the final MBBS marks of all the students belonging to different media of instruction during their school education, we did not find any statistically significant difference between their scores (P=0.1149).

Table 2: Comparison of academic performance of medical students with different media of instruction during their school education

Medium of instruction	Hindi	English	Marathi	Urdu	P-value (One-way ANOVA)
Percentage of final MBBS marks [Mean (SD)]	60.90 (5.31)	59.91 (3.7)	58.86 (4.35)	57.66 (4.77)	0.1149 (NS)

P = NS: Statistically not significant.

Discussion

English is considered a foreign language for Indian students. All the professional institutions have English as a medium of education. There is a common belief in the society that students weak in English language may not understand and reproduce the knowledge in examinations and also, the failure and poor performance in examinations by the medical students may be because of this factor. So, in recent years there has been a dramatic surge in English medium schools in India with many parents insisting to admit their children in those schools rather than in vernacular schools. This hypothesis was assumed in our study. We included the freshly passed final year MBBS students and compiled their academic performance in university examinations. The present study shows statistically no significant difference between mean marks obtained by the students of different media of instruction in their school education. But, when compared individually, all the students that scored highest marks in the exam belonged to Marathi medium which is the most prevalent language in this region. This indicates that students from vernacular medium had no deficits in English language to the extent that can adversely affect their comprehension and performance. This disproves the general assumption that, to be proficient in medical academics, one needs command over English language.

Mother tongue is defined by UNESCO as "the language which a person acquires in early years and which normally becomes their natural instrument of thought and communication." According to UNESCO, mother tongue education is "Education which uses its medium of instruction a person's mother tongue, that is, the language a person has acquired in early years and which normally has become his or her natural instrument of thought and communication." The importance of mother tongue in the cognitive, linguistic, personal and educational development of students cannot be ignored.[3]

There is no doubt that the basic knowledge of English language is must for achieving excellence in medical education worldwide. Despite international communication among clinicians and scientists occurring almost exclusively in English, communication with patient and colleagues within individual countries, teaching, and some scientific activities are still conducted in the local mother tongues.[4] The vast knowledge of medical sciences cannot be memorized but can be retained by understanding and active learning. A learner can do this efficiently by communicating in his own language.

In countries like India, the foundations of reasoning and memory in basic subjects are mostly founded in the vernacular languages i.e. primary language (L1), with minimal exposure to English as a secondary language (L2). Even then, we found statistically no difference in their performance on comparing with that of English medium students. This indicates that basic education in mother tongue may reinforce the learning in secondary language. Even though medium of instruction is English in Russia, China, Japan, Mexico and other countries, their medical education system also give enough importance to native languages other than English and they have produced excellent human resources trained in medicine as well as biomedical research. Many Indian students learn their languages to undergo medical training in these countries.[5]

Studies on advantages of teaching medicine in English, assisted by using student's mother tongue, had been done before in other countries.[6-8] This inclusion of the mother language in teaching medicine is seen as a way to free learners from the linguistic bias of thinking in one language and studying in another i.e. students with background of vernacular medium school read medicine in English and interpret in vernacular languages.[9]

Many studies in literature show the important role of mother tongue for second language acquisition. Primary language (L1) helps learners to arrange and rearrange the secondary language (L2) data for better understanding and interpretation. Thus, L2 acquisition is a developmental process, assisted by L1.

When learning a new language, we build brain networks to process and represent the acquired words and syntax and integrate these with existing language representations i.e. the brain is able to reuse characteristics of the mother

tongue when the new language being taught is grammatically similar. Results of a study by Weber et al (2016) indicated an overlap in neural mechanisms for native and new language constructions with sufficient structural similarities.[10] Studies have shown positive effects of mother tongue on comprehension itself. Price et al (1999) observed that comprehension of words in mother tongue activated more of the temporal lobe including temporal pole than did words in second language.[11]

Similar results were obtained in a study conducted by An E He (2012) in China, who pointed out the potential advantages of systematic use of mother tongue as learning or teaching resource in target language instruction. They observed that use of L1 as learning and teaching resources provided a support for learners. By making explicit reference to learners' conceptual understanding of mother tongue, and by raising their conscious awareness of similarities and differences between Chinese and English, learners' existing comprehension could be enhanced. Also, using L1 as learning and teaching resources increases learning efficiency and smoothened the learning process. Taking advantage of what students have already known conceptually, strategically, and linguistically allowed a "all round development" and "intellectual continuity" in language development.[12] Similarly, Sabbour et al (2012) suggested that teaching in Arabic language was appropriate in some specialties of medicine in Arab countires.[9] Khattak et al (2005), in a similar study in Pakistan, concluded that there is no effect of language as a medium of education during primary and secondary school upon the results of university professional MBBS examinations.[13]

As we consider this as a pilot study, further research involving more number of students from different regions in India is suggested to get more details on this issue. Also, similar studies should be carried out on medical students to correlate media of instruction with their professional performance qualitatively by interviewing them and assessing through questionnaires.

Conclusion

The present study shows no significant effect of medium of instruction during school education on the performance of students in medical colleges. So, it gives a message to the community that it is needless to emphasize on English medium of instruction for school education and students from vernacular medium schools can very well cope with English language during medical academics. Learning medicine in English, being the universal medium of instruction, may prove more efficient if it is supported by teaching and learning major concepts in students' mother tongue.

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Original Research Article

A Study on Cross Sectional Online Assessment of Attitude of Medical Students Towards Mental Illnesses

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Conflict of interest: Nil

Abstract

Background: Attitudes and belief toward mental illnesses are important factors that affect perception of mental health. Knowing the attitude of medical students towards psychiatry and mental illnesses is of utmost importance as they are future care provider. Current study is conducted to assess the attitude of medical students towards mentally ill patients and mental illnesses, to identify correlation of attitude score with personal and family history of mental illness and, to compare the score among students of the three year-wise groups.

Method: The study population included 219 students of first, second and third professional MBBS. We designed an online data collection tool and executed it using the Google Forms. The Google Form link to the questionnaire was sent to the enrolled participants via the identified WhatsApp groups or individual number. Beliefs toward Mental Illness (BMI) scale was used to assess attitude towards mental illnesses which is a 21-item self-report measure of negative stereotypical views of mental illness. The results of the study were examined and analyzed by using Statistical Package for Social Sciences (SPSS 25.0).

Results: Out of total 21 items of the BMI scale, students showed positive attitude on majority of items. The mean score for BMI scale and per item mean score for the scale were towards positive attitude. Majority of students agree that a mentally ill person is more likely to harm others than a normal person and that mental disorders would require a much longer period of time to be cured than would other general diseases. Higher per item mean score for dangerousness and, incurability subscale showed their negative attitude. An increasing trend of positive attitude has been seen with an increase of education level and exposure towards the subject.

Conclusions: Medical students show variable scores on belief towards mental illness scale, its subscales and, individual items. Admitting this prevailing stigma needs to be acknowledged and openly discussed with medical students in order to overcome these views. Providing adequate education on mental illnesses and attached negative attitudes or myths can change these negative beliefs.

Keywords: Medical students, psychiatry, mental illnesses, stigma, dangerousness.

1. Introduction:

Attitudes and belief toward mental illnesses are important factors that affect perception of mental health. The prejudiced and negative attitudes or stigma towards people with mental illness are widespread. In our society, health professionals have similar views about those with mental health problems and mentally ill patients. Literature suggests that people diagnosed with mental illness are considered by the majority of the society as people who are dangerous, loathed, stranger and somebody whose actions cannot be predicted.[1] Globally, psychiatry as a subject, psychiatrists as professionals, and patients with psychiatric disorders are subjected to cultural stereotypes and negative attitude by the general population. What is of alarming concern is that these prejudices exist within the medical community as well.[2-6] Stigma toward mental illness is an influential factor leading to negative views among medical students toward psychiatry. Lack of knowledge and awareness about mental illnesses among the students is associated with the negative attitudes towards mental illness in the community. For medical students during their training, educational intervention targeted towards these negative attitudes may be more effective than doctors who have already completed their training because research has shown as they carry on through their career, their attitude harden and become more resistant to change.[7] The concept of iatrogenic stigma is used to describe the stigma caused or perpetuated by mental health professionals.[8] This stigma and negative attitudes can affect the quality of life for people with mental illness. There may be various reasons for this negative attitude such as lack of accurate information about mental illness and lack of contact with individuals with mental illness.[9]

While some studies have suggested that aspiring young doctors have a favorable opinion about psychiatry as a branch[10], other studies have suggested that medical students' attitude toward psychiatry is unfavorable.[11-17]

A doctor's attitude towards persons with psychiatric illness and psychiatry should involve an impression of an empathetic listener and should have non-judgmental approach. Knowing the attitude of medical students towards psychiatry and mental illnesses is of utmost importance as they are future care provider. To improve psychiatric training in this population beliefs and attitude toward psychiatric illnesses and need to be assessed and understood.

The reasons for studying the attitude specifically among medical students are that firstly as a doctor they can play an important role in decreasing negative attitude and, secondly the results from the study will help to focus strategies to change attitudes of this group. The comparison among various groups in present study will help in understanding the impact of successive undergraduate training years. The findings may help in understanding the various points of strength and lacunae in the current undergraduate curriculum regarding mental health.

Objectives:

The objectives of the current online study were-

1. To assess the attitude of medical students towards mentally ill patients and mental illnesses
2. Correlation of attitude score with personal and family history of mental illness, and
3. Comparison among students of the three year-wise groups.

2. Methodology

Study population and study area: The study population includes all the students who have

enrolled in MBBS course (first year, second year and final year) at Ananta Institute of Medical Science and Research Centre, Rajsamand, Rajasthan. Those students who will give their consent to participate in the study will be included and rests will be excluded at their will.

Study Duration: one year, June 2020 to May 2021.

Sampling techniques and sample size

Samples were obtained using stratified random sampling method. The 3 batches of medical students viz first year professional, second year professional and third year professional which were considered as strata collectively develop a sampling frame of 450 students. The minimum sample size on assumption of 95% level of significance, 5% error and 85% expected proportion was 196. After 12% adjustment of non- responders' students the final sample size was 219.

Undergraduates in the 1st year had not received formal exposure to psychiatry yet, students of 2nd year also have not attended clinical posting or lecture in psychiatry while students of Final year students had completed clinical posting and theory lectures in psychiatry. The institute is having well-functioning psychiatry department with adequate teaching staff and a good in-flow of patients in the psychiatry OPD as well as inpatient department.

Study procedure and statistical Analysis: After unlock 1.0 was announced by the Government of India from 8th of June 2020, the cases of COVID-19 were increasing all over India including Rajasthan. Hence there was risk of disease transmission by taking interview in person therefore we decided to use WhatsApp Messenger for enrolling potential participants and Google forms for filling up their response. The study was approved by institute ethics committee.

Tools: We designed an online data collection tool and executed it using the Google Forms (via docs.google.com/forms). The Google Form link to the questionnaire was sent to the enrolled participants via the identified WhatsApp groups or individual number.

Socio-demographic variables included age, gender, marital status, background, past personal history of mental illness, known history of mental illness in the family were described using descriptive statistics.

Beliefs toward Mental Illness (BMI) scale was used to assess attitude towards mental illnesses. The BMI scale is a 21-item self-report measure of negative stereotypical views of mental illness. (18) There is a total Score and the score of three sub-scales based on factor analysis: dangerousness, poor social and interpersonal skills, and incurability. There are five items in subscale dangerousness, ten items in poor interpersonal and social skills scale and six items in incurability subscale. Items are rated on a six-point Likert scale ranging from 'completely disagree' (0) to 'completely agree' (5), with higher scores reflecting more negative beliefs. In the primary validity study, Cronbach's alpha was high among American (0.89) and Asian students (0.91). The measure holds promising evidence of validity.

The results of the study were examined and analyzed by using Statistical Package for Social Sciences (SPSS 25.0). The categorical variables were described by numbers and percentages while continuous variables were described by average and standard deviation. Normality of attitude was checked using Kolmogrov-Smirnov test. After testing normality condition, the association and relationship between the variables were tested Pearson correlation by Student's t test and one way analysis of variance (ANOVA). The level of significance was considered at $P<0.05$.

3. Results

A total 219 number of students were participated in the online study. The sample comprised of 41.55% of male students and 58.44% of female students. Majority of the students were unmarried (97.26%), belonging to urban background (79.45%), having negative past personal history of psychiatric illness (86.75%) and negative family history for psychiatric illnesses (75.79%).

Table 1: Socio-demographic characteristics of respondents

Variables	Participants N (%)
Sex	
Male	**91 (41.55%)**
Female	**128 (58.44%)**
Marital Status	
Married	**6 (2.73%)**
Unmarried	**213 (97.26%)**
Place of residence	
Urban	**174 (79.45%)**
Rural	**45 (20.54%)**
MBBS Batch	
First year professional	**49 (22.37%)**
Second year professional	**138 (63.01%)**
Third year professional	**32 (14.61%)**
Had mental illness in past:	
Yes	**29 (13.24%)**
No	**190 (86.75%)**
Is someone in your family/ friends/ relative is having mental illness:	**53 (24.21%)**
Yes	**166 (75.79%)**
No	
If yes, then	
Friends	**7(13.2%)**
Family	**26(49.05 %)**
Relative	**20(37.73%)**

Table 1 shows socio-demographic characteristics of respondents.

Attitudes of students towards mental illness

a) Attitude by Items of the subscales

Table 2: Dangerousness subscale of BMI scale (item wise responses, percentage of participants regarding statements on the beliefs about mental illness)

Statement	**Response***					
	0	**1**	**2**	**3**	**4**	**5**
A mentally ill person is more likely to harm others than a normal person	28 (12.8%)	15 (6.8%)	36 (16.4%)	85 (38.8%)	26 (11.9%)	29 (13.2%)
	79 (36%)			140 (64%)		
Mental disorders would require a much longer period of time to be cured than would other general diseases	10 (4.6%)	8 (3.7%)	19 (8.7%)	55 (25.1%)	51 (23.3%)	76 (34.7%)
	37 (17%)			182 (83%)		
It may be a good idea to stay away from people who have psychological disorder because their behaviour is dangerous	73 (33.3%)	47 (21.5%)	41 (18.7%)	41 (18.7%)	7 (3.2%)	10 (4.6%)
	161 (74%)			58 (26%)		
Mentally ill people are more likely to be criminals	69 (31.5%)	47 (21.5%)	35 (16.0%)	45 (20.5%)	13 (5.9%)	10 (4.6%)
	151 (69%)			68 (31%)		
I am afraid of people who are suffering from psychological disorder because they may harm me	80 (36.5%)	47 (21.5%)	31 (14.2%)	50 (22.8%)	4 (1.8%)	7 (3.2%)
	158 (72%)			61 (28%)		

* Denotes 0 = Completely disagree, 1 = Largely disagree, 2 = somewhat disagree, 3 = somewhat agree, 4 = Largely agree, 5 = Completely agree

Table 2 shows item wise responses and percentage of participants regarding statements on the beliefs about mental illness on dangerousness subscale of the BMI scale

Table 3: Poor social and interpersonal skills subscale of BMI scale (item wise responses, percentage of participants regarding statements on the beliefs about mental illness)

Statement	**Response**					
	0	**1**	**2**	**3**	**4**	**5**
The term 'psychological disorder' makes me feel embarrassed	123 (56.2%)	30 (13.7%)	16 (7.3%)	24 (11.0%)	12 (5.5%)	14 (6.4%)
	169 (77%)			50 (23%)		
A person with psychological disorder should have a job with only minor responsibilities	43 (19.6%)	30 (13.7%)	49 (22.4%)	58 (26.5%)	27 (12.3%)	12 (5.5%)
	122 (56%)			97 (44%)		

I am afraid of what my boss, friends and others would think if I were diagnosed as having a psychological disorder	70 (32.0%)	24 (11.0%)	24 (11.0%)	57 (26.0%)	17 (7.8%)	27 (12.3%)
	118 (54%)			101 (46%)		
It might be difficult for mentally ill people to follow social rules such as being punctual or keeping promises	37 (16.9%)	29 (13.2%)	55 (25.1%)	38 (17.4%)	37 (16.9%)	23 (10.5%)
	121 (55%)			98 (45%)		
I would be embarrassed if people knew that I dated a person who once received psychological treatment	131 (59.8%)	29 (13.2%)	17 (7.8%)	26 (11.9%)	12 (5.5%)	4 (1.8%)
	177 (72%)			61 (28%)		
A person with psychological disorder is less likely to function well as a parent	43 (19.6%)	45 (20.5%)	35 (16.0%)	57 (26.0%)	22 (10.0%)	17 (7.8%)
	123 (56%)			96 (44%)		
I would be embarrassed if a person in my family became mentally ill	150 (68.5%)	26 (11.9%)	15 (6.8%)	13 (5.9%)	7 (3.2%)	8 (3.7%)
	191 (87%)			28 (13%)		
Mentally ill people are unlikely to be able to live by themselves because they are unable to assume responsibilities	45 (20.5%)	51 (23.3%)	50 (22.8%)	43 (19.6%)	12 (5.5%)	18 (8.2%)
	146 (67%)			73 (33%)		
Most people would not knowingly be friends with a mentally ill person	33 (15.1%)	22 (10.0%)	36 (16.4%)	62 (28.3%)	27 (12.3%)	39 (17.8%)
	91 (42%)			128 (58%)		
I would not trust the work of a mentally ill person assigned to my work team	61 (27.9%)	40 (18.3%)	44 (20.1%)	53 (24.2%)	10 (4.6%)	11 (5.0%)
	145 (66%)			74 (34%)		

0 = Completely disagree, 1 = Largely disagree, 2 = somewhat disagree, 3 = somewhat agree, 4 = Largely agree, 5 = Completely agree

Table 3 shows item wise responses and percentage of participants regarding statements on the beliefs about mental illness on poor social and interpersonal skills subscale of the BMI scale

Table 4: Incurability subscale of BMI scale (item wise responses, percentage of participants regarding statements on the beliefs about mental illness)

Statement	**Response**					
	0	**1**	**2**	**3**	**4**	**5**
Psychological disorder is recurrent	17 (7.8%)	17 (7.8%)	45 (20.5%)	77 (35.2%)	34 (15.5%)	29 (13.2%)
	79 (36%)			140 (64%)		
Individuals diagnosed as mentally ill suffer from its symptoms throughout their life	53 (24.2%)	46 (21.0%)	41 (18.7%)	53 (24.2%)	10 (4.6%)	16 (7.3%)
	140 (64%)			79 (36%)		
People who have once received psychological treatment, are likely to need further treatment in the future	19 (8.7%)	38 (17.4%)	29 (13.2%)	82 (37.4%)	29 (13.2%)	22 (10.0%)
	86 (39)			133 (61%)		
I believe that psychological disorder can never be completely cured	139 (63.5%)	19 (8.7%)	21 (9.6%)	17 (7.8%)	9 (4.1%)	14 (6.4%)
	179 (82%)			40 (18%)		
The behaviour of people who have psychological disorders is unpredictable	19 (8.7%)	24 (11.0%)	33 (15.1%)	65 (29.7%)	38 (17.4%)	40 (18.3%)
	76 (35%)			143 (65%)		
Psychological disorder is unlikely to be cured regardless of treatment	53 (24.2%)	31 (14.2%)	46 (21.0%)	46 (21.0%)	17 (7.8%)	26 (11.9%)
	130 (59%)			89 (41%)		

0 = Completely disagree, 1 = Largely disagree, 2 = somewhat disagree, 3 = somewhat agree, 4 = Largely agree, 5 = Completely agree

Table 4 shows item wise responses and percentage of participants regarding statements on the beliefs about mental illness on incurability subscale of the BMI scale

b) Attitudes by Subscale

There are five items in subscale dangerousness, ten items in poor interpersonal and social skills scale and six items in incurability subscale.

Table 5: Per item Mean and 95% CI for the three subscale and overall score of BMI scale

Subscale	**M(SD)**	**95 %CI**
Dangerousness	2.17(0.90)	2.77, 1.56
Poor interpersonal and social skills	1.77(0.92)	2.99, 0.54
Incurability	2.21(0.92)	2.94, 1.47
Full BMI scale	1.99(0.80)	4.22, -0.24

* M- Mean, SD- Standard deviation, CI- Confidence interval

Table 5 shows per item mean and 95% confidence interval for the three subscales and overall score of BMI scale.

c) Associates of attitudes

The differences in the attitude scores in different independent variables have two categories were determined by independent sample t tests. And, difference in attitude score in independent variables having more than two categories was determined by the one-way ANOVA.

As per Kolmogrov-Smirnov test statistic (D)results in 0.04762 which means that data is normally distributed. So independent sample t test has been applied to find out difference in attitude score by socio demographic characteristics.

Table 6: Difference in attitude score by socio-demographic characteristics

Characteristics	M(SD)	Diff.*(95% CI)	p-value
Sex			
Male	42.67(17.20)	1.24(-3.31,5.79)	0.59
Female	41.43(16.61)		
Marital status			
Married	60.17(9.06)	18.73(5.20,32.27)	**0.007**
Unmarried	41.43(16.72)		
Place of residence			
Urban	42.80(16.32)	4.18(-1.35, 9.71)	0.13
Rural	38.62(18.48)		
Had mental illness in past			
Yes	40.10(15.14)	2.12(-4.50, 8.74)	0.52
No	42.23(17.09)		
Is someone in your family/ friends/ relative is having mental illness:			
Yes	39.64(17.34)	3.03(-2.19, 8.27)	0.25
No	42.68(16.65)		

*Diff. =Difference in mean, (lower bound, upper bound)

Table 6 shows difference in attitude score by socio-demographic characteristics. Married students (N=6) had higher BMI score than unmarried students (N=213) and the difference was statistically significant. On further analysis it was found that of these six married students, five had positive response for history of mental illness in family, friend or any relative, also two had positive history of past mental illness. The difference among groups was not statistically significant for other characteristics.

Table 7: Difference in attitude towards mental illness by education level of students

Characteristics	M(SD)	F- value	p-value	p-value trend
Batch		9.11	**<0.0001**	**<0.0001**
I MBBS	48.11(14.34)			
II MBBS	43.63(14.71)			
III MBBS	41.08(15.21)			

*M= mean, SD= standard deviation, F=degree of freedom, p= p value

Table 6 shows that There is increase trend in positive attitude in medical students with increase in their education level ($p<0.0001$).

There was significantly positive attitude towards mental illness among III MBBS students than II MBBS and, among II MBBS than I MBBS ($p<0.0001$). An increasing trend of positive attitude has been seen with an increase of education level and exposure towards the subject.

4. Discussion

The current online study was planned to assess the attitude of medical students towards mentally ill patients and mental illnesses, to find correlations of attitude score with sociodemographic and clinical variables and, to compare the score among students of the three year-wise groups.

Out of total 21 items of the BMI scale, students showed positive attitude on majority of items (fifteen items) and negative attitude on few items (six items). The mean score for BMI scale was 41.99 and per item mean score for the scale was 1.99. This score is towards positive attitude. Jilowa et al also found in their study that Nearly 84% of second-year medical students and 52% of interns had positive attitude toward psychiatry. (19) In their study, Risal et al also found overall positive or neutral attitudes towards mental illness and psychiatry among the medical students and interns in their institute. (20)

In our study we found that majority of students agree that a mentally ill person is more likely to harm others than a normal person (64%) and that mental disorders would require a much longer period of time to be cured than would other general diseases (83%). Kodakandla et al conducted a study on Attitude of interns towards mental illness and psychiatry and found that majority of the interns believed that mentally ill person is more likely to harm others and that mental illness require a much longer time to be cured than other general diseases. (21) In our study majority (58 percent) of students agree that most people would not knowingly be friends with a mentally ill person. Jyothi NU et al also found majority (96 percent) of participants agreed with the statement. (22)

In our study we found that majority of students agree that psychological disorder is recurrent (64%), that people who have once received psychological treatment are likely to need further treatment in the future (61%), and that the behaviour of people who have psychological disorders is unpredictable (65%). Kodakandla et al also found that majority of participants (76%) believed that psychological disorder is recurrent and that the behavior of patients with psychological disorder is unpredictable (79%); two third of them (68%) were of the opinion that people who have once received psychological treatment are likely to need further treatment in the future. (21) Jyothi NU et al also found similar findings in a study on college students. (22)

Students showed per item mean score 1.77 for poor interpersonal and social skill subscale which is towards positive attitude. Higher per item mean score 2.17 for dangerousness subscale and 2.21 for incurability showed their negative attitude. In a community Study on Attitudes to and Knowledge of Mental Illness in Tehran, Ghanean H et al found that around half participants agreed that people with a mental illness “are dangerous”. (23) Contrary to our findings *Kodakandla et al* found that only one third (31%) interns believed that psychological illness is unlikely to be cured regardless of the treatment. (21)

Married students showed statistically significant higher BMI score compared to unmarried students. On further analysis it was found that of these six married students, five had positive response for history of mental illness in family, friend or any relative and, two had positive history of past mental illness. So,

these two factors might have caused higher stigma in this small sample. The attitude score was not associated statistically significantly with other sociodemographic and clinical variables.

There was significantly positive attitude towards mental illness among III MBBS students than II MBBS and, among II MBBS than I MBBS ($p<0.0001$). An increasing trend of positive attitude has been seen with an increase of education level and exposure towards the subject. Similar to our study Aruna et al also highlighted exposure to psychiatry could improve the knowledge base of medical students. (24) Tharyan et al also found that psychiatric education positively influences the attitudes of medical students towards mental illness and some aspects of psychiatry. (25) However, providing clinical training in psychiatry during under graduation seems to improve the attitude toward people with mental illness. (16, 25-27) The favorable impact of psychiatry posting on the attitude of medical students towards mentally ill has been found in previous studies from western countries. (28) Work by Mas and Hatim (2002) from Malaysia found that final year MBBS students had more favorable attitude towards mentally ill as compared to the first-year students. (29)

The National medical commission (formerly Medical Council of India) has implemented Attitude, Ethics and Communication module (AETCOM) in all medical colleges in India in August 2019. (30) The cognitive components, behavioural attitudes and ethical dimensions of AETCOM module will change the approach of future doctors to psychiatry and person with psychiatric illness. Focusing more on clinical exposure and skills the new competency based medical education (CBME) programme has increased the duration of undergraduate clinical posting to total four weeks and total 40 hours for teaching from two weeks and 25 hours pre CBME respectively. This sequential introduction of clinical posting during second professional MBBS followed by theory class and clinical posting during third MBBS part-I will be more helpful in understanding of the subject. In future, mandating psychiatry as an independent subject of examination in under graduation assessment may prove a milestone step in medical education. So, it may be expected that this increased exposure will help in removing the existing negative attitudes towards psychiatry and person with psychiatric illness.

Suggestions:

Admitting the prevailing stigma needs to be acknowledged and openly discussed with medical students in order to overcome these views. Prevailing stigma and the negative attitudes about mental illnesses affect both patient caring and psychiatry as a career choice. The development of educational strategies enabling initial interest shown during the early clinical exposure needs to be maintained. Providing public education on mental illnesses and attached negative attitudes or myths can change these negative beliefs in general public. To promote psychiatry as a career, interested students need to have increased access to an in-depth experience of psychiatry, including “enrichment activities” such as electives in psychiatry.

Conclusions:

Medical students show variable scores on belief towards mental illness scale, its subscales and, individual items. Admitting this prevailing stigma needs to be acknowledged and openly discussed with medical students in order to overcome these views. Providing adequate education on mental illnesses and attached negative attitudes or myths can change these negative beliefs.

Implications of the Study:

This study will help in understanding of belief of medical students towards mental illnesses. The comparison among various groups in

present study will help in understanding the impact of successive undergraduate training years.

Limitations:

This was a cross sectional study with small sample size.

Future Direction:

Future studies can be undertaken with large sample size to determine the changes in belief of medical students admitted year 2019 onwards.

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Original Research Article

A Cross Sectional Study on Assessment of Attitude Among Health Professionals Towards the Problem of Substance Abuse at Ananta Hospital, Rajsamand

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Abstract

Background: Drug abuse affects the health and lives of millions of individuals across the world. Discrimination faced by substance users and stigmatization becomes a barrier for them thus these patients do not receive the required care and treatment they deserve. The negative perception of healthcare professionals leads to poor therapeutic alliance between them and the patients of substance use. Current study aims to determine and assess the attitudes of the health professionals towards patients with substance use problems and to identify factors causing diverse attitudes of health professionals towards these patients.

Method:A questionnaire based cross sectional study was undertaken at Ananta hospital Rajsamand (a tertiary health care centre) which included 134 health professionals both doctor and nursing staff for a duration of one year who provided their consent for this project. The socio- demographic details of every participant was collected and all of them were given the DDPPQ tool which assessed their attitudes and perception towards drug and drug use problems.

Results: Younger age group of health professionals showed better outlook towards patients of drug abuse. A linear regression of gender, professional roles (i.e. doctors and nurses), past history of substance abuse and known history of substance abuser in the family with the principal component does not yield any significant results. Majority of the participants had either neutral opinion or positive opinion towards the problem of drug use and the drug users.

Conclusions: Healthcare professionals with age on the lower side had more positive regards and significantly positive attitudes towards the problems of substance use and therefore the

therapeutic compliance was better. Healthcare delivery needs unbiased and non-judgmental attitude of healthcare professionals towards patients of substance abuse, so in an attempt to provide holistic approach and care that overlooks socio-demographic and clinical profiles, professionals should have adequate and appropriate training and exposure accordingly.

Keywords: Professionals, nursing, staff, substance, drug, perception, attitudes, stigmatization.

Introduction

Drug abuse is a global phenomenon which affects almost every country with a variable extent. Abuse of illicit drug affects the health and lives of many individuals across the globe. The criminalization of this addictive behavior damages the reputation of the engaged person and it also deters other people, leading to stigmatization of the problem in the society. Stigmatization also discourages illicit drug users from getting health care due to fear of poor treatment by health care providers or fear of trouble with the authorities[1,2]. While stigma and discrimination may serve as deterrents to illicit drug use, these attitudes also contribute to discrimination and stigmatization experienced by illicit drug users which may be bad for drug user's health[3]. Negative attitudes of health professionals towards patients with an alcohol or other drug addiction are known to lead to poor communication between professional and patient, diminished therapeutic alliance, and mis-attribution of physical illness symptoms to substance use problems, also referred to as diagnostic overshadowing[4,5].

In this scenario, medical professionals are key persons in the provision of care for persons who exhibit problems related to use of the substances of abuse. Personal factors[6] and deficient medical education about addiction in health professionals[7] influence the under-diagnosis of substance abuse disorders. Studies have found that physicians were significantly less satisfied when caring for patients with drug problems compared to other illnesses[8]. A study on nurses found that nurses struggled with the care for patients who use illicit drugs and they had less motivation, satisfaction, role support and education[9]. Another study found that staff who had received training held fewer negative attitudes towards illicit substance users regardless of their length of clinical work experience or type of work setting[10]. Another study found that health professionals' regard was lowest for patients with drug and alcohol problems, lowest regard was found among physicians who did not work in specialized addiction services[11]. This study found that specially trained personnel's in this field such as psychologists, social workers, and professionals in the addiction services showed the highest regard while physicians who did not work in specialized addiction services had lowest regard. People with drug related disorders deserve the same level of care as patient with any other health condition. Health service need to be able to identify drug use and drug use disorder at an early stage and provide prevention, treatment and harm reduction intervention. We could not find any study in our region addressing health professional attitudes towards persons with problems related to substance use.

Aims and Objectives

Current study aims to assess and determine the attitudes of the health professionals

towards patients with substance use problems and to identify factors causing diverse attitudes of health professionals towards these patients.

Methods

Study area

The study was conducted at Ananta Hospital Rajsamand (attached to Ananta Institute of Medical Science and Research Centre, Rajsamand, Rajasthan) a tertiary care hospital.

Study Design

Questionnaire based cross sectional study

Study Participants

Health Professionals (Including doctors and nursing staff)

Study duration

One Year, September 2019 to August 2020.

Sample size

A total population of health care professional of 200 working in Ananta Institute of Medical Science and Research Centre, Rajsamand, Rajasthan, a tertiary care hospital. Minimum of 134 participants were expected to participate according to the following calculation.

$N^* = N*X / (X + N - 1)$,

where,

$$X = Z^2_{1-\alpha}\, p(1-P)/d^2$$

where alpha (α) = 0.05, estimated proportion (p) = 0.50, estimated error (d) = 0.05 and N is the population size

The Finite Population Correction is used to adjust a variance estimate when sampling without replacement.[15]

A stratified random sampling technique has been used for collection of data. A validated 22-item DDPPQ questionnaire tool has been used in the study.

Statistical analysis

Questionnaire data was analyzed using SPSS version 24. Socio demographic data were summarized using frequencies and percentages. Means and standard deviation were used for continuous variables. Mann Whitney U test was used to compare the difference among professional groups i.e. doctors and nurses. The relationship between DDPPQ scores and other relevant variables was analyzed by using Pearson Product-Moment Correlation Co-efficient. The regression analysis has been done to find out relationship between independent and dependent variables. Statistical significance was taken at the 5% level.

Data Collection Procedure

The 22-item validated version of Drug and Drug problems perception questionnaire (DDPPQ) instrument was used for the study[12]. The validated DDPPQ, comprises of 22 items and is a shorter questionnaire, having retained only the most reliable items from the original instrument. The items of the validated questionnaire are numbered consecutively from one to twenty-two. The validated DDPPQ is a self-complete 'paper and pencil' questionnaire. Respondents are asked to rate their level of agreement on a series of 22 statements about working with people who use licit or illicit drugs in a nontherapeutic way. There are seven possible responses to each item on a scale of Strongly agree' to 'Strongly disagree'. Low scores denote positive attitudes, whereas high scores are associated with negative views. Several of the items are worded negatively. These are Items 15, 16, 17 and 18. For the purpose of this study, the DDPPQ were expressed on a 5-point Likert scale ranging from 1 = strongly agree, 2 = agree, 3 =neither agree nor disagree, 4 = disagree to 5= strongly disagree

.A 5 - point Likert-type scale instead of 7-point was used to increase response rate and response quality along with reducing respondents' frustration level[13]. Factor structure of the validated DDPPQ has yielded its six factors which are role adequacy, motivation, role legitimacy, task specific self-esteem, role support and work satisfaction

Study Variables

The independent variables in the study are the socio-demographic characteristics of the study participants such as gender, age, profession, work motivation and role support of health professional. The dependent variables, attitude and perception are measured by six factors/ subscale measure (using 5- point Likert scale) in the DDPPQ. Questionnaire data was analyzed using SPSS version 24. Socio-demographic data were summarized using frequencies and percentages. Data was analyzed by using unrelated T-test, Mann Whitney U test and Pearson product moment correlation coefficient.

For the questionnaire survey, 22 items of validated version of DDPPQ questionnaire was distributed individually to the 152 professional group members in a sealed envelope and returned back in same sealed condition in order to maintain privacy of participants. One hundred and thirty-four participants returned the completely filled up questionnaire. All professional group members i.e. both doctors and nursing staff members responses to the given DDPPQ questionnaire were calculated to give a total attitude score. The minimum score for the DDPPQ is 22 and the maximum score is 110. The higher the score obtained indicates an increasingly more negative attitude.

Results

Table 1: gives description of number of participants according to the gender as well their professional roles.

Group	Number (Total=134)	Percentage
Doctors	85	63.4 %
Males	53	39.5 %
Females	32	23.8 %
Nursing staff	49	36.5 %
Males	30	22.3 %
Females	19	14.1 %

Table 1. Profile of the Sample

Table 2: shows profile of the sample according to professional group and gender.

	Number of responses	Score Range	Mean Score (SD)	Z score	P* Value
Doctors	85	24-76	49.63 (8.95)	-0.30	0.75
Nursing Staff	49	33-68	49.46 (9.52)		

Table 2. The DDPPQ Score Range for Professional Groups

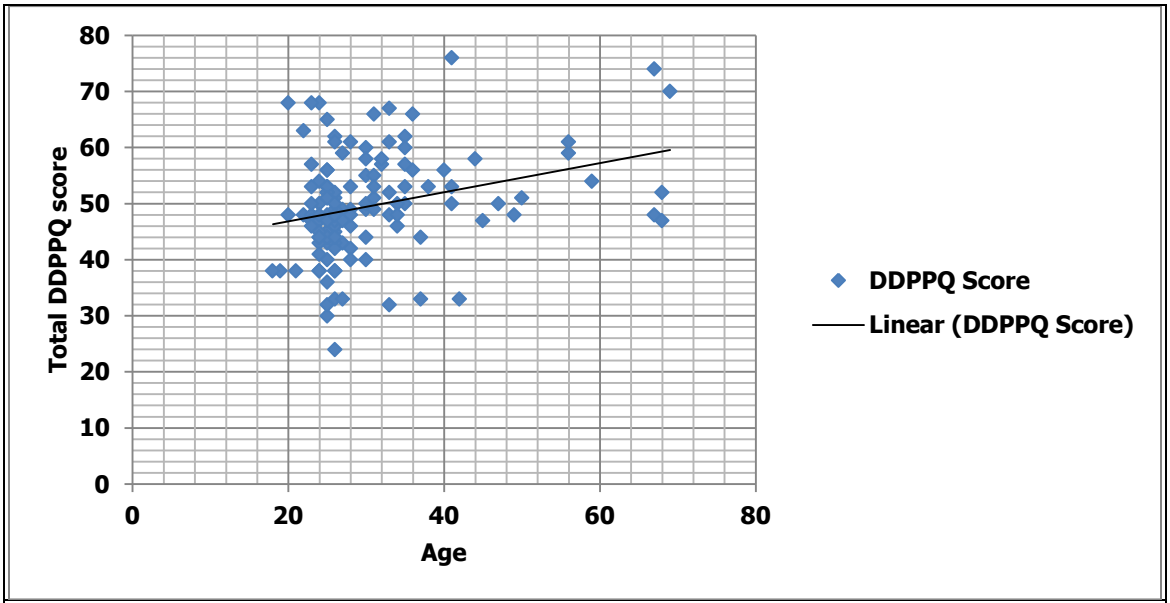
Mann Whitney U test. * The result is significant at $p<0.05$

Table 2 shows the DDPPQ score range for the participants. A Mann-Whitney U test was conducted to compare DDPPQ scores between doctor and nursing staff. The result is not significant at $p<0.05$. There is no difference between the groups.

Age of Participants Versus DDPPQ Score

Mean age of the total sample was 30.56 years (standard deviation 10.38). Mean age for doctors' group was 32.85 years (standard deviation= 11.86) and for nursing staff group was 26.59 years (standard deviation=5.21).

There is significant correlation between the age of the professional group members i.e., both doctors and nursing staff members and their respective DDPPQ scores when calculated using Pearson Product – Moment Correlation Co-efficient (2 tailed) $r = 0.29$, $n = 134$, $p = 0.00067$.



Graph 1: Distribution Graph of Age Versus Total DDPPQ Score

The graph indicates weak positive correlation between age of the participants and their corresponding DDPPQ score.

Family History versus DDPPQ Score

Participants were also asked if they had any family history of substance abuse and past history of substance abuse.

Table 3: Comparisons among Health Professional having Family History of Substance Abuse and Past History of Substance Abuse

	Response	Number of Responses	Range	Mean (Standard Deviation)	Z Score	p*Value
Family history of substance abuse	Positive	22	43-63	52.09(5.97)	-1.786	0.074
	Negative	112	24-76	49.08(9.57)		
Past history of substance abuse	Positive	23	38-65	50.17(7.16)	-0.393	0.694
	Negative	111	24-76	49.45 (9.51)		

Mann Whitney U test. * The result is significant at $p<0.05$

In Table 3, comparisons among Health professional having family history of substance abuse and past history of substance abuse are described. Using Mann- Whitney U test, we found that there is no statistical difference between the groups of health professional having past history of substance abuse and health professional who don't have past history of substance and the groups of health professional having family history of substance abuse and health professional who don't have family history of substance abuse.

A linear regression of gender, professional roles (i.e., doctors and nurses), past history of substance abuse and known history of substance abuser in the family with the principal component has not yielded any significant results.

Table 4: Health Professional Therapeutic Commitments towards Drug Abusing Patients on various Subscales of DDPPQ and total Mean Score

Subscales	Number of Questions	Mean Score Per Question (LikertScore = 1-5)	Standard Deviation
Role adequacy	8	1.99	0.65
Role Legitimacy	3	1.85	0.71
Role support	3	1.92	0.64
Work satisfaction	4	2.18	0.76
Motivation	1	3.58	1.17
Task specific Self Esteem	3	3.39	1.07
Total Score	22	49.57 (possible score 22-110)	9.13
Note: lower score denotes higher therapeutic commitment.			

Table – 4 shows a mean of total score of 49.57 (SD = 9.13) with a possible score between 22 and 110. **The diverse attitudes of Health Professionals towards substance abusers**

Table 5: Percentage of Participants in three Categories

	Frequency	Percentage
Positive [a]	36	26.86
Neutral [b]	91	67.92
Negative [c]	7	5.22
	134	100
a= Total score from 22 to 44; b) total score from 45 to 66; c) total score from 67 to 110		

The total DDPPQ scores were divided into three categories i.e. (1) Positive perception (distinctly defined perception of role), (2) Negative perception (lack of distinctly defined perception of role) and (3) neutral perception (neither distinctly defined perception of role nor lack of distinctly defined perception of role). The range for all three perceptions was determined by the possibility maximum and minimum score in 5 point- Likert scale. Table 5 shows percentage of participants in these three categories.

Discussion

Current study aimed to assess and determine the attitudes of health professionals towards patients with substance use problems in our region and to identify factors causing diverse attitudes of health professionals towards these patients. There was weak positive correlation between age of the participants and their

corresponding DDPPQ score that is older health professionals had relatively negative attitude. This was in contrast to a study that found that older nurses believed more strongly that alcoholism is an illness[14]. The two professionals' groups were assessed by comparing health professionals having family history of substance abuse and past history of substance abuse, and it was found that there is no statistical difference between the two groups of health professional. The mean DDPPQ score in these groups ranged towards lower side denoting positive attitude towards these patients, means their past or family history of substance use didn't significantly affect the attitude. Our study found that there was no statistically significant difference between the DDPPQ scores between the two groups i.e., doctors and nursing staff.

Considering all participants in a group, the lower skewed total mean DDPPQ score of 49.57 (SD = 9.13, with a possible score between 22 and 110) in our study correlated with a more positive attitude and higher therapeutic commitment to drug abusing patients. On mean Likert-format response per question (of 1= Strongly agree to 5= Strongly disagree), the highest therapeutic commitment is reflected in role legitimacy subscale which indicated the degree that professional group members felt that drug abuse history taking and counseling was a professional responsibility. Role support and Role adequacy followed the next which reflected that professional group members felt that they have adequate knowledge of drug and drug related challenges. Also whenever required, they will get support or help to resolve drug related problem. Highly skewed score in motivation and self-esteem subscale reflected lower therapeutic commitment. Role support, role adequacy, role legitimacy and work satisfaction were all somehow interconnected with each other at the basic level along with motivation and self-esteem to aid in understanding of the plight of patients of substance abuse and thereby providing therapeutic care and overall management to such patients. Our findings are in contrast to another study which found that healthcare providers struggled with the care for patients who used illicit drugs and they had less motivation, satisfaction, role support and education.[9]Crothers and Dorrian also found high scores regarding work satisfaction which indicated that nurses' attitudes regarding how much they like, and feel rewarded by, working with patients with alcohol problems, are an important determinant of the extent to which nurses are actually willing to engage in this work[15].

In an attempt to identify diverse attitudes of health professionals towards substance abusers, the sample participants were divided into three categories for ease of understanding - Positive perception, Negative perception and neutral perception; and it was found that number of healthcare professionals having neutral perception were maximum, followed by those having positive perception and least holding negative approach to the drug abuse patients. In a study nurses appeared to have, on average, attitudes that were consistently quite positive, if not neutral[14]. As healthcare professionals are the chief gatekeepers in the management of patients who suffer from substance use disorder, there is need of the hour to change both the neutral and negative attitude of the health care workers into positive attitude. To improve local services, Howard et al recommended that a training strategy should be developed with consideration to a structured programme covering all aspects of providing care to inpatients with co-occurring mental health and substance use problems; implementing training and support structures for staff will enable them to deliver more recovery and client centered interventions for patients with these co-occurring issues[10].

Healthcare delivery needs unbiased and non-judgmental attitude of healthcare professionals towards patients of substance abuse, so in an attempt to provide holistic approach and care that overlooks socio-demographic and clinical profiles, professionals should have adequate and appropriate training and exposure accordingly. We propose some ways that can be executed systematically to bring about the necessary change in the attitudes of a healthcare professional- First and foremost is sensitization of healthcare professionals (both the doctors as well as the nursing staff) which is primarily important to achieve better outcomes in management of patients of substance use disorders. Secondly, there are ways to be incorporated at the grass root level which directly and/or indirectly will have an impact on the management of such patients include: (i) training – providing education and skills to the professionals and conducting workshops at regular intervals, teaching institute – both the medical colleges and the nursing colleges are jointly responsible in training the students who take up this field and providing opportunities for them to learn,(ii) exposure – mandatory rotatory postings for every undergraduate medical/nursing student to understand patients from having them visit an addiction wing facility of outdoor and indoor patients run by the department of psychiatry at the institute where they come across such patients of substance abuse.

Conclusion

Our study found that the younger age group healthcare professionals had more positive outlook and attitude towards substance users. The lower skewed total mean score of participants denoted more positive attitude and higher therapeutic commitment. Subdivision of the participants in three groups to a step forward revealed that majority of them had either positive or neutral attitude towards patients with problem of substance abuse, leaving a minority or handful percentage of participants who had negative perception and attitude.

Implications of the Study

our study will help in identifying diverse attitude of health professional towards patients with substance use disorders and the associated factors. Awareness and proper education along with skills instilled among these healthcare professionals will strengthen the belief and trust of the patient receiving treatment and management during the prolonged period provided for deaddiction. The provision of adequate, timely guidance and motivation at every step to reduce the use of illicit substances, would help in controlling the menace of drug abuse can be well achieved.

Limitations

This was a cross sectional study with small sample size.

Future Direction

Future studies can be undertaken with large sample size to determine the changes in attitudes and knowledge of healthcare professionals prior to any kind of exposure or training received and followed up by assessing them after they have achieved skills, knowledge and training in the field of addiction psychiatry.

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Section Psychiatry

How Stigma and Discrimination are Perceived by Rural or Urban Patients Suffering from Schizophrenia? An Exploratory Cross – Sectional Study from Western India

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Original Article

ABSTRACT

Background: *Stigma is conceptualized as an attribute which is deeply discrediting and makes the person carrying it different from other and of a less desirable kind. Current study aimed to describe the nature and direction of experienced stigma; and discrimination reported by people with schizophrenia.* ***Methods:*** *One hundred and fifty patients diagnosed with Schizophrenia were selected from the Out Patient service of Psychiatry Department of a medical college general hospital. The experiences of stigma and discrimination were assessed using a semi-structured instrument developed by national working group for India by the world psychiatric association steering committee.* ***Results****: Differences were seen between rural and urban respondents. Patients from rural background more often reported these experiences: society treats differently, ridiculing by others, offensive comments, hiding from relatives, rejecting attitude of peoples around, attribution of supernatural cause as most common source of stigma, social exploitation, not fully accepted in the family, pushed into unacceptable social situation and sexual harassment. Reported narratives provided the direct view of these patients.* ***Conclusions****: Stigma experience is pervasive: it deeply affects the social, occupational and emotional wellbeing of patients with schizophrenia and should be included in clinical management. Effective anti-stigma intervention should target on improving attitudes and the condition for social integration in the community, empowering people with schizophrenia to challenge self-stigmatization and discrimination behavior towards them.*

Key words: *Schizophrenia, Stigma, Discrimination, Experiences, Attitude.*

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INTRODUCTION

Schizophrenia is the most debilitating chronic psychiatric disorder which usually affects adolescents and young adults, disrupting pursuit of their educational and occupational goals. The disorder is associated with significant stigma and discrimination, which further increase the burden on these patients and their families. The essence of stigma is a negative and prejudicial attitude toward someone with a mental illness. Many people with mental illness describe the effect of stigma as severe, and more difficult to deal with as compared to the mental health problem itself. Discrimination occurs when people with mental illness are treated unfairly, or are denied their rights because of their mental illness. Individuals with schizophrenia often face social isolation; discrimination in housing, education and employment opportunities, and other forms of prejudice.[1]The stigma often extends to family members and to those who provide health care services to patients with the disorder. Major international studies suggest that schizophrenia has better prognosis in low-income nations and in rural settings.[2-4] The industrialization hypothesis has been advanced to explain this differential outcome which argues that industrial economies and attendant life styles lead to poor support, intolerance, rejection, isolation, segregation and institutionalization of the severely mentally ill.[5] The value placed on the autonomous individual in industrialized settings therefore accentuates social extrusion of the chronic mentally ill patient who assumes personal responsibility for the illness. In consequence, prognosis worsens in urban industrialized settings.

Studies on stigma and mental illness in the Indian setting have focused both on measurements of stigma and on locally important socio-cultural factors shaping stigma.[6-9] Numerous other studies have addressed public attitudes

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towards mental illness.[10-12] The nature, determinants, and consequences of stigma vary across culture and region. Hence, there is a need for studies to understand the stigma specific to a particular region to plan intervention. Better understanding and identification of determinants may suggest ways to reduce stigma and help prevent its adverse consequences.

With this background, this study was aimed to study stigma and discrimination perceived by patients with schizophrenia and, its comparison between rural and urban patients.

METHODS

2.1 Material

This was a cross sectional study conducted at psychiatry OPD of Civil hospital Ahmedabad, Gujarat. Clearance from the institutional review board was taken prior to conducting the study. The sample consisted of one hundred fifty patients diagnosed with schizophrenia independently by two psychiatrists as per criteria laid down by diagnostic and statistical manual (DSM IV-TR). Information from the caregivers and the patient case file along with a mental status examination also were used for diagnostic confirmation. The purpose of the study was explained to patients and their caregivers. The consent of the caregiver was also taken. The patients' responses were recorded.

2.2 Inclusion criteria:

1. A patient with a diagnosis of schizophrenia under continuous remission of at least six-month period according to DSM IV-TR criteria.
2. Provision of the consent.

2.3 Exclusion criteria:

1. Those patients with co-morbid axis I /II disorder.
2. The patient having co-existing medical or substance use disorder other than nicotine.

2.4 Instruments for the study

A semi structured interview developed in an earlier study.[13] This instrument has been used on over 1000 patient in four cities, as a part of the Indian initiative of the world psychiatric program to reduce the stigma and discrimination because of schizophrenia. It consists of two parts: first part of the scale elicits the socio-demographic information of the respondents while second part of the scale measures stigma and discrimination experiences including nature of stigma experiences, attitude of relatives, friends and caregiver, source of stigma, consequences of stigma, patient's view how stigma could be reduced and to what level, comparison of severity of mental illness to other medical illness bringing disability. The verbatim regarding patient's stigma experience in areas like personal, family, social, occupational and in marital life also were recorded.

2.5 Statistical analysis

Both quantitative and qualitative analysis were done using computer. The data from urban and rural areas were compared to find out any difference. Quantitative data was analyzed by t-test and chi-square test. The narratives were read to identify the themes of stigma. For natural and objective analyses, the data were coded manually into constructs that emphasized stigmatizing experiences in various spheres of patient's life.

RESULTS

3.1 Socio-demographic characteristics:

The table 1 shows socio-demographic characters of the sample (N=150).

As shown in Table 1, majority of the patients were male (64%), Hindu by religion (86.6%), of age range 21-30 years (42%), married (49.3%), educated up to class 10th (69.3%), living in a joint family (52%), unemployed (62%), having income under 1000 rupees per month (68%).

Disease related characteristics: Seventy-nine (52.6%) patients (rural=18, urban=61) were having paranoid subtype of the disorder. One hundred thirty-six (90.6%) patients (rural=36 and urban=100) were having duration of illness more than two years.

Table: 1 Demographic characteristic

S. No.	Sample (N=150)	Rural N=39 (26%)	Urban N=111 (74%)
1.	**Religion**		
	Hindu (130, 86.6%)	33 (84.6%)	96 (86.5%)
	Muslim (17, 11.3%)	05 (12.8%)	12 (10.8%)
	Others (3, 2%)	01 (2.5%)	03 (2.7%)
2.	**Gender**		
	Male (96, 64%)	23 (59%)	73 (65.8%)
	Female (54, 36%)	16 (41%)	38 (34.2%)
3.	**Age (years)**		
	21-30 (63, 42%)	20 (51.2%)	39 (35.1%)
	31-40(42, 28%)	08 (20.5%)	34 (30.6%)
	41-50 (28, 18.6%)	09 (23.0%)	19 (17.2%)
	>50 (17, 11.3%)	02 (5.1%)	15 (13.5%)
4.	**Marital status**		
	Married (74, 49.3%)	18 (46.1%)	56 (50.4%)
	Unmarried (39, 26%)	09 (23.1%)	30 (27.0%)
	Divorced (19, 12.6%)	03 (7.7%)	16 (14.4%)
	Other (18, 12%)	09 (23.1%)	09 (8.1%)
5.	**Education**		
	Illiterate (18, 12%)	06 (15.4%)	12 (10.8%)
	Up to class X (104, 69.3%)	24 (61.5%)	80 (72.1%)
	Higher (28, 18.6%)	09 (23.0%)	19 (17.2%)
6.	**Family type**		
	Nuclear (68, 45.3%)	14 (35.89%)	54 (48.6%)
	Joint (78, 52%)	24 (61.5%)	54 (48.6%)
	Other (4, 2.6%)	01 (2.5%)	03 (2.7%)
7.	**Employment**		
	Employed (57, 38%)	08 (20.5%)	49 (44.1%)
	Unemployed (93, 62%)	31 (79.5%)	62 (55.8%)
8.	**Income (rupees per month)**		
	<1000 (102, 68%)	31 (79.5%)	71 (64%)
	>1000 (48, 32%)	08 (20.5%)	40 (36.0%)

Table 2 shows various stigma variables experienced by the patients.

Table 2: Common stigma experienced by patients

Variable	Rural N, (%)	Urban N, (%)	Chi square
Society treats differently	27(69.2%)	60 (54.0%)	X^2=2.73, df=1, p=0.09
Ridiculing by others	29(74.4)	67(60.4)	X^2=2.45, df=1, p=0.11
Offensive comments	30(76.9)	62(55.9)	X^2=5.40, df=1, p=0.02
Hide from relatives	26(56.7)	57(51.3)	X^2=2.74, df=1, p=0.09
Difficulty in getting marriage proposal	09(23.1)	36(32.4)	X^2=1.20, df=1, p=0.27

Table 3 shows various consequences of the stigma and discrimination experienced by the patients. Other findings of the study were as mentioned here. The most common reported source of stigma was attribution of supernatural cause in rural patients (41%) while in urban patients it was

not being able to work due to illness (39.6%). Avoidance was the most common attitude of relatives towards patients in both regions (51.2% rural, 41.4% urban).

Table 3: Consequences of the stigma and discrimination

Variable	Rural N, (%)	Urban N, (%)	Chi square
Avoid disclosing the mental illness histories in jobs/application	03 (7.69%)	21 (18.92%)	X^2=2.71, df=1, p =0.100
Social exploitation	25 (64.10%)	40(36.04%)	X^2=9.26, df=1, p=0.002
Not fully accepted in the family	29 (74.36%)	61 (54.95%)	X^2=4.53, DF=1, p=0.03
Pushed into unacceptable social situation	11 (28.2%)	15 (13.5%)	X^2=4.35, DF=1, p=0.04
Sexual harassment	14 (35.9%)	20 (18.0%)	X^2=5.26, DF=1, p=0.02
Living alone	24 (61.5%)	80 (72.1%)	X^2=1.5, DF=1, p=0.22

Friends and relative either stopped visiting at all or visited less frequently in rural patients (43.5%), while 42.3% urban patients reported that friends and relatives stopped visiting at all. In rural area, patients attributed their illness to faulty biological functioning (33.3%) while in urban area patients accepted that they are mentally ill (45.0%). Mental illness was reported as most disabling illness by 71.7% rural and 54.0% urban patients. Forty one percent rural patients while 34.2% urban patients reported that stigma can be partially cured. Involvement in advocacy activities was reported to be an effective strategy to reduce stigma by 64.2% rural and 55.8% urban patients. Most of the patients (94.8% rural and 77.4% urban) reported that concealing or selective disclosure of the illness is not an effective strategy to reduce stigma. Increasing awareness of the mental illnesses was reported to be an effective way to reduce stigma (69.2% rural, 65.7% urban).

Common stigmatizing verbatim reported by the patients:

I. Common stigmatizing verbatim reported by rural patients:

- "In the society, nobody enquires about me. Nobody loves me. Nobody even looks at me. They call me 'mad', and laugh at me. They don't even invite me at their home on festivals. Due to my illness, my marriage is not getting fixed."

-"In my village when houses were repaired, everybody got the letter but they didn't provide the same for met. Nobody wants to come and meet me. Today I have a broken house to stay pending repair work. I asked for help from my friends and relatives but nobody comes forward. Every times during rain, water comes into my house no body helps me."

II. Common stigmatizing verbatim reported by urban patients:

- "When I fell ill, everyone in my house kept nagging me all day. They didn't give me food. They used to beat me and threw me out of house, when I went to my mother's place, there also people used to nag me. In the beginning, my husband was cooperative, but now he doesn't talk to me much and does not maintain sexual relationship with me."

- "Neighbors don't talk to me. When I go to collect water in the morning, they keep on pushing me, they throw my vessels away. They abuse me and also hit me. My house owner keeps on telling me and my family members to vacant the house."

Consequences of Stigma

I. Experiences related to personal area:

- "I was bright in study prior to the illness, but I quitted my study as I failed in 10th. My memory power went down. My writing is also getting bad. I can't work at my home as I get tremor at my hand. I am unmarried yet, few relative come for my younger sister but when they knew about my illness, they went away."

II. Experiences related to Occupational area:

- "At my work place, people call me "mad". My boss gets angry on me every day and says that my head is empty. He always says me that they will sack me. At lunch hour I am not allowed to have lunch while everybody else is going for lunch. I get half the salary others get."

III. Experiences of stigma and discrimination in Social life:

- "I have one house with 2 BHK in Ahmedabad. When some relatives come to the city, though they stay at my house but nobody of them takes lunch or drinks water at my house. They stay only up to next morning and leave afterwards. Neighbors don't talk to me. They said me that I am mad. They give me work always without giving me any money, and upon asking, they refuse for the money."

- "Before illness, I was living in rented house. I was an inspector in IT department. People used to meet me and respect me, but when owner of the house knew about my illness, he asked me to vacate his house. Today I am living in small house alone. People avoid me."

IV. Experiences related to marital life:

- "Because of illness I am not able to work in my land. My land remains uncultivated. My desire for sex has come to an end. My penis is not erectile any more. Due to this, my wife left me and went to her parents place. Today she has got married to another person."

- "I was married in great pomp. My mental illness started at my in laws place. Initially they used to beat me a lot, they took me to a faith healer, after that they left me to my mother's place. My mother tried for many attempts one after another for my marriage. Every time, as my wife knew about my illness, she divorced me."

V. Experiences of stigma and discrimination in Family:

- "I had to hide my illness because mine and my sister's marriage were at stake. I got married in far Village, but when knew about my illness, they sent back me to my maternal home. I was pregnant at that time. After delivery, they called me back but when I was breast feeding my baby, my mother in law took my baby away and told, "You are mental and the child will also become mental if you breast feed the baby."

- "Nobody takes care of me at home even if I am ill and I need medication regarding this. When I told my brother and father about this, so they became angry on me and said you are mad, go wherever you want to, we do not have time for you"

VI. Impact of illness on General Life

a. Hiding of illness:

- "I have to stay in my house all day hiding my illness. Whenever I come at the window, my mother gets angry on me and directs me to go inside. She tells me that if people will know about my illness then nobody will marry me and my sister."

b. Decrease in Work efficiency and cognitive function:

- "Welding was my profession earlier but today I cannot concentrate on my work properly. I have been injured also because of this."

c. Visiting of Friends and Relative:

- "Since the starting of my illness, people are scared of me and they don't come near me. I had to live alone at home."

d. People's reaction after knowing their illness:

- "If any one comes from my family, they talk only one thing, to take medicine but nobody talks to me more than this. I have to live alone."

e. Most Disabling Illness:

- "Mental health problems should not occur. It becomes difficult to work. I am feeling better till I take medicine but my memory is decreasing. Nothing is remembered. I have to take pills to sleep in night."

DISCUSSION

The present study was aimed to study stigma and discrimination perceived by patients with schizophrenia and, its comparison between rural and urban patients. Majority of the patients were male, Hindu by religion, of age range 21-30 years, married, educated up to class 10th, living in a joint family, unemployed, having income under 1000 rupees per month. Findings of present study revealed that patients from rural background had more often stigmatizing and discriminating experiences compared to patients from urban background.

In our study, 62% patients were unemployed. Due to unemployment and chronic nature of illness, patients are not able to do their work as efficient as of their same age group in the society, which becomes the main culprit associated to creation of stigma. Stigmatization in the workplace and the related denial of access to job are the most important experiences of social exclusion. These experiences are recognized as the main factors producing and maintaining a high rate of unemployment among those with schizophrenia. In our study too, 21 (18.9%) urban and 3 (7.6%) rural patients reported avoiding disclosure of mental illness histories in job/applications.

In the present study, patients from rural background more often reported these experiences: society treats differently (p=0.09), ridiculing by others (p=0.11), offensive comments (p=0.02), hiding from relatives (p=0.09). Jadhav S et al also reported that rural Indians show significantly higher stigma scores.[14] Similar to our study an Indian study by Loganathan S et al reported that rural respondents experience more ridicule, shame, and discrimination but they reported that urban respondents feel the need to hide their illness.[15] Fear of rejection may be a need to hide their illness from others particularly in rural areas. In our study, more urban patients reported difficulty in getting married compared to rural patients (p=0.1). Weiss et al,[16] studying psychiatric stigma across cultures, pointed out that "in Bangalore the main concerns the sample had, were related to lowering their own chance of entering a good marriage and decreasing the chance of one of their relatives". Disclosing the diagnosis of schizophrenia becomes stigmatizing due to fear of being ridiculed, discriminated, leading to loss of job or not being able to get a job, and difficulty in getting married for the patient as well as family members. So, family members handle with it by hiding the diagnosis or not disclosing the presence of illness.

In our study, more rural patients reported social exploitation (p=0.002), not fully accepted in the family (p=0.03), pushed into unacceptable social situation (p=0.04), and sexual harassment (p=0.02) as a consequence of stigma and discrimination compared to urban patients. Jadhav et al also found that rural Indians showed a more stigmatizing attitude towards severe mental illness. Their study also showed greater stigma and a punitive attitude amongst rural Indians as compared to urban Indians.

In our study, rural patients reported attribution of supernatural cause as the most common source of stigma. Studies support this finding that in rural areas, the frequent association of mental illness with malevolent spiritual forces induces many families with a member with mental illness to seek help from shamans.[17,18] In rural areas, lack of adequate education regarding mental illnesses leads to such beliefs. Jadhav et al also concluded that urban Indians have a more liberal and tolerant attitude but were also more excluding of those with mental illness at work.[14] In our study too, not being able to work due to illness was the most common reported source of stigma in urban patients (39.6%).

In our study, rural patients reported rejecting attitude of peoples around while urban patients reported nagging and uncooperative attitude of the family members and society. Stigma led to painful experiences related to patient's personal and occupational area, social life, marital and family life. Fact of hiding the diagnosis of schizophrenia was also reported by the patients. Resulted decrease in cognitive functioning and impaired work efficiency also was reported by the subjects. The extent of the discrimination due to the illness resulted in stopped or less frequent visiting of the friends and relatives to the patients. The people around made either limited or no communication with the patients. Patients reported schizophrenia as the most disabling illness of all the illnesses.

Lack of correct knowledge is the variable associated with more stigma responses. Setting up programs directed towards modifying the attitudes of employers, as well as greater attention to the employment-related training of social workers could constitute useful instruments to improve labor market access for people with schizophrenia. These programs should help convincing employers that people with schizophrenia are highly motivated and can provide important contributions. At the same time, people with schizophrenia might need specific support in re-entering the labor market, such as Individual Placement and Support (ISP) Programs [19, 20]. Better integration in the labor market has been shown to improve clinical outcome[21-23] and reduce the risk of hospitalization.[24]

Stigma and negative public attitudes for a patient with schizophrenia is widely prevalent both in rural as well as urban areas. Therefore, while patients continue to consider stigma as a central obstacle to their integration into the community, they themselves contribute to this process by accepting public stereotypes as applicable to themselves. As a result, majority of them don't confront negative reaction, and lose self-esteem, isolate themselves and get worse. Our data from patient verbatim also highlighted that patient focus on the stigmatization experiences and on their ideas of the cause of stigma; while hardly offering any suggestions for anti-stigma intervention. Suggestion of participant mainly concerned the improvement of information on mental health issues among the public (66.7%). Participant did not seem to envisage many opportunities for positive change and found it difficult to formulate specific proposal on what could be done to improve their situation. Sorting out this difficulty might help reducing perceived stigma, discrimination and their consequences. Spending more time with a patient, may reduce stigmatizing and discriminating attitude presumably through the mechanism of exposure induced reduction of negative stereotype about the mental illness. Alexander & Link concluded that increasing personal contact with psychiatric patient could reduce people's stigmatizing

attitudes.[25] Couture & Penn also concluded that both retrospective and prospective contact tends to reduce stigmatizing views of persons with a mental illness.[26] Our findings suggest that people with schizophrenia are not fully accepted in the family, especially in rural areas. This suggests that certain factor could be more powerful than negative stereotypes in interpersonal stigmatization which can be overcome by provision of the scientific knowledge of the mental illnesses and re-integration of the patient in the community through psychosocial approaches.

Similar to our findings, Chinese families too, frequently concealed the mental illness of their members.[27] Family members act as both stigmatizer as well as victim of stigmatization themselves.[28] Because of this paradoxical role dualism, family members might project their anger towards a patient for causing them added suffering. This negative affective state, we suspect, could heighten the chronic burden of care. Providing adequate non-pharmacological measures may help family members in such circumstances of negative affective state. Provision of psychiatric care must move beyond symptoms control to diminish intentional as well as subtle forms of stigmatization in the patients' social life. Effective anti-stigma intervention should target on improving attitudes and the condition for social integration in the community, empowering people with schizophrenia to challenge self-stigmatization and discrimination behavior towards them. Regarding the work-related stigma, we believe that a combination of corporate education programme, legal measures and advocacy efforts are needed.

CONCLUSION

Stigma experience is pervasive: it deeply affects the social, occupational and emotional wellbeing of patients with schizophrenia and should be included in clinical management. Higher level of stigma is related to low education level, unemployment status. The provision of accurate information through trusted community sources and open dialogue may help to dispel myths, correct faulty assumption and increase the involvement of participation of community in dragging out the root source of stigma. Family programmes should be started early in an attempt to reduce stigma from significant others and to transform the family into a long recourse for psychiatric rehabilitation. Effective anti-stigma intervention should address chiefly two targets: improving attitudes and condition for social integration in the community and; empowering patients with schizophrenia to challenge self-stigmatization and discriminatory behavior towards them.

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Section Psychiatry

How Stigma and Discrimination are Perceived by Rural or Urban Patients Suffering from Schizophrenia? An Exploratory Cross – Sectional Study from Western India

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Original Article

ABSTRACT

Background: *Stigma is conceptualized as an attribute which is deeply discrediting and makes the person carrying it different from other and of a less desirable kind. Current study aimed to describe the nature and direction of experienced stigma; and discrimination reported by people with schizophrenia.* ***Methods:*** *One hundred and fifty patients diagnosed with Schizophrenia were selected from the Out Patient service of Psychiatry Department of a medical college general hospital. The experiences of stigma and discrimination were assessed using a semi-structured instrument developed by national working group for India by the world psychiatric association steering committee.* ***Results****: Differences were seen between rural and urban respondents. Patients from rural background more often reported these experiences: society treats differently, ridiculing by others, offensive comments, hiding from relatives, rejecting attitude of peoples around, attribution of supernatural cause as most common source of stigma, social exploitation, not fully accepted in the family, pushed into unacceptable social situation and sexual harassment. Reported narratives provided the direct view of these patients.* ***Conclusions****: Stigma experience is pervasive: it deeply affects the social, occupational and emotional wellbeing of patients with schizophrenia and should be included in clinical management. Effective anti-stigma intervention should target on improving attitudes and the condition for social integration in the community, empowering people with schizophrenia to challenge self-stigmatization and discrimination behavior towards them.*

Key words: *Schizophrenia, Stigma, Discrimination, Experiences, Attitude.*

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INTRODUCTION

Schizophrenia is the most debilitating chronic psychiatric disorder which usually affects adolescents and young adults, disrupting pursuit of their educational and occupational goals. The disorder is associated with significant stigma and discrimination, which further increase the burden on these patients and their families. The essence of stigma is a negative and prejudicial attitude toward someone with a mental illness. Many people with mental illness describe the effect of stigma as severe, and more difficult to deal with as compared to the mental health problem itself. Discrimination occurs when people with mental illness are treated unfairly, or are denied their rights because of their mental illness. Individuals with schizophrenia often face social isolation; discrimination in housing, education and employment opportunities, and other forms of prejudice.[1]The stigma often extends to family members and to those who provide health care services to patients with the disorder. Major international studies suggest that schizophrenia has better prognosis in low-income nations and in rural settings.[2-4] The industrialization hypothesis has been advanced to explain this differential outcome which argues that industrial economies and attendant life styles lead to poor support, intolerance, rejection, isolation, segregation and institutionalization of the severely mentally ill.[5] The value placed on the autonomous individual in industrialized settings therefore accentuates social extrusion of the chronic mentally ill patient who assumes personal responsibility for the illness. In consequence, prognosis worsens in urban industrialized settings.

Studies on stigma and mental illness in the Indian setting have focused both on measurements of stigma and on locally important socio-cultural factors shaping stigma.[6-9] Numerous other studies have addressed public attitudes

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towards mental illness.[10-12] The nature, determinants, and consequences of stigma vary across culture and region. Hence, there is a need for studies to understand the stigma specific to a particular region to plan intervention. Better understanding and identification of determinants may suggest ways to reduce stigma and help prevent its adverse consequences.

With this background, this study was aimed to study stigma and discrimination perceived by patients with schizophrenia and, its comparison between rural and urban patients.

METHODS

2.1 Material

This was a cross sectional study conducted at psychiatry OPD of Civil hospital Ahmedabad, Gujarat. Clearance from the institutional review board was taken prior to conducting the study. The sample consisted of one hundred fifty patients diagnosed with schizophrenia independently by two psychiatrists as per criteria laid down by diagnostic and statistical manual (DSM IV-TR). Information from the caregivers and the patient case file along with a mental status examination also were used for diagnostic confirmation. The purpose of the study was explained to patients and their caregivers. The consent of the caregiver was also taken. The patients' responses were recorded.

2.2 Inclusion criteria:

1. A patient with a diagnosis of schizophrenia under continuous remission of at least six-month period according to DSM IV-TR criteria.
2. Provision of the consent.

2.3 Exclusion criteria:

1. Those patients with co-morbid axis I /II disorder.
2. The patient having co-existing medical or substance use disorder other than nicotine.

2.4 Instruments for the study

A semi structured interview developed in an earlier study.[13] This instrument has been used on over 1000 patient in four cities, as a part of the Indian initiative of the world psychiatric program to reduce the stigma and discrimination because of schizophrenia. It consists of two parts: first part of the scale elicits the socio-demographic information of the respondents while second part of the scale measures stigma and discrimination experiences including nature of stigma experiences, attitude of relatives, friends and caregiver, source of stigma, consequences of stigma, patient's view how stigma could be reduced and to what level, comparison of severity of mental illness to other medical illness bringing disability. The verbatim regarding patient's stigma experience in areas like personal, family, social, occupational and in marital life also were recorded.

2.5 Statistical analysis

Both quantitative and qualitative analysis were done using computer. The data from urban and rural areas were compared to find out any difference. Quantitative data was analyzed by t-test and chi-square test. The narratives were read to identify the themes of stigma. For natural and objective analyses, the data were coded manually into constructs that emphasized stigmatizing experiences in various spheres of patient's life.

RESULTS

3.1 Socio-demographic characteristics:

The table 1 shows socio-demographic characters of the sample (N=150).

As shown in Table 1, majority of the patients were male (64%), Hindu by religion (86.6%), of age range 21-30 years (42%), married (49.3%), educated up to class 10th (69.3%), living in a joint family (52%), unemployed (62%), having income under 1000 rupees per month (68%).

Disease related characteristics: Seventy-nine (52.6%) patients (rural=18, urban=61) were having paranoid subtype of the disorder. One hundred thirty-six (90.6%) patients (rural=36 and urban=100) were having duration of illness more than two years.

Table: 1 Demographic characteristic

S. No.	Sample (N=150)	Rural N=39 (26%)	Urban N=111 (74%)
1.	**Religion**		
	Hindu (130, 86.6%)	33 (84.6%)	96 (86.5%)
	Muslim (17, 11.3%)	05 (12.8%)	12 (10.8%)
	Others (3, 2%)	01 (2.5%)	03 (2.7%)
2.	**Gender**		
	Male (96, 64%)	23 (59%)	73 (65.8%)
	Female (54, 36%)	16 (41%)	38 (34.2%)
3.	**Age (years)**		
	21-30 (63, 42%)	20 (51.2%)	39 (35.1%)
	31-40(42, 28%)	08 (20.5%)	34 (30.6%)
	41-50 (28, 18.6%)	09 (23.0%)	19 (17.2%)
	>50 (17, 11.3%)	02 (5.1%)	15 (13.5%)
4.	**Marital status**		
	Married (74, 49.3%)	18 (46.1%)	56 (50.4%)
	Unmarried (39, 26%)	09 (23.1%)	30 (27.0%)
	Divorced (19, 12.6%)	03 (7.7%)	16 (14.4%)
	Other (18, 12%)	09 (23.1%)	09 (8.1%)
5.	**Education**		
	Illiterate (18, 12%)	06 (15.4%)	12 (10.8%)
	Up to class X (104, 69.3%)	24 (61.5%)	80 (72.1%)
	Higher (28, 18.6%)	09 (23.0%)	19 (17.2%)
6.	**Family type**		
	Nuclear (68, 45.3%)	14 (35.89%)	54 (48.6%)
	Joint (78, 52%)	24 (61.5%)	54 (48.6%)
	Other (4, 2.6%)	01 (2.5%)	03 (2.7%)
7.	**Employment**		
	Employed (57, 38%)	08 (20.5%)	49 (44.1%)
	Unemployed (93, 62%)	31 (79.5%)	62 (55.8%)
8.	**Income (rupees per month)**		
	<1000 (102, 68%)	31 (79.5%)	71 (64%)
	>1000 (48, 32%)	08 (20.5%)	40 (36.0%)

Table 2 shows various stigma variables experienced by the patients.

Table 2: Common stigma experienced by patients

Variable	Rural N, (%)	Urban N, (%)	Chi square
Society treats differently	27(69.2%)	60 (54.0%)	X^2=2.73, df=1, p=0.09
Ridiculing by others	29(74.4)	67(60.4)	X^2=2.45, df=1, p=0.11
Offensive comments	30(76.9)	62(55.9)	X^2=5.40, df=1, p=0.02
Hide from relatives	26(56.7)	57(51.3)	X^2=2.74, df=1, p=0.09
Difficulty in getting marriage proposal	09(23.1)	36(32.4)	X^2=1.20, df=1, p=0.27

Table 3 shows various consequences of the stigma and discrimination experienced by the patients. Other findings of the study were as mentioned here. The most common reported source of stigma was attribution of supernatural cause in rural patients (41%) while in urban patients it was

not being able to work due to illness (39.6%). Avoidance was the most common attitude of relatives towards patients in both regions (51.2% rural, 41.4% urban).

Table 3: Consequences of the stigma and discrimination

Variable	Rural N, (%)	Urban N, (%)	Chi square
Avoid disclosing the mental illness histories in jobs/application	03 (7.69%)	21 (18.92%)	X^2=2.71, df=1, p =0.100
Social exploitation	25 (64.10%)	40(36.04%)	X^2=9.26, df=1, p=0.002
Not fully accepted in the family	29 (74.36%)	61 (54.95%)	X^2=4.53, DF=1, p=0.03
Pushed into unacceptable social situation	11 (28.2%)	15 (13.5%)	X^2=4.35, DF=1, p=0.04
Sexual harassment	14 (35.9%)	20 (18.0%)	X^2=5.26, DF=1, p=0.02
Living alone	24 (61.5%)	80 (72.1%)	X^2=1.5, DF=1, p=0.22

Friends and relative either stopped visiting at all or visited less frequently in rural patients (43.5%), while 42.3% urban patients reported that friends and relatives stopped visiting at all. In rural area, patients attributed their illness to faulty biological functioning (33.3%) while in urban area patients accepted that they are mentally ill (45.0%). Mental illness was reported as most disabling illness by 71.7% rural and 54.0% urban patients. Forty one percent rural patients while 34.2% urban patients reported that stigma can be partially cured. Involvement in advocacy activities was reported to be an effective strategy to reduce stigma by 64.2% rural and 55.8% urban patients. Most of the patients (94.8% rural and 77.4% urban) reported that concealing or selective disclosure of the illness is not an effective strategy to reduce stigma. Increasing awareness of the mental illnesses was reported to be an effective way to reduce stigma (69.2% rural, 65.7% urban).

Common stigmatizing verbatim reported by the patients:

I. Common stigmatizing verbatim reported by rural patients:

- "In the society, nobody enquires about me. Nobody loves me. Nobody even looks at me. They call me 'mad', and laugh at me. They don't even invite me at their home on festivals. Due to my illness, my marriage is not getting fixed."

-"In my village when houses were repaired, everybody got the letter but they didn't provide the same for met. Nobody wants to come and meet me. Today I have a broken house to stay pending repair work. I asked for help from my friends and relatives but nobody comes forward. Every times during rain, water comes into my house no body helps me."

II. Common stigmatizing verbatim reported by urban patients:

- "When I fell ill, everyone in my house kept nagging me all day. They didn't give me food. They used to beat me and threw me out of house, when I went to my mother's place, there also people used to nag me. In the beginning, my husband was cooperative, but now he doesn't talk to me much and does not maintain sexual relationship with me."

- "Neighbors don't talk to me. When I go to collect water in the morning, they keep on pushing me, they throw my vessels away. They abuse me and also hit me. My house owner keeps on telling me and my family members to vacant the house."

Consequences of Stigma

I. Experiences related to personal area:

- "I was bright in study prior to the illness, but I quitted my study as I failed in 10th. My memory power went down. My writing is also getting bad. I can't work at my home as I get tremor at my hand. I am unmarried yet, few relative come for my younger sister but when they knew about my illness, they went away."

II. Experiences related to Occupational area:

- "At my work place, people call me "mad". My boss gets angry on me every day and says that my head is empty. He always says me that they will sack me. At lunch hour I am not allowed to have lunch while everybody else is going for lunch. I get half the salary others get."

III. Experiences of stigma and discrimination in Social life:

- "I have one house with 2 BHK in Ahmedabad. When some relatives come to the city, though they stay at my house but nobody of them takes lunch or drinks water at my house. They stay only up to next morning and leave afterwards. Neighbors don't talk to me. They said me that I am mad. They give me work always without giving me any money, and upon asking, they refuse for the money."

- "Before illness, I was living in rented house. I was an inspector in IT department. People used to meet me and respect me, but when owner of the house knew about my illness, he asked me to vacate his house. Today I am living in small house alone. People avoid me."

IV. Experiences related to marital life:

- "Because of illness I am not able to work in my land. My land remains uncultivated. My desire for sex has come to an end. My penis is not erectile any more. Due to this, my wife left me and went to her parents place. Today she has got married to another person."

- "I was married in great pomp. My mental illness started at my in laws place. Initially they used to beat me a lot, they took me to a faith healer, after that they left me to my mother's place. My mother tried for many attempts one after another for my marriage. Every time, as my wife knew about my illness, she divorced me."

V. Experiences of stigma and discrimination in Family:

- "I had to hide my illness because mine and my sister's marriage were at stake. I got married in far Village, but when knew about my illness, they sent back me to my maternal home. I was pregnant at that time. After delivery, they called me back but when I was breast feeding my baby, my mother in law took my baby away and told, "You are mental and the child will also become mental if you breast feed the baby."

- "Nobody takes care of me at home even if I am ill and I need medication regarding this. When I told my brother and father about this, so they became angry on me and said you are mad, go wherever you want to, we do not have time for you"

VI. Impact of illness on General Life

a. Hiding of illness:

- "I have to stay in my house all day hiding my illness. Whenever I come at the window, my mother gets angry on me and directs me to go inside. She tells me that if people will know about my illness then nobody will marry me and my sister."

b. Decrease in Work efficiency and cognitive function:

- "Welding was my profession earlier but today I cannot concentrate on my work properly. I have been injured also because of this."

c. Visiting of Friends and Relative:

- "Since the starting of my illness, people are scared of me and they don't come near me. I had to live alone at home."

d. People's reaction after knowing their illness:

- "If any one comes from my family, they talk only one thing, to take medicine but nobody talks to me more than this. I have to live alone."

e. Most Disabling Illness:

- "Mental health problems should not occur. It becomes difficult to work. I am feeling better till I take medicine but my memory is decreasing. Nothing is remembered. I have to take pills to sleep in night."

DISCUSSION

The present study was aimed to study stigma and discrimination perceived by patients with schizophrenia and, its comparison between rural and urban patients. Majority of the patients were male, Hindu by religion, of age range 21-30 years, married, educated up to class 10th, living in a joint family, unemployed, having income under 1000 rupees per month. Findings of present study revealed that patients from rural background had more often stigmatizing and discriminating experiences compared to patients from urban background.

In our study, 62% patients were unemployed. Due to unemployment and chronic nature of illness, patients are not able to do their work as efficient as of their same age group in the society, which becomes the main culprit associated to creation of stigma. Stigmatization in the workplace and the related denial of access to job are the most important experiences of social exclusion. These experiences are recognized as the main factors producing and maintaining a high rate of unemployment among those with schizophrenia. In our study too, 21 (18.9%) urban and 3 (7.6%) rural patients reported avoiding disclosure of mental illness histories in job/applications.

In the present study, patients from rural background more often reported these experiences: society treats differently (p=0.09), ridiculing by others (p=0.11), offensive comments (p=0.02), hiding from relatives (p=0.09). Jadhav S et al also reported that rural Indians show significantly higher stigma scores.[14] Similar to our study an Indian study by Loganathan S et al reported that rural respondents experience more ridicule, shame, and discrimination but they reported that urban respondents feel the need to hide their illness.[15] Fear of rejection may be a need to hide their illness from others particularly in rural areas. In our study, more urban patients reported difficulty in getting married compared to rural patients (p=0.1). Weiss et al,[16] studying psychiatric stigma across cultures, pointed out that "in Bangalore the main concerns the sample had, were related to lowering their own chance of entering a good marriage and decreasing the chance of one of their relatives". Disclosing the diagnosis of schizophrenia becomes stigmatizing due to fear of being ridiculed, discriminated, leading to loss of job or not being able to get a job, and difficulty in getting married for the patient as well as family members. So, family members handle with it by hiding the diagnosis or not disclosing the presence of illness.

In our study, more rural patients reported social exploitation (p=0.002), not fully accepted in the family (p=0.03), pushed into unacceptable social situation (p=0.04), and sexual harassment (p=0.02) as a consequence of stigma and discrimination compared to urban patients. Jadhav et al also found that rural Indians showed a more stigmatizing attitude towards severe mental illness. Their study also showed greater stigma and a punitive attitude amongst rural Indians as compared to urban Indians.

In our study, rural patients reported attribution of supernatural cause as the most common source of stigma. Studies support this finding that in rural areas, the frequent association of mental illness with malevolent spiritual forces induces many families with a member with mental illness to seek help from shamans.[17,18] In rural areas, lack of adequate education regarding mental illnesses leads to such beliefs. Jadhav et al also concluded that urban Indians have a more liberal and tolerant attitude but were also more excluding of those with mental illness at work.[14] In our study too, not being able to work due to illness was the most common reported source of stigma in urban patients (39.6%).

In our study, rural patients reported rejecting attitude of peoples around while urban patients reported nagging and uncooperative attitude of the family members and society. Stigma led to painful experiences related to patient's personal and occupational area, social life, marital and family life. Fact of hiding the diagnosis of schizophrenia was also reported by the patients. Resulted decrease in cognitive functioning and impaired work efficiency also was reported by the subjects. The extent of the discrimination due to the illness resulted in stopped or less frequent visiting of the friends and relatives to the patients. The people around made either limited or no communication with the patients. Patients reported schizophrenia as the most disabling illness of all the illnesses.

Lack of correct knowledge is the variable associated with more stigma responses. Setting up programs directed towards modifying the attitudes of employers, as well as greater attention to the employment-related training of social workers could constitute useful instruments to improve labor market access for people with schizophrenia. These programs should help convincing employers that people with schizophrenia are highly motivated and can provide important contributions. At the same time, people with schizophrenia might need specific support in re-entering the labor market, such as Individual Placement and Support (ISP) Programs [19, 20]. Better integration in the labor market has been shown to improve clinical outcome[21-23] and reduce the risk of hospitalization.[24]

Stigma and negative public attitudes for a patient with schizophrenia is widely prevalent both in rural as well as urban areas. Therefore, while patients continue to consider stigma as a central obstacle to their integration into the community, they themselves contribute to this process by accepting public stereotypes as applicable to themselves. As a result, majority of them don't confront negative reaction, and lose self-esteem, isolate themselves and get worse. Our data from patient verbatim also highlighted that patient focus on the stigmatization experiences and on their ideas of the cause of stigma; while hardly offering any suggestions for anti-stigma intervention. Suggestion of participant mainly concerned the improvement of information on mental health issues among the public (66.7%). Participant did not seem to envisage many opportunities for positive change and found it difficult to formulate specific proposal on what could be done to improve their situation. Sorting out this difficulty might help reducing perceived stigma, discrimination and their consequences. Spending more time with a patient, may reduce stigmatizing and discriminating attitude presumably through the mechanism of exposure induced reduction of negative stereotype about the mental illness. Alexander & Link concluded that increasing personal contact with psychiatric patient could reduce people's stigmatizing

attitudes.[25] Couture & Penn also concluded that both retrospective and prospective contact tends to reduce stigmatizing views of persons with a mental illness.[26] Our findings suggest that people with schizophrenia are not fully accepted in the family, especially in rural areas. This suggests that certain factor could be more powerful than negative stereotypes in interpersonal stigmatization which can be overcome by provision of the scientific knowledge of the mental illnesses and re-integration of the patient in the community through psychosocial approaches.

Similar to our findings, Chinese families too, frequently concealed the mental illness of their members.[27] Family members act as both stigmatizer as well as victim of stigmatization themselves.[28] Because of this paradoxical role dualism, family members might project their anger towards a patient for causing them added suffering. This negative affective state, we suspect, could heighten the chronic burden of care. Providing adequate non-pharmacological measures may help family members in such circumstances of negative affective state. Provision of psychiatric care must move beyond symptoms control to diminish intentional as well as subtle forms of stigmatization in the patients' social life. Effective anti-stigma intervention should target on improving attitudes and the condition for social integration in the community, empowering people with schizophrenia to challenge self-stigmatization and discrimination behavior towards them. Regarding the work-related stigma, we believe that a combination of corporate education programme, legal measures and advocacy efforts are needed.

CONCLUSION

Stigma experience is pervasive: it deeply affects the social, occupational and emotional wellbeing of patients with schizophrenia and should be included in clinical management. Higher level of stigma is related to low education level, unemployment status. The provision of accurate information through trusted community sources and open dialogue may help to dispel myths, correct faulty assumption and increase the involvement of participation of community in dragging out the root source of stigma. Family programmes should be started early in an attempt to reduce stigma from significant others and to transform the family into a long recourse for psychiatric rehabilitation. Effective anti-stigma intervention should address chiefly two targets: improving attitudes and condition for social integration in the community and; empowering patients with schizophrenia to challenge self-stigmatization and discriminatory behavior towards them.

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Role of age at onset in the clinical presentation of bipolar disorder in Indian population

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Abstract

Objective: The objective of this study was to determine any association of age at onset (AAO) with clinical presentation of bipolar disorder (BD) and family history of illness. **Materials and Methods:** A hospital-based cross-sectional observational study was conducted including 162 patients having a diagnosis of BD current episode manic. Individuals were divided into three subgroups according to AAO, i.e., early-onset BD (EOBD) (AAO ≤21 years), intermediate-onset BD (AAO – 22–34 years), and late-onset BD (AAO ≥35 years). The subgroups were compared on clinical variables; items of the Young Mania Rating Scale (YMRS), Hamilton Depression Rating Scale (HAM-D), and Scale for the Assessment of Positive Symptoms (SAPS); and family history of illness. **Results:** The early-onset group had significantly more episodes per year than the other groups ($P < 0.001$). The prevalence of family history of mood disorder was also significantly higher in the early-onset group than the other subgroups. AAO was found to be significantly associated with different items of YMRS, HAM-D, and SAPS. The early-onset group had higher rating on irritability, motor activity–energy, sexual interest, depressed mood, delusions, and thought disorders, whereas the late-onset group had higher rating on elevated mood. **Conclusion:** EOBD can be considered as a specific phenotype of BD, which is more homogenous, severe, and inheritable form of illness.

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Full Text

Bipolar disorder (BD) is a chronic mental disorder characterized by alternating episodes of depression, euthymia, (hypo) mania, and mixed states.[1] The usual age of onset of BD is before 30 years, and almost 90% of patients have onset before 50 years of age.[2],[3] BD has been reported to have a genetic basis with heritability of at least 60%–85%.[4],[5] A number of studies have attempted to identify the susceptibility loci adding evidence of linkage in multiple genomic regions.[6] However, these genetic studies have given conflicting results; which may be due to the lack of consensus regarding the proper definition of the affected phenotype and the questionable homogeneity of bipolar illness.[4],[5],[6] Thus, attention is shifting toward the study of clinical indicators of BD that are familial and may be useful for identifying inheritable forms of the illness.

Classifications such as the Diagnostic and Statistical Manual of Mental Disorders-5 defined certain specifiers of BD that have proven phenomenological relevance.[7] However, most are of limited utility in identifying homogeneous subgroups. There is a necessity to identify reliably defined clinical features that are clinically valid and associated with underlying genetic process. These features can help in identifying genotypes and making informed treatment decisions.[8]

There is considerable evidence to suggest that the clinical expression of BD differs according to age at onset (AAO), which has therefore been identified as a potential specifier of interest, especially patients having early onset of illness have specific clinical features and outcomes different from those of later onset of illness.[8],[9],[10] In this regard, multiple admixture studies have revealed that such patients could be categorized into three homogeneous subgroups (early-onset BD [EOBD], intermediate-onset BD [IOBD], and late-onset BD [LOBD]).[11],[12],[13],[14],[15],[16],[17],[18]

By making subgroups based on these cutoff points, the present study was aimed to compare the clinical presentation using the items of the Young Mania Rating Scale (YMRS), Hamilton Depression Rating Scale (HAM-D), and Scale for the Assessment of Positive Symptoms (SAPS) and to compare the presence of family history of the illness in Indian population. Such subgrouping may help in identifying phenotypes among BD patients.

Materials and Methods

A hospital-based cross-sectional observational study was conducted at the psychiatry department of the tertiary care hospital of western India. The study was conducted over a period extending from June 2018 to December 2018. Ethical clearance was taken from the research review board and ethical committee of the institution. Informed written consent was obtained from all the legal guardians of participants before inclusion in the study.

A consecutive sample of 162 patients admitted to the inpatient department with a diagnosis of BD current episode manic (as per the Diagnostic and Statistical Manual of Mental Disorders-5 criterion) was included in the study. The diagnosis was confirmed by applying the Mini-International Neuropsychiatric Interview (MINI).[19] Patients with history of intake of any psychiatric medicine in the last 2 weeks were excluded from the study because it can alter the severity of the symptoms. Patients suffering from mental retardation, dementia, comorbid psychiatric and substance-related disorder (as confirmed by using the MINI), and any other acute medical illness were excluded from the study.

Study participants were divided into three subgroups according to AAO, namely EOBD (AAO ≤21 years), IOBD (AAO = 22–34 years), and LOBD (AAO ≥35 years). There were 67, 59, and 36 patients in early, intermediate, and late-onset groups, respectively. The cutoff for AAO was determined on the basis of a review article by Geoffroy et al.[20] The cutoff value of 21 years for early onset was also recommended in other studies.[21],[22]

AAO was defined as “the age at which the patient first met criteria for a depressive episode, mania or hypomania as indicated by patient history, recall of family members and medical records.” This definition is close to the exact beginning of the illness and had been found to be highly reliable.[23]

After applying stringent inclusion and exclusion criteria, participants were subjected to the tools of study. Clinical interviews and symptom ratings according to the YMRS,[24] HAM-D,[25] and SAPS[26] were performed at the first presentation in the outpatient department.

These subgroups were compared with the following tools of the study:

Sociodemographic and clinical variables – A semi-structured pro forma was used to record the sociodemographic variables including age, sex, residence, occupation, marital status, monthly income, and education. Items occupation, education, and monthly income were adopted from the modified Kuppuswamy's socioeconomic scale.[27] This information was gathered from first-degree relatives and the patient himselfClinical assessment – The clinical variables were gathered through a clinical interview of participants and their immediate family members. The selection of clinical variables was based on literature review[28] and clinical observation. The clinical variables included number and duration of the illness (chronicity) and AAO of the illnessFamily history of mood disorder in first-degree relatives – Familial psychiatric illness was investigated using the Family Interview for Genetics Studies[29] applied by a trained psychiatrist. A complete family history of psychiatric illness of first-degree relatives was obtained from each proband and at least one first-degree relative. The information was supplemented by medical reports of relatives.Symptom-related variables – It was assessed using YMRS, HAM-D, and SAPS. Items were removed from the rating scales that were a priori considered redundant among them (i.e., similar symptoms rated more than once). Like, the HAM-D scale ratings of early, late, and middle insomnia; psychomotor agitation; and impaired insight were removed in favor of the YMRS ratings of items decreased sleep, disruptive or aggressive behavior, and impaired insight, respectively. The SAPS behavioral rating domain was removed in favor of YMRS ratings of disruptive or aggressive behavior and inappropriate appearance. The YMRS rating of content and language-thought disorder was removed in favor of the more comprehensive rating of delusion, hallucination, and thought disorder on the SAPS. Thus, a total of 24 symptom (9 from YMRS, 12 from HAM-D, and 3 from SAPS) ratings were analyzed.

Statistical analysis

Categorical/nominal variables were summarized as frequency and percentage and were analyzed using Chi-square test. Continuous variables were expressed as mean and standard deviation and were analyzed using one-way analysis of variance test or Kruskal–Wallis test as appropriate. The level of significance was set at $P < 0.05$. All analysis was performed using statistical software IBM SPSS Statistics for Windows, Version 19.0. (trial version) Armonk, NY: IBM Corp.

Results

A total of 162 patients were included in the final analysis. More than half (59.3%) of the patients were male. The three groups did not differ significantly regarding the gender distribution. Majority of the patients were from rural background (85.8%), married (74%), and belonged to lower socioeconomic status [Table 1].{Table 1}

There was a significant difference between the three subgroups regarding episodes per year; the early-onset group had significantly more episodes per year ($P < 0.001$) [Table 2]. The prevalence of family history of mood disorder was also significantly higher in the early-onset subgroup ($P < 0.001$) [Table 3].{Table 2}{Table 3}

Among these 35 affected families of early-onset probands, 51 first-degree relatives were found to be affected from mood disorder. Among these 51 first-degree relatives, 33 (64.7%) precipitated illness before the age of 21 years which indicates that they lay in the same early-onset group.

Manic, depressive, and psychotic symptoms revealed a significant difference in symptom profiles between the early, intermediate, and late-onset groups ($P < 0.001$). It was found that among different YMRS, HAM-D, and SAPS items, the EOBD group had significantly greater scores on irritability, motor activity–energy, sexual interest, depressed mood, delusions, and thought disorders than the other groups. Similarly, the LOBD group had a significantly greater score on elevated mood than the other groups [Table 4].{Table 4}

Discussion

BD patients were divided into three subgroups based on AAO (EOBD, IOBD, and LOBD), and a significant difference was found between the three subgroups on clinical presentation (different items of YMRS, HAM-D, and SAPS scale) and the presence of family history of the illness. Similarly, a previous study had divided BD patients into early-onset (age ≤20 years), intermediate-onset (age >20 to ≤30 years), and late-onset (age >30 years) subgroups. They found early-onset patients having more scores in hypersexuality, disinhibition, depressed mood, psychotic symptoms, and overall severity, whereas late-onset patients had greater scores on the Depression Rating Scale.[30] A study from Turkey also supported the hypothesis that adolescent-onset mania may be a different subtype than adult-onset mania with respect to type of episode, phenomenology, and clinical features.[31]

In the present study, depressed mood had a higher rating in the EOBD subgroup than the other groups, as was similarly reported by other studies from different countries.[30],[32] Another finding of the present study was that the psychotic symptoms, including delusions and thought disorder, were more common in the early-onset group, as was similarly reported by other researchers.[33] On the other hand, the LOBD group had a greater score on elevated mood. Supporting this, a study on geriatric population reported a greater average YMRS item rating for happiness and cheerfulness in elders with late onset compared to those with early-onset illness.[34]

In this study, early-onset patients experienced more number of episodes per year than the other groups, which indicates that they are more prone to be rapid cyclers. Supporting this, a previous study also reported that onset before 19 years of age eventually leads to the development of rapid cycling.[28]

Upon direct comparison of the EOBD and LOBD subgroups (the cutoff points were AAO before 18 years and after 40 years for the two subgroups), past literatures suggest that early-onset patients had more psychotic symptoms, mixed features, and family history of affective illness. EOBD and LOBD differ in clinical expression and familial risk and may therefore be considered to be different subtypes of manic-depressive illness.[33]

The family history of illness was significantly higher in the EOBD subgroup in the current study, and most of the first-degree relatives (64.7%) lied in the same proband (early onset) which supports the hypothesis that EOBD is a more heritable form of illness. Similarly, studies have found that bipolar siblings are much more likely to belong to the same theoretical AAO subgroup than to different subgroups.[11],[16] This finding confirms intrafamilial correlation for AAO in bipolar affective disorder. The existence of three “AAO subgroups” and the clustering of siblings in the same subgroup might be attributable to different genetic vulnerability factors supporting the view of genetic heterogeneity in BD.

Conclusion

AAO of BD is significantly associated with their clinical presentation and prevalence of family history of illness. The EOBD subgroup had significantly greater scores on several YMRS, HAM-D, and SAPS items, and greater prevalence of family history of illness can be considered as a specific phenotype of BD patients, which is more homogenous, severe, and heritable form of illness, could be a potential target for future genetic researches. AAO can be used a valid marker to identify homogenous subgroups in BD patients.

Limitations

Only patients of mania were included, and depressive patients were excluded for proper comparison of one aspect of illness. There is no standard definition of cutoff value of AAO, and the possibility of recall bias in reporting AAO could not be ruled out.

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Conflicts of interest

There are no conflicts of interest.

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Table 1

Characteristics	EOBD (*n*=67), *n* (%)	IOBD (*n*=59), *n* (%)	LOBD (*n*=36), *n* (%)	Total (*n*=162), *n* (%)	χ^2 (df)	*P*
Gender						
Female	25 (37.3)	25 (42.4)	16 (44.4)	66 (40.7)	0.596 (2)	0.742
Male	42 (62.7)	34 (57.6)	20 (55.6)	96 (59.3)		
Locality						
Urban	5 (7.5)	17 (28.8)	1 (2.8)	23 (14.2)	16.69 (2)	<0.001
Rural	62 (92.5)	42 (71.2)	35 (97.2)	139 (85.8)		
Marital status						
Married	33 (49.2)	51 (86.4)	36 (100)	120 (74.1)	38.79 (2)	<0.001
Unmarried	34 (50.8)	8 (13.6)	0	42 (25.9)		
Education						
Up to primary	8 (11.9)	2 (3.4)	0	10 (6.1)	52.23 (6)	<0.001
Up to secondary	12 (17.9)	18 (30.5)	12 (33.3)	42 (25.9)		
Above secondary	38 (56.7)	17 (28.8)	0	55 (34)		
Illiterate	9 (13.4)	22 (37.3)	24 (66.7)	55 (34)		
Occupation						
Unemployed	33 (49.3)	25 (42.4)	14 (38.9)	72 (44.4)	21.27 (10)	0.019
Unskilled worker	6 (9)	8 (13.6)	6 (16.7)	20 (12.3)		
Semi-skilled	3 (4.5)	2 (3.4)	8 (22.2)	13 (8)		
Skilled worker	2 (3)	6 (10.2)	1 (2.8)	9 (5.6)		
Clerical	21 (31.3)	18 (30.5)	7 (19.4)	46 (28.4)		
Semi-profession	2 (3)	0	0	2 (1.2)		
Profession	0	0	0	0		
Monthly income (Rs.)						
≤1589	4 (6)	2 (3.4)	0	6 (3.7)	25.040 (10)	0.005
1590-4726	15 (22.4)	12 (20.3)	16 (44.4)	43 (26.5)		
4727-7877	28 (41.8)	25 (42.4)	8 (22.2)	61 (37.7)		
7878-11816	12 (17.9)	12 (20.3)	12 (33.3)	36 (22.2)		
11,817-15,753	0	4 (6.8)	0	4 (2.5)		
15,754-31,506	8 (11.9)	4 (6.8)	0	12 (7.4)		
≥31,507	0	0	0	0		

P value calculated using Chi-square test. EOBD - Early-onset bipolar disorder; IOBD - Intermediate-onset bipolar disorder; LOBD - Late-onset bipolar disorder

Table 2

	Mean (SD)			*F* (df)	*P**
	EOBD	IOBD	LOBD		
Age of presentation (years)	23.5 (8.3)	35.1 (10.3)	48.9 (5.4)	104.36 (161)	<0.001
Age at onset (years)	16.5 (2.6)	26.1 (3.2)	43.4 (5.4)	653.79 (161)	<0.001
Episodes per year	1.8 (1.9)	0.8 (0.8)	0.6 (0.5)	12.80 (161)	<0.001

**P* value calculated by using one-way ANOVA test. SD - Standard deviation; EOBD - Early-onset bipolar disorder; IOBD - Intermediate-onset bipolar disorder; LOBD - Late-onset bipolar disorder; ANOVA - Analysis of variance

Table 3

Family history of mood disorder	EOBD, *n* (%)	IOBD, *n* (%)	LOBD, *n* (%)	Total, *n* (%)
Present	35 (52.2)	10 (16.9)	6 (16.6)	51 (31.5)
Absent	32 (47.8)	49 (83.1)	30 (83.4)	111 (68.5)

χ^2=22.8 at df=2, *P*<0.001 (S). EOBD - Early-onset bipolar disorder; IOBD - Intermediate-onset bipolar disorder; LOBD - Late-onset bipolar disorder

Table 4

Scale	Items	EOBD (*n*=67)	IOBD (*n*=59)	LOBD (*n*=36)	*F* (df)	*P*
YMRS	Elevated mood	2.94 (0.92)	3.17 (0.87)	3.67 (0.68)	8.57 (161)	<0.001
	Increased motor activity-energy	3.14 (0.81)	2.23 (0.87)	1.78 (0.93)	34.11 (161)	<0.001
	Sexual interest	1.12 (0.95)	0.62 (0.66)	0.33 (0.48)	14.12 (161)	<0.001
	Sleep	3.07 (1.08)	3.22 (1.19)	3.33 (0.83)	0.74 (161)	0.477
	Irritability	3.88 (2.60)	2.31 (1.81)	1.16 (1.39)	21.20 (161)	<0.001
	Speech (rate and amount)	5.31 (1.83)	5.42 (2.04)	5.78 (1.49)	0.78 (161)	0.461
	Disruptive-aggressive behavior	3.49 (2.45)	2.92 (2.55)	3.33 (0.96)	1.04 (161)	0.357
	Appearance	0.69 (0.701)	1.25 (1.14)	0.93 (0.81)	5.99 (161)	0.003
	Insight	3.88 (0.41)	3.80 (0.48)	3.67 (0.68)	2.02 (161)	0.136
HAM-D	Depressed mood	0.93 (0.81)	0.64 (0.67)	0.39 (0.31)	7.89 (161)	<0.001
	Feeling of guilt	0.39 (0.60)	0.49 (0.65)	0.31 (0.53)	1.05 (161)	0.354
	Suicide	0.67 (1.09)	0.85 (1.23)	0.54 (1.04)	0.90 (161)	0.410
	Work and activities	0.94 (1.25)	0.83 (1.33)	1.11 (1.47)	0.50 (161)	0.610
	Retardation	0.37 (0.81)	0.37 (0.72)	0.46 (0.78)	0.19 (161)	0.827
	Anxiety psychic	0.60 (1.10)	0.75 (1.33)	0.49 (1.04)	0.58 (161)	0.559
	Anxiety somatic	0.34 (0.67)	0.51 (0.73)	0.37 (0.69)	1.00 (161)	0.368
	Somatic symptoms gastrointestinal	0.39 (0.72)	0.34 (0.61)	0.40 (0.74)	0.12 (161)	0.890
	Somatic symptoms general	0.55 (0.82)	0.32 (0.60)	0.60 (0.77)	2.18 (161)	0.117
	Genital symptoms	0.48 (0.68)	0.41 (0.65)	0.40 (0.65)	0.25 (161)	0.782
	Hypochondriasis	0.19 (0.47)	0.24 (0.47)	0.17 (0.45)	0.30 (161)	0.739
	Loss of weight	0.43 (0.49)	0.47 (0.50)	0.40 (0.49)		0.787
SAPS	Hallucinations	0.67 (1.34)	0.88 (1.52)	0.43 (1.01)	1.44 (161)	0.285
	Delusions	3.74 (2.93)	2.71 (2.41)	2.43 (2.32)	3.82 (161)	0.024
	Positive formal thought disorder	3.44 (3.12)	2.38 (2.11)	2.11 (1.56)	4.41 (161)	0.014

P value calculated using one-way ANOVA test. EOBD - Early-onset bipolar disorder; IOBD - Intermediate-onset bipolar disorder; LOBD - Late-onset bipolar disorder; YMRS - Young Mania Rating Scale; HAM-D - Hamilton Depression Rating Scale; SAPS - Scale for the Assessment of Positive Symptoms; ANOVA - Analysis of variance

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A Study on Assessment of Family Burden, Quality of Life and Mental Health in Caregivers of Patients with Schizophrenia

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ABSTRACT

Background: *Caregivers of patient with schizophrenia face a lot of burden which hampers their quality of life as well as mental health. This study was conducted to evaluate perceived burden of care, quality of life, and mental health in caregivers of schizophrenia patients and to explore the correlation between above parameters and total duration of illness of the patient with schizophrenia.* ***Methods****: The study was conducted at a tertiary care center. Participants were 99 caregivers of the patient with schizophrenia that were screened to ascertain whether they met the selection criteria. Perceived burden was scored by Family burden scale which is a semi structured interview schedule. Quality of life scale (WHO QoL-BREF Hindi version), was used to assess Quality of life. Modified Mini International Neuropsychiatric Interview was used to examine mental health of caregivers.* ***Results****: In the present study, total duration of schizophrenia showed statistically significant negative correlation with quality of life of caregiver. In the study, though the correlation between perceived family burden and total duration of schizophrenia was positive but it was not statistically significant. The burden also had statistically significant negative correlation with socioeconomic status and quality of life of the caregiver. The caregivers with high likelihood of mental illness scored significantly higher burden than other two groups.* ***Conclusions****: Caregivers of persons with schizophrenia do perceive burden, on account of which and along with lower socioeconomic status they experience poor quality of life and compromised mental health.*

Key words: *Burden of care, Schizophrenia, Quality of life, Duration of illness, Mental health.*

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INTRODUCTION

Schizophrenia is a debilitating psychiatric disorder which not only influences the lives of those affected but also of their families. Schizophrenia is ranked among the top 25 leading causes of disability worldwide in 2013.[1] Of all the mental illnesses responsible for suffering in society, schizophrenia probably causes lengthier hospitalization, more chaos in family life, exorbitant costs to individuals and governments and fears than any other illness.[2]

In the past few decades, a shift towards community care and the deinstitutionalization of psychiatric patients has resulted in transferring of responsibility and day-to-day care of such patients to family members.[3] Families are thus assigned the role of primary caretakers for two reasons. First, there is a

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paucity of trained professionals required to execute psychosocial interventions and second, most Indian families would like to be meaningfully involved in all aspects of care of their ill relative.[4] Caregivers have to deal with patient's symptoms, and help patients in activities of daily living.

The caregiver is seen as the person who provides the most support to the patient, often devoting substantial number of hours each day towards taking care of the patient.[5] Caregivers spend a substantial amount of time interacting with their care recipients, while providing care in a wide range of activities. The patient's illness, behaviors, disabilities and perceived disruptions of the caregivers' lives are the stressors appraised by the caregivers.[6] The behavior of the patients with schizophrenia requires that the caregivers place their needs and wishes after those of their wards; consequently, the phenomenon has been labeled as a burden.[7-10] It refers to the presence of problems, difficulties or adverse events which affect the lives of caregivers.

There are stressful effects on the caregivers' own mental and physical health, like the feelings of stigmatization, inability to make or fulfill personal plans, empathic suffering for the pain of the ill member, worries for the ill member's future, especially if he/she is young. The behaviors of the patients and their management are issues that create ongoing tensions between the patients and their families.[11]

In India, care for other family members is an obligation and all caregivers perceive the burden. Providing care to a person with schizophrenia is often consistent and ongoing for long periods; and the role of the caregiver is stressful. The physical, mental and emotional toll of caregiving can be devastating and may lead to injury or illness of the caregiver.[12-16]

The stresses of caring for a relative with schizophrenia might lead to poorer quality of life and greater chances of physical and mental illness. Greater degree of depression and stress and low rating of subjective well-being in caregivers has been reported.[17-19]

The present study examines the caregiving burden and its correlates in primary caregivers of a patient with schizophrenia. This study aimed to evaluate perceived burden of care, quality of life, and mental health in caregivers of schizophrenia patients and to explore the correlation between above parameters and total duration of illness.

METHODS

A cross sectional observational study was carried out on caregivers of schizophrenia patient. Study was approved by research review board and ethical committee of the institution. The study included 99 caregivers of patients (The diagnosis was reviewed and confirmed by two psychiatrists independently based on ICD-10 criteria). An informed consent was obtained from the subjects prior to participation in the study. To include in study, the subjects were screened with a screening proforma that encompassed all the exclusion criteria. Those subjects who satisfied the screening process were recruited in the study. An informed consent was obtained from the patients and caregivers prior to participation in the study. This was followed by recording of socio-demographic profile and clinical profile. Each participant in the study was subjected to instruments of the study. This was followed by statistical analysis with the help of computer.

The study was conducted in the Department of Psychiatry, SMS Medical College, Jaipur which a tertiary care center. The study was conducted from 1st January 2012 to 31st December 2012. Family members of the patient attending the OPD or IPD were included in this study. They were screened by history to ascertain whether they met the selection criteria.

Inclusion criteria: Patients of either gender aged 18-60 years having diagnosis of schizophrenia as per ICD-10criteria, total duration of illness at least one year, who were living with a caregiver / family member for at least one year and provided informed consent; were included in the study.

Caregivers of either gender, aged 18-60 years, who were responsible for patient's care, living with the patient for at least one year and were spending more time with the patient than other family members, who were literate enough to read and understand the questionnaires and provided informed consent; were included in the study.

Exclusion criteria: Patients having a serious physical disability and Mental retardation were excluded. Caregivers with a physical disability (e.g. blind, deaf, speech problems), diagnosed psychiatric disorders, mental retardation and dementia, abusing substance other than nicotine, having color blindness; were excluded.

The subjects were interviewed after examination using the following instruments-

1. Consent form: This form was in Hindi language and was given before including the subject in study. The informed written consent was taken from each subject.

2. Socioeconomic status score was assessed using modified kuppuswamy scale for socioeconomic status.

3. Family Burden scale:[20] This is a semi structured interview schedule comprising of 24 items grouped under these areas: financial burden, disruption of routine family activities, disruption of family leisures, and disruption of family interaction, effect on physical health of others and effect on mental health of others. The burden is rated on a 3- point scale for each item, and a standard question to assess the subjective burden is also included. This scale has been developed for the Indian set up, keeping in the mind the socioeconomic and cultural conditions in the India. The validity and reliability of the scale have been found to be satisfactory. The interrelated reliability for each item was reported to be more than 0.78 by the authors, which indicates that the present schedule is a reliable tool.

4. Quality of life scale (WHO QoL-BREF version): .[21] An abbreviated version (WHOQOL-Bref, Hindi) of 26 items is developed using data from the field-trial version of the WHOQOL- 100. The WHOQOL-Bref contains two items from the overall QOL and general health, and one item from each of the remaining 24 facets included in the WHOQOL-l00. This scale provides a profile of scores on four dimensions

of quality of life: physical health, psychological, social relationship, and environment. Its 26-items look at domain level profiles and are self-administered. Higher scores mean higher quality of life.

5. Modified mini International Neuropsychiatric Interview (MINI) (22): It is a 22 item questionnaire that is administered by a clinician in about 15 minutes. The tool uses a set of gateway questions that relate to signs of distress that may be attributable to a diagnosable psychiatric disorder. The screen is divided into 3 sections to capture the three major categories of mental illness as follows: Section A- Mood Disorders, Section B-Anxiety Disorders, and Section C- Psychotic Disorders. Scoring of the Modified Mini Screen is straightforward and additive. A "YES" response to a question on the screen converts to 1 point. The clinician adds all the positive (yes) responses for a total score, which ranges from 1 to 22 points. There are three different cut points and each cut point determines a different plan of action for the client.

CUTPOINT 1 is score ≤ 5. No further action is needed. This plan of action is based only on the screen, but a screening tool should never replace clinical judgment and critical observations by staff.

CUTPOINT 2 is between 6 and 9. The treatment team determines whether there is a need for a mental health assessment. If it is determined that a mental health assessment is not required, enhanced ongoing monitoring for mental health needs will be implemented as part of the initial comprehensive treatment plan. If it is determined that a mental health assessment is needed, action proceeds as listed below for CUTPOINT 3.

CUTPOINT 3 is any one of the following: - Adults who scored ≥ 10 or adults who answered "yes" to question 4or Adults who answered "yes" to both questions 14 and 15. For cut point 3, the client will receive a mental health assessment, which means an evaluation to determine whether a client has unmet mental health needs and includes recommendations for treatment or further evaluation if indicated. Question 4 relates to suicidality. Any client who answers YES to this question should be referred for a mental health assessment regardless of the total score. Questions 14 and 15 refer to Post Traumatic Stress Disorder (PTSD). PTSD does not only address combat/war, but also addresses experiences of physical and sexual abuse, as well as other trauma. If both questions 14 and 15 are answered YES, the client should be referred for a mental health assessment regardless of the client's total score.

Data analysis

Statistical analysis was done with the help of computer. Quantitative data was expressed as frequencies and quantitative data as mean and standard deviation. Group comparisons for quantitative data were done with the help of non-parametric test i.e. Independent-Samples Kruskal-Wallis Test as the data did not have normal distribution and homogeneity of variance. Further group differences were obtained with the help of post-hoc analysis (group-wise comparisons). Correlations were computed by Pearson's correlation analysis.

RESULTS

The sample in present study comprised of 99 subjects. Table 1 shows socio-demographic and clinical variables of patients and caregivers and mean scoring on the three scales.

Table 1: Socio-demographic, clinical variables of patients and caregivers and scoring on the three tools:

S. No.	Variable	Details
1.	Patient's age	22 to 65 years (Mean =39.68, SD=12.06)
2.	Patients gender	Male = 69 Female = 30
3.	Patients marital status:	Married = 90 Unmarried = 9
4.	Total duration of illness of patient	1-30 years (Mean= 10.08, SD= 7.06)
5.	Caregiver's age	18-56 years (Mean=32.66, SD=11.81)
6.	Caregiver's gender	Male = 86 Female = 13
7.	Mean family burden total score of the sample	36.35 (SD=10.67)
8.	Mean Quality of life total score of the sample	70.48 (SD=15.58)
9.	The number of caregivers in Modified MINI cut-points	Cutpoint 1: 29 (29.3%) Cutpoint 2: 24 (24.2%) Cutpoint 3: 46 (46.5%)

SD=Standard deviation

Table 2 shows that of total duration of illness is inversely correlated with the quality of life score, and is directly correlated with the family burden score.

Table 2: Correlations of total duration of illness with family burden and Quality of life

		FBS Score	QoL score
TDI	Pearson Correlation	0.025	-0.246
	Sig. (2-tailed)	0.808	**0.014**

TDI= total duration of illness, **FBS**= Family burden scale, **QoL**= Quality of life

Table 3 shows family burden total score is negatively correlated with both socioeconomic status score and quality of life total score.

Table 3: Correlations of family burden with socioeconomic status and quality of life

		SES Total score	Total QoL Score
FBS	Pearson's Correlation	-0.210	-0.477
	Signi. (2-tailed)	**0.037**	**0.000**

FBS= family burden scale, SES= socioeconomic status, QoL= quality of life

Table 4 (a) shows Independent Sample Kruskal-Wallis test for Family Burden Scale Total score and table 4 (b) shows its further Post hoc analysis.

Table 4 (a): Independent Sample Kruskal-Wallis test Family Burden Scale Total score

Sample (N)	Mean(SD)	Test statistics	df	Asymptotic value
MINI Cutpoint 1(29)	29.59(11.6)			
MINI Cutpoint 2 (24)	35.17(10.7)	20.6	2	**0.00**
MINI Cutpoint 3 (46)	41.24(7.5)			

N= number, SD= Standard deviation, df= degree of freedom

Table 4 (b): Post hoc analysis

Sample	Test statistic	Std. error	Std.test statistic	Sig.	Adj.sig
MINI Cutpoint 1-2	-12.7	7.9	-1.6	0.10	0.323
MINI Cutpoint 1-3	-30.3	6.8	-4.4	0.00	**0.000**
MINI Cutpoint 3-2	-17.5	7.2	-2.4	0.015	**0.045**

DISCUSSION

In the present study, total duration of schizophrenia showed statistically significant negative correlation with quality of life of caregiver. In the study, though the correlation between perceived family burden and total duration of schizophrenia was positive but it was not having statistical significance. The burden also had statistically significant negative correlation with socioeconomic status and quality of life of the caregiver. The caregivers with high likelihood of mental illness scored significantly higher burden than other two groups.

The duration of caregiving did not vary significantly with the total burden score in the study, which emphasizes that longer (after one year) periods of caregiving did not necessarily result in greater caregiver's burden. The trend is that prolonged caregiving does not result in increased burden or psychological distress. It is seen that with increasing duration of patient's illness, the family tends to adjust its ways and means according to patient's illness and hence, burden felt is not as much as expected. This finding is consistent with other studies.[1] also found that the duration of illness of the patients did not correlate with the carers' burden or needs. McDonell et al.[26] also reported that duration of the illness was not a significant independent predictor of burden. Contrary to our findings, total burden was found to be significantly more if duration of illness was more.[27] Leyla et al.[28] also observed that the burden of care was positively correlated with the total duration of illness.

Total duration of illness had significant negative correlation with quality of life score. ZamZam et al.[29] also reported that less duration of illness was significantly associated with higher scores in all domains of the caregivers' Quality of life. So it is suggested that the threatening nature of positive symptoms and more negative symptoms of schizophrenia make the patient more intolerable to caregivers as the illness becomes more chronic. Sales.[30] also reported that caregivers have poor quality of life as they are burdened and strained for long duration. The chronic burden of everyday living profoundly reduces the quality of life and declines satisfaction.

In the present study, family burden score had negatively significant correlation with both socioeconomic status and quality of life scores. Besides providing care for ill member, caregivers also have to solve financial problems and find out sources of money. Family burden in caregivers of patients is a disability related to work, participation in household duties and lack of self-care, satisfaction with mental health services, and social relationships, nuisances, and burden due to restricted social life and leisure activities, worries about the patients' health, future, and safety. Other studies.[31,32] also found supporting results. Two studies.[33,34] also showed that low income was associated with a higher degree of burden on the caregivers. Lower income is a stressor that influences perception of caregiver's burden while providing care for the ill family member.

As per modified MINI groups (according to Cutpoint 1-3), these groups differed significantly in the mean of burden score and it was found that more caregivers fall in high likelihood of mental illness group (cutpoint-3) and this group scored significantly higher burden than other two groups. Aydın et al 2009 also reported that as the burden of care increased, the level of anxiety and depression in caregivers also increased. Similar to our study, Noh and Turner.[35] also reported that burden was a major source of stress. Lowyck et al.[36] also concluded that key relatives taking care of the patient do experience an ample amount of burden, on both a practical and emotional level; and the number of the symptoms exhibited by the patient was an influence on family burden.

CONCLUSION

In this study, the authors found that the duration of schizophrenia does not significantly influence the level of burden but it does significantly affect the quality of life. The caregivers of lower socioeconomic status perceived higher family burden and have poor quality of life. The caregivers with higher family burden also showed significantly higher likelihood of developing mental illness. Though it was a cross-sectional study with small sample size, but it can be a directive for future case control studies that may be done on longitudinal basis with large sample sizes to allow generalization of the significant findings and promote holistic management of families harboring person with chronic mental illness.

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Original Research Article

A Cross Sectional Study on Assessment of Attitude Among Health Professionals Towards the Problem of Substance Abuse at Ananta Hospital, Rajsamand

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Abstract

Background: Drug abuse affects the health and lives of millions of individuals across the world. Discrimination faced by substance users and stigmatization becomes a barrier for them thus these patients do not receive the required care and treatment they deserve. The negative perception of healthcare professionals leads to poor therapeutic alliance between them and the patients of substance use. Current study aims to determine and assess the attitudes of the health professionals towards patients with substance use problems and to identify factors causing diverse attitudes of health professionals towards these patients.

Method:A questionnaire based cross sectional study was undertaken at Ananta hospital Rajsamand (a tertiary health care centre) which included 134 health professionals both doctor and nursing staff for a duration of one year who provided their consent for this project. The socio- demographic details of every participant was collected and all of them were given the DDPPQ tool which assessed their attitudes and perception towards drug and drug use problems.

Results: Younger age group of health professionals showed better outlook towards patients of drug abuse. A linear regression of gender, professional roles (i.e. doctors and nurses), past history of substance abuse and known history of substance abuser in the family with the principal component does not yield any significant results. Majority of the participants had either neutral opinion or positive opinion towards the problem of drug use and the drug users.

Conclusions: Healthcare professionals with age on the lower side had more positive regards and significantly positive attitudes towards the problems of substance use and therefore the

therapeutic compliance was better. Healthcare delivery needs unbiased and non-judgmental attitude of healthcare professionals towards patients of substance abuse, so in an attempt to provide holistic approach and care that overlooks socio-demographic and clinical profiles, professionals should have adequate and appropriate training and exposure accordingly.

Keywords: Professionals, nursing, staff, substance, drug, perception, attitudes, stigmatization.

Introduction

Drug abuse is a global phenomenon which affects almost every country with a variable extent. Abuse of illicit drug affects the health and lives of many individuals across the globe. The criminalization of this addictive behavior damages the reputation of the engaged person and it also deters other people, leading to stigmatization of the problem in the society. Stigmatization also discourages illicit drug users from getting health care due to fear of poor treatment by health care providers or fear of trouble with the authorities[1,2]. While stigma and discrimination may serve as deterrents to illicit drug use, these attitudes also contribute to discrimination and stigmatization experienced by illicit drug users which may be bad for drug user's health[3]. Negative attitudes of health professionals towards patients with an alcohol or other drug addiction are known to lead to poor communication between professional and patient, diminished therapeutic alliance, and mis-attribution of physical illness symptoms to substance use problems, also referred to as diagnostic overshadowing[4,5].

In this scenario, medical professionals are key persons in the provision of care for persons who exhibit problems related to use of the substances of abuse. Personal factors[6] and deficient medical education about addiction in health professionals[7] influence the under-diagnosis of substance abuse disorders. Studies have found that physicians were significantly less satisfied when caring for patients with drug problems compared to other illnesses[8]. A study on nurses found that nurses struggled with the care for patients who use illicit drugs and they had less motivation, satisfaction, role support and education[9]. Another study found that staff who had received training held fewer negative attitudes towards illicit substance users regardless of their length of clinical work experience or type of work setting[10]. Another study found that health professionals' regard was lowest for patients with drug and alcohol problems, lowest regard was found among physicians who did not work in specialized addiction services[11]. This study found that specially trained personnel's in this field such as psychologists, social workers, and professionals in the addiction services showed the highest regard while physicians who did not work in specialized addiction services had lowest regard. People with drug related disorders deserve the same level of care as patient with any other health condition. Health service need to be able to identify drug use and drug use disorder at an early stage and provide prevention, treatment and harm reduction intervention. We could not find any study in our region addressing health professional attitudes towards persons with problems related to substance use.

Aims and Objectives

Current study aims to assess and determine the attitudes of the health professionals

towards patients with substance use problems and to identify factors causing diverse attitudes of health professionals towards these patients.

Methods

Study area

The study was conducted at Ananta Hospital Rajsamand (attached to Ananta Institute of Medical Science and Research Centre, Rajsamand, Rajasthan) a tertiary care hospital.

Study Design

Questionnaire based cross sectional study

Study Participants

Health Professionals (Including doctors and nursing staff)

Study duration

One Year, September 2019 to August 2020.

Sample size

A total population of health care professional of 200 working in Ananta Institute of Medical Science and Research Centre, Rajsamand, Rajasthan, a tertiary care hospital. Minimum of 134 participants were expected to participate according to the following calculation.

$N^* = N*X / (X + N - 1)$,

where,

$$X = Z^2_{1-\alpha}\, p(1-P)/d^2$$

where alpha (α) = 0.05, estimated proportion (p) = 0.50, estimated error (d) = 0.05 and N is the population size

The Finite Population Correction is used to adjust a variance estimate when sampling without replacement.[15]

A stratified random sampling technique has been used for collection of data. A validated 22-item DDPPQ questionnaire tool has been used in the study.

Statistical analysis

Questionnaire data was analyzed using SPSS version 24. Socio demographic data were summarized using frequencies and percentages. Means and standard deviation were used for continuous variables. Mann Whitney U test was used to compare the difference among professional groups i.e. doctors and nurses. The relationship between DDPPQ scores and other relevant variables was analyzed by using Pearson Product-Moment Correlation Co-efficient. The regression analysis has been done to find out relationship between independent and dependent variables. Statistical significance was taken at the 5% level.

Data Collection Procedure

The 22-item validated version of Drug and Drug problems perception questionnaire (DDPPQ) instrument was used for the study[12]. The validated DDPPQ, comprises of 22 items and is a shorter questionnaire, having retained only the most reliable items from the original instrument. The items of the validated questionnaire are numbered consecutively from one to twenty-two. The validated DDPPQ is a self-complete 'paper and pencil' questionnaire. Respondents are asked to rate their level of agreement on a series of 22 statements about working with people who use licit or illicit drugs in a nontherapeutic way. There are seven possible responses to each item on a scale of Strongly agree' to 'Strongly disagree'. Low scores denote positive attitudes, whereas high scores are associated with negative views. Several of the items are worded negatively. These are Items 15, 16, 17 and 18. For the purpose of this study, the DDPPQ were expressed on a 5-point Likert scale ranging from 1 = strongly agree, 2 = agree, 3 =neither agree nor disagree, 4 = disagree to 5= strongly disagree

.A 5 - point Likert-type scale instead of 7-point was used to increase response rate and response quality along with reducing respondents' frustration level[13]. Factor structure of the validated DDPPQ has yielded its six factors which are role adequacy, motivation, role legitimacy, task specific self-esteem, role support and work satisfaction

Study Variables

The independent variables in the study are the socio-demographic characteristics of the study participants such as gender, age, profession, work motivation and role support of health professional. The dependent variables, attitude and perception are measured by six factors/ subscale measure (using 5- point Likert scale) in the DDPPQ. Questionnaire data was analyzed using SPSS version 24. Socio-demographic data were summarized using frequencies and percentages. Data was analyzed by using unrelated T-test, Mann Whitney U test and Pearson product moment correlation coefficient.

For the questionnaire survey, 22 items of validated version of DDPPQ questionnaire was distributed individually to the 152 professional group members in a sealed envelope and returned back in same sealed condition in order to maintain privacy of participants. One hundred and thirty-four participants returned the completely filled up questionnaire. All professional group members i.e. both doctors and nursing staff members responses to the given DDPPQ questionnaire were calculated to give a total attitude score. The minimum score for the DDPPQ is 22 and the maximum score is 110. The higher the score obtained indicates an increasingly more negative attitude.

Results

Table 1: gives description of number of participants according to the gender as well their professional roles.

Group	Number (Total=134)	Percentage
Doctors	85	63.4 %
Males	53	39.5 %
Females	32	23.8 %
Nursing staff	49	36.5 %
Males	30	22.3 %
Females	19	14.1 %

Table 1. Profile of the Sample

Table 2: shows profile of the sample according to professional group and gender.

	Number of responses	Score Range	Mean Score (SD)	Z score	P* Value
Doctors	85	24-76	49.63 (8.95)	-0.30	0.75
Nursing Staff	49	33-68	49.46 (9.52)		

Table 2. The DDPPQ Score Range for Professional Groups

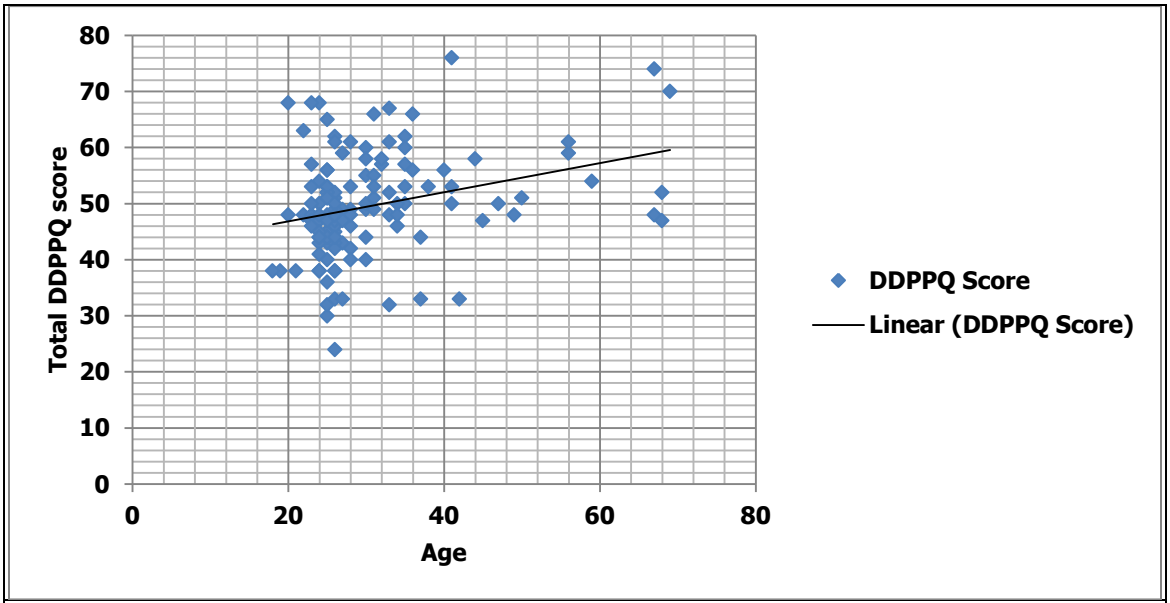
Mann Whitney U test. * The result is significant at $p<0.05$

Table 2 shows the DDPPQ score range for the participants. A Mann-Whitney U test was conducted to compare DDPPQ scores between doctor and nursing staff. The result is not significant at $p<0.05$. There is no difference between the groups.

Age of Participants Versus DDPPQ Score

Mean age of the total sample was 30.56 years (standard deviation 10.38). Mean age for doctors' group was 32.85 years (standard deviation= 11.86) and for nursing staff group was 26.59 years (standard deviation=5.21).

There is significant correlation between the age of the professional group members i.e., both doctors and nursing staff members and their respective DDPPQ scores when calculated using Pearson Product – Moment Correlation Co-efficient (2 tailed) $r = 0.29$, $n = 134$, $p = 0.00067$.



Graph 1: Distribution Graph of Age Versus Total DDPPQ Score

The graph indicates weak positive correlation between age of the participants and their corresponding DDPPQ score.

Family History versus DDPPQ Score

Participants were also asked if they had any family history of substance abuse and past history of substance abuse.

Table 3: Comparisons among Health Professional having Family History of Substance Abuse and Past History of Substance Abuse

	Response	Number of Responses	Range	Mean (Standard Deviation)	Z Score	p*Value
Family history of substance abuse	Positive	22	43-63	52.09(5.97)	-1.786	0.074
	Negative	112	24-76	49.08(9.57)		
Past history of substance abuse	Positive	23	38-65	50.17(7.16)	-0.393	0.694
	Negative	111	24-76	49.45 (9.51)		

Mann Whitney U test. * The result is significant at $p<0.05$

In Table 3, comparisons among Health professional having family history of substance abuse and past history of substance abuse are described. Using Mann- Whitney U test, we found that there is no statistical difference between the groups of health professional having past history of substance abuse and health professional who don't have past history of substance and the groups of health professional having family history of substance abuse and health professional who don't have family history of substance abuse.

A linear regression of gender, professional roles (i.e., doctors and nurses), past history of substance abuse and known history of substance abuser in the family with the principal component has not yielded any significant results.

Table 4: Health Professional Therapeutic Commitments towards Drug Abusing Patients on various Subscales of DDPPQ and total Mean Score

Subscales	Number of Questions	Mean Score Per Question (LikertScore = 1-5)	Standard Deviation
Role adequacy	8	1.99	0.65
Role Legitimacy	3	1.85	0.71
Role support	3	1.92	0.64
Work satisfaction	4	2.18	0.76
Motivation	1	3.58	1.17
Task specific Self Esteem	3	3.39	1.07
Total Score	22	49.57 (possible score 22-110)	9.13
Note: lower score denotes higher therapeutic commitment.			

Table – 4 shows a mean of total score of 49.57 (SD = 9.13) with a possible score between 22 and 110. **The diverse attitudes of Health Professionals towards substance abusers**

Table 5: Percentage of Participants in three Categories

	Frequency	Percentage
Positive [a]	36	26.86
Neutral [b]	91	67.92
Negative [c]	7	5.22
	134	100
a= Total score from 22 to 44; b) total score from 45 to 66; c) total score from 67 to 110		

The total DDPPQ scores were divided into three categories i.e. (1) Positive perception (distinctly defined perception of role), (2) Negative perception (lack of distinctly defined perception of role) and (3) neutral perception (neither distinctly defined perception of role nor lack of distinctly defined perception of role). The range for all three perceptions was determined by the possibility maximum and minimum score in 5 point- Likert scale. Table 5 shows percentage of participants in these three categories.

Discussion

Current study aimed to assess and determine the attitudes of health professionals towards patients with substance use problems in our region and to identify factors causing diverse attitudes of health professionals towards these patients. There was weak positive correlation between age of the participants and their

corresponding DDPPQ score that is older health professionals had relatively negative attitude. This was in contrast to a study that found that older nurses believed more strongly that alcoholism is an illness[14]. The two professionals' groups were assessed by comparing health professionals having family history of substance abuse and past history of substance abuse, and it was found that there is no statistical difference between the two groups of health professional. The mean DDPPQ score in these groups ranged towards lower side denoting positive attitude towards these patients, means their past or family history of substance use didn't significantly affect the attitude. Our study found that there was no statistically significant difference between the DDPPQ scores between the two groups i.e., doctors and nursing staff.

Considering all participants in a group, the lower skewed total mean DDPPQ score of 49.57 (SD = 9.13, with a possible score between 22 and 110) in our study correlated with a more positive attitude and higher therapeutic commitment to drug abusing patients. On mean Likert-format response per question (of 1= Strongly agree to 5= Strongly disagree), the highest therapeutic commitment is reflected in role legitimacy subscale which indicated the degree that professional group members felt that drug abuse history taking and counseling was a professional responsibility. Role support and Role adequacy followed the next which reflected that professional group members felt that they have adequate knowledge of drug and drug related challenges. Also whenever required, they will get support or help to resolve drug related problem. Highly skewed score in motivation and self-esteem subscale reflected lower therapeutic commitment. Role support, role adequacy, role legitimacy and work satisfaction were all somehow interconnected with each other at the basic level along with motivation and self-esteem to aid in understanding of the plight of patients of substance abuse and thereby providing therapeutic care and overall management to such patients. Our findings are in contrast to another study which found that healthcare providers struggled with the care for patients who used illicit drugs and they had less motivation, satisfaction, role support and education.[9]Crothers and Dorrian also found high scores regarding work satisfaction which indicated that nurses' attitudes regarding how much they like, and feel rewarded by, working with patients with alcohol problems, are an important determinant of the extent to which nurses are actually willing to engage in this work[15].

In an attempt to identify diverse attitudes of health professionals towards substance abusers, the sample participants were divided into three categories for ease of understanding - Positive perception, Negative perception and neutral perception; and it was found that number of healthcare professionals having neutral perception were maximum, followed by those having positive perception and least holding negative approach to the drug abuse patients. In a study nurses appeared to have, on average, attitudes that were consistently quite positive, if not neutral[14]. As healthcare professionals are the chief gatekeepers in the management of patients who suffer from substance use disorder, there is need of the hour to change both the neutral and negative attitude of the health care workers into positive attitude. To improve local services, Howard et al recommended that a training strategy should be developed with consideration to a structured programme covering all aspects of providing care to inpatients with co-occurring mental health and substance use problems; implementing training and support structures for staff will enable them to deliver more recovery and client centered interventions for patients with these co-occurring issues[10].

Healthcare delivery needs unbiased and non-judgmental attitude of healthcare professionals towards patients of substance abuse, so in an attempt to provide holistic approach and care that overlooks socio-demographic and clinical profiles, professionals should have adequate and appropriate training and exposure accordingly. We propose some ways that can be executed systematically to bring about the necessary change in the attitudes of a healthcare professional- First and foremost is sensitization of healthcare professionals (both the doctors as well as the nursing staff) which is primarily important to achieve better outcomes in management of patients of substance use disorders. Secondly, there are ways to be incorporated at the grass root level which directly and/or indirectly will have an impact on the management of such patients include: (i) training – providing education and skills to the professionals and conducting workshops at regular intervals, teaching institute – both the medical colleges and the nursing colleges are jointly responsible in training the students who take up this field and providing opportunities for them to learn,(ii) exposure – mandatory rotatory postings for every undergraduate medical/nursing student to understand patients from having them visit an addiction wing facility of outdoor and indoor patients run by the department of psychiatry at the institute where they come across such patients of substance abuse.

Conclusion

Our study found that the younger age group healthcare professionals had more positive outlook and attitude towards substance users. The lower skewed total mean score of participants denoted more positive attitude and higher therapeutic commitment. Subdivision of the participants in three groups to a step forward revealed that majority of them had either positive or neutral attitude towards patients with problem of substance abuse, leaving a minority or handful percentage of participants who had negative perception and attitude.

Implications of the Study

our study will help in identifying diverse attitude of health professional towards patients with substance use disorders and the associated factors. Awareness and proper education along with skills instilled among these healthcare professionals will strengthen the belief and trust of the patient receiving treatment and management during the prolonged period provided for deaddiction. The provision of adequate, timely guidance and motivation at every step to reduce the use of illicit substances, would help in controlling the menace of drug abuse can be well achieved.

Limitations

This was a cross sectional study with small sample size.

Future Direction

Future studies can be undertaken with large sample size to determine the changes in attitudes and knowledge of healthcare professionals prior to any kind of exposure or training received and followed up by assessing them after they have achieved skills, knowledge and training in the field of addiction psychiatry.

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Impact of Cognition and Clinical Factors on Functional Outcome in Patients with Bipolar Disorder

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Abstract

Objective: To examine the role of different clinical variables and cognition on functional outcome in patients with bipolar disorder.
Methods: A total of 61 euthymic patients with bipolar disorder and 30 healthy individuals were included in the study. The patients were divided into low functioning (n = 30) or high functioning (n = 31) subgroups based on functioning level measured by Global Assessment of Functioning Scale score. Groups were subjected to neurocognitive and clinical assessment.
Results: Clinical variables differed significantly between low and high functioning patient groups, namely total number of episodes, depressive episodes, and time since the last episode. These variables were also correlated significantly with Global Assessment of Functioning Scale score. All 3 groups differed significantly for digit span backward test, verbal learning and memory test, Trail Making Test, and Stroop Colour Test. Digit span backward test, Trail Making Test, and Stroop Colour Test were significantly correlated with Global Assessment of Functioning Scale score.
Conclusions: Total episodes, depressive episodes, time since the last episode, and cognitive dysfunction correlated with poor functioning. Executive dysfunction was the strongest predictor of psychosocial outcome in euthymic bipolar patients. Long-term therapeutic interventions should target relapse prevention with special consideration given to depressive episodes and cognitive rehabilitation.

Key words: *Bipolar disorder; Cognition; Depressive disorder*

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Introduction

Bipolar disorder has traditionally been associated with a better outcome than schizophrenia.[1] Nonetheless generally little attention has been paid to psychosocial outcomes in patients with bipolar disorder. Recent studies indicate that functioning varies considerably as far as the outcome is concerned: some patients function well in between episodes whereas others have substantial dysfunction in significant functional domains, even during euthymic periods.[2-4]

Several clinical variables are associated with poor functioning in patients with bipolar disorders including number of episodes,[5] persistent subsyndromal symptoms,[6] prior number of psychiatric hospitalisations,[7] co-morbid substance use disorder,[8,9] side-effects of medicine, history of psychotic symptoms,[4,10] early age at onset,[4,11] longer duration of mood episodes,[12] and low premorbid functioning.[13] Growing evidence suggests that bipolar disorder patients experience prominent neurocognitive impairment not only during acute mood episodes[14,15] but also during euthymia.[16,17] The cognitive deficits intrinsic to bipolar disorder itself typically coalesce around problems with attentional processing, executive function, and verbal memory.[18,19]

Functional outcome in bipolar disorder is significantly influenced by clinical variables related to the illness and cognitive functioning. The current study aimed to assess the relationship of these factors to functional outcomes in bipolar disorder.

Methods

This was a cross-sectional hospital-based analytical observational study carried out between 16 February 2014 and 28 December 2014 on euthymic bipolar patients who attended the outpatient department of the psychiatric centre, SMS Medical College Jaipur, India. Ethical approval was obtained from the research review board and ethical

committee of the institution. Informed written consent was obtained from all participants prior to participation in the study.

A total of 61 patients were included over a period of 1 year. Male and female patients with bipolar disorder (according to the ICD-10 research criteria and confirmed by clinical interview of the participants and their immediate family members) aged 18 to 55 years who were currently euthymic (defined as Young Mania Rating Scale[20] score of ≤ 6 and 17-item Hamilton Rating Scale for Depression[21] score of ≤ 8) were recruited. Participants were required to have at least 7 years of formal education to reduce the confounding effect of education on cognitive tests.

Patients with a history of head injury, neurological illness, any other co-morbid psychiatric illness or substance abuse in the last year except nicotine abuse (assessed by the Mini-International Neuropsychiatric Interview [MINI]),[22] mental retardation or any clinical condition that could affect cognitive performance, significant medical illness, electroconvulsive therapy in the last year, or physical disability (e.g. blind, deaf, speech problems, paralysis, amputation) were excluded.

Thirty healthy individuals, carefully matched with participating patients for age, gender, locality and education, were recruited from "bystanders" of the patients (e.g. spouse, distant relative, or the person accompanying the patient) to reduce the effect of confounding variables. Those who had a history of psychiatric illness (by MINI[22]) or a history of psychiatric illness in a first-degree relative (confirmed by clinical interview) were excluded from the study.

The patients were divided into low functioning (n = 30) and high functioning (n = 31) subgroups based on functioning level as measured by Global Assessment of Functioning Scale (GAF) score.[23] The GAF[23] assesses psychological, social, and occupational functioning with a possible score of 1 to 100. A score of 60 was set as the cut-off to distinguish patients with high and low functioning. As per the DSM-IV-TR, a score of > 60 (61-70) indicates some mild difficulty in social, occupational or academic activities or satisfactory activity. Nonetheless in general, the patient works quite well and has significant interpersonal relationships. A score of ≤ 60 indicates moderate to severe impairment in functioning. This cut-off has been recommended by earlier studies to distinguish poor functioning patients with psychiatric disorders.[12,24] We used the GAF score to measure psychosocial functioning in the month prior to rating. After applying inclusion and exclusion criteria, 3 groups were assessed.

Socio-demographic profile included name, age, gender, name of father / husband, address, marital status, education, occupation, type of family, and monthly income. Clinical variables were recorded following clinical interview of participants and their immediate family members. Number and type of episodes, duration of illness (chronicity), age at onset of the illness, number of hospitalisations, time since the last episode, and history of psychotic symptoms were recorded. The investigator was blinded to the group category.

Neuropsychological assessments used in this study included the digit span forward test[25] and the Trail Making Test part A[26] for testing attention and concentration; Trail Making Test part B,[26] the digit span backward test[25] and the Stroop Colour Test[27] for executive function; and verbal learning and memory test in Hindi.[28]

Assessment was performed in a fixed order in a quiet room by a trained psychiatrist who was blinded to the group category and took 45 minutes to 1 hour to complete.

Statistical Analysis

Data were analysed using the Statistical Package for the Social Sciences (SPSS Windows version 19.0; IBM Corp, Armonk [NY], United States). Socio-demographic variables of the 3 groups (high functioning, low functioning, and healthy controls) were compared using analysis of variance and Chi-square test as appropriate. Clinical variables of the 2 patient groups (low and high functioning) were compared using independent-samples *t* test and Chi-square test as appropriate. Multivariate analysis of variance (MANOVA) was performed to assess the difference in neurocognitive test results between the 3 groups followed by Tukey's post-hoc analysis that was significant on MANOVA analysis. Descriptive statistics were expressed as mean and frequency as appropriate. Pearson's correlation was applied to determine correlation among variables. Variables significantly correlated with GAF score were introduced into the linear regression analysis to identify better predictors of functional outcome. A p value < 0.05 was considered significant.

Results

The socio-demographic profiles of the 3 groups were comparable. Most patients were married (78%), Hindu (89%), and male (60%) with a rural background (75%) and belonged to an upper lower or lower middle class family (91%). Most patients (54%) lived in a nuclear family. The mean durations of education were 8.6, 8.5 and 8.9 respectively in low functioning, high functioning, and control groups (Tables 1 and 2).

Table 3 shows the comparison of clinical variables between low and high functioning groups. A significant difference was evident in the total number of episodes (p = 0.003), depressive episodes (p = 0.001), and time since the last episode (p = 0.000).

Table 4 shows the correlation of different clinical variables with GAF score. In Pearson's correlation analysis, total number of episodes (r = –0.459, p = 0.000), number of manic episodes (r = –0.299, p = 0.02), depressive episodes (r = –0.481, p = 0.000), and time since the last episode (r = 0.698, p = 0.000) were significantly correlated with GAF score.

With regard to neurocognitive variables, MANOVA yielded Pillai's F of 4.976 (p = 0.000) for the main

Table 1. Socio-demographic characteristics of the sample.*

	Groups			X^2 value	p Value
	Low functioning (n = 30)	High functioning (n = 31)	Healthy controls (n = 30)		
Marital status				1.520	0.82
Married	22 (73)	24 (77)	25 (83)		
Unmarried	7 (23)	6 (19)	5 (17)		
Widowed / separated	1 (3)	1 (3)	0		
Gender				0.181	0.91
Male	19 (63)	18 (58)	18 (60)		
Female	11 (37)	13 (42)	12 (40)		
Socio-economic status				2.398	0.88
Lower	3 (10)	1 (3)	2 (7)		
Upper lower	15 (50)	15 (48)	16 (53)		
Lower middle	12 (40)	14 (45)	11 (37)		
Upper middle	0	1 (3)	1 (3)		
Upper	0	0	0		
Religion				0.253	0.88
Hindu	27 (90)	28 (90)	26 (87)		
Muslim	3 (10)	3 (10)	4 (13)		
Locality				0.181	0.91
Rural	22 (73)	24 (77)	22 (73)		
Urban	8 (27)	7 (23)	8 (27)		
Family type				4.438	0.35
Nuclear	16 (53)	20 (65)	13 (43)		
Nuclear extended	7 (23)	6 (19)	12 (40)		
Joint	7 (23)	5 (16)	5 (17)		

* *Data are shown as No. (%) of subjects, unless otherwise specified*

Table 2. Comparison of age and years of education among groups with analysis of variance.

	Mean ± standard deviation			p Value
	Low functioning group	High functioning group	Healthy controls	
Age (years)	32.9 ± 10.4	34.4 ± 7.6	31.7 ± 8.4	0.49
Years of education	8.6 ± 1.3	8.5 ± 1.1	8.9 ± 1.5	0.47

effect, indicating an overall difference in neurocognitive performance between groups. As shown in Table 5, multivariate analysis revealed that the 3 groups differed significantly for digit span backward test ($p = 0.01$), verbal learning and memory test ($p = 0.001$), Trail Making Test part A and B ($p = 0.000$), and all the 3 Stroop Colour Tests ($p = 0.000$). Multiple comparisons by Tukey's post-hoc analysis were made to determine which 2 groups differed significantly in head-to-head comparison. Table 6 shows the mean difference and p value for each comparison. Digit span backward test, Trail Making Test (part A and B), and Stroop Colour Test were significantly correlated with GAF score (Table 7).

In an attempt to find the predictors of psychosocial functioning, those variables that correlated with psychosocial outcome ($p < 0.05$) were introduced in the linear regression analysis. Variables significantly correlated with GAF score were total number of episodes, number of manic episodes, number of depressive episodes, time since the last episode, digit span backward test, Trail Making Test (part A and B), and Stroop Colour Test. This model accounted for the 65.5% variance in psychosocial functioning ($F = 15.22$, $t = 5.26$, $p = 0.000$). The better predictors of psychosocial functioning among all the variables were time since the last episode ($ß = 0.475$, $p = 0.000$) and interference Stroop Colour Test ($ß = –0.290$, $t = 2.82$, $p = 0.01$).

Table 3. Comparison of clinical variables between low and high functioning groups by independent-samples t test.*

	Groups		*t* Value	p Value
	Low functioning (n = 30)	High functioning (n = 31)		
Age at onset	21.5 ± 7.4	23.1 ± 8.6	-0.76	0.45
Total duration of illness	11.4 ± 8.1	11.3 ± 6.0	0.04	0.97
Total No. of episodes	9.2 ± 5.4	5.7 ± 3.2	3.06	0.003
Manic episodes	4.3 ± 1.4	3.5 ± 2.3	1.6	0.12
Depressive episodes	4.9 ± 4.2	2.2 ± 1.3	3.46	0.001
No. of hospitalisations	1.8 ± 2.1	1.3 ± 0.1	1.04	0.30
Time since last episode (months)	13.8 ± 13.7	43.8 ± 29.7	-5.44	0.000
GAF scores	50.5 ± 7.3	83.1 ± 7.7	-16.9	0.000
Psychotic symptoms				
Present	20 (66.7)	19 (61.3)	0.19	0.66
Absent	10 (33.3)	12 (38.7)		

Abbreviation: *GAF = Global Assessment of Functioning Scale.*

* *Data are shown as mean ± standard deviation or No. (%) of subjects, unless otherwise specified.*

Table 4. Correlation of clinical variables with Global Assessment of Functioning Scale score by Pearson's correlation test.

	Pearson's correlation (*r*)	p Value
Age at onset	-0.026	0.84
Total duration of illness	-0.071	0.59
Total No. of episodes	-0.459	0.000
Manic episodes	-0.299	0.02
Depressive episodes	-0.481	0.000
No. of hospitalisations	-0.177	0.17
Time since last episode (months)	0.698	0.000

Table 5. Neurocognitive performance of the groups upon multivariate analysis of variance.*

	Group			p Value
	Low functioning group	High functioning group	Healthy controls	
Digit span test				
Forward	4.97 ± 0.89	5.06 ± 0.99	5.23 ± 0.68	0.49
Backward	3.40 ± 0.62	3.77 ± 0.80	4.00 ± 0.74	0.01
Verbal learning and memory test	49.97 ± 15.16	55.03 ± 11.62	63.33 ± 11.94	0.001
Trail Making Test				
Part A (sec)	69.23 ± 30.87	50.87 ± 19.38	32.92 ± 17.88	0.000
Part B (sec)	137.13 ± 41.57	110.32 ± 33.33	64.67 ± 46.39	0.000
Stroop Colour Test				
Colour card time (sec)	24.97 ± 3.87	20.48 ± 3.47	19.20 ± 5.55	0.000
Word card time (sec)	35.80 ± 6.80	27.84 ± 4.93	24.03 ± 10.12	0.000
Interference time (sec)	46.20 ± 10.63	35.29 ± 9.91	29.37 ± 12.15	0.000

* *Data are shown as mean ± standard deviation.*

Table 6. Tukey's post-hoc analysis on neurocognitive tests.

	LF vs. HF		LF vs. controls		HF vs. controls	
	Mean difference	**p Value**	**Mean difference**	**p Value**	**Mean difference**	**p Value**
Digit span backward test	-0.37	0.12	-0.60	0.01	-0.23	0.45
Verbal learning and memory test	-5.07	0.29	-13.37	0.000	-8.30	0.04
Trail Making Test part A	18.36	0.01	36.33	0.000	17.97	0.01
Trail Making Test part B	26.81	0.03	72.47	0.000	45.66	0.000
Stroop Colour Test colour card	4.48	0.000	5.77	0.000	1.28	0.49
Stroop Colour Test word card	7.96	0.000	11.77	0.000	3.80	0.13
Stroop Colour Test interference	10.91	0.001	16.83	0.000	5.92	0.09

Abbreviations: *HF = high functioning; LF = low functioning.*

Table 7. Correlation of neurocognitive tests with Global Assessment of Functioning Scale score by Pearson's correlation test.

	Pearson's correlation (*r*)	**p Value**
Digit span test		
Forward correct responses	0.213	0.10
Backward correct responses	0.323	0.01
Verbal learning and memory test — correct responses recalled	0.098	0.45
Trail Making Test		
Part A time	-0.403	0.001
Part B time	-0.509	0.000
Stroop Colour Test		
Colour card time	-0.516	0.000
Word card time	-0.533	0.000
Interference time	-0.561	0.000

Discussion

The present study was designed to assess the impact of clinical and cognitive factors on functional outcome in euthymic patients with bipolar disorder. Patients were divided into low and high functioning groups based on GAF score (cut-off, 60) and several clinical factors compared. Those selected in this study were based on earlier studies.[5,6,11,12] Neurocognitive performance was assessed by comparing the low and high functioning groups with the controls for digit span test, Trail Making Test, Stroop Colour Test, and verbal learning and memory test. Further analysis of the relationship of GAF score with clinical and cognitive factors was performed to identify better predictors of functional outcome in bipolar disorder. All 3 groups were comparable for age, gender, locality, education, and other socio-demographic variables.

Impact of Clinical Factors on Functional Outcome

Several clinical variables have been identified to be associated with poor functioning in patients with bipolar disorder. In this study, low and high functioning groups differed significantly in the total number of episodes, depressive episodes, and time since the last episode. There was no difference in age at onset, total duration of illness, number of hospitalisations, or a history of psychotic symptoms. Total number of episodes, depressive episodes, and time since the last episode were significantly correlated with GAF score. Time since the last episode was the best predictor of psychosocial functioning.

The total number of episodes was associated with functional impairment. The mean total numbers of episodes were 9.2 and 5.7 in low and high functioning groups, respectively. Total number of episodes was negatively correlated with GAF score (Pearson's correlation $r = –0.459$,

p = 0.000). This finding is in line with earlier studies that reported a higher number of episodes has a more negative impact on social functioning.[5,29,30] It is possible that more episodes may cause long-lasting biochemical changes in the brain that may impact global functioning in bipolar patients.[31] Another possible explanation is that patients with multi-episode bipolar disorder are more prone to cognitive impairment that may in turn further worsen psychosocial outcome and employment.[32-34] Nonetheless this study did not determine the correlation of clinical variables with cognitive functioning. A further possible explanation is that recurrent mood episodes and longer active phase of illness result in interrupted educational and vocational pursuits and repeated disruption of interpersonal engagement.[35,36]

In this study the number of depressive episodes was more strongly correlated with functional outcome than manic and total number of episodes (Table 4). The mean numbers of depressive episodes were 4.9 and 2.2 in low and high functioning groups, respectively. Another study[5] showed similar findings where number of previous depressive episodes was a stronger determinant of outcome than past manias. Other studies[37,38] also found that depressive episodes are strongly associated with poor functioning in bipolar disorder. Another study[39] found that the number of manic episodes was associated with poor functional outcome only, but not the depressive episodes.

There are several possible explanations for the association between high rates of depressive episodes and impaired functioning. Some authors suggest that bipolar disorder patients perceive depressive phases as weaker than manic episodes.[40] Another possible explanation is that depressive episodes are often associated with cognitive impairment that may worsen global functioning along the course of bipolar illness. Alternatively, it is possible that functional impairment may itself have a role in the development of depressive relapses.[5]

In this study time since the last episode was the best predictor of psychosocial functioning in euthymic patients with bipolar disorder. Time since the last episode also differed significantly between low and high functioning groups (13.8 vs. 43.8 months). It was positively correlated with GAF score and indicates that the longer the time a patient in a euthymic state, the better the outcome. Thus, our study suggests that interventions directed at prevention of relapse into further episodes will result in better psychosocial outcomes.

Impact of Neurocognitive Performance on Functional Outcome

In the present study various neurocognitive tests were performed to assess the cognitive domains of executive functioning (interference Stroop Colour Test, Trail Making Test part B, digit span backward test), attention and concentration (digit span forward test, Trail Making Test part A), and verbal learning and memory (verbal learning and memory test) because these are among the most important cognitive domains for daily functioning.[41] Both low and high functioning groups performed poorer than the control group on the digit span backward test, Trail Making Test, verbal learning and memory test, and Stroop Colour Test. These findings show that euthymic patients with bipolar disorder have cognitive deficits in all the domains studied, i.e. executive functioning, attention and concentration, and verbal learning and memory. This is in accordance with existing literature. Meta-analytic studies suggest that euthymic patients with bipolar disorder have neurocognitive impairment in the domains of attention and processing speed, verbal learning, memory, and executive functioning.[17,42]

On post-hoc analysis, comparison between low and high functioning groups revealed that the former performed poorer in Trail Making Test and Stroop Colour Test. Furthermore digit span backward test, Trail Making Test (part A and B), and Stroop Colour Test were significantly correlated with GAF score and interference Stroop Colour Test was the best predictor of functional outcome. These findings show dysfunction in attention, psychomotor speed, working memory, ability to shift strategy, inhibitory control, and fluid cognitive flexibility cumulatively denote executive dysfunction in low functioning group. Thus, executive functioning is a better predictor of functional outcome than the other domains studied. These findings were supported by Martino et al[43] who found significant associations of functional capacity with measures of attention (digit span forward test, Trail Making Test part A) and executive functions (Trail Making Test part B, verbal fluency test) in a sample of 48 euthymic patients with bipolar disorder. Similarly, Mur et al[44] found that impaired executive function and loss of inhibition might be an important feature of bipolar disorder and suggested that these executive-type cognitive traits may constitute an endophenotype for further studies of the aetiology of bipolar disorder. Dixon et al[45] have observed a shared pattern of executive dysfunction in manic, depressed and euthymic patients, with respect to strategic thinking, inhibitory control and response initiation, independently of mood state, and it is now apparent that all 3 phases of the illness demonstrate cognitive deficits. In an Indian study by Trivedi et al,[46] euthymic bipolar patients showed significant differences in executive functions compared with normal controls.

Martinez-Aran et al[12] found that bipolar patients in general showed poorer cognitive performance than healthy controls. This was most evident in low functioning patients and particularly for verbal memory and executive function measures. The best predictor of psychosocial functioning was verbal memory.[12] Impaired attention and executive functioning can interfere with almost every facet of human life. Executive domains of cognition are required in every task of daily living. It is possible that cognitive impairment, especially in the executive domain, significantly disrupts functioning of patients, even in the euthymic phase. This poor functioning is one of the main factors that explains why bipolar disorder has been ranked seventh among the worldwide causes of non-fatal disease burden, as measured

in disability-adjusted life years by the World Health Organization.[47] Recent studies have highlighted the modest impact of available interventions on functional recovery for a large proportion of bipolar disorders,[48] and called for a research agenda that specifically addresses these issues.

The cognitive deficits that persist during the stable phase of illness, even after subsidence of active symptoms, suggest that some illness process is continued that was present before the illness was first diagnosed. Thus, our findings also indicate that these cognitive deficits may be considered endophenotypes of bipolar disorder. Bora et al[49] conducted a meta-analyses of 18 cognitive variables in studies that compared performance of euthymic bipolar disorder patients (45 studies; 1423 subjects) or first-degree relatives of bipolar disorder patients (17 studies; 443 subjects) with healthy controls and found that response inhibition deficit, a potential marker of ventral prefrontal dysfunction, was the most prominent endophenotype of bipolar disorder. This study provides some initial confirmatory evidence although further studies are required to establish these findings.

Limitations

The sample size was small so results cannot be generalised. The main limitation of the present study was the superficial separation of the patients into 2 groups based on a cut-off GAF score. Nonetheless it is probably useful to distinguish patients with no or mild impairment (high functioning group) in psychosocial outcome from those patients with severe or moderate impairment (low functioning group). Another relevant issue is the differences between patients and controls with respect to medication. This could partly explain the differences in neurocognitive performance. Although cognitive dysfunctions may be related to the effects of medication, they do not appear to be a primary effect of pharmacological treatment. The medication profile revealed that our patients were prescribed 4 kinds of medication: lithium, antiepileptics, antipsychotics (no patient was on conventional antipsychotics), and antidepressants. According to the literature there is no or little effect of medicines on cognition. With respect to lithium, a longitudinal study[50] showed stable cognitive performance over a 6-year follow-up period. Regarding antiepileptics, research has found only a little evidence of cognitive impairment.[51] Antipsychotics also have a neutral effect upon cognition, although some studies report improvement.[52] In this study mixed episodes were not included in the results and discussion because we found mixed episodes in few patients only and analysis was not possible with so little data. We were unable to determine the association between clinical variables and cognition.

Conclusions

The present findings suggest that cognitive factors and clinical variables related to illness severity contribute to psychosocial outcome in bipolar disorder. Total number of episodes, depressive episodes, and time since the last episode correlated with poor functioning. Long-term therapeutic interventions that target relapse prevention with special consideration given to depressive episodes are required. Cognitive dysfunction is also correlated with poor functioning. It was most pronounced in low functioning group, but also evident in high functioning group. Executive dysfunction seems to be a strong predictor of psychosocial outcome in euthymic bipolar patients. These factors should be considered more widely with respect to the long-term management of bipolar disorder. The current treatments for bipolar disorder patients are limited with regard to functional recovery. More focus should be placed on psychopharmacological as well as psychosocial interventions, such as psycho-education, family intervention, and cognitive rehabilitation targeting relapse prevention and cognitive improvement.

In future, longitudinal follow-up studies with improved methodology and larger sample size could be planned to assess the progression of illness and cognitive dysfunctions and their impact on psychosocial functioning, as well as to establish the therapeutic efficacy of newer interventions that target relapse prevention and cognitive enhancement.

Declaration

The authors have disclosed no conflicts of interest in this study.

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Original Research Article

A Study on Cross Sectional Online Assessment of Attitude of Medical Students Towards Mental Illnesses

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Abstract

Background: Attitudes and belief toward mental illnesses are important factors that affect perception of mental health. Knowing the attitude of medical students towards psychiatry and mental illnesses is of utmost importance as they are future care provider. Current study is conducted to assess the attitude of medical students towards mentally ill patients and mental illnesses, to identify correlation of attitude score with personal and family history of mental illness and, to compare the score among students of the three year-wise groups.

Method: The study population included 219 students of first, second and third professional MBBS. We designed an online data collection tool and executed it using the Google Forms. The Google Form link to the questionnaire was sent to the enrolled participants via the identified WhatsApp groups or individual number. Beliefs toward Mental Illness (BMI) scale was used to assess attitude towards mental illnesses which is a 21-item self-report measure of negative stereotypical views of mental illness. The results of the study were examined and analyzed by using Statistical Package for Social Sciences (SPSS 25.0).

Results: Out of total 21 items of the BMI scale, students showed positive attitude on majority of items. The mean score for BMI scale and per item mean score for the scale were towards positive attitude. Majority of students agree that a mentally ill person is more likely to harm others than a normal person and that mental disorders would require a much longer period of time to be cured than would other general diseases. Higher per item mean score for dangerousness and, incurability subscale showed their negative attitude. An increasing trend of positive attitude has been seen with an increase of education level and exposure towards the subject.

Conclusions: Medical students show variable scores on belief towards mental illness scale, its subscales and, individual items. Admitting this prevailing stigma needs to be acknowledged and openly discussed with medical students in order to overcome these views. Providing adequate education on mental illnesses and attached negative attitudes or myths can change these negative beliefs.

Keywords: Medical students, psychiatry, mental illnesses, stigma, dangerousness.

1. Introduction:

Attitudes and belief toward mental illnesses are important factors that affect perception of mental health. The prejudiced and negative attitudes or stigma towards people with mental illness are widespread. In our society, health professionals have similar views about those with mental health problems and mentally ill patients. Literature suggests that people diagnosed with mental illness are considered by the majority of the society as people who are dangerous, loathed, stranger and somebody whose actions cannot be predicted.[1] Globally, psychiatry as a subject, psychiatrists as professionals, and patients with psychiatric disorders are subjected to cultural stereotypes and negative attitude by the general population. What is of alarming concern is that these prejudices exist within the medical community as well.[2-6] Stigma toward mental illness is an influential factor leading to negative views among medical students toward psychiatry. Lack of knowledge and awareness about mental illnesses among the students is associated with the negative attitudes towards mental illness in the community. For medical students during their training, educational intervention targeted towards these negative attitudes may be more effective than doctors who have already completed their training because research has shown as they carry on through their career, their attitude harden and become more resistant to change.[7] The concept of iatrogenic stigma is used to describe the stigma caused or perpetuated by mental health professionals.[8] This stigma and negative attitudes can affect the quality of life for people with mental illness. There may be various reasons for this negative attitude such as lack of accurate information about mental illness and lack of contact with individuals with mental illness.[9]

While some studies have suggested that aspiring young doctors have a favorable opinion about psychiatry as a branch[10], other studies have suggested that medical students' attitude toward psychiatry is unfavorable.[11-17]

A doctor's attitude towards persons with psychiatric illness and psychiatry should involve an impression of an empathetic listener and should have non-judgmental approach. Knowing the attitude of medical students towards psychiatry and mental illnesses is of utmost importance as they are future care provider. To improve psychiatric training in this population beliefs and attitude toward psychiatric illnesses and need to be assessed and understood.

The reasons for studying the attitude specifically among medical students are that firstly as a doctor they can play an important role in decreasing negative attitude and, secondly the results from the study will help to focus strategies to change attitudes of this group. The comparison among various groups in present study will help in understanding the impact of successive undergraduate training years. The findings may help in understanding the various points of strength and lacunae in the current undergraduate curriculum regarding mental health.

Objectives:

The objectives of the current online study were-

1. To assess the attitude of medical students towards mentally ill patients and mental illnesses
2. Correlation of attitude score with personal and family history of mental illness, and
3. Comparison among students of the three year-wise groups.

2. Methodology

Study population and study area: The study population includes all the students who have

enrolled in MBBS course (first year, second year and final year) at Ananta Institute of Medical Science and Research Centre, Rajsamand, Rajasthan. Those students who will give their consent to participate in the study will be included and rests will be excluded at their will.

Study Duration: one year, June 2020 to May 2021.

Sampling techniques and sample size

Samples were obtained using stratified random sampling method. The 3 batches of medical students viz first year professional, second year professional and third year professional which were considered as strata collectively develop a sampling frame of 450 students. The minimum sample size on assumption of 95% level of significance, 5% error and 85% expected proportion was 196. After 12% adjustment of non- responders' students the final sample size was 219.

Undergraduates in the 1st year had not received formal exposure to psychiatry yet, students of 2nd year also have not attended clinical posting or lecture in psychiatry while students of Final year students had completed clinical posting and theory lectures in psychiatry. The institute is having well-functioning psychiatry department with adequate teaching staff and a good in-flow of patients in the psychiatry OPD as well as inpatient department.

Study procedure and statistical Analysis: After unlock 1.0 was announced by the Government of India from 8th of June 2020, the cases of COVID-19 were increasing all over India including Rajasthan. Hence there was risk of disease transmission by taking interview in person therefore we decided to use WhatsApp Messenger for enrolling potential participants and Google forms for filling up their response. The study was approved by institute ethics committee.

Tools: We designed an online data collection tool and executed it using the Google Forms (via docs.google.com/forms). The Google Form link to the questionnaire was sent to the enrolled participants via the identified WhatsApp groups or individual number.

Socio-demographic variables included age, gender, marital status, background, past personal history of mental illness, known history of mental illness in the family were described using descriptive statistics.

Beliefs toward Mental Illness (BMI) scale was used to assess attitude towards mental illnesses. The BMI scale is a 21-item self-report measure of negative stereotypical views of mental illness. (18) There is a total Score and the score of three sub-scales based on factor analysis: dangerousness, poor social and interpersonal skills, and incurability. There are five items in subscale dangerousness, ten items in poor interpersonal and social skills scale and six items in incurability subscale. Items are rated on a six-point Likert scale ranging from 'completely disagree' (0) to 'completely agree' (5), with higher scores reflecting more negative beliefs. In the primary validity study, Cronbach's alpha was high among American (0.89) and Asian students (0.91). The measure holds promising evidence of validity.

The results of the study were examined and analyzed by using Statistical Package for Social Sciences (SPSS 25.0). The categorical variables were described by numbers and percentages while continuous variables were described by average and standard deviation. Normality of attitude was checked using Kolmogrov-Smirnov test. After testing normality condition, the association and relationship between the variables were tested Pearson correlation by Student's t test and one way analysis of variance (ANOVA). The level of significance was considered at $P<0.05$.

3. Results

A total 219 number of students were participated in the online study. The sample comprised of 41.55% of male students and 58.44% of female students. Majority of the students were unmarried (97.26%), belonging to urban background (79.45%), having negative past personal history of psychiatric illness (86.75%) and negative family history for psychiatric illnesses (75.79%).

Table 1: Socio-demographic characteristics of respondents

Variables	Participants N (%)
Sex	
Male	**91 (41.55%)**
Female	**128 (58.44%)**
Marital Status	
Married	**6 (2.73%)**
Unmarried	**213 (97.26%)**
Place of residence	
Urban	**174 (79.45%)**
Rural	**45 (20.54%)**
MBBS Batch	
First year professional	**49 (22.37%)**
Second year professional	**138 (63.01%)**
Third year professional	**32 (14.61%)**
Had mental illness in past:	
Yes	**29 (13.24%)**
No	**190 (86.75%)**
Is someone in your family/ friends/ relative is having mental illness:	**53 (24.21%)**
Yes	**166 (75.79%)**
No	
If yes, then	
Friends	**7(13.2%)**
Family	**26(49.05 %)**
Relative	**20(37.73%)**

Table 1 shows socio-demographic characteristics of respondents.

Attitudes of students towards mental illness

a) Attitude by Items of the subscales

Table 2: Dangerousness subscale of BMI scale (item wise responses, percentage of participants regarding statements on the beliefs about mental illness)

Statement	**Response***					
	0	**1**	**2**	**3**	**4**	**5**
A mentally ill person is more likely to harm others than a normal person	28 (12.8%)	15 (6.8%)	36 (16.4%)	85 (38.8%)	26 (11.9%)	29 (13.2%)
	79 (36%)			140 (64%)		
Mental disorders would require a much longer period of time to be cured than would other general diseases	10 (4.6%)	8 (3.7%)	19 (8.7%)	55 (25.1%)	51 (23.3%)	76 (34.7%)
	37 (17%)			182 (83%)		
It may be a good idea to stay away from people who have psychological disorder because their behaviour is dangerous	73 (33.3%)	47 (21.5%)	41 (18.7%)	41 (18.7%)	7 (3.2%)	10 (4.6%)
	161 (74%)			58 (26%)		
Mentally ill people are more likely to be criminals	69 (31.5%)	47 (21.5%)	35 (16.0%)	45 (20.5%)	13 (5.9%)	10 (4.6%)
	151 (69%)			68 (31%)		
I am afraid of people who are suffering from psychological disorder because they may harm me	80 (36.5%)	47 (21.5%)	31 (14.2%)	50 (22.8%)	4 (1.8%)	7 (3.2%)
	158 (72%)			61 (28%)		

* Denotes 0 = Completely disagree, 1 = Largely disagree, 2 = somewhat disagree, 3 = somewhat agree, 4 = Largely agree, 5 = Completely agree

Table 2 shows item wise responses and percentage of participants regarding statements on the beliefs about mental illness on dangerousness subscale of the BMI scale

Table 3: Poor social and interpersonal skills subscale of BMI scale (item wise responses, percentage of participants regarding statements on the beliefs about mental illness)

Statement	**Response**					
	0	**1**	**2**	**3**	**4**	**5**
The term 'psychological disorder' makes me feel embarrassed	123 (56.2%)	30 (13.7%)	16 (7.3%)	24 (11.0%)	12 (5.5%)	14 (6.4%)
	169 (77%)			50 (23%)		
A person with psychological disorder should have a job with only minor responsibilities	43 (19.6%)	30 (13.7%)	49 (22.4%)	58 (26.5%)	27 (12.3%)	12 (5.5%)
	122 (56%)			97 (44%)		

I am afraid of what my boss, friends and others would think if I were diagnosed as having a psychological disorder	70 (32.0%)	24 (11.0%)	24 (11.0%)	57 (26.0%)	17 (7.8%)	27 (12.3%)
	118 (54%)			101 (46%)		
It might be difficult for mentally ill people to follow social rules such as being punctual or keeping promises	37 (16.9%)	29 (13.2%)	55 (25.1%)	38 (17.4%)	37 (16.9%)	23 (10.5%)
	121 (55%)			98 (45%)		
I would be embarrassed if people knew that I dated a person who once received psychological treatment	131 (59.8%)	29 (13.2%)	17 (7.8%)	26 (11.9%)	12 (5.5%)	4 (1.8%)
	177 (72%)			61 (28%)		
A person with psychological disorder is less likely to function well as a parent	43 (19.6%)	45 (20.5%)	35 (16.0%)	57 (26.0%)	22 (10.0%)	17 (7.8%)
	123 (56%)			96 (44%)		
I would be embarrassed if a person in my family became mentally ill	150 (68.5%)	26 (11.9%)	15 (6.8%)	13 (5.9%)	7 (3.2%)	8 (3.7%)
	191 (87%)			28 (13%)		
Mentally ill people are unlikely to be able to live by themselves because they are unable to assume responsibilities	45 (20.5%)	51 (23.3%)	50 (22.8%)	43 (19.6%)	12 (5.5%)	18 (8.2%)
	146 (67%)			73 (33%)		
Most people would not knowingly be friends with a mentally ill person	33 (15.1%)	22 (10.0%)	36 (16.4%)	62 (28.3%)	27 (12.3%)	39 (17.8%)
	91 (42%)			128 (58%)		
I would not trust the work of a mentally ill person assigned to my work team	61 (27.9%)	40 (18.3%)	44 (20.1%)	53 (24.2%)	10 (4.6%)	11 (5.0%)
	145 (66%)			74 (34%)		

0 = Completely disagree, 1 = Largely disagree, 2 = somewhat disagree, 3 = somewhat agree, 4 = Largely agree, 5 = Completely agree

Table 3 shows item wise responses and percentage of participants regarding statements on the beliefs about mental illness on poor social and interpersonal skills subscale of the BMI scale

Table 4: Incurability subscale of BMI scale (item wise responses, percentage of participants regarding statements on the beliefs about mental illness)

Statement	**Response**					
	0	**1**	**2**	**3**	**4**	**5**
Psychological disorder is recurrent	17 (7.8%)	17 (7.8%)	45 (20.5%)	77 (35.2%)	34 (15.5%)	29 (13.2%)
	79 (36%)			140 (64%)		
Individuals diagnosed as mentally ill suffer from its symptoms throughout their life	53 (24.2%)	46 (21.0%)	41 (18.7%)	53 (24.2%)	10 (4.6%)	16 (7.3%)
	140 (64%)			79 (36%)		
People who have once received psychological treatment, are likely to need further treatment in the future	19 (8.7%)	38 (17.4%)	29 (13.2%)	82 (37.4%)	29 (13.2%)	22 (10.0%)
	86 (39)			133 (61%)		
I believe that psychological disorder can never be completely cured	139 (63.5%)	19 (8.7%)	21 (9.6%)	17 (7.8%)	9 (4.1%)	14 (6.4%)
	179 (82%)			40 (18%)		
The behaviour of people who have psychological disorders is unpredictable	19 (8.7%)	24 (11.0%)	33 (15.1%)	65 (29.7%)	38 (17.4%)	40 (18.3%)
	76 (35%)			143 (65%)		
Psychological disorder is unlikely to be cured regardless of treatment	53 (24.2%)	31 (14.2%)	46 (21.0%)	46 (21.0%)	17 (7.8%)	26 (11.9%)
	130 (59%)			89 (41%)		

0 = Completely disagree, 1 = Largely disagree, 2 = somewhat disagree, 3 = somewhat agree, 4 = Largely agree, 5 = Completely agree

Table 4 shows item wise responses and percentage of participants regarding statements on the beliefs about mental illness on incurability subscale of the BMI scale

b) Attitudes by Subscale

There are five items in subscale dangerousness, ten items in poor interpersonal and social skills scale and six items in incurability subscale.

Table 5: Per item Mean and 95% CI for the three subscale and overall score of BMI scale

Subscale	**M(SD)**	**95 %CI**
Dangerousness	2.17(0.90)	2.77, 1.56
Poor interpersonal and social skills	1.77(0.92)	2.99, 0.54
Incurability	2.21(0.92)	2.94, 1.47
Full BMI scale	1.99(0.80)	4.22, -0.24

* M- Mean, SD- Standard deviation, CI- Confidence interval

Table 5 shows per item mean and 95% confidence interval for the three subscales and overall score of BMI scale.

c) Associates of attitudes

The differences in the attitude scores in different independent variables have two categories were determined by independent sample t tests. And, difference in attitude score in independent variables having more than two categories was determined by the one-way ANOVA.

As per Kolmogrov-Smirnov test statistic (D)results in 0.04762 which means that data is normally distributed. So independent sample t test has been applied to find out difference in attitude score by socio demographic characteristics.

Table 6: Difference in attitude score by socio-demographic characteristics

Characteristics	M(SD)	Diff.*(95% CI)	p-value
Sex			
Male	42.67(17.20)	1.24(-3.31,5.79)	0.59
Female	41.43(16.61)		
Marital status			
Married	60.17(9.06)	18.73(5.20,32.27)	**0.007**
Unmarried	41.43(16.72)		
Place of residence			
Urban	42.80(16.32)	4.18(-1.35, 9.71)	0.13
Rural	38.62(18.48)		
Had mental illness in past			
Yes	40.10(15.14)	2.12(-4.50, 8.74)	0.52
No	42.23(17.09)		
Is someone in your family/ friends/ relative is having mental illness:			
Yes	39.64(17.34)	3.03(-2.19, 8.27)	0.25
No	42.68(16.65)		

*Diff. =Difference in mean, (lower bound, upper bound)

Table 6 shows difference in attitude score by socio-demographic characteristics. Married students (N=6) had higher BMI score than unmarried students (N=213) and the difference was statistically significant. On further analysis it was found that of these six married students, five had positive response for history of mental illness in family, friend or any relative, also two had positive history of past mental illness. The difference among groups was not statistically significant for other characteristics.

Table 7: Difference in attitude towards mental illness by education level of students

Characteristics	M(SD)	F- value	p-value	p-value trend
Batch		9.11	**<0.0001**	**<0.0001**
I MBBS	48.11(14.34)			
II MBBS	43.63(14.71)			
III MBBS	41.08(15.21)			

*M= mean, SD= standard deviation, F=degree of freedom, p= p value

Table 6 shows that There is increase trend in positive attitude in medical students with increase in their education level ($p<0.0001$).

There was significantly positive attitude towards mental illness among III MBBS students than II MBBS and, among II MBBS than I MBBS ($p<0.0001$). An increasing trend of positive attitude has been seen with an increase of education level and exposure towards the subject.

4. Discussion

The current online study was planned to assess the attitude of medical students towards mentally ill patients and mental illnesses, to find correlations of attitude score with sociodemographic and clinical variables and, to compare the score among students of the three year-wise groups.

Out of total 21 items of the BMI scale, students showed positive attitude on majority of items (fifteen items) and negative attitude on few items (six items). The mean score for BMI scale was 41.99 and per item mean score for the scale was 1.99. This score is towards positive attitude. Jilowa et al also found in their study that Nearly 84% of second-year medical students and 52% of interns had positive attitude toward psychiatry. (19) In their study, Risal et al also found overall positive or neutral attitudes towards mental illness and psychiatry among the medical students and interns in their institute. (20)

In our study we found that majority of students agree that a mentally ill person is more likely to harm others than a normal person (64%) and that mental disorders would require a much longer period of time to be cured than would other general diseases (83%). Kodakandla et al conducted a study on Attitude of interns towards mental illness and psychiatry and found that majority of the interns believed that mentally ill person is more likely to harm others and that mental illness require a much longer time to be cured than other general diseases. (21) In our study majority (58 percent) of students agree that most people would not knowingly be friends with a mentally ill person. Jyothi NU et al also found majority (96 percent) of participants agreed with the statement. (22)

In our study we found that majority of students agree that psychological disorder is recurrent (64%), that people who have once received psychological treatment are likely to need further treatment in the future (61%), and that the behaviour of people who have psychological disorders is unpredictable (65%). Kodakandla et al also found that majority of participants (76%) believed that psychological disorder is recurrent and that the behavior of patients with psychological disorder is unpredictable (79%); two third of them (68%) were of the opinion that people who have once received psychological treatment are likely to need further treatment in the future. (21) Jyothi NU et al also found similar findings in a study on college students. (22)

Students showed per item mean score 1.77 for poor interpersonal and social skill subscale which is towards positive attitude. Higher per item mean score 2.17 for dangerousness subscale and 2.21 for incurability showed their negative attitude. In a community Study on Attitudes to and Knowledge of Mental Illness in Tehran, Ghanean H et al found that around half participants agreed that people with a mental illness “are dangerous”. (23) Contrary to our findings *Kodakandla et al* found that only one third (31%) interns believed that psychological illness is unlikely to be cured regardless of the treatment. (21)

Married students showed statistically significant higher BMI score compared to unmarried students. On further analysis it was found that of these six married students, five had positive response for history of mental illness in family, friend or any relative and, two had positive history of past mental illness. So,

these two factors might have caused higher stigma in this small sample. The attitude score was not associated statistically significantly with other sociodemographic and clinical variables.

There was significantly positive attitude towards mental illness among III MBBS students than II MBBS and, among II MBBS than I MBBS ($p<0.0001$). An increasing trend of positive attitude has been seen with an increase of education level and exposure towards the subject. Similar to our study Aruna et al also highlighted exposure to psychiatry could improve the knowledge base of medical students. (24) Tharyan et al also found that psychiatric education positively influences the attitudes of medical students towards mental illness and some aspects of psychiatry. (25) However, providing clinical training in psychiatry during under graduation seems to improve the attitude toward people with mental illness. (16, 25-27) The favorable impact of psychiatry posting on the attitude of medical students towards mentally ill has been found in previous studies from western countries. (28) Work by Mas and Hatim (2002) from Malaysia found that final year MBBS students had more favorable attitude towards mentally ill as compared to the first-year students. (29)

The National medical commission (formerly Medical Council of India) has implemented Attitude, Ethics and Communication module (AETCOM) in all medical colleges in India in August 2019. (30) The cognitive components, behavioural attitudes and ethical dimensions of AETCOM module will change the approach of future doctors to psychiatry and person with psychiatric illness. Focusing more on clinical exposure and skills the new competency based medical education (CBME) programme has increased the duration of undergraduate clinical posting to total four weeks and total 40 hours for teaching from two weeks and 25 hours pre CBME respectively. This sequential introduction of clinical posting during second professional MBBS followed by theory class and clinical posting during third MBBS part-I will be more helpful in understanding of the subject. In future, mandating psychiatry as an independent subject of examination in under graduation assessment may prove a milestone step in medical education. So, it may be expected that this increased exposure will help in removing the existing negative attitudes towards psychiatry and person with psychiatric illness.

Suggestions:

Admitting the prevailing stigma needs to be acknowledged and openly discussed with medical students in order to overcome these views. Prevailing stigma and the negative attitudes about mental illnesses affect both patient caring and psychiatry as a career choice. The development of educational strategies enabling initial interest shown during the early clinical exposure needs to be maintained. Providing public education on mental illnesses and attached negative attitudes or myths can change these negative beliefs in general public. To promote psychiatry as a career, interested students need to have increased access to an in-depth experience of psychiatry, including “enrichment activities” such as electives in psychiatry.

Conclusions:

Medical students show variable scores on belief towards mental illness scale, its subscales and, individual items. Admitting this prevailing stigma needs to be acknowledged and openly discussed with medical students in order to overcome these views. Providing adequate education on mental illnesses and attached negative attitudes or myths can change these negative beliefs.

Implications of the Study:

This study will help in understanding of belief of medical students towards mental illnesses. The comparison among various groups in

present study will help in understanding the impact of successive undergraduate training years.

Limitations:

This was a cross sectional study with small sample size.

Future Direction:

Future studies can be undertaken with large sample size to determine the changes in belief of medical students admitted year 2019 onwards.

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USE OF AVERSION THERAPY IN DISSOCIATIVE PSEUDO-SEIZURE PATIENTS

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Abstract
Background: psychological methods are less commonly used in treatment of psychiatric illnesses in hospital setup. In some psychiatric illnesses drug use has limiting effect in full cure of illness due to psychosocial dynamics associated with those illnesses.
Aim: In dissociative conversion disorder one theory states that primary gain is conversion of mental or emotional feeling into physical symptoms and secondary gain is any other external benefit from physical symptom occurred in primary gain. Like in a disturbed marital conflict wife develops episodic unresponsiveness (pseudo seizures) as primary gain and revived attention and care of husband due to this episodic unresponsiveness (pseudo seizures) as secondary gain. It is hypothesized that dissociative conversion reaction develops and become resistant by getting these two primary and secondary gains. Our study aim at providing unpleasant mild aversive electric current to the subjects along with standard pharmacotherapy to make patient condition to this painful stimulus and end their maladaptive behavior.
Material and Methods: Structured Clinical Interview for DSM-5 was used for making diagnosis and Dissociative Experiences Scale and Global Assessment of Functioning (GAF) for evaluating the response of treatment. Mild electric current (30 mili columb) was used in test group along with standard treatment group.
Results: In test group improvement in terms of Dissociative Experiences Scale and Global Assessment of Functioning (GAF) and number of episodes of unresponsiveness was better.
Conclusion: Use of mild electric current as aversive stimulus as compared to standard treatment group was found more affective mode of treatment
Keywords: dissociative, conversion, aversion therapy, pseudo seizures, electric current

Introduction

Conversion reaction (functional neurological mental disorder) is mental illness in which sensory and motor abnormality is seen without any focal physical or nervous system lesion. According to DSM 5 following diagnostic criterion are included[1]

1-one or more symptoms of altered voluntary sensory or motor functioning

2-clinical findings provide incompatibility between symptoms and recognized neurological condition

3- Symptoms not explained by other physical or mental condition

4-Symptoms producing significant distress in social, occupational or emotional and other area of functioning

Aversion therapy is a type of behavioral therapy that make patients give up their undesirable habit by causing them to associate it with a distressing event. This conditioning is meant to cause the patient to associate this stimulus with unpleasant type of sensations with the intention of stopping the targeted unwanted behavior. Aversion therapies can be of many types, like using unpleasant-tasting substances ie chili or denatonium benzoate on the fingernails to discourage nail biting[2]; pairing of some painful event with undesired behavior, pairing the use of an emetic substance with alcohol[3] or pairing unwanted behavior with electric shocks[4].

Pattern of use of aversion can be

1-Negative reinforcement (a.k.a. escape). In this type of reinforcement pattern aversion stimulus is removed after occurrence of the particular desired behavior. In the Skinner Box experiment, the aversive stimulus might be an electric current continuously inside the box; negative reinforcement would happen when the rat presses a lever to turn off the current. This is also known as escape learning[5].

2-Positive punishment ("punishment") when an aversive stimulus is provided to stop some undesired behavior. like in skinner box aversive stimulus will be a shot of current if

it goes to a particular chamber to stop rat entering in that specified box chamber [6].

It is evident from review of journals published in Indian Journal of Psychiatry (IJP) that only about 2% related to use of psycho-social methods of treatment, in comparison to 16% that are published in the British Journal of Psychiatry[7]. It signifies that most psychiatrist in India relay mostly on pharmacological methods of treatment and psychological methods to treat psychiatric illnesses are mostly ignored. This study was planned to incorporate psychological principals in treatment psychiatric illnesses with pharmacological treatment plans to maximize the treatment benefit[8].

Material and Methods

DSM-5 was used for making diagnosis and Dissociative Experiences Scale and Global Assessment of Functioning (GAF) and World Health Organization Quality of Life (WHOQOL)-BREF for evaluating the response of treatment. Mild electric current (30 mili columb) was used in test group along with standard treatment group.

DSM 5 criterion of conversion reaction was used including four criterion

A-One or more symptoms of altered voluntary sensory or motor functioning

B-Clinical findings provide incompatibility between symptoms and recognized neurological condition

C- Symptoms not explained by other physical or mental condition

D-Symptoms producing significant distress in social, occupational or emotional and other area of functioning

Global Assessment of Functioning, or GAF, scale is used to rate the seriousness of mental illness. It use to measure how much a person's mental illness symptoms affect his or her daily life on a scale of 0 to 100[9]. It is a continuous scale and measure psychological, social and occupational impairment due to mental illness. Physical and environmental functioning not rated on it.

100-91	Superior functioning in wide range
90-81	Absent and minimal symptoms
80-71	Transient symptoms
70-61	Some mild symptoms
60-51	Moderate symptoms
51-41	Serious symptoms
40-31	Impairment in reality testing
30-21	Delusion and hallucination present
20-11	Some danger of self /other harm
10-01	Persistent danger of self/ other harm
0	Inadequate information

MICHELE A. PACKARD, suggests that

GAF Score 1 – 30 the patient is a candidate for inpatient care and need high level of psychiatric /psychological help

GAF Score 31 - 69 the patient is a candidate for outpatient care –for pharmacotherapy/psychotherapy

GAF Score 70 - > In most cases, no treatment is needed because the patient is functioning too well to be a candidate for any therapy.

If after getting treatment of one month GAF score of a patient become more than 70, it will be considered as improvement in our study

The World Health Organization Quality of Life (WHOQOL)-BREF

The WHOQOL-BREF has broad groups one is Overall quality of life (QOL) and other is General Health and 24 items divided into four major domains: Physical health domain comprising 7 items (DOM1), psychological health domain contains 6 items (DOM2), social relationships domain contains 3 items (DOM3) and environmental health domain contains 8 items (DOM4)[10].

Statistical analysis

Our research data was analyzed using graphpad instat and spss software. The Student t test was applied to derive statistical significance between compared groups. Division of study (50) and control group (50) was based on simple computer randomization.

Results

By using self-developed socio-demographic profile for data extraction table 1 is made by incorporating the data in appropriate classification module.

Table 1: Sociodemographic features

		Study group n=50	Control group n=50
Age (mean±SD)		23±6	24±7.2
Sex	Male	5(10%)	7(14%)
	Female	45 (90%)	43 (86%)
Religion	Hindu	40 (80 %)	41(82%)
	Muslim	9(18%)	8(16%)
	Other	1(2%)	1(2%)
Education	Illiterate	2(4%)	3(6%)
	undergraduae	32(64%)	30(60%)
	Graduate	6(12%)	7(14%)

GAF score of control group	Subject falling in GAF category	
	Before treatment 0 month	After treatment 1 month
100-91	0	0
90-81	0	5
80-71	0	8
70-61	1	9
60-51	6	5
51-41	11	6
40-31	12	8
30-21	18	9
20-11	2	0
10-01	0	0
0	0	0
Having score more than 70	0	13
Having score less than 70	50	37

2X2 contingency table	Outcome 1	Outcome 2	total
Group 1	0	50	**50**
Group 2	13	37	**50**
Total	**13**	**87**	**100**

Fisher's exact test-The two-tailed P value is less than 0.0001

GAF score of study group	Subject falling in GAF category	
	Before treatment 0 month	After treatment 1 month
100-91	0	0
90-81	0	5
80-71	0	13
70-61	1	19
60-51	8	5
51-41	10	3
40-31	13	2
30-21	12	3
20-11	5	0
10-01	1	0
0	0	0
Having score more than 70	0	32
Having score less than 70	50	18

2X2 contingency table	Outcome 1	Outcome 2	Total
Group 1	0	50	**50**
Group 2	32	18	**50**
Total	32	68	**100**

Fisher's exact test-The two-tailed P value is less than 0.0001

Study and control group treatment outcome compression after receiving treatment

	control	study
Having score more than 70	13	32
Having score less than 70	37	18

2x2 contingency table	Outcome 1	Outcome 2	Total
Group 1	32	18	50
Group 2	13	37	50
Total	45	55	100

Fisher's exact test-The two-tailed P value equals 0.0003.The association between rows (groups) and columns (outcomes) is considered to be extremely statistical ly significant.

World Health Organization Quality of Life (WHOQOL)-BREF scoring data

	Control group N=50	Study group n=50	P
Score on 0(mean±SD)	32±6	33±4	0.3292
Score on 1 month(mean±SD)	67±4	80±4	0.0001

Discussion

It is evident from study results on global assessment of functioning there is improvement after one month of treatment. If we compare control and study groups on global assessment of functioning we can see that improvement after incorporation of aversion therapy was more as compared to control group.

Comparison on world health organization World Health Organization Quality of Life (WHOQOL)-BREF scoring demonstrate the same finding that there is improvement after one month of treatment in both control and study group, and same time the improvement in study group receiving aversion therapy along with standard pharmacotherapy was more.

Conclusion

Aversion therapy when coupled with standard pharmacotherapy is more effective in treatment of conversion reaction related pseudo-seizures. It is than recommended to try as a non-harmful and cost effective way of treatment

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Section Psychiatry

Original Article

A Prospective Study on Association of Social Anxiety in Patients Suffering from Various Clinical Presentations of Acne Vulgaris

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ABSTRACT

Background: *Acne vulgaris is a common illness of adolescence. During adolescence, the importance of body image and the cosmetic problems that this illness may cause, it is important that the level of social anxiety should be studied in acne patients.*
Methods: *100 acne vulgaris cases were included in this study. This study conducted in the department of Psychiatry in Ananta Institute of Medical Sciences and Research Centre. The duration of study over a period of six month.*
Results: *This study showed that amongst acne patients having social anxiety majority had acne lesions localized on face (36,7%), almost all had clinically very severe (100%) acne and none of them subjectively perceived their acne lesions as mild.*
Conclusions*: This study concludes that, clinician's evaluation is objective and more precise and valuable, but the self-perception of a patient has a greater effect on his/her psychological condition.*

Keywords: *Acne vulgaris, Social anxiety, Psychiatric disorders*

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INTRODUCTION

There are several researches on the relationships between dermatological illnesses and psychiatric disorders for a long time. But a few studies have been done on the role of psychological factors on dermatological illnesses.[1] It has been observed that psychiatric and psychological factors play a role in at least 30% of dermatological patients.[2] Apart from this, dermatosis seems to have psychological consequences.[3] Skin diseases may lead to anxiety, depression, or other psychological problems to the same degree as illnesses like arthritis, which may lead to disability. Various factors which are concerned with the patient and illness, such as gender, age, and lesion localization, play a vital role.[4]

It is well known that acne is a chronic inflammatory disease. It is characterized by lesions, such as pilosebaceous gland comedones, papules, pustules, and nodules. Mostly, it starts during adolescence and regresses during the mid-20s. It is more common and severe in males.[5] It has been estimated that almost 85% of adolescents and young adults are in some way affected by it.[6] Among the skin diseases, acne is the most frequently encountered disease. The relationship between acne and psychological factors has been

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investigated for a very long time. Emotional stress can aggravate acne. As a result of having acne, patients may experience psychological and psychiatric problems.[7]

The importance attributed to the theories about the role of psychogenic factors in the pathogenesis of acne is gradually decreasing. The effect of acne on patient emotional wellbeing is still an investigation topic, though research results are inconsistent.[8] Although there are numerous studies that debate the psychological problems and psychiatric symptoms that result from acne. Social anxiety and its related factors have not been studied adequately. Acne vulgaris is a common illness of adolescence. During adolescence, the importance of body image and the cosmetic problems that this illness may cause, it is important that the level of social anxiety should be studied in acne patients.

The purpose of this study was to determine the level of social anxiety in acne patients and to examine its relationship to socio demographics, clinical features, depression symptoms, self-esteem, and negative automatic thoughts.

METHODS

Study population: - 100 acne vulgaris cases were included in this study.

Study Area: - This study conducted in the department of Psychiatry in Ananta Institute of Medical Sciences and Research Centre

Study Duration: -The duration of study over a period of six month.

Data collection: - These patients with definitive diagnosis of acne vulgaris were referred to psychiatrist for further assessment. After exclusion of co-morbid medical and dermatological and pre-existing psychiatric disease taking detailed history; 100 consecutive patients with definitive diagnosis of acne vulgaris, were briefed about the study and recruited after obtaining written informed consent. They were asked to subjectively rate their acne severity on visual analogue scale (VAS). Level of social anxiety was assessed using Liebowitz Social Anxiety Scale (LSAS). Acne related clinical variables (site of lesions, clinical and subjective severity) were noted on specially designed semi structured Performa.

Data analysis:- Data were analyzed by using Microsoft excel.

RESULTS

In our study, 100 total numbers of cases were included. Out of 100, 49% were belonging to 21-25 age group followed by other age group. In the present study,36% had social phobia,39% social anxiety & 32% social avoidance. This study showed that amongst acne patients having social anxiety majority had acne lesions localized on face (36,7%), almost all had clinically very severe (100%) acne and none of them subjectively perceived their acne lesions as mild. However, these clinical variables of acne had statistically non-significant impact on presence of social anxiety.

Table 1: Distribution of cases according to age

Age Group	No. of cases	Percentage
15-20	17	17%
21-25	49	49%
26-30	34	34%
Total	100	100%

Table 2: Distribution of cases according to social anxiety

Social anxiety	No. of cases	Percentage
Social phobia	36	36%
Social Anxiety	39	39%
Social Avoidance	32	32%

Table 3: Impact of clinical variables of acne on social anxiety according to Localization

Localization	LSAS more than cut off Social Anxiety	
	Yes	No
Mostly on Face	33	57
Mostly on Body	2	5
Equally distributed	1	2

Table 4: Impact of clinical variables of acne on social anxiety according to GAGS

Clinical Acne Severity by GAGS	LSAS more than cut off Social Anxiety	
	Yes	No
Mild (1-18)	12	17
Moderate (19-30)	16	38
Severe (31-38)	4	9
Very severe (>39)	4	0

DISCUSSION

The present study was a cross sectional study. This study consisted of 100 consecutive patients diagnosed with acne presenting to dermatology OPD. The age group of 15-30 years was assessed for social anxiety after exclusion of other dermatological, medical and pre-existing psychiatric disease. When the importance of body image and resultant cosmetic problems is considered, it will definitely have impact on level of social anxiety in acne patients. Similar results were found in a study done by Yarpuz AY et al using LSAS, reported that 25.6%, 32.9%, 27.7% of the acne patients scored above the cut-off point of LSAS total scores, LSAS-Anxiety and LSAS-Avoidance subscale respectively.[9] the occurrence of acne in adolescence is at its peak and this is the time when teenagers are learning to form relationships. So, the level of social anxiety is high at this time. Therefore, acne patients may lack the self-confidence to go out with friends and make these bonds. This problem can lead to negative appraisal, feeling of shame and social uneasiness that they would be judged as unattractive by others. Further, they can develop social anxiety and social avoidance and in extreme cases social phobia also.

Ritvo E et al, conducted a survey by interviewing teens they observed that most of the teen respondents who had acne, stay off facebook for a year (59%) or not go on a date for a year (30%).[10] When acne localizes primarily on the face, it has a greater effect on psychological functioning. It causes less distress when it is on the back or the chest, it can be covered with clothing. Korczak et al, showed that frequent recurrence can result in disappointment of acne sufferer especially when lesions are on face.[11] This study found

statistically no significant difference between 3 localization group (face, body and equal distribution) amongst patients with acne having social anxiety. A study by Gupta et al reported that the patients with mild-moderate acne severity experience stress and had social anxiety. Results concluded that for acne to lead to psychological problems it need not be severe.[12] These findings contrast with the findings of our study, in which acne patients having social anxiety had clinically very severe (100%) acne. In another study it was found that patients evaluate the severity level of acne, especially when localized on the face.[13]

CONCLUSION

In the present study out of 100 patients of acne vulgaris, 36% had social anxiety. Patients with clinically and subjectively perceived severe acne had more social anxiety. Though a clinician's evaluation is objective and more precise and valuable, but the self-perception of a patient has a greater effect on his/her psychological condition.

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USE SPIRITUALITY RELATED BELIEFS IN TREATMENT OF PSYCHIATRIC ILLNESSES

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Abstract
Background: Spirituality is a theme of religion and philosophy, which are Humanities and work on empirical principals. Psychology and psychiatry are developed from philosophy but have scientific attitude. Patient care is a complex issue and needs conversion of both of these principles.
Aim: We made an attempt to evaluate that use of spirituality principles in patient's treatment is helpful or not.
Material and methods: Total 510 patients were evaluated. Study group of 260 patients were given spiritual consideration in standard treatment and control group of 250 patients were only given standard treatment. World Health Organization Quality of Life (WHOQOL)-BREF raw score were compared using student t test.
Results: We found that there was significantly more improvement in study group as compared to control group in terms of World Health Organization Quality of Life (WHOQOL)-BREF score.
Conclusion: We arrived at the conclusion that spiritual consideration gives added improvement in treatment of psychiatric illnesses. We should not ignore spiritual beliefs of patients.
Keywords: spirituality, beliefs, psychiatric illness, psychology

Introduction:

Science in itself always use to challenge the existence of god or super natural power, but in every culture there are belief systems which are deeply rooted in spiritual beliefs. Many times these belief systems make persons belief firmly that a particular type of illness is a result of some super natural power like god or demon. This belief can hamper improvement in psychiatric illness on treatment. Psychiatry as a science denies existence of such super natural causes of illness in first glance as a branch of science, but this ignorance creates a grey area where unscientific treatment methods and faith-healing blossom. Religious belief in faith-healing does not depend on any scientific evidence that this can achieve any evidence-based outcome (*Village, Andrew 2005*). If a patient is willing to opt for faith-healing, a psychiatrist has options like one can reject the request, can keep oneself detached from the issue, approve the request and try to understand the practices concerned so as one can make a reasoned decision (Sarkar S, Seshadri 2015). But the choice is mostly towards rejection of request due to lack of understanding of spiritual angle of the treatment.

Some studies show that prayers for patients can speed up their recovery from illnesses (3). Faith healing practices are associated with improving mental well-being (4). On the same ground a systematic review failed to establish that distant healing can be achieved by prayer(5). In this regard despite weak evidence that prayers and faith-based practices have a therapeutic effect, the psychological benefit of such interventions cannot be ignored(6). One study of physicians and patients in an outpatient setting found that 91 percent of patients believe in God, compared with 64 percent of physicians(7).

There is no need to challenge or accept faith-healing on scientific grounds, if it benefits patient even in a minor fraction without any harm, it can be welcomed. Psychotherapy deals with changing maladaptive thoughts to healthy one and for this using spiritual belief system is not a sin. So the thought of spiritual counselling comes in mind. Spiritual counselling is a psychological tool which uses person's spiritual belief system for mental healing.

Western scientific principal that is more modern, denies traditional methods as non-scientific (8) but in highly spiritual countries where spiritual beliefs are so dominating one cannot ignore them in whole. Studies

say that spiritual assessment of patient not only fastens patient's healing but also strengthen the bondage between doctor and patient (9)

Material and Methods

Participants and procedures

Our study was conducted in Udaipur district of Rajasthan, India. In this region people of various religions i.e. Hindu, Muslim, Sikh and Jain are in good number and have high faith in religious rituals. A stratified random sample design was used for data collection and conducting study. HOPE questions and The World Health Organization Quality Of Life (WHOQOL)-BREF were applied at 0, 1 and 6 months interval. Our study spanned 6 months. Total 610 persons visiting in outpatient department (age range 18 to 60) were evaluated. 100 were excluded because they had low score on spirituality scale (HOPE question). Out of this 260 adults were included in study group and 250 in control group. Study group was allowed to incorporate spiritual methods of their own choice in treatment. Control group was strictly refused to go for any type of spiritual treatment (faith healing, prayer, sacred place visit, meeting spiritual guru, etc). Along with this both the groups received standard psychiatric treatment for their disease. Informed consent and ethical committee approval was taken accordingly.

Data collection tools

1. HOPE questions-The HOPE questions were developed as a tool to help practicing doctors begin the process of incorporating a spiritual assessment into the medical interview of their patients. These questions have not been validated by any research. The strength of this approach is that it allows exploration of an individual's general spiritual beliefs and concerns and serves as natural follow-up to discussion of other spiritual support systems (10). The HOPE questions cover the basic areas of inquiry for doctors to use in formal spiritual assessments of their patients

HOPE Approach to Spiritual Assessment

a) Spiritual Resources - What are your sources of hope or comfort?
b) Organized Religion - Are you a member of an organized religion?
c) Personal Spirituality - Do you have spiritual beliefs, separate from organized religion?
d) Effects on Care - Do you wish to consult with a religious or spiritual leader when you are ill or making decisions about your healthcare?
2. The World Health Organization Quality of Life (WHOQOL)-BREF

The WHOQOL-BREF has two items from the Overall QOL and General Health and 24 items divided into four domains: Physical health 7 items (DOM1), psychological health 6 items (DOM2), social relationships 3 items (DOM3) and environmental health 8 items (DOM4)(12).

Statistical analysis

Data was analyzed using graphpad instat and SPSS software. Student's t-test was applied to derive statistical significance.

Results

Self-developed socio-demographic profile was used for data extraction. Table 1 incorporates the data in appropriate classification module.

Table 1: Sociodemographic features

		Study group n=260	Control group n=250
Age (mean±SD*)		29±6	30±7.2
Sex	Male	142 (54.6)	136 (54.4)
	Female	118 (46.4)	114 (46.6)
Religion	Hindu	210 (80.7)	240(96)
	Muslim	49(18.9)	20(4)
	Other	1(0.4)	0(0)
Education	Illiterate	69(26.2)	12(4.8)
	undergraduate	140(53.8)	182(72.8)
	Graduate	52(20)	56(22.4)

*SD – Standard deviation

Persons with high spirituality based on HOPE questionnaire were included and persons with low spirituality were excluded from the study.

	Included in study	Excluded from study	
Subjects	510	100	
HOPE questionnaire response	Spiritual	Non spiritual	
World Health Organization Quality of Life (WHOQOL)-BREF			
	Study group N=260	Control group n=250	P value
Score at 0 month (mean±SD)	45±7	44±9	0.1610
Score at 1 month (mean±SD)	62±4	52±5	0.0001
Score at 6 month (mean±SD)	72±5	60±7	0.0001

Discussion

The study was planned to see the effect of spiritual belief consideration in improvement of psychiatric patients. The persons were first screened for having spiritual beliefs by using HOPE questions. Persons low on spiritual beliefs was excluded from the study. Included patients were classified in study group and control group on the basis of random classification. Study group patients were allowed to use their spiritual methods of treatment along with standard drug treatment provided to them. Control group patients were denied of having any spiritual treatment of their choice and only provided standard drug treatment. Both the groups were provided standard drug treatment based on their respective classification according to international classification of disease 10 (ICD 10).World Health Organization Quality of Life (WHOQOL)-BREF scoring at 0, 1 and 6 month demonstrated gradual improvement in terms of World Health Organization Quality of Life (WHOQOL)-BREF score in control and study groups. Analysis demonstrated more improvement in study group as compared to control group. This difference was statistically significant and not a spurious finding.

Conclusion

This study demonstrated clear cut improvement in study group (62±4) as compared to control group (52±5) after 1 month of treatment. It also demonstrated improvement in study group (72±5) as compared to control group (60±7) after 6 months of treatment. Both the results were statistically significant with p value of 0.0001. This is clear from this study that spiritual belief consideration is very significant for speedy and complete improvement of psychiatric patients and it should be judicially applied in treatment protocol.

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Section Psychiatry

How Stigma and Discrimination are Perceived by Rural or Urban Patients Suffering from Schizophrenia? An Exploratory Cross – Sectional Study from Western India

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Original Article

ABSTRACT

Background: *Stigma is conceptualized as an attribute which is deeply discrediting and makes the person carrying it different from other and of a less desirable kind. Current study aimed to describe the nature and direction of experienced stigma; and discrimination reported by people with schizophrenia.* ***Methods:*** *One hundred and fifty patients diagnosed with Schizophrenia were selected from the Out Patient service of Psychiatry Department of a medical college general hospital. The experiences of stigma and discrimination were assessed using a semi-structured instrument developed by national working group for India by the world psychiatric association steering committee.* ***Results****: Differences were seen between rural and urban respondents. Patients from rural background more often reported these experiences: society treats differently, ridiculing by others, offensive comments, hiding from relatives, rejecting attitude of peoples around, attribution of supernatural cause as most common source of stigma, social exploitation, not fully accepted in the family, pushed into unacceptable social situation and sexual harassment. Reported narratives provided the direct view of these patients.* ***Conclusions****: Stigma experience is pervasive: it deeply affects the social, occupational and emotional wellbeing of patients with schizophrenia and should be included in clinical management. Effective anti-stigma intervention should target on improving attitudes and the condition for social integration in the community, empowering people with schizophrenia to challenge self-stigmatization and discrimination behavior towards them.*

Key words: *Schizophrenia, Stigma, Discrimination, Experiences, Attitude.*

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INTRODUCTION

Schizophrenia is the most debilitating chronic psychiatric disorder which usually affects adolescents and young adults, disrupting pursuit of their educational and occupational goals. The disorder is associated with significant stigma and discrimination, which further increase the burden on these patients and their families. The essence of stigma is a negative and prejudicial attitude toward someone with a mental illness. Many people with mental illness describe the effect of stigma as severe, and more difficult to deal with as compared to the mental health problem itself. Discrimination occurs when people with mental illness are treated unfairly, or are denied their rights because of their mental illness. Individuals with schizophrenia often face social isolation; discrimination in housing, education and employment opportunities, and other forms of prejudice.[1]The stigma often extends to family members and to those who provide health care services to patients with the disorder. Major international studies suggest that schizophrenia has better prognosis in low-income nations and in rural settings.[2-4] The industrialization hypothesis has been advanced to explain this differential outcome which argues that industrial economies and attendant life styles lead to poor support, intolerance, rejection, isolation, segregation and institutionalization of the severely mentally ill.[5] The value placed on the autonomous individual in industrialized settings therefore accentuates social extrusion of the chronic mentally ill patient who assumes personal responsibility for the illness. In consequence, prognosis worsens in urban industrialized settings.

Studies on stigma and mental illness in the Indian setting have focused both on measurements of stigma and on locally important socio-cultural factors shaping stigma.[6-9] Numerous other studies have addressed public attitudes

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towards mental illness.[10-12] The nature, determinants, and consequences of stigma vary across culture and region. Hence, there is a need for studies to understand the stigma specific to a particular region to plan intervention. Better understanding and identification of determinants may suggest ways to reduce stigma and help prevent its adverse consequences.

With this background, this study was aimed to study stigma and discrimination perceived by patients with schizophrenia and, its comparison between rural and urban patients.

METHODS

2.1 Material

This was a cross sectional study conducted at psychiatry OPD of Civil hospital Ahmedabad, Gujarat. Clearance from the institutional review board was taken prior to conducting the study. The sample consisted of one hundred fifty patients diagnosed with schizophrenia independently by two psychiatrists as per criteria laid down by diagnostic and statistical manual (DSM IV-TR). Information from the caregivers and the patient case file along with a mental status examination also were used for diagnostic confirmation. The purpose of the study was explained to patients and their caregivers. The consent of the caregiver was also taken. The patients' responses were recorded.

2.2 Inclusion criteria:

1. A patient with a diagnosis of schizophrenia under continuous remission of at least six-month period according to DSM IV-TR criteria.
2. Provision of the consent.

2.3 Exclusion criteria:

1. Those patients with co-morbid axis I /II disorder.
2. The patient having co-existing medical or substance use disorder other than nicotine.

2.4 Instruments for the study

A semi structured interview developed in an earlier study.[13] This instrument has been used on over 1000 patient in four cities, as a part of the Indian initiative of the world psychiatric program to reduce the stigma and discrimination because of schizophrenia. It consists of two parts: first part of the scale elicits the socio-demographic information of the respondents while second part of the scale measures stigma and discrimination experiences including nature of stigma experiences, attitude of relatives, friends and caregiver, source of stigma, consequences of stigma, patient's view how stigma could be reduced and to what level, comparison of severity of mental illness to other medical illness bringing disability. The verbatim regarding patient's stigma experience in areas like personal, family, social, occupational and in marital life also were recorded.

2.5 Statistical analysis

Both quantitative and qualitative analysis were done using computer. The data from urban and rural areas were compared to find out any difference. Quantitative data was analyzed by t-test and chi-square test. The narratives were read to identify the themes of stigma. For natural and objective analyses, the data were coded manually into constructs that emphasized stigmatizing experiences in various spheres of patient's life.

RESULTS

3.1 Socio-demographic characteristics:

The table 1 shows socio-demographic characters of the sample (N=150).

As shown in Table 1, majority of the patients were male (64%), Hindu by religion (86.6%), of age range 21-30 years (42%), married (49.3%), educated up to class 10th (69.3%), living in a joint family (52%), unemployed (62%), having income under 1000 rupees per month (68%).

Disease related characteristics: Seventy-nine (52.6%) patients (rural=18, urban=61) were having paranoid subtype of the disorder. One hundred thirty-six (90.6%) patients (rural=36 and urban=100) were having duration of illness more than two years.

Table: 1 Demographic characteristic

S. No.	Sample (N=150)	Rural N=39 (26%)	Urban N=111 (74%)
1.	**Religion**		
	Hindu (130, 86.6%)	33 (84.6%)	96 (86.5%)
	Muslim (17, 11.3%)	05 (12.8%)	12 (10.8%)
	Others (3, 2%)	01 (2.5%)	03 (2.7%)
2.	**Gender**		
	Male (96, 64%)	23 (59%)	73 (65.8%)
	Female (54, 36%)	16 (41%)	38 (34.2%)
3.	**Age (years)**		
	21-30 (63, 42%)	20 (51.2%)	39 (35.1%)
	31-40(42, 28%)	08 (20.5%)	34 (30.6%)
	41-50 (28, 18.6%)	09 (23.0%)	19 (17.2%)
	>50 (17, 11.3%)	02 (5.1%)	15 (13.5%)
4.	**Marital status**		
	Married (74, 49.3%)	18 (46.1%)	56 (50.4%)
	Unmarried (39, 26%)	09 (23.1%)	30 (27.0%)
	Divorced (19, 12.6%)	03 (7.7%)	16 (14.4%)
	Other (18, 12%)	09 (23.1%)	09 (8.1%)
5.	**Education**		
	Illiterate (18, 12%)	06 (15.4%)	12 (10.8%)
	Up to class X (104, 69.3%)	24 (61.5%)	80 (72.1%)
	Higher (28, 18.6%)	09 (23.0%)	19 (17.2%)
6.	**Family type**		
	Nuclear (68, 45.3%)	14 (35.89%)	54 (48.6%)
	Joint (78, 52%)	24 (61.5%)	54 (48.6%)
	Other (4, 2.6%)	01 (2.5%)	03 (2.7%)
7.	**Employment**		
	Employed (57, 38%)	08 (20.5%)	49 (44.1%)
	Unemployed (93, 62%)	31 (79.5%)	62 (55.8%)
8.	**Income (rupees per month)**		
	<1000 (102, 68%)	31 (79.5%)	71 (64%)
	>1000 (48, 32%)	08 (20.5%)	40 (36.0%)

Table 2 shows various stigma variables experienced by the patients.

Table 2: Common stigma experienced by patients

Variable	Rural N, (%)	Urban N, (%)	Chi square
Society treats differently	27(69.2%)	60 (54.0%)	X^2=2.73, df=1, p=0.09
Ridiculing by others	29(74.4)	67(60.4)	X^2=2.45, df=1, p=0.11
Offensive comments	30(76.9)	62(55.9)	X^2=5.40, df=1, p=0.02
Hide from relatives	26(56.7)	57(51.3)	X^2=2.74, df=1, p=0.09
Difficulty in getting marriage proposal	09(23.1)	36(32.4)	X^2=1.20, df=1, p=0.27

Table 3 shows various consequences of the stigma and discrimination experienced by the patients. Other findings of the study were as mentioned here. The most common reported source of stigma was attribution of supernatural cause in rural patients (41%) while in urban patients it was

not being able to work due to illness (39.6%). Avoidance was the most common attitude of relatives towards patients in both regions (51.2% rural, 41.4% urban).

Table 3: Consequences of the stigma and discrimination

Variable	Rural N, (%)	Urban N, (%)	Chi square
Avoid disclosing the mental illness histories in jobs/application	03 (7.69%)	21 (18.92%)	X^2=2.71, df=1, p =0.100
Social exploitation	25 (64.10%)	40(36.04%)	X^2=9.26, df=1, p=0.002
Not fully accepted in the family	29 (74.36%)	61 (54.95%)	X^2=4.53, DF=1, p=0.03
Pushed into unacceptable social situation	11 (28.2%)	15 (13.5%)	X^2=4.35, DF=1, p=0.04
Sexual harassment	14 (35.9%)	20 (18.0%)	X^2=5.26, DF=1, p=0.02
Living alone	24 (61.5%)	80 (72.1%)	X^2=1.5, DF=1, p=0.22

Friends and relative either stopped visiting at all or visited less frequently in rural patients (43.5%), while 42.3% urban patients reported that friends and relatives stopped visiting at all. In rural area, patients attributed their illness to faulty biological functioning (33.3%) while in urban area patients accepted that they are mentally ill (45.0%). Mental illness was reported as most disabling illness by 71.7% rural and 54.0% urban patients. Forty one percent rural patients while 34.2% urban patients reported that stigma can be partially cured. Involvement in advocacy activities was reported to be an effective strategy to reduce stigma by 64.2% rural and 55.8% urban patients. Most of the patients (94.8% rural and 77.4% urban) reported that concealing or selective disclosure of the illness is not an effective strategy to reduce stigma. Increasing awareness of the mental illnesses was reported to be an effective way to reduce stigma (69.2% rural, 65.7% urban).

Common stigmatizing verbatim reported by the patients:

I. Common stigmatizing verbatim reported by rural patients:

- "In the society, nobody enquires about me. Nobody loves me. Nobody even looks at me. They call me 'mad', and laugh at me. They don't even invite me at their home on festivals. Due to my illness, my marriage is not getting fixed."

-"In my village when houses were repaired, everybody got the letter but they didn't provide the same for met. Nobody wants to come and meet me. Today I have a broken house to stay pending repair work. I asked for help from my friends and relatives but nobody comes forward. Every times during rain, water comes into my house no body helps me."

II. Common stigmatizing verbatim reported by urban patients:

- "When I fell ill, everyone in my house kept nagging me all day. They didn't give me food. They used to beat me and threw me out of house, when I went to my mother's place, there also people used to nag me. In the beginning, my husband was cooperative, but now he doesn't talk to me much and does not maintain sexual relationship with me."

- "Neighbors don't talk to me. When I go to collect water in the morning, they keep on pushing me, they throw my vessels away. They abuse me and also hit me. My house owner keeps on telling me and my family members to vacant the house."

Consequences of Stigma

I. Experiences related to personal area:

- "I was bright in study prior to the illness, but I quitted my study as I failed in 10th. My memory power went down. My writing is also getting bad. I can't work at my home as I get tremor at my hand. I am unmarried yet, few relative come for my younger sister but when they knew about my illness, they went away."

II. Experiences related to Occupational area:

- "At my work place, people call me "mad". My boss gets angry on me every day and says that my head is empty. He always says me that they will sack me. At lunch hour I am not allowed to have lunch while everybody else is going for lunch. I get half the salary others get."

III. Experiences of stigma and discrimination in Social life:

- "I have one house with 2 BHK in Ahmedabad. When some relatives come to the city, though they stay at my house but nobody of them takes lunch or drinks water at my house. They stay only up to next morning and leave afterwards. Neighbors don't talk to me. They said me that I am mad. They give me work always without giving me any money, and upon asking, they refuse for the money."

- "Before illness, I was living in rented house. I was an inspector in IT department. People used to meet me and respect me, but when owner of the house knew about my illness, he asked me to vacate his house. Today I am living in small house alone. People avoid me."

IV. Experiences related to marital life:

- "Because of illness I am not able to work in my land. My land remains uncultivated. My desire for sex has come to an end. My penis is not erectile any more. Due to this, my wife left me and went to her parents place. Today she has got married to another person."

- "I was married in great pomp. My mental illness started at my in laws place. Initially they used to beat me a lot, they took me to a faith healer, after that they left me to my mother's place. My mother tried for many attempts one after another for my marriage. Every time, as my wife knew about my illness, she divorced me."

V. Experiences of stigma and discrimination in Family:

- "I had to hide my illness because mine and my sister's marriage were at stake. I got married in far Village, but when knew about my illness, they sent back me to my maternal home. I was pregnant at that time. After delivery, they called me back but when I was breast feeding my baby, my mother in law took my baby away and told, "You are mental and the child will also become mental if you breast feed the baby."

- "Nobody takes care of me at home even if I am ill and I need medication regarding this. When I told my brother and father about this, so they became angry on me and said you are mad, go wherever you want to, we do not have time for you"

VI. Impact of illness on General Life

a. Hiding of illness:

- "I have to stay in my house all day hiding my illness. Whenever I come at the window, my mother gets angry on me and directs me to go inside. She tells me that if people will know about my illness then nobody will marry me and my sister."

b. Decrease in Work efficiency and cognitive function:

- "Welding was my profession earlier but today I cannot concentrate on my work properly. I have been injured also because of this."

c. Visiting of Friends and Relative:

- "Since the starting of my illness, people are scared of me and they don't come near me. I had to live alone at home."

d. People's reaction after knowing their illness:

- "If any one comes from my family, they talk only one thing, to take medicine but nobody talks to me more than this. I have to live alone."

e. Most Disabling Illness:

- "Mental health problems should not occur. It becomes difficult to work. I am feeling better till I take medicine but my memory is decreasing. Nothing is remembered. I have to take pills to sleep in night."

DISCUSSION

The present study was aimed to study stigma and discrimination perceived by patients with schizophrenia and, its comparison between rural and urban patients. Majority of the patients were male, Hindu by religion, of age range 21-30 years, married, educated up to class 10th, living in a joint family, unemployed, having income under 1000 rupees per month. Findings of present study revealed that patients from rural background had more often stigmatizing and discriminating experiences compared to patients from urban background.

In our study, 62% patients were unemployed. Due to unemployment and chronic nature of illness, patients are not able to do their work as efficient as of their same age group in the society, which becomes the main culprit associated to creation of stigma. Stigmatization in the workplace and the related denial of access to job are the most important experiences of social exclusion. These experiences are recognized as the main factors producing and maintaining a high rate of unemployment among those with schizophrenia. In our study too, 21 (18.9%) urban and 3 (7.6%) rural patients reported avoiding disclosure of mental illness histories in job/applications.

In the present study, patients from rural background more often reported these experiences: society treats differently (p=0.09), ridiculing by others (p=0.11), offensive comments (p=0.02), hiding from relatives (p=0.09). Jadhav S et al also reported that rural Indians show significantly higher stigma scores.[14] Similar to our study an Indian study by Loganathan S et al reported that rural respondents experience more ridicule, shame, and discrimination but they reported that urban respondents feel the need to hide their illness.[15] Fear of rejection may be a need to hide their illness from others particularly in rural areas. In our study, more urban patients reported difficulty in getting married compared to rural patients (p=0.1). Weiss et al,[16] studying psychiatric stigma across cultures, pointed out that "in Bangalore the main concerns the sample had, were related to lowering their own chance of entering a good marriage and decreasing the chance of one of their relatives". Disclosing the diagnosis of schizophrenia becomes stigmatizing due to fear of being ridiculed, discriminated, leading to loss of job or not being able to get a job, and difficulty in getting married for the patient as well as family members. So, family members handle with it by hiding the diagnosis or not disclosing the presence of illness.

In our study, more rural patients reported social exploitation (p=0.002), not fully accepted in the family (p=0.03), pushed into unacceptable social situation (p=0.04), and sexual harassment (p=0.02) as a consequence of stigma and discrimination compared to urban patients. Jadhav et al also found that rural Indians showed a more stigmatizing attitude towards severe mental illness. Their study also showed greater stigma and a punitive attitude amongst rural Indians as compared to urban Indians.

In our study, rural patients reported attribution of supernatural cause as the most common source of stigma. Studies support this finding that in rural areas, the frequent association of mental illness with malevolent spiritual forces induces many families with a member with mental illness to seek help from shamans.[17,18] In rural areas, lack of adequate education regarding mental illnesses leads to such beliefs. Jadhav et al also concluded that urban Indians have a more liberal and tolerant attitude but were also more excluding of those with mental illness at work.[14] In our study too, not being able to work due to illness was the most common reported source of stigma in urban patients (39.6%).

In our study, rural patients reported rejecting attitude of peoples around while urban patients reported nagging and uncooperative attitude of the family members and society. Stigma led to painful experiences related to patient's personal and occupational area, social life, marital and family life. Fact of hiding the diagnosis of schizophrenia was also reported by the patients. Resulted decrease in cognitive functioning and impaired work efficiency also was reported by the subjects. The extent of the discrimination due to the illness resulted in stopped or less frequent visiting of the friends and relatives to the patients. The people around made either limited or no communication with the patients. Patients reported schizophrenia as the most disabling illness of all the illnesses.

Lack of correct knowledge is the variable associated with more stigma responses. Setting up programs directed towards modifying the attitudes of employers, as well as greater attention to the employment-related training of social workers could constitute useful instruments to improve labor market access for people with schizophrenia. These programs should help convincing employers that people with schizophrenia are highly motivated and can provide important contributions. At the same time, people with schizophrenia might need specific support in re-entering the labor market, such as Individual Placement and Support (ISP) Programs [19, 20]. Better integration in the labor market has been shown to improve clinical outcome[21-23] and reduce the risk of hospitalization.[24]

Stigma and negative public attitudes for a patient with schizophrenia is widely prevalent both in rural as well as urban areas. Therefore, while patients continue to consider stigma as a central obstacle to their integration into the community, they themselves contribute to this process by accepting public stereotypes as applicable to themselves. As a result, majority of them don't confront negative reaction, and lose self-esteem, isolate themselves and get worse. Our data from patient verbatim also highlighted that patient focus on the stigmatization experiences and on their ideas of the cause of stigma; while hardly offering any suggestions for anti-stigma intervention. Suggestion of participant mainly concerned the improvement of information on mental health issues among the public (66.7%). Participant did not seem to envisage many opportunities for positive change and found it difficult to formulate specific proposal on what could be done to improve their situation. Sorting out this difficulty might help reducing perceived stigma, discrimination and their consequences. Spending more time with a patient, may reduce stigmatizing and discriminating attitude presumably through the mechanism of exposure induced reduction of negative stereotype about the mental illness. Alexander & Link concluded that increasing personal contact with psychiatric patient could reduce people's stigmatizing

attitudes.[25] Couture & Penn also concluded that both retrospective and prospective contact tends to reduce stigmatizing views of persons with a mental illness.[26] Our findings suggest that people with schizophrenia are not fully accepted in the family, especially in rural areas. This suggests that certain factor could be more powerful than negative stereotypes in interpersonal stigmatization which can be overcome by provision of the scientific knowledge of the mental illnesses and re-integration of the patient in the community through psychosocial approaches.

Similar to our findings, Chinese families too, frequently concealed the mental illness of their members.[27] Family members act as both stigmatizer as well as victim of stigmatization themselves.[28] Because of this paradoxical role dualism, family members might project their anger towards a patient for causing them added suffering. This negative affective state, we suspect, could heighten the chronic burden of care. Providing adequate non-pharmacological measures may help family members in such circumstances of negative affective state. Provision of psychiatric care must move beyond symptoms control to diminish intentional as well as subtle forms of stigmatization in the patients' social life. Effective anti-stigma intervention should target on improving attitudes and the condition for social integration in the community, empowering people with schizophrenia to challenge self-stigmatization and discrimination behavior towards them. Regarding the work-related stigma, we believe that a combination of corporate education programme, legal measures and advocacy efforts are needed.

CONCLUSION

Stigma experience is pervasive: it deeply affects the social, occupational and emotional wellbeing of patients with schizophrenia and should be included in clinical management. Higher level of stigma is related to low education level, unemployment status. The provision of accurate information through trusted community sources and open dialogue may help to dispel myths, correct faulty assumption and increase the involvement of participation of community in dragging out the root source of stigma. Family programmes should be started early in an attempt to reduce stigma from significant others and to transform the family into a long recourse for psychiatric rehabilitation. Effective anti-stigma intervention should address chiefly two targets: improving attitudes and condition for social integration in the community and; empowering patients with schizophrenia to challenge self-stigmatization and discriminatory behavior towards them.

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Gender differences and suicide intent among patients with depression

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Abstract
Suicide is a word that many people like to avoid. Talking about suicide makes most people cringe and makes them very uncomfortable. Suicide affects teenagers and young adults around the globe each year. There are well-documented gender differences in adolescent suicidal behavior; death by suicide is more common in males, while nonfatal suicide attempts are more common among females. Over the past three decades, researchers have documented the effectiveness of a myriad of suicide prevention initiatives. However, there has been insufficient attention to which types of suicide prevention interventions are effective in changing attitudes and behaviors for young males and females. The aim of the study was to assess the level of Suicide Ideation among male and female patients of depression. The sample of 70 patients suffering from depression were selected from the OPD and IPD of Department of Psychiatry, Pacific Institute of Medical Sciences (PIMS), Udaipur on the availability basis. Beck Scale for Suicide Ideation (BSS) was administered on the male and female patients suffering from depression. The scoring of the tests was done according to the manual. Results showed that female patients suffering from depression were found to perceive more suicidal ideation and intent as compared to the male patients suffering from depression. It was concluded that intervention strategies must be prepared for the depressive disorder patients along with the other treatment strategies.

Keywords: male, female, depression patients, suicide ideation

Introduction
Suicide is a leading cause of death and a significant mental health problem worldwide [1, 2]. Suicide is defined as death caused by self-directed injurious behavior with any intent to die as a result of the behavior [3]. Adolescence is a period of marked risk for suicidality [1]. For youth between the ages of 10 and 24, suicide is the third leading cause of death, significantly superseding the rate for adults aged 35 to 54 [4]. Males are more likely to die as a result of suicide: the male-to-female ratio of death by suicide is four to one in the U.S. [1, 2, 4].

Suicide attempt is defined as a non-fatal self-directed potentially injurious behavior with any intent to die as a result of the behavior; a suicide attempt may or may not result in injury [3]. In almost all regions of the world, nonlethal suicide attempts are more common in females [2]. Males are more likely to use more lethal means than females, partially accounting for the different pattern for suicidedeaths and attempts [1, 5]. Gender differences also exist in attitudes about suicide with males tending topossess more maladaptive attitudes about suicide than females [6]. These patterns are evident across development from adolescents to elderly adults [1, 7], yet are generally more robust among individuals 15 to 29 years of age [2].

Taking into consideration such robust gender differences, one might expect that validated approaches to suicide prevention would also commonly consider gender differences when planning and evaluating the effects of interventions. Unfortunately, there has been insufficient attention to individual differences in risk for suicidality and intervention response [8]. Prominent reviews of suicide prevention literature have rarely focused on the role of gender [5, 9]. Recently, this oversight has been identified by Klimes-Dougan, Klingbeil, and Meller [10], who called for further inquiry into the issue of gender differences in suicide prevention programming.

Review of literature
Perhaps the strongest evidence of gender differences in response to curricula was reported in the work of Shaffer *et al.* [11]. A pretest-posttest design was used to evaluate a suicide prevention program in four high schools. The program consisted of a mixture of teacher instruction and discussion. Few positive effects of the program were found. Having participated in the intervention, male suicide attempters were significantly more likely to feel that the program "will make it harder to deal with my friends' problems," and were significantly more likely to "know someone who was upset a lot by the program." More males than females who had attempted suicide and more male non-attempters found the programs boring. Attempters exposed to the program were less likely to recommend the presentation of the program to other students and were more likely to agree that talking about suicide "makes some kids more likely to try to kill themselves." These results were highly controversial, leading some to question the utility of curriculum programs.

Within a college student sample, Garlow*et al.* [12] assessed the results of the American Foundation for Suicide Prevention College Screening Project at Emory University. A nine-item depression module measured suicidal ideation, past suicidal attempts, episodes of deliberate self-harm, and

symptoms of distress. Although more females (n = 519) than males (n = 205) volunteered to participate in this study, a larger proportion of male respondents (14.6%) were willing to report suicidal ideation than females (9.83%). The authors hypothesized that the emphasis of depression in the screen may have caused the female-rich sample and suggested that an emphasis on anger or stress may have been more successful in attracting male participants [12].

A study by Miller, Coombs, Leeper, and Barton [13] compared several central city counties in the United States in a) suicide mortality rates, and b) presence and frequency of suicide prevention centers, crisis centers, and mental health facilities. Using data from the National Center for Health Statistics, the authors focused on regions that had recently initiated prevention centers *versus* counties in which the number of centers remained the same. They found that the implementation of suicide prevention centers favorably impacted and minimized suicide rates in white females younger than twenty-four years of age, the most frequent callers to crisis centers. Counties in which the number of centers remained stagnant housed increased mortality rates for both males and females [13].

Methodology

Objectives

The objective of the present research work was to assess the level of Suicide Ideation among male and female patients of depression.

Hypothesis

There will be a significant difference between the level of Suicide Ideation among male and female patients of depression.

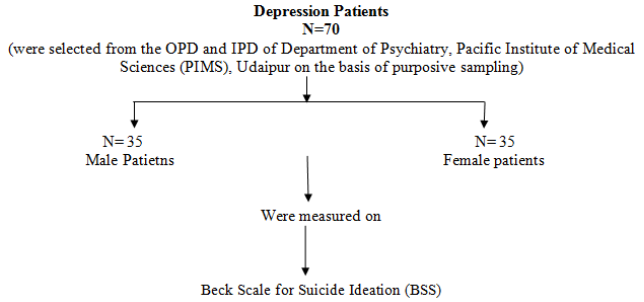
Variables

- Male patients of depression
- Female patients of depression
- Suicide Ideation

Sample

The sample of 70 patients suffering from depression were selected from the OPD and IPD of Department of Psychiatry, Pacific Institute of Medical Sciences (PIMS), Udaipur on the availability basis. The sampling technique used was purposive sampling and the sample was randomly selected as per the inclusion criteria.

Research Plan



Inclusion Criteria

The sample was further limited to -

1. Patients of the age range of 20-40 years were taken.
2. Patients with 1- 3 years of duration of illness were included.
3. The locale of the study was Udaipur city of the State of Rajasthan.
4. Informed consent.

Exclusion criteria

1. Patients having the treatment history of less than 1 month.
2. Uncooperative patients were excluded.
3. Patients having any other comorbid mental or physical illness were excluded.

Tools Employed

- Beck Scale for Suicide Ideation (BSS) [14]

Procedure

After deciding the research plan, design and sample, rapport was established amongst the patients. Tests were administered on the male and female patients on the basis of the study. Beck Scale for Suicide Ideation (BSS) was administered on the male and female patients suffering from depression. The scoring of the tests was done according to the manual. Results and interpretations were carried out according to the data obtained after statistical analysis.

Controls

1. In order to manage the bias due to order of the items of the scale, the scale was administered in the random order.
2. To control the extraneous variables all, the testing work was done by the investigator himself.
3. The confidentiality of the results was assured.

Statistical Analysis

For analyzing the data for assessing the suicide ideation of male and female patients suffering from depression, Frequency, Percentage and other descriptive statistics were used.

Results and Discussion

The purpose of the study was to assess the level of suicide ideation among male and female patients of depression. The sample of 70 patients suffering from depression were selected from the OPD and IPD of Department of Psychiatry, Pacific Institute of Medical Sciences (PIMS), Udaipur on the availability basis. The sampling technique used was purposive sampling and the sample was randomly selected as per the inclusion criteria. The Becks Suicide Ideation Scale was administered over these patients to basically assess the impact of depression and gender on the frequency of the occurrence of suicidal thoughts. The results obtained were tabulated and the interpretation was drawn as follows-

Table 1 highlights the number of respondents taken into the study, it may be seen that total 70 patients were selected from the IPD and OPD where 35 were female and 35 were male. When male patients were taken into account, 20 male patients and 20 female patients were included under the age group of between 20-30 years and 15male patients and 15 female patients were in the age groups of 30-40 years. When the duration of illness was considered, out of the 35 male and 35 female patients suffering from depression, 10 male and female patients out of them were having the duration of illness of 1-2 years whereas 25 of the male and female

patients suffering from depression were between the duration of illness of 2-3 years.

After the administration of BSS, the results were quite significant. The data was tabulated in table 2 where it may be clearly observed that patients perceive a great deal of problems and feel sad, hopeless and worthless. This pressure overpowers their mind to a lot of extent which makes them feel like nothing can support them, they have no future and the only was left now is to quit.

Table 1: Showing sample distribution of patients suffering from depression.

S. No.	Category	Gender				Total
		Male (N=35)		Female (N=35)		
		Freq	%	Freq	%	
1.	Age (20-. yrs)	20	28.5%	20	28.5%	40
2.	Age (30-40 yrs)	15	21.4%	15	21.4%	30
3.	DOI (1-2yr)	10	14.2%	10	14.2%	20
4.	DOI (2-3yr)	25	35.7%	25	35.7%	50

Table 2: Indicating percentage of depressive patients suffering from high, medium and low level of suicide intent.

Class	BSIS		
	Category	Frequency	Percentage
Male	High	9	25.7%
	MEDIUM	15	42.8%
	LOW	11	31.4%
	Category	Frequency	Percentage
Female	HIGH	14	40%
	MEDIUM	12	34.2%
	LOW	9	25.7%

As seen from the table, majority of the male patients perceived medium (42.8%) and low (31.4%) level of suicide ideation. It was seen that 25.7% of the male depression patients had high level of suicide ideation. The results indicated that male patients suffering from depression do perceive suicide ideation.

When level of suicide ideation of female patients suffering from depression was examined, it was found that 40% had high and 34.2% perceived medium level of suicide ideation. Only 25.7% of the female patients were seem to have low level of perception towards suicide intent. The Results clearly indicate that 68.5% of the total male patients perceived suicidal thoughts during depression and 74.2% of the female patients suffering from depression were found to have high and medium level of suicide ideation in their lives. The data obtained do indicate that female patients perceive more suicidal thoughts in comparison to male patients. More female patients were seeming to have high level of suicide ideation as compared to male patients.

Similar study was conducted by Li *et al*., (2019) [15] where it was found that Major depressive disorder (MDD) is associated with high risk of suicide. Conventional neuroimaging works showed abnormalities of static brain activity and connectivity in MDD with suicidal ideation (SI). However, little is known regarding alterations of brain dynamics. More broadly, it remains unclear whether temporal dynamics of the brain activity could predict the prognosis of SI. The study suggested that alterations of temporal variability in regions involved in executive and emotional processing are associated with SI in MDD patients. This novel predictive model using the dynamics of intrinsic brain activity could be useful in developing neuromarkers for clinical applications [15].

Thus, it may be said that along with the treatment for depression, the patients should also be given some intervention to reduce the occurrence of suicidal thoughts among the patients. proper counselling, guidance and treatment for both depression and eliminating any self-harm behavior may be given to the patients to decrease the incident of suicide.

Conclusions

It may be concluded by the results obtained that people in the India, are facing a lot of pressure from their external surroundings for performing well. This pressure is becoming one of the major factors in discouraging the person and increasing hopelessness which leads to increase in the level of suicide intent. Thus, major steps should be taken against changing the perception of the public.

Implications

Based on the above discussion, many strategies and directions may be advised for future researches in this area such as: -

1. Further studies are needed with larger sample size and deeper evaluation to generalize the result.
2. Some other variables may be included to achieve better information on the topic.
3. Further interventions and follow ups may be given to such students and feedback may be taken.
4. Training may be provided to these students on the certain technique of stress management and medication which insure longevity and would enhance quality of life.
5. Counseling strategies may be offered for enhancing physical, mental, emotional and cognitive state of these patients.

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Original Research Article

Examining the role of Duration of illness on the level of mental disability in Obsessive Compulsive Disorder

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Abstract

Recent literature considers duration of illness (DI) and duration of untreatedillness (DUI) as important factors influencing outcome in many psychiatric conditions. The aimof the present article is to analyze the relationship between DI and DUI, and pharmacologicalresponse in the different psychiatric disorders with particular emphasis on neurodegenerativeaspects. An updated review of the current literature was conducted through PubMed in orderto compare different studies focused on DI and DUI, and treatment response in major psychosesand in depressive/anxiety disorders. A significant body of evidence shows that a prolongedDI and DUI is associated with brain abnormalities and poor treatment response, particularly inschizophrenia. Nevertheless, an increasing number of studies point toward a similar conclusionin mood and anxiety disorders as well, even though fewer studies have been published in thisfield. The present study was undertaken to assess and compare the disability in patients with obsessive compulsive disorder (OCD) using Indian Disability Evaluation Assessment Scale (IDEAS). Results indicated Significant disabilityin work and global score was seen in patients of obsessive-compulsive disorder with duration of illness >5 yr. it was concluded that these illnesses affect all areas of daily functioning leading to greaterdisability, and thus increasing the burden on the family, pose greater challenge for therehabilitation of patients and their inclusion in the mainstream of the family and society. Furtherstudies on a larger sample need to be done to confirm the finding.

Keywords: obsessive-compulsive disorder, Indian Disability Evaluation Assessment Scale, duration of illness, disability.

Introduction

Disability associated with psychiatric disorders is considered an important public health problem in developing countries like India [1]. Disability due to psychiatric illness refers to dysfunction or inadequate performance in specific activities of daily living which are normally expected from a person according to his age, sex and societal role [2].

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About one-third of patients having Major Depressive Disorder (MDD) and Bipolar Affective Disorder (BPAD) have a severe disability. Self-care and work were the dysfunctional areas in MDD while BPAD affected all areas of functioning [3,4].

Non-psychotic disorders such as OCD also run a chronic course and can cause disability. It is reported that about 16-17% OCD and anxiety disorders result in significant disability [3]. However, Olfson et al., did not observe any significant disability in OCD [5]. OCD is the only non-psychotic illness for which the government of India sanctions disability benefits. Effective treatment and the issue of monetary benefit for the disabled by the government assume importance

in this context. In this background, it is important to assess the extent of disability in OCD.

Obsessive Compulsive Disorder (OCD) is characterized by recurrent obsessions or compulsions that are severe enough to be time-consuming or cause marked distress or significant impairment and is given disability benefits as per the existing Indian disability act.

Psychiatric disorders are one of the most common and prevalent illnesses that widely affect world population accounting for nearly 31 per cent of world's disability. Five of the 10 leading causes of disability worldwide are in the category of mental disorders: major depression, alcohol use, bipolar affective disorder, schizophrenia and obsessive-compulsive disorder[6]. Psychiatric illnesses like schizophrenia, bipolar affective disorder and obsessive-compulsive disorder, impact negatively on the academic, occupational, social and family functioning of the patients.

It has been demonstrated that in the patients of mood and anxiety disorders, residual disability and poor quality of life continue even after completion of symptom-linked treatment[7,8]. There is amelioration of symptoms with pharmacotherapy, but social functioning and quality of life improve only with concerted efforts at rehabilitation that take longer intervals of time[9].

There is limited available literature which assessed disability among non-psychotic illnesses in Indian setup. However, there are some community-based studies to assess mental disability in mental disorders [10]. Hence, the present study was planned to assess disability in OCD.

Methodology

Patients attending outpatient section of Department of Psychiatry, Pacific Institute of Medical Sciences, Udaipur, Rajasthan, India, were screened to include in this cross-sectional study. Those diagnosedto be suffering from schizophrenia and obsessive compulsive disorder by ICD-10 DCR [11], with duration of illness of minimum two years without any exacerbation or hospitalization, and accompanied with a primary care giver were assessed further.All patients with co-morbid medical andpsychiatric illness, likely to contribute in disability,were excluded. Informed consent was taken from theprimary care giver. The target was to include about 30 consecutive patients for each illness. IDEAS wasapplied in all the patients who fulfilled the selection criteria to measure the disability.

A total of 27 patients of (27 with obsessive-compulsive disorder) wereincluded in this study. Of the 30 patients of obsessive compulsive disorder initially included, 3 patients were excluded as they were found to have conditions likely to cause disability per se (one had a seizure disorder, another had a history of intermittent excessive alcohol abuse, and the third one developed severe anxiety symptoms).

Results and Discussion

Many patients with OCD were from urban background in our study. The poor representation of rural population may be due to the inability to understand this being an illness. It has been shown that obsessive-compulsive disorder produces a significant impact on daily living. [12,13]

Table 1: Socio-demographic characteristics of patients with obsessive-compulsive disorder

Category	Sub-divisions	OCD No.	Percentage (Round off)
Age groups	16-30	14	52
	31-45	11	41
	46-50	2	7
Gender	Male	15	56
	Female	12	44
Domicile	Urban	18	67
	Rural	9	33
Religion	Hindu	21	78
	Muslim	6	22

Table 2: Assessment on various items of IDEAS in patients of obsessive-compulsive disorder between duration of illness 2-5 yr and >5 yr

Duration of illness	Self-care	Interpersonal Activities	Communication and Understanding	Work	Global Disability score
2-5 years (N=8)	0.2 ± 0.1	0.63 ± 0.52	0.75 ± 0.89	0.50 ± 0.53	3.13 ± 0.83
>5 years (N=19)	0.58 ± 0.96	1.16 ± 0.9	1.52 ± 1.02	1.79 ± 1.18*	7.95 ± 3.34**

Values are mean ± SD

P *<0.01, **<0.001 compared to those with OCD (2-5 year duration)

In our study, there was more work impairment in patients with OCD with duration of illness more than 5 years than in patients with duration of illness between 2-5 year; this however, needs confirmation in a larger sample. The factors responsible for deterioration inthe working ability of patients with obsessive compulsive disorder need to be explored in further studies. The disability produced in areas of self-care, interpersonal activities and communication and understanding remained stable over the time. Koran et. al[14]reported that 22 per cent of OCD patients were unemployed, however, Khanna et. al [15]did not substantiate the same findings. Notably these twostudies did not include the patients with duration ofillness more than 2 yr.

Other workers [17,18]also reported that patients with OCD had greater disruption on their careers and relationships with family and friends. However, in these studies [16-18], no attempt was made to match the patients on the basis of duration of illness.

It appears that the instrument IDEAS is sensitive enough to pick up disability even at mild severity of illness. However, results of our study should be interpreted with caution. This was a cross-sectional small sample study, based on exclusively hospital-based outpatient sample, and therefore, is not likely to be representative sample of patients in community. Moreover, the premorbid assessment using standardized instruments was not carried out. The relationship between disability and socio-demographic variables like family structure, family income etc., needs to be evaluated in further studies.

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RESEARCH ARTICLE

PREVALENCE OF ABNORMALITIES DETECTED BY MAGNETIC RESONANCE IMAGING (MRI) IN PATIENTS WITH KNEE TRAUMA AT A TERTIARY CARE TEACHING HOSPITAL OF SOUTHERN RAJASTHAN

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ABSTRACT

Background: Magnetic Resonance Imaging (MRI) is the most commonly used imaging modality in the evaluation of knee injuries. So, this study was planned to use MRI in determining the incidence of knee lesions in traumatic knee patients and their relation with the age and sex of the patients.
Materials and Methods: This prospective study was performed for a period of 1 year after taking the permission from institutional ethics committee in a tertiary care teaching hospital. Patients referred to the Department of Radiology with post traumatic knee joint symptoms were recruited. Patients' socio-demographic data, clinical history and physical examination findings were recorded to correlate the findings. MRI Acquisition Knees were imaged by using Siemens Avanto MR machine with a superconducting magnet and field strength of 1.5 tesla using dedicated knee coil (Flex).
Results: Total 63 patients were examined by MRI and the most common age group was found to be 21-30 years. 88.89% knee lesions were found in male. Joint Effusion was found to be most frequent lesion in symptomatic knee constituting 94.64%. Amongst the ligament injury, ACL was found be highest approximately 50% in patients with complete tear in 57.14%. Amongst the menisci injury medial meniscus injury was found be highest approximately 72.72 % with grade III in 43.75%.
Conclusion: MRI was found to be good diagnostic tool for evaluation of traumatic knee lesions.

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INTRODUCTION

The knee joint is the largest and most heavily loaded joint of the human body (Potocnik *et al.*, 2008). In the knee joint, the bones, cartilage, menisci, joint capsule, ligaments, muscles, and tendons interact in a unique manner, providing both stability and mobility (Brantigan and Voshell, 1941). The knee is one of the most frequently injured joints and at the time of injury to knee joint these structures are vulnerable to be affected, some are easily and frequently affected during injury and some are rarely (Beynnon, 1998; Ryder *et al.*, 1997). Different techniques have provided a tremendous amount of information about degeneration, prevention and treatment of disorders and injuries in the knee. (Potocnik *et al.*, 2008; Pena *et al.*, 2006)

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Compared to arthroscopy, which is considered the reference standard, the sensitivity and specificity of MR images are high for detecting abnormalities in knee joints (Oei *et al.*, 2003; Vincken *et al.*, 2002). So, MRI is the most commonly used imaging modality in the evaluation of the knee joint, and has an acceptable accuracy in the detection of menisci and anterior cruciate ligament (ACL) injury (Crues *et al.*, 1987). MRI produces excellent pictures of articular cartilage, synovium and bone marrow that might be expected to produce information that correlates better with the patient experience of symptoms and guides treatment planning. From all knee soft tissue structures, the ligaments and joint capsule are the most frequently injured structures (Beynnon, 1998). Knee pain and related symptoms may come as a result of damage to one or more of the soft tissue structures that stabilize and cushion the knee joint. Post traumatic knee complaints are the most common reason for patients to come in hospital. Traumatic knee complaints can be caused by e.g. bone bruise, fracture,

and/or soft tissue injuries such as lesions of menisci, cruciate ligaments, collateral ligaments and muscles (Oei *et al.*, 2003; Belo *et al.*, 2010). MRI showed a sensitivity of 86%, 91%, 76%, a specificity of 95%, 81%, 93% and an accuracy of 93%, 86%, 89% for anterior cruciate ligament, medial and lateral meniscus lesions respectively (Crawford *et al.*, 2007). There are no data available on prevalence of such lesions in our institute and also this type of study was not conducted in this region of Rajasthan. So, this study was planned to determine the incidence of common knee lesions in symptomatic knee injury patients by using MRI.

MATERIALS AND METHODS

This prospective study was carried out for a period of 1 year after taking the permission from institutional ethics committee. A total of 63 patients referred to the Department of Radiology with post traumatic knee joint symptoms were recruited. Informed consent was obtained after explaining about the nature of exam and also the socio-demographic data, clinical history and physical examination findings were recorded to correlate the findings. Patients who had no clinical evidence of knee joint involvement were not included in this study.

Procedure

MRI Acquisition Knees were imaged by using Siemens Avanto MR machine with a superconducting magnet and field strength of 1.5 tesla using dedicated knee coil (Flex). Each examination consisted of the following: coronal intermediate-weighted (repetition time msec/echo time msec, 2200/20) and T2- weighted (2200/80) dual spin-echo images (number of signals acquired, two; section thickness, 5 mm; intersection gap, 0.5 mm; field of view, 160 mm; acquisition matrix, 205×256; and number of sections, 18), sagittal intermediate-weighted (2200/20) and T2- weighted 4 (2200/80) dual spin-echo images (number of signals acquired, two; section thickness, 4 mm; intersection gap, 0.4 mm; field of view, 160 mm; acquisition matrix, 205×256; and number of sections, 20), sagittal three dimensional T1- weighted spoiled gradient-echo frequency-selective fat suppressed images (46/2.5; one signal acquired; flip angle, 40°; section thickness, 3 mm; section overlap, 1.5 mm; no gap; field of view, 180 mm; acquisition matrix, 205×256; and number of sections, 80), and transverse intermediate weighted (2500/7.1) and T2-weighted (2500/40) turbo spin echo fat-suppressed images (number of signals acquired, two; section thickness, 2 mm; no gap; field of view, 180 mm; acquisition matrix, 205×256; and number of sections, 62). Total acquisition time, which included the initial survey sequence, was 30 minutes. Protocol of examination was in line with European society of musculoskeletal radiology (ESSR). It starts with the patient in supine position and slightly externally rotates the foot by about 10-15 degrees to stretch the anterior cruciate ligament. Pack some cushions around the knee to help it stay motion free. A small cushion under the ankle helps to keep the leg straight. Evaluation of the knee including the patello-femoral joint, medial and lateral compartments as well as related tendons and ligaments and the popliteal fossa is performed with a high resolution proton density sequence acquired in 3 planes: Axial, Sagittal and Coronal. Evaluation of bone marrow for contusion requires a T2 fat saturation sequence in either coronal or sagittal planes. If the patient has a suspicious mass then T1 fat saturation images are helping to determine if the mass is benign or malignant and better delineate its full extent. Obtained MRI images were diagnosed by an experienced musculoskeletal radiologist for the presence of ligament injury, tear, strain and laxity, as well as menisci degeneration and tear, Joint effusion, subchondral and bone marrow edema, bony contusion, bursitis, baker cyst and tumor were noted in all patients.

Statistical analysis

Data were expressed in percentages in comparison tables and graphs. Statistical analysis was performed using Microsoft Excel Software and the standard Statistical Package for the Social Sciences version 15 for windows.

RESULTS

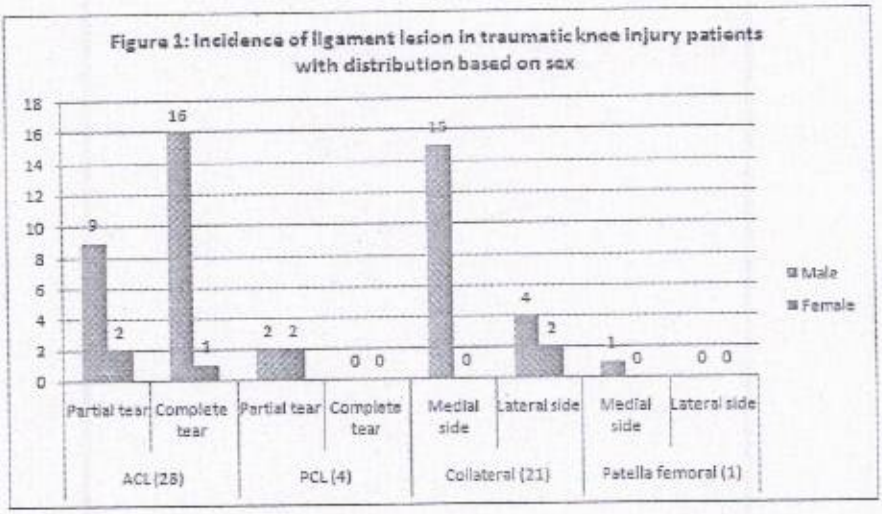
Total 63 patients were recruited with in a study period of 1 year. MRI of symptomatic or traumatic injured knee was conducted. Of these 63 patients 56(88.89%) were male and 7 (11.11%) were female, with male to female ration of 8:1. Mean age of the patients was 31 years (range 11 to 59 years). They were classified into age groups and out of these groups 28 were found to be in age group between 21-30 years. In this age group 2 were female and 26 were male patients. Table 1 Effusion was most frequently found in symptomatic knee constituting 94.64% followed by bone marrow edema (69.64%), and ACL (50%). Patello femoral ligament injury (1.79%) was found to be least affected Table 2. Figure 1 shows the incidence of ligament lesion in the form of partial/complete tear or medial/lateral side injury and figure 2 shows menisci injury in different grades. These injuries are distributed according to sex.

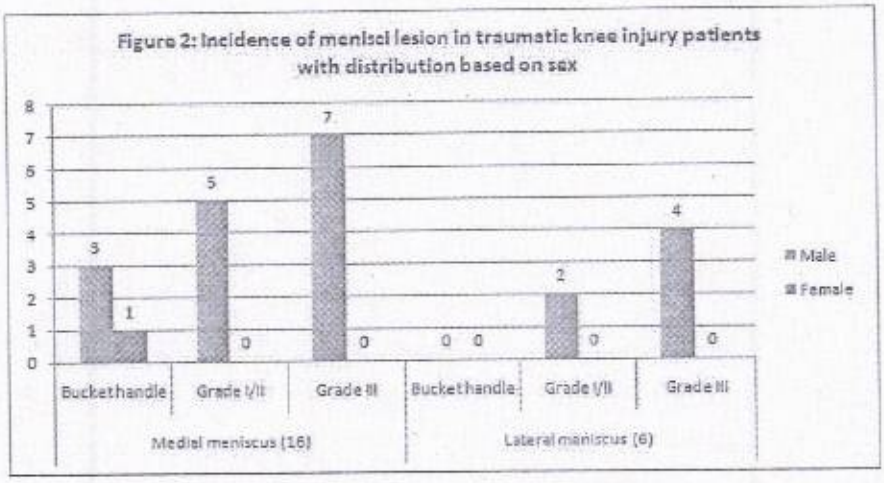
Table 1. Distribution of patients according to age and sex

Age group	Male	Female
<10	0	0
11-20	8	2
21-30	26	2
31-40	13	1
41-50	6	2
51-60	3	0
>60	0	0

Table 2. Incidence of all lesion detected by MRI in traumatic knee injury patients

Sr. No.	Knee lesion	Male	Female	Total Patients (56)
1	Anterior Cruciate Ligament (ACL)	25	3	28 (50%)
2	Posterior Cruciate Ligament (PCL)	2	2	4 (14%)
3	Menisci injury (MI)	21	1	22 (39.29%)
4	Collateral ligament (CL)	19	2	21 (37.5%)
5	Patello femoral ligament (PFL)	1	0	1 (1.79%)
6	Bone Contusion/ marrow edema	36	3	39 (69.64%)
7	Joint effusion	48	5	53 (94.64%)





DISCUSSION

MRI is invaluable in preventing unnecessary surgery, and recommends it whenever ligamentous injury is suspected. Also, there are studies that support the view that the diagnostic accuracy of the MRI could affect in a critical way the treatment pathway of knee injuries. A lot of surgeons tend to suppose that MRI is an accurate, non-invasive diagnostic method of the knee injuries, adequate to lead to decisions for conservative treatment and save a patient from unnecessary arthroscopy (Zhang and Jordan, 2010). This could be because of more activities in young males as compared to females and are more prone to road traffic accidents and frequent injuries during sports. Fifteen percent of physical activity–related injuries are found in the knee, and the risk of sustaining a knee injury is especially high in the age group of 15 to 25 years (Haapasalo *et al.*, 2006). Joint Effusion was found to be most frequent lesion in symptomatic knee constituting 94.64%. In another study joint infusion was reported in 63.8% (Mansour *et al.*, 2015). Higher percentage of joint effusion in our study shows that we tried to include even small effusion where predominant injury could be ligament or menisci and one another could be that in our study most of the patients were of recent history of trauma.

Amongst the ligament injury ACL was found be highest approximately 50% in patients with complete tear in 57.14%. This much percentage of ACL injury in our study could be explained because in our study most of the injury found in young male patients and this type of injuries are mostly found in sports person (Gianotti *et al.*, 2009). One study conducted in 2006 also shown ACL as the most common injured ligament. (Majewski *et al.*, 2006) Collateral ligament injury was found in 37.5% patients with medial side injury represents in 71.43%. One study has also shown that highest incidence of complete tear in ACL (Oei *et al.*, 2005). Menisci injury was found in 39.29% patients. In our study most of the menisci injury was found in young male as compared to female only one. Similar results have reported by other studies too of higher incidence of menisci injuries in young male (Nikolaou *et al.*, 2008; Khanda *et al.*, 2008). Amongst the menisci injury medial meniscus injury was found be highest approximately 72.72 % with grade III in 43.75%. Lateral meniscus injury was found in 27.28 % patients with grade III in 66.67%. This results are consistent with another study where medial menisci lesion were common than lateral menisci (Boks *et al.*, 2006). Grade I/II injury (signal changes) are less common in our study because these are not true tear and mostly occur with degeneration changes in

knee joint and more common in 3rd and 4th decade (Stoller *et al*., 1987) and in our study most of the patients were in age group 21-30.

Conclusion

To conclude, amongst ligament injury ACL was found to be most affected ligament and medical meniscus was found to be most commonly affected menisci in traumatic knee injury patients. Joint effusion and marrow edema were found to be associated in most of the cases.

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Research Article

Comparison of colour Doppler ultrasound and ankle-brachial pressure index measurements in peripheral vascular disease in type 2 diabetic patients with foot infections

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ABSTRACT

Background: Peripheral vascular disease is diagnosed by definitive history of intermittent claudication or if one or more of peripheral pulses are absent in one or both lower limbs. Diagnostic testing for peripheral vascular disease must be accurate, inexpensive, widely accessible, easy to perform and preferably non-invasive. A variety of non-invasive techniques are available to detect the presence of peripheral vascular disease as well as to localize areas of stenosis, assess severity of disease and follow patients for disease progression or response to therapy. In this study we compare the specificity and sensitivity of ankle brachial pressure index with colour Doppler ultrasound for diagnosis of peripheral vascular disease in type 2 diabetes.

Methods: This prospective study was carried out in the department of General surgery, GMCH, Udaipur, Rajasthan, India, from September 2014 to February 2016 after taking the permission from institutional ethical committee. A total of 50 patients were selected. The selected patients were evaluated by detailed clinical history, physical examination, local examination, ankle brachial pressure index (ABPI), colour doppler study and other relevant investigations. The ABPI ratio was calculated in every patient and an ABPI less than 0.9 in either foot was defined to have PVD. Colour duplex ultrasound was done in all selected patients. Imaging of peripheral arteries of the lower limbs was done using high resolution colour duplex ultrasound. PVD was diagnosed if the stenosis in the artery was greater than 50% or presence of occlusion.

Results: Total 50 patients having type 2 diabetes mellitus with foot infection were included and most of the patients were between 40-60 years of age (68%) with males preponderance. In our study 12 (24%) patients had normal ABPI of 1.0 to 1.29 and 22 (44%) patients were in the range of mild to moderate PVD with ABPI between 0.41 to 0.90. Colour doppler was used as a standard diagnostic test for PVD & out of 50 patients, 36 (72%) showed involvement of arteries and among them both anterior and posterior tibial arteries were involved in 12 (24%) patients. In our study colour doppler ultrasound was used as standard diagnostic method for PVD. The sensitivity, specificity, positive predictive value and negative predictive value of ABPI against colour duplex ultrasound were calculated.

Conclusions: In our study it's concluded that ABPI is a good initial screening tool for peripheral vascular disease, but some patients with significant stenosis or in whom collaterals have developed in lower extremity would be missed, if ABPI measurement alone is used for diagnosis of peripheral vascular disease.

Keywords: Peripheral vascular disease, Diabetes, Foot infections, Colour doppler ultrasound, Ankle-brachial pressure index

INTRODUCTION

Diabetes is known for its micro and macro vascular complications like retinopathy, neuropathy, nephropathy, cardiovascular and peripheral vascular diseases and infections.

The major risk factors leading to diabetic foot ulcer is poor diabetes control, which results in neuropathic and vascular changes. Currently, foot problems are an important cause of morbidity in diabetes. Foot ulceration precedes the majority of amputation in diabetics. Diabetes accounts for up to 50% of non-traumatic leg amputations and 1% of diabetic people have undergone amputation.

Prevention and early treatment of foot ulcers require multidisciplinary teamwork from nurses, chiropodiatrists and doctors, preferably at primary care level. Rapid assessment and timely intervention can make the difference between limbs salvage and limb loss.

The diabetic foot is mainly because of peripheral neuropathy, arteriopathy and superimposed infection. Peripheral vascular diseases are a group of common degenerative (organic) and vasospastic (functional) disease processes that result in significant morbidity and are strong predictors of subsequent mortality.

Gangrene of the lower extremities as a result of advanced vascular disease is about 100 times more common in diabetics than non-diabetics. The primary cause of mortality in patients with PVD is myocardial infarction (60%), stroke (12%) and other complications of diabetes. A significant cause of morbidity in patients with peripheral vascular disease in diabetics is ischemic limb loss. Approximately 2% of non-diabetic patients with intermittent claudication require amputation. This rate increases to 7% for patients with diabetes mellitus.

According to American Diabetes Association revised criteria diabetes is diagnosed by.[1]

Criteria for the diagnosis of diabetes mellitus

- Symptoms of diabetes plus random blood glucose concentration ≥11.1 mmol/L (200 mg/dL) or
- Fasting plasma glucose ≥7.0 mmol/L (126 mg/dL) or
- A1C >6.5% or
- Two-hour plasma glucose ≥11.1 mmol/L (200 mg/dL) during an oral glucose tolerance test.

Risk factors for the development of diabetic peripheral vascular disease are genetic predisposition, age, duration of diabetes, smoking, hypertension, hypertriglyceridemia, hypercholesterolemia, truncal obesity, hyperinsulinemia, proteinuria, dialysis and drugs (β-blockers, ionotropic agents). Among them most important are age, duration of diabetes, genetic predisposition and smoking. Peripheral vascular disease is diagnosed by definitive history of intermittent claudication or if one or more of peripheral pulses are absent in one or both lower limbs. The absence of pedal pulses in the presence of a palpable popliteal pulse is a classic finding in diabetic arterial disease because of the selective involvement of the tibial arteries below the knee.

Diagnostic testing for peripheral vascular disease must be accurate, inexpensive, widely accessible, easy to perform and preferably noninvasive. A variety of noninvasive techniques are available to detect the presence of peripheral vascular disease as well as to localize areas of stenosis, assess severity of disease and follow patients for disease progression or response to therapy.

These are:

- ABPI test.
- Doppler ultrasonography and color flow imaging.
- MRI and MR angiography.
- CT angiography.

The ankle-brachial pressure index (ABPI) is the ratio of systolic pressure at the ankle to that in the arm. The highest pressure in the dorsalis pedis, posterior tibial or peroneal artery serves as the numerator, with the highest brachial systolic pressure being the denominator.[2]

According to American College of Cardiology and American Heart Association, ABPI ratios are interpreted as follows:

>1.30: Non-compressible vessels
1.00 to 1.29: Normal
0.91 to 0.99: Borderline (equivocal)
0.41 to 0.90: Mild to moderate PVD
0.00 to 0.40: Severe PVD[3]

The recent ACC/AHA practice guidelines for PVD management recommend that a resting ABPI should be obtained for the following group of patients:

- Individuals with suspected PVD due to exertional leg symptoms or non-healing wounds.
- Individuals aged 70 years or old.
- Individuals between 50 and 70 years of age who have a history of tobacco use or diabetes.
- Individuals with diabetes who are younger than 50 years and who have additional risk factors for PVD such as smoking, hypertension, hyperlipidemia or diabetes of >10 yrs duration.

Arterial duplex ultrasonographic examination of the lower extremities can be used to diagnose PVD. It is especially helpful in determining the location of disease and in delineating between stenotic and occlusive lesion, an added benefit when preparing for an intervention. Gray scale imaging is used to characterize the morphology of the vessel, ascertain the presence or absence of plaque & assess plaque calcification and characteristics. Management of diabetic foot includes

improvement of patient's nutrition, correction of anemia and strict glycemic control. Risk factors like smoking, hypertension, hyperlipidemia should be under strict control. The offloading is avoidance of all mechanical stress on the affected limb. The wounds should be swabbed and cultured. The surgical probing, drainage and debridement should be done under antibiotic coverage.

The arterial angioplasty, stenting, endarterectomy or arterial bypass is done for revascularization of diabetic foot. In recent years, several new treatment strategies have been developed to stimulate wound healing in the diabetic foot ulcers. These are topical growth factors, extracellular matrix products, bioengineered human skin, and hyperbaric oxygen therapy, granulocyte macrophage colony stimulating factor and collagen granules.

METHODS

This study was conducted on patients of type 2 diabetes mellitus with foot infection admitted in Geetanjali Medical College & Hospital, Udaipur from September 2014 to February 2016. A total of 50 patients were selected. The selected patients were evaluated by detailed clinical history, physical examination, local examination, ABPI, colour Doppler study and other relevant investigations. The ankle brachial pressure index ratio was calculated in every patient and an ABPI less than 0.9 in either foot was defined to have PVD.

Blood pressure recordings were done on the brachial pulse in the upper limb by palpatory method using the usual sphygmomanometer, cuff and brachial systolic pressure noted. In the lower limb similar recordings were done by using the same cuff around the calf and palpating dorsalis pedis and posterior tibial pulses. The mean of these two readings was taken as the ankle pressure. All readings being done in supine position after ten minutes rest.

ABPI was calculated as:

$$\text{ABPI} = \frac{\text{Systolic ankle pressure}}{\text{Systolic brachial pressure}}$$

Colour duplex ultrasound was done in all selected patients. Imaging of peripheral arteries of the lower limbs was done using high resolution colour duplex ultrasound.

The superficial femoral artery was traced up to the popliteal fossa and the profound was evaluated in its proximal segment. The popliteal vessels, anterior tibial, peroneal, posterior tibial and dorsalis pedis were also evaluated. PVD was diagnosed if the stenosis in the artery was greater than 50% or presence of occlusion.

Statistical analysis

All data were tabulated and statistical analysis was performed. The sensitivity, specificity, positive predictive value and negative predictive value of ABPI against colour duplex ultrasound were calculated. In brief, these were calculated as follow:

$$\text{Sensitivity} = \frac{\text{Number of true positive subjects}}{\text{Total number of subjects diagnosed as PVD by CDU}}$$

$$\text{Specificity} = \frac{\text{Number of true negative subjects}}{\text{Total number of subjects Negative for PVD as diagnosed by CDU}}$$

$$\text{Positive predictive value} = \frac{\text{Number of true positive subjects}}{\text{Total subjects diagnosed as pvd by ABPI}}$$

$$\text{Negative predictive value} = \frac{\text{Number of true negative subjects}}{\text{Total subjects diagnosed as PVD by ABPI}}$$

RESULTS

This study was conducted in Geetanjali Medical College and Hospital, Udaipur, Rajasthan, India. On 50 patients suffering from diabetes mellitus with foot infections.

Age distribution

Out of the 50 patients, 34 (68%) were aged between 40 to 60 years of age, 4 (8%) were aged below 40 years and 12 (24%) patients were aged more than 60 years. Youngest patient was 36 years old & oldest patient was 73 years old (Table 1).

Table 1: Age distribution.

Age (Years)	No. of patients	Percentage
Below 40	04	08
40-60	34	68
Above 60	12	24

Sex distribution

In our study out of 50 patients, 36 (72%) were males & 14 (28%) were females. The male to female ratio was 2.5: 1 (Table 2).

Table 2: Sex distribution.

Sex	No. of patients	Percentage
Male	36	72
Female	14	28

Table 3: Associated factors.

	Yes		No	
	No. of patients	Percentage	No. of patients	Percentage
Walking bare feet	32	64	18	36
H/o smoking	24	48	26	52
H/o ulcer or amputation	18	36	32	64

Associated factors

Out of 50 patients, 32 (64%) patient were in a habit of walking bare feet either at home or at work and 24 (48%) patients were smokers. It shows that walking bare feet was associated with increased incidence of diabetic foot (Table 3).

Ankle Brachial Pressure Index

ABPI in normal patients is between 1.0 to 1.29 and in our study 12 (24%) patients had ABPI of >1.0. ABPI between 0.91 to 0.99 indicates borderline PVD and in our study 10 (20%) patients had ABPI between 0.91 to 0.99. In our study, 22 (44%) patients were in the range of mild to moderate PVD with ABPI between 0.41 to 0.90 (Table 4).

Table 4: ABPI.

ABPI	No. of patients	Percentage
>1.0	12	24
0.91 to 0.99	10	20
0.41 to 0.90	22	44
<0.40	06	12

Colour Doppler study

In our study, colour Doppler was used as standard diagnostic test for PVD. Out of 50 patients, 36 (72%) showed involvement of arteries & 14 (28%) patients showed normal study (Table 5).

Table 5: Colour Doppler study.

Colour Doppler study	No. of patients	Percentage
Involvement of arteries	36	72
Normal study	14	28

Involvement of arteries in colour Doppler study

In our study out of 50 patients colour Doppler shows involvement of arteries in 36 (72%) patients. Out of 36 patients, calf vessel involvement was seen in 27 (54%) patients. Only anterior tibial artery was involved in 9 (18%) patients, posterior tibial in 6 (12%) patients and both anterior and posterior tibial were involved in 12 (24%) patients. Popliteal artery involved in 4 (8%) patients and superficial femoral artery in 5 (10%) patients (Table 6).

Table 6: Involvement of arteries in colour Doppler study.

Involvement of arteries	No. of patients	Percentage
Anterior tibial only	09	18
Posterior tibial only	06	12
Both anterior and post tibial	12	24
Popliteal	04	08
Superficial femoral	05	10

Sensitivity and specificity of ABPI vs colour Doppler ultrasound

In our study, out of 50 patients, ABPI showed PVD in 28 (56%) patients and absence of PVD in 22 (44%) patients. Colour Doppler ultrasound was used as standard diagnostic method for PVD in this study. Colour Doppler showed PVD in 36 (72%) patients. Out of the 36 patients diagnosed to have PVD by CDU, only 26 were categorized as PVD by ABPI. Thus 10 patients would have remained undiagnosed if ABPI alone was used for diagnosis. Conversely 2 patients out of the 28 patients diagnosed as having PVD by ABPI were classified as normal by the CDU. Hence sensitivity of ABPI is 72.22 % & specificity of ABPI is 85.71% in comparison with colour Doppler ultrasound. Positive predictive value of ABPI is 92.85% and negative predictive value of ABPI is 54.54% (Table 7).

Table 7: Sensitivity and specificity of ABPI vs colour Doppler ultrasound.

ABPI	Colour Doppler ultrasound		Total
	Abnormal (+)	Normal (-)	
Abnormal (+)	26	02	28
Normal (-)	10	12	22
Total	36	14	50

Amputation

In this study, out of 50 patients, 17 (34%) patients required amputation, out of which 10 (20%) patients required minor amputation of toes and 7 (14%) required major amputation (Table 8).

Table 8: Amputation.

Amputation	No. of patients	Percentage
Minor	10	20
Minor	07	14
Total	17	34

DISCUSSION

The spectrum of diabetic complication is very wide, and to some extent unpredictable. Advances insulin therapy and oral hypoglycemic agents have led to an increase in the life span of patients affected with diabetes mellitus. This has in turn led to an increase in the incidence of complications of diabetes like retinopathy, neuropathy, vascular diseases and nephropathy. Foot problems are the most common indications for hospital admission in diabetes. They account for approximately 20 percent of all hospital admission in diabetics.

Peripheral vascular disease plays an important role in the pathogenesis of foot ulcer and good circulation is required for early healing. Hence there is a need for early diagnosis of peripheral vascular disease in diabetics with foot infections. The noninvasive tests are of great value in assessing the vascular supply of the foot and evaluating the healing potential of foot ulcers and local amputations. Among these tests ABPI is one of the easiest, most widely reproducible and cost effective method of determining the degree of diminished arterial circulation in lower limb.

Earlier studies by Strandezz DE, Bell JW[4] have suggested ABPI as a reliable method for diagnosis of PVD and ABPI value of <0.9 has 98 % sensitivity compared to angiography. Premalatha et al[5] in their study compared CDU and ABPI measurement in 100 type 2 diabetic patients with foot infections and found that ABPI had sensitivity of 70.6% and specificity of 88.5%. They concluded that ABPI is a good initial screening tool but some patients with significant stenosis would be missed, if ABPI alone is used for diagnosis of PVD.

In our study, ABPI measurement had 85.71% specificity and 72.22% sensitivity as compared to 88.5% and 70.6% in Premalatha et al[5] study (Table 7). The low sensitivity indicates that ABPI measurement would miss some of the patient with PVD. The reason being, there may be higher ABPI values in spite of stenosis probably due to collateral circulation that maintains blood flow to the lower limb beyond the obstruction. Higher ABPI values also suggest calcification of vessels.

If ABPI alone is used, many patients with severe stenosis in the peripheral artery will be diagnosed as normal. But in view of the ease of performing the test and its low cost, ABPI would be a good initial screening test.

If ABPI is abnormal, the diagnosis of PVD is almost certain. If ABPI is normal and the patient is asymptomatic no further testing is required because even if PVD is present it is likely to be clinically insignificant. If however, there are clinical symptoms of PVD and the ABPI is normal, a CDU should be performed before PVD is definitely excluded. CDU however needs more expensive equipment, is technically more difficult, needs a highly skilled radiologist to perform, is not available widely and cannot be carried out at smaller centers.

Venkata et al[6] in his study showed that maximum number (54%) of patients were in the age group of 51-60 years and 65% patients were male. In our study, 34 (68%) patients were between the age of 40 to 60 years and 36 (72%) patients were male patients. Bild et al[7] stated that alteration in foot dynamics due to ulceration or amputation can cause the abnormal distribution of plantar pressures and results in formation of new ulcers. In our study, 18 (36%) of patients had previous history of amputation or ulcers. Also 32 (64%) of patients were in a habit of working bare feet either indoor or outdoor (Table 3).

Logerfo and Coffman[8] stated that the arterial occlusion commonly involves the tibial arteries (calf vessels). In our study, involvements of peripheral arteries were found in 27 (54%) patients (Table 6); out of that involvement of anterior and posterior tibial both were present in 12 (44.4%) patients. In our study, 17 (34%) patients required amputation. In a similar study by Zafar,[9] 17 (36%) patients out of 48 patients required amputation of minor and major types. In Reiber,[10] study out of 50 patients, 20 (40%) required amputation.

CONCLUSION

In our study it's concluded that ABPI is a good initial screening tool for peripheral vascular disease, but some patients with significant stenosis or in whom collaterals have developed in lower extremity would be missed, if ABPI measurement alone is used for diagnosis of peripheral vascular disease.

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Original Research Paper

Correlation of Placental Thickness with Gestational age and Other Fetal Parameters - A Cross Sectional Study

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Abstract

Introduction: *Exact determination of gestational age is crucial for appropriate antepartum care as well as successful outcome of deliveries. The exact knowledge of gestational age is also important for undertaking various diagnostic procedures that needs to be performed within a narrow range of a particular gestational age. While fetal biometry is one of the most common method of determination of gestational age and weight alternative methods such as measurement of placental thickness can also be used for determination of gestational age and other parameters in doubtful situations. We conducted this cross sectional study to find out whether placental thickness can be used for estimation of gestational age and other parameters.*

Materials and Methods: *This was a cross sectional study in which 403 pregnant women in their second and trimester were included on the basis of a predefined inclusion and exclusion criteria. Gestational age and other fetal parameters were determined on the basis of bio-physical parameters. The placental thickness was measured at the level of umbilical cord insertion and maximum thickness was determined in the cross section. Statistical analysis was done using SPSS software. P value less than 0.05 was taken as statistically significant.*

Results: *In this study of 403 women the mean age was found to be 28.36 +/- 7.6 years. In majority of the cases placenta was either anterior (42.4%) or posterior (30.5%). Placental thickness of 36.51 ±\ 4.67 was found to be corresponding to the gestational age of 37 weeks (Full-Term Gestation). The mean placental thickness was found to be having a linear relationship with gestational age and other fetal parameters and statistical association between placental thickness and gestational age as well as other fetal parameters was found to be significant.*

Conclusion: *Placental Thickness can be used for determination of gestational age and other fetal parameters in doubtful cases.*

Keywords: *Placental Thickness, Second and Third Trimester, Gestational Age, Biometry.*

Introduction

Accurate estimation of foetal maturity is one of the most common problems that an obstetrician faces. Estimation of gestation age (foetal maturity) is of critical importance in clinical practice not only to ensure appropriate management of new-

borns but also to distinguish pre-term from term infants[1]. The best antepartum care and successful deliveries of babies always revolve around the accurate knowledge of the gestational age (GA). It is also very important to differentiate between normal and growth restricted foetuses. The exact knowledge of gestational age is also important for undertaking various diagnostic procedures (Chorionic villous sampling and amniocentesis) that need to be performed within a narrow range of a particular gestational age. While fetal biometry is one of the most common method of determination of gestational age and weight alternative methods such as measurement of placental thickness can also be used for determination of gestational age and other parameters in doubtful situations[2].

Proper assignment of expected date of delivery is of utmost importance in the interpretation of biochemical tests such as screening for the expanded biochemical markers (HCG, Alfa Fetoprotein and the oestrogen and progesterone level) for the risk assessment of various foetal anomalies, to plan and execute therapeutic manoeuvres and to determine the optional management in certain difficult situations like intrauterine growth restriction, gestational diabetes and Rh disease[3]. Moreover when an anomaly is detected, the interventional modality which is used, is influenced by the gestational age. All the important clinical decisions, which include caesarean section, elective labour induction, etc., depend on the knowledge of gestational age. Hence an accurate establishment of expected date of delivery is fundamental to the management of high risk pregnancies[4].

Introduction of obstetric ultrasonography in the early 1970s led to a marked improvement in the evaluation of foetal and placental anatomy, as well as foetal growth. Now, it appears as the most effective technique to estimate gestational age (GA). Fetal biometry (Biparietal diameter, Head circumference, abdominal circumference and femur length) is routinely used to determine gestational age after 12 weeks of pregnancy[5].

It is important to know that ultrasonography is highly observer dependent investigation.

Moreover the position of the baby many times makes it difficult to accurately take biometric parameters. Many authors, such as Wolfson et al, have concluded that the bi-parietal diameter was not reliable in the foetuses which had premature rupture of membranes. So, there is a need of another parameter for supplementing the gestational age estimation with minimal error. Placental thickness is an important parameter in estimating fetal growth, the placental thickness changes with increasing growth of fetus. It is different in all 3 trimesters. So, it can be used as another parameter to estimate gestational age (GA). Various studies have reported that the placental thickness not only reflects the gestational age of the fetus but also may be useful in diagnosing conditions such as intrauterine growth restriction (placental thickness < 25mm) or gestational diabetes (Placental 10 thickness > 40mm)[6].

We conducted this cross sectional study to find out whether placental thickness can be used for estimation of gestational age and other parameters.

Materials and Methods

This was a Cross sectional study with an analytical design carried out amongst pregnant women referred to radio-diagnosis department of a tertiary care medical college situated in an urban area. 403 Pregnant women who were referred for Level II obstetric ultrasound scan (in their 2nd and 3rd trimester) were included in this study on the basis of a predefined inclusion and exclusion criteria. Informed consent was obtained from all the women. Previous scans, if already done, were analysed and if any abnormality was detected in previous scan it was noted down.

Study Protocol

After taking a detailed history, the antenatal women were examined for placental thickness, gestational age, Biparietal Diameter (BPD), the Abdominal Circumference (AC), the Head

Circumference (HC), the Femur length (FL) by USG using 1-5 MHZ convex array transducer.

Subjects were scanned with moderately distended bladder in supine position. The transducer was placed on the skin surface after applying the coupling agent. Placental thickness in mm was measured at the site of cord insertion. The transducer was oriented to scan perpendicular to both the chorionic and basal plates, as tangential scan would have distorted the measurement of thickness of placenta. All placental measurements were taken during the relaxed phase of uterus as contractions can spuriously increase the placental thickness.

Collected data (Annexure I) was entered in the MS Excel spread sheet, coded appropriately and will be cleaned for any possible errors. Analysis was carried out using Statistical package for social sciences (SPSS) for Windows version 17.0, Released 2008 (SPSS Inc., Chicago, IL). Normally distributed data was presented as means and standard deviation, or 95% confidence intervals (CI). Placental thickness was measured in mm along with their respective standard deviation (SD) were computed for each gestational age from 12 to 40 weeks. The 95 % C.I was calculated. Correlational analysis including Pearson's and Spearman's analysis was used for the multiple variables to establish the degree of relationship between PT, FL, HC, AC & BPD. The level of significance was determined and p value of <0.05 was taken as statistically significant.

Inclusion Criteria

1. Singleton pregnancies, 12-40 weeks.
2. The known last menstrual period.
3. A history of regular menstruation.
4. No known maternal and fetal chromosomal /structural abnormalities.

Exclusion Criteria

1. Pregnant females not knowing their LMP.
2. Patients with irregular menstrual cycle.
3. First trimester gestations
4. Multiple pregnancies.
5. Known cases of Eclampsia, PIH, gestational diabetes or maternal systemic diseases.

Results

In this study of 403 women the most common age group was found to be between 26- 30 years (47.9%) followed by 20-25 years (30.8%) and more than 30 years (20.6%). Only 3 patients (0.7%) were found to be below 20 years of age.

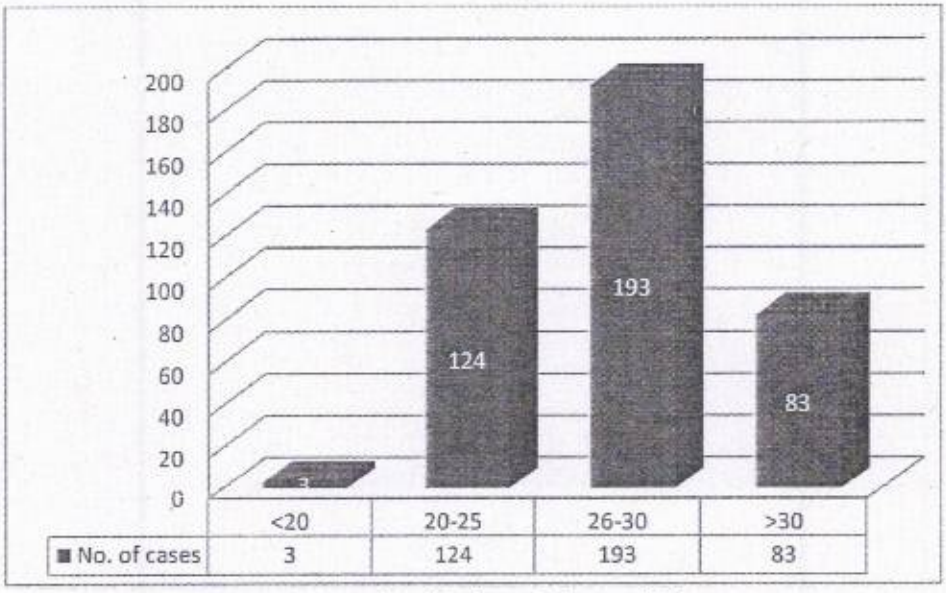

Figure 1: Age distribution of the studied cases

It was observed that in majority of the pregnant females (42%), the placenta was attached anteriorly to the uterus. This pattern was followed by posterior attachment (30%), and fundal posterior (14%) attachments as the most frequent types. Fundal attachment (1.9%) was observed to be the least common type.

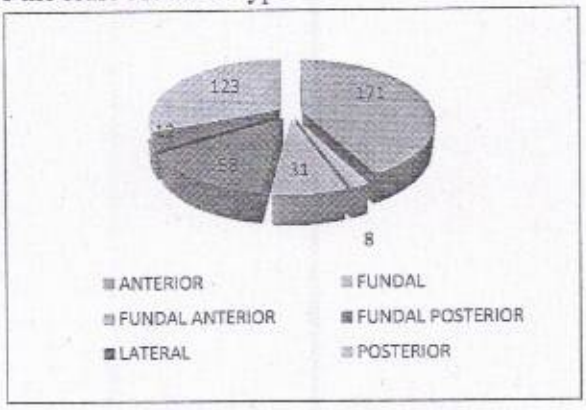

Figure 2: Location of attachment of the placenta

Pearson's analysis was used to depict correlation between the gestational age and placental thickness. The two variables depicted strong positive correlation (r= 0.967) & p-value :< 0.001 between the gestational age of 14-35 weeks whereas the placental thickness depicted statistically significant but a weak positive correlation with gestational age of >35 weeks. The range of placental thickness varied between 11-38 mm during the gestational age 14-35 weeks. The thickness of placenta varied between 30-43 mms and the mean value was about 35.35 mm when it was measured between 35-39 weeks period of gestation.

Table 1: Correlation of gestation age14-35 weeks and >35 weeks by ultrasonography and placenta thickness (mm)

	Range	Mean	SD	r	P-value
Gestational Age (weeks) by USG	14-35	25.60	6.29	0.967	<0.001 (HS)
Placenta thickness (mm)	11-38	25.34	6.26		
Gestational Age (weeks) by USG	35-39	36.19	1.17	0.432	<0.001 (HS)
Placenta thickness (mm)	30-43	35.35	3.77		

The analysis of placental thickness and gestational age showed that the mean placental thickness increases with each passing gestational week, till 37 weeks period of gestation but then a decrease in thickness was observed after 38 weeks period of gestation.

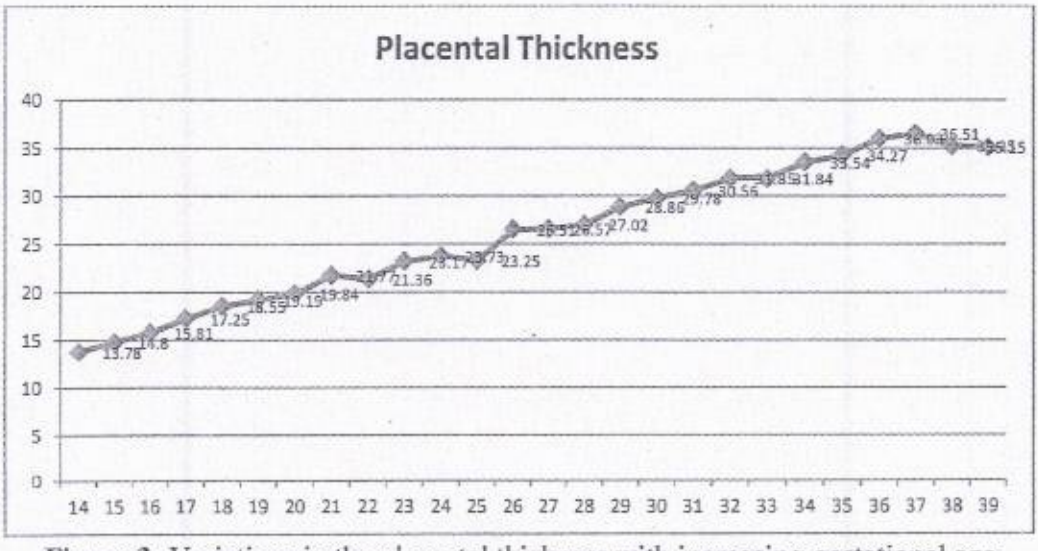

Figure 3: Variations in the placental thickness with increasing gestational age

The analysis of the variations in the placental thickness with increase in the period of gestation showed that the difference in the placental thickness with time were statistically significant with a p-value<0.001.

Table 2: Comparison of the placental thickness with gestational age

Gestational Age (Weeks)	Number Of Cases	Placental Thickness ± SD (mm)
14-20	88	17.63 ± 2.58
21-27	73	23.87 ± 2.94
28-32	91	29.87 ± 2.22
33-40	151	34.50 ± 3.42
Total	403	27.85 ± 7.19

The changes in placental thickness and other anthropometric parameters with increase in gestational age. The maximum mean placental thickness achieved was 36.51 mm at 37 weeks period of gestation. Other parameters also increased steadily and corresponded well with the actual gestational age.

Table 3: Relationships between placental thickness, gestational age, bi-parietal diameter, head circumference, abdominal circumference and femur length

Gestational Age (Weeks)	PT (mm)	BPD (Weeks)	HC (Weeks)	AC (Weeks)	FL (Weeks)
14	13.78	14.23	14.00	14.23	14.08
15	14.80	15.20	15.00	15.10	14.90
16	15.81	16.13	15.63	16.13	15.75
17	17.25	18.00	17.00	17.50	16.50
18	18.55	17.90	17.80	18.60	18.70
19	19.19	19.09	18.86	18.86	19.18
20	19.84	20.09	19.91	19.83	19.78
21	21.77	20.83	20.75	21.25	21.00
22	21.36	22.17	22.17	22.33	38.58
23	23.17	24.00	23.75	23.75	23.75
24	23.73	24.30	23.40	23.50	23.80
25	23.25	25.00	24.00	25.00	24.00
26	26.51	25.89	25.67	37.11	26.33
27	26.57	27.06	26.94	27.13	27.13
28	27.02	27.40	27.40	27.67	27.53
29	28.86	29.17	28.94	28.83	29.17
30	29.78	30.42	29.92	30.42	30.17
31	30.56	30.95	31.00	31.23	31.14
32	31.85	32.33	31.79	32.00	32.17
33	31.84	32.95	33.05	33.00	33.09
34	33.54	33.79	34.18	33.54	33.86
35	34.27	34.76	35.30	34.68	35.43
36	36.03	35.93	36.21	36.00	36.54
37	36.51	36.75	36.70	36.75	37.20
38	35.25	37.92	38.00	38.08	38.17
39	35.15	38.00	38.50	38.25	38.50

The comparison of the bi-parietal diameter, head circumference, abdominal circumference and femur lengthduring different periods of gestation was done. It was observed that the difference in these variables with time were statistically significant with a p-value<0.001.

Table 4: Comparison of the bi-parietal diameter, head circumference, abdominal circumference and femur length with gestational age

Gestational Age (Weeks)	Number Of Cases	BPD (Weeks)	HC (Weeks)	AC (Weeks)	FL (Weeks)
14-20	88	17.76+2.33	17.52 +2.30	17.69+ 2.22	17.67+ 2.38
21-27	73	24.15+2.62	23.89 +2.60	25.49+ 12.19	26.81+ 23.32
28-32	91	30.31+2.10	30.07 +2.08	30.26+ 1.99	30.30 + 2.03
33-40	151	35.13+1.83	35.42 +1.79	35.11+ 1.97	35.54 + 1.99
Total	403	28.26+7.11	28.21 +7.29	28.47+ 8.62	28.87 + 12.10
P-Value		<0.001	<0.001	<0.001	<0.001

In the second trimester of the pregnancy Placental thickness depicted maximum correlation with the gestational age(r= 0.916; p<0.001), followed by bi-parietal diameter(r= 0.907; p<0.001) and head circumference (r= 0.898; p<0.001). It depicted weak and poor correlation with abdominal circumference (r= 0.482; p<0.001) and femur length (r= 0.236; p<0.001). Femur length also depicted weakest correlation (r= 0.267; p<0.001) with the gestational age. Overall, weakest correlation was seen between femur length and abdominal circumference (r=0.149; p-value :> 0.05).

Table 5: Correlation between placental thickness, gestational age and other growth parameters; bi-parietal diameter (BPD), head circumference (HC), femur length (FL) and abdominal circumference (AC) in the second trimester of pregnancy (13-27 weeks

	Gestational Age By USG (weeks)	Placental Thickness (mm)	BPD (Weeks)	HC (Weeks)	AC (Weeks)	FL (Weeks)
Gestational Age By USG(weeks)	1					
Placental Thickness (mm)	.916**	1				
BPD (Weeks)	.955**	.907**	1			
HC (Weeks)	.959**	.898**	.953**	1		
AC (Weeks)	.512**	.482**	.500**	.510**	1	
FL (Weeks)	.267**	.236**	.281**	.269**	.149	1

In the third trimester of the pregnancy only good positive correlation was seen between the placental thickness and Bi-parietal diameter (r= 0.705; p<0.001), gestational age (r= 0.702; p<0.001), femur length (r= 0.699; p<0.001), head circumference (r= 0.696; p<0.001) and abdominal circumference (r= 0.693; p<0.001) that were depicted in weeks. Overall, excellent correlation was seen between gestational age and the head circumference in weeks (r= 0.931; p<0.001) and femur length (r= 0.931; p<0.001) and only good correlation was seen with placental thickness (r= 0.702; p<0.001)

Table 6: Correlation between placental thickness and the growth parameters; bi-parietal diameter (BPD) and abdominal circumference (AC) in the third trimester of pregnancy (28-40 weeks)

	Gestational Age By USG (weeks)	Placental Thickness (mm)	BPD (Weeks)	HC (Weeks)	AC (Weeks)	FL (Weeks)
Gestational Age By USG(weeks)	1					
Placental Thickness (mm)	.702**	1				
BPD (Weeks)	.929**	.705**	1			
HC (Weeks)	.931**	.696**	.898**	1		
AC (Weeks)	.925**	.693**	.876**	.892**	1	
FL (Weeks)	.931**	.699**	.890**	.898**	.904	1

The correlational analysis of the different fetal growth parameters and gestational age (GA) showed that GA depicted strong positive correlation with all the parameters except FL

(femur length, weeks) where it depicted week positive correlation. Femur length depicted weakest positive correlation with most of the other parameters ranging from r=0.464 to 0.531.

Table 7: Correlation matrix showing the correlation coefficient 'r' values between gestational age, Placental Thickness, Bi-parietal Diameter, Head Circumference, Abdominal Circumference and Femur Length.

	GA by USG (Weeks)	Placental Thickness (mm)	BPD (Weeks)	HC (Weeks)	AC (Weeks)	FL (Weeks)
GA by USG (Weeks)	1					
Placental Thickness (mm)	0.946	1				
BPD (Weeks)	0.987	0.945	1			
HC (Weeks)	0.987	0.942	0.982	1		
AC (Weeks)	0.805	0.771	0.799	0.802	1	
FL (Weeks)	0.560	0.531	0.563	0.559	0.464	1

The age of the pregnant females ranged between 15-46 years (mean value: 27.29 + 4.97 years). Mean gestational age of the fetuses ranged between 14-39 weeks (mean value: 28.25 + 7.15 years). (Table 12) Similarly, the Placental Thickness, Bi-parietal Diameter, Head Circumference, Abdominal Circumference and Femur Length ranged between 11-43 weeks (mean value: 27.85 + 7.19 weeks), 14-40 weeks (mean value: 28.26 + 7.11 weeks), 13-40 weeks (mean value: 28.21 + 7.30 weeks), 13-126 weeks (mean value: 28.47 + 8.62 weeks) and 13-222 weeks (mean value: 28.87 + 12.10 weeks) respectively.

Table 7: Mean values of mother's age, gestational age, Placental Thickness, Bi-parietal Diameter, Head Circumference, Abdominal Circumference and Femur Length observed during the ultrasonography

	Range	Mean+ SD
Age of pregnant Females (yrs.)	15-46	27.29 +4.97
Gestational Age By USG (Weeks)	14-39	28.25+7.15
Placental Thickness (mm)	11-43	27.85+7.19
BPD (Weeks)	14-40	28.26+7.11
HC (Weeks)	13-40	28.21+7.30
AC (Weeks)	13-126	28.47+8.62
FL (Weeks)	13-222	28.87+12.10

Discussion

The current study presented data based on 403 mothers enrolled as study participants according to their age. Distribution of the pregnant mothers by age as well as position of the placenta was observed to be similar to several studies conducted by other researchers in the region[7].

In this study, data has been generated and analyzed for different gestational ages in the different trimesters of pregnancy. The mean PT was 23.8 (2.94) mm and 34.5 (3.42) mm in the second and third trimester, respectively. In the present study, a mean PT was 35.15 mm at 39 weeks of gestation. This was lower than to the value reported by researchers from Nigeria who reported a mean PT of 45 (6.4) mm and 42 (2.9) mm at 39 weeks of gestation[8,9]. The reason for difference can be difference in genetic structure of two populations. However, PT at 39 weeks' gestation was closer to that reported by Mital *et al.* (37.5 mm) who conducted similar work in India[10]. Further studies exploring the genetic differences in placental thickness can explain the extent and reason for differences.

Placental thickness and estimated fetal birth weight have a significantly high positive correlation in both the trimesters as noted by other researchers also[11]. The usefulness of this relationship between placental thickness and estimated fetal weight is that subnormal placental thickness for a gestational age may be the earliest indicator of fetal growth retardation.

In an Indian study, mid pregnancy placental volume was suggested to be significantly related to placental weight at birth and also the birth weight of new born independent of maternal size. Further Clapp et al evaluated placental growth and reported second-trimester placental volumes and growth rates as good predictors of size at birth in

healthy, active women. As found in other studies, a significant correlation between placental growth rate and gestational age was reported in this study as well. Significant positive correlations between placental thickness and estimated gestational in the second and third trimesters ($p < 0.05$) was also demonstrated[12].

Placental thickness was depicted to increase proportionally with each passing week of gestation. The placental thickness depicted statistically significant but a weak positive correlation with gestational age of >35 weeks. The overall thickness varied between 13.7- 36.5 mm which is lower than that reported by Noor et al[13]. The thickness of placenta varied between 34.2-35.15 mms and the mean value was about 35.4 mm when it was measured between 35-39 weeks period of gestation.

The variations in the placental thickness with increasing gestational age in 403 pregnant females evaluated during different period of gestation was observed which demonstrated an increase in mean placental thickness with each passing gestational week, till 37 weeks period of gestation followed by a decrease in thickness after 38 weeks period of gestation. This implies that PT increases linearly and attains its maximum thickness at 39 weeks of gestation. The maximum PT obtained during this study was less than the value of 47 mm reported by a Nigerian study[9]. A few previous reports from non- Indian populations reported normal placenta to be lower than <40 mm in thickness at any stage of pregnancy[14,15]. This implies that placenta of the Indian population is normally thinner than Nigerian populations and is similar to Caucasian populations.

The results of the present study are consistent with the observations made by authors of previous studies[16]. Average placental thickness was reported to be roughly equivalent to gestational age (in weeks). (23, 34) They reported that the mean thickness of the placenta was 3.90±1.1cm which increased till 38 weeks of gestation, thereafter decreased. This finding is consistent with our findings. Mital et al. also found similar trends in the values of mean placental thickness (in mm) and increasing in gestational age (in weeks). The placental thickness coincided almost exactly with the gestational age in weeks in two studies from India[17]. Baghel et al. reported that placental thickness in millimeters almost coincides with gestational age in weeks at 24 weeks (24.5 mm at 24 weeks), 32 (31.8 mm at 32 weeks) and 36 weeks (35.5 mm at 36 weeks)[18]. Nyberg and Finberg also reported that as a rule of thumb, placental thickness parallels gestational age (in weeks)[19]. Similarly in a recent study by Karthikeyan et alhad reported that placental thickness can be used as a predictor of the gestational age, and additionally suggested that subnormal PT for the corresponding GA should be evaluated for any disease condition[20].

Conclusion

There is a strong linear relationship between placental thickness and gestational age and other fetal parameters in second and third trimester pregnancy. The relation was found to be statistically significant. Placental Thickness can be used for determination of gestational age and other fetal parameters in doubtful cases.

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EVALUATION OF ANATOMIC VARIATIONS IN CORONARY ARTERY ON 64-SLICE COMPUTED TOMOGRAPHY ANGIOGRAPHY (CTA)

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ABSTRACT

Objective: We retrospectively evaluated anatomic variants and anomalies of coronary arteries and found their incidence in 106 patients with the help of the 64-slice Computed Tomography Angiography (CTA).

Materials and Methods: CT data of 106 patients who underwent 64-slice CT angiography (CTA) because of screening or suspected coronary artery disease were retrospectively reviewed in Department of Radiology, Geetanjali Medical College and Hospital, Udaipur. In each case, anatomic variants and anomalies were investigated.

Results: The coronary artery system was right dominant in 85%, left dominant in 12% and co-dominant in 2.8 % of the cases. Ramus intermedius was present in 16.9%. Conus artery from Right coronary artery found in 72.6%, with a same ostium was observed in 10.3 % and in 16.9 % conus arteries originating with separate ostia were visualized. The sinus node artery (SNA) originated from the right coronary artery (RCA) in 66.9% and from the Left Circumflex artery (Cx) in 33%. LMCA was absent in 0.9%. Myocardial bridging was observed in 11.3%.

Conclusion: Complex anatomy of the coronary artery tree can precisely be showed by 64-slice CTA. This technology is an appropriate substitute to conventional coronary angiography in distinguishing coronary artery variations and anomalies.

Keywords: Anatomic Variations, Coronary Artery

INTRODUCTION

Coronary artery anomalies can be fatal during or subsequent to heavy physical activity, usually in young population. The information of coronary anomalies is also crucial for cardiologist before performing any invasive procedure in coronary artery disease patients. The coronary anomalies cause 11.8% deaths in young athletes in USA.(1) An another study depicted that 12% of sports-related sudden cardiac deaths and 1.2% of non-sports-related deaths were originated from coronary abnormalities in 14 to 40 year-old persons. (2)

Screening of coronary anomalies in population is becoming viable with Contrast-enhanced CT angiography. In comparison with Conventional angiography, coronary CTA has developed into an imperative non-invasive modality in the diagnosis of coronary artery disorders. High temporal and spatial resolution capabilities of multislice computed tomography (MSCT) scanners enable detailed 3D visualization of complex coronary artery anatomy without motion artefact. The introduction of new generation MSCT, making novel, detailed coronary artery studies possible. The origin, course, variations and anomalies of the

coronary artery along with, the anatomy of the heart can now be meticulously studied with coronary CTA.(3,4) Furthermore, radiologists now have more skill in interpretation of images on normal anatomy in terms of anatomic anomalies and their cross-sectional images, which shows the way to improved diagnostic precision.(5) In this study, we aimed to recognize the 64-slice CTA appearance of the anatomic variations and anomalies of the coronary arteries and find out their incidence in a population of 106 patients.

MATERIALS AND METHODS

Population

CT data of 106 patients (91 male, 15 female, , range 31–78 years), who underwent 64-slice coronary CTA from January 2007 to December 2012 in Department of Radiology ,GMCH, Udaipur, were retrospectively assessed for anatomical variations and anomalies of coronary arteries. Patients were included who were advised by clinicians for coronary CTA screening or suspected coronary artery disease (CAD).The Institutional Review Board approved the study protocol.

CT scan and reconstruction parameters

All evaluations were carried out with a 64-slice CT scanner (Sensation 64, Siemens- Forcheim, Germany) with the subsequent parameters: slices/collimation 64/0.6 mm, rotation time 330 ms, effective temporal resolution (with 180° algorithm) 165 ms, 120 kv, 950 mAs, table feed/s 11.63 mm, effective slice thickness 0.6 mm, reconstruction increment 0.3 mm, field of view (FOV) 140–180 mm, isotropic voxel resolution of $0.4 \times 0.4 \times 0.4$ mm.

Blood urea and serum creatinine levels were estimated before the procedure. Patients were premedicated with tablet propronalol (40 mg); those have a heart rate more than 75 beats/min one hour before the scan. Sublingual nitro-glycerine was also given to the patient just before the scan. After sensitivity test a bolus of 100 ml of high iodinated contrast material (350 mg/ml ultarvist German remedies) was injected with a flow rate of 5 ml/s, followed by a 40-ml saline chaser into an antecubital vein of the right arm. Synchronization between arterial route of contrast and coronary CTA was done with the help of bolus-tracking technique. Collection of data were done in end-diastolic phase (from -300 to -450 ms just prior the peak of the successive R wave) or end-sistolic phase by retrospective gating to get a clear image of the right coronary artery (RCA).

Image analysis

Image analysis was carried out to another workstation where the reconstructed Images at optimal phase were transferred. Interpretation of radiological images were done in axial projection initially with the following tools ,like Volume-Rendering Technique (VRT) with transparent background display, curved planar reformat (CPR), thin-slab maximum intensity projection (thin MIP) and multiplanar reconstructions (MPR).Evaluation of images starts from examining the dominance of the coronary artery , their branching pattern, the origin, course, and supplying region of the major coronary arteries were assessed. The origin of the posterior descending artery (PDA) is deciding factor for dominance pattern in coronary artery. Right dominance were defined as when PDA originating from the right coronary artery (RCA) in coronary artery systems and when PDA arising from the left main coronary artery (LMCA) were defined as left dominant. Coronary artery systems where PDA was come up from the RCA and most of part of the left ventricle's posterior wall was supplied by posterolateral branches (PLB) from the circumflex artery (Cx) were termed as co-dominant. (6)

Coronary artery anomalies were classified according to Angelini et al. They classify coronary anomalies according to their origination, course, termination and anomalies of intrinsic coronary artery anatomy. (7)

RESULTS

Prevalence of normal variations and anomalies of coronary arteries observed in this study is demonstrated in Tables 1. Total 106 patients were screened through CTA. Right dominance was revealed in 90 patients (85.0%), left dominance in thirteen (12 %), and co-dominance in three (2.8%). The Most common origin of conus artery was from RCA in 77 out of 106 cases (72.6 %), the conus artery is also originated from same ostium or the right sinus valsalva in 13/106 cases (12 %), and it had a separate ostium origin in the remaining 18 cases (16.9%). The sinus node artery (SNA) originated from the RCA in 71 cases (66.9 %) and the left main coronary artery (LMCA) in 35 cases (33 %).The Ramus intermedius branch were found in 18 cases. The variation in LAD was found as type I in 26 cases (24.5%), type II in 37 cases (34.9 %), type III in 25 cases (23.5 %) and type IV in 18 cases (16.9%).Type I is described as not supplying the apex, type II partially supplying the apex and type III supplying entire the apex and type IV wraps around the apex.

Coronary artery anomalies were observed in a total of 13 cases (57.8%). One case (0.9%) had no Left Main Coronary Artery (LMCA). Left anterior Descending (LAD) and Left Circumflex (LCx) had outflows with separate ostia from the left sinus valsalva due to the absence of the LMCA. In this case LAD and LCx originated from the sinus valsalva between the aortic annulus and sino-tubular junction and blood flow was not low or high.

The LMCA trunk presented a variable length (mean 11.35±3.3 mm, range 1.2–18.7 mm, : <1 cm (n=34, 33%), 1–2 cm (n=72, 67.9%).

When coronary arteries runs via myocardium, it is called as Myocardial bridging, was observed in 12 of 106 cases (11.3%). The mid-distal segment of the Left Anterior Descending was commonly affected by myocardial bridging.

DISCUSSION

The appropriate knowledge of coronary artery variant or anomaly is very helpful to avoid difficulties during cardiac interventions or complications during graft surgery. Angioplasty process requires a precise anatomical evaluation of the coronary artery branching for revascularization purposes. (8) Coronary anomalies are relatively asymptomatic and sometimes accidentally discovered. The coronary anomalies may be the cause of severe complications, so they are not be consider just rare. (9)

Interpretations of coronary CTA images should be commenced by the study of dominance of the coronary artery system. Earlier studies on coronary CTA examination have essentially commented on this aspect .(10,11) Co- dominance is described by different authors but there is no marked concord on co-dominance and some authors defined that if the PDA and the posterior left ventricular branches together supply blood to the infero-lateral section of the posterior septum. (11, 12) Previous studies were revealed that the rate of right dominance was 80-85%, left dominance was 7-9%, and co-dominance was 5-8%. (10, 11, 12) In our study, right dominance was found in 85%(90 cases), left dominance in 12%(thirteen cases) and co-dominance in 2.8%(three cases).The rates of right and left dominance of this study were somehow similar with the earlier studies, but the lower co-dominance rates may be clarified by the fact that different authors had no agreement on co-dominance of the coronary arteries.

The conus artery commonly originates from the RCA but it may also originate from the right sinus valsalva via a separate orifice. (13) In our study, the conus artery originates from the right coronary artery in 77(72.6 %) patients , common origin from same ostium (right conus artery and right coronary artery from right sinus of Valsalva) was seen in 11(10.3%) patients and separate ostium (aortic) origin of conus artery was seen in 18(16.9%) patients. The origin of conus artery

according to a study was, from RCA 83.1% and from same ostium 16.86%.(14) In contrast to this study our study shows a higher incidence of conus artery origin from separate ostium (10.3%).It may be because of geographical and racial difference.

In our study, it was found that the SNA originated from the RCA in 71 cases (66.9 %), from the Left Cx in 35 cases (33%). Our findings well correlated with the literature which has observed that the SNA is most commonly originated from the RCA. (14)

Anatomically LMCA has two branches, LAD and Cx but sometimes it may trifurcate and the third branch is called as Ramus intermedius which is the most common variation in LMCA. The Ramus intermedius artery itself has variable branching. The Ramus intermedius can be of two types .When it supplies the anterior wall, it is identified as a diagonal branch and when it supplies the lateral wall, it is described as an obtuse marginal branch. In our study, the Ramus intermedius variation was found in 18 cases (16.9 %), this branch is one of most common variations observed in the left coronary arterial system with an incidence rate of 33%.Our observation was lower than the previous studies. (5, 15)

The incidence of the absence of a LMCA is very low in previous studies from 0.41 to 0.52% (16, 17) however Cademartiri et al. notified a high incidence rate of 3.3%.(18) We found only one case (0.9%) of the absence of the LMCA .The incidence rate for the absence of the LMCA in our study was comparable to the former observations. (5, 15) The absence of a LMCA does not have any clinical consequences and does not affect blood flow to myocardium. Although The lack of information about this anomaly may lead to misdiagnosis for example a normal LAD and Cx can be considered stenotic mistakenly in case of the absence of a LMCA. (16) Such errors can be avoided when screening of coronary artery performed by CTA and identification of such anomalies is important before planning invasive procedure for the LMCA. (17, 19)

The coronary arteries usually have an epicardial course but occasionally they may have an intra-myocardial segment. This condition is described as myocardial bridging .The incidence rates for this have been reported as 0.5-2.5% in invasive coronary angiographies while the rates are higher (10.9-43.3%) in 64 and 128 slice CT angiographies. (14,18) Normally this does not cause a problem for a person who have it, but it may rarely result in acute myocardial infarction (MI), acute coronary syndrome, coronary spasm, rupture of ventricular septum, arrhythmia, or even sudden death. Though, in arrhythmic patients with angina, myocardial bridging should be excluded. (5,20,21)We found that the myocardial bridging was observed in a total of 12 cases (11.3%) in the current study. Myocardial bridging was most frequently observed in the mid-distal segment of the LAD. Our study revealed that CTA is very precise in detecting myocardial bridging.

Anomalies of coronary arteries may generally do not create a significant risk to myocardial perfusion but sometimes these may lead to fatal pathologies which may couse in sudden cardiac casualty and myocardial ischemia. Sudden cardiac deaths among young people after exercise or sport activity are due to coronary artery anomalies.(22) Invasive coronary angiography does not give a complete information, and the details are limited about the origin of anomalies. (23) New – generation CT modality provide an accurate and detailed information about all the of the above coronary artery variations to cardiologists.

CONCLUSION

In conclusion, the 64-slice CT is an efficient diagnostic tool to evaluate the anatomic variations and anomalies of the coronary arteries and give comprehensive and accurate information about it. The coronary CTA can replace the percutaneous invasive procedures or preoperative catheter angiography for coronary arteries, and it may also be more beneficial to patients because of its low radiation dosage relative to invasive angiography,

the opportunity to use less of a contrasting agent, the increase in the number of cross-section, test duration, shortening the improvement in temporal resolution and its non-invasive approach increasingly supports the use of this technique.

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Table 1: The prevalence of anatomic variations of coronary arteries, and the percentages of patients

Anatomic variation of coronary arteries	N (106)	%
Dominance		
Right	90	85
Left	13	12
Co-dominance	3	2.8
Conus Artery Origin		
From Right coronary artery	77	72.6
From Same ostium	11	10.3
From Separate ostium	18	16.9
Sinus Nod artery		
Right coronary artery origin	71	66.9
Left Circumflex artery origin	35	33
Ramus Intermedius	18	16.9
Left Anterior Descending artery		
Type I	26	24.5
Type II	37	34.9
Type III	25	23.5
Type IV	18	16.9
Coronary artery anomalies related to their anatomy		
Absent left main coronary artery	1	0.9
Myocardial bridging	12	11.3

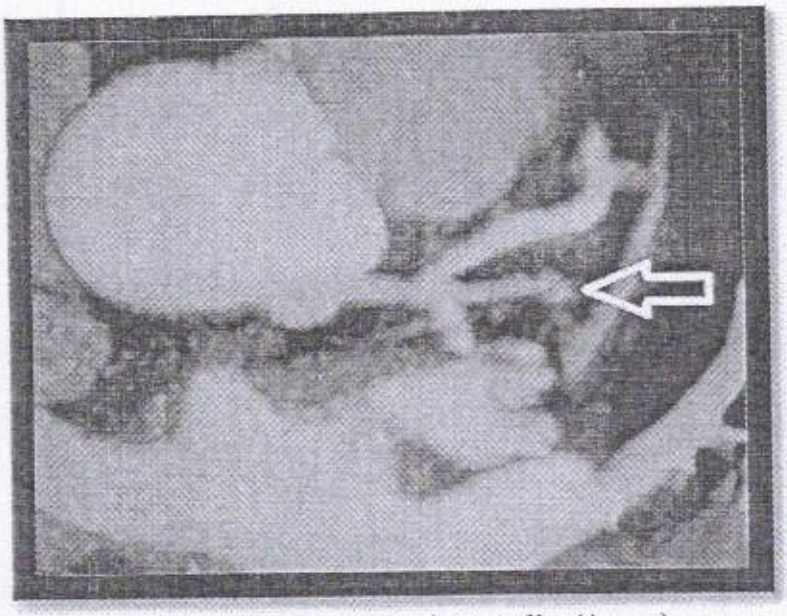

Figure 1 Showing Ramus intermedius (Arrow)

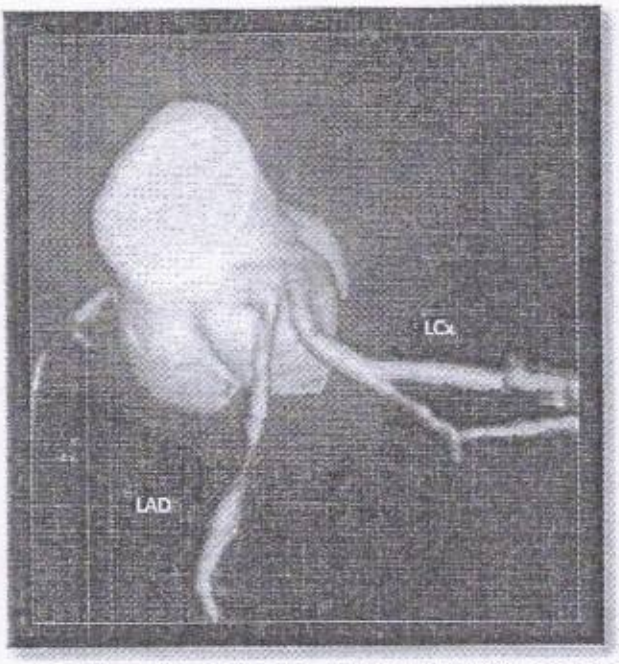

Figure 2.Showing absent Left main coronary artery (LMCA) and origin of Left Anterior Descending (LAD)and Left circumflex (LCx)from the left sinus valsalva

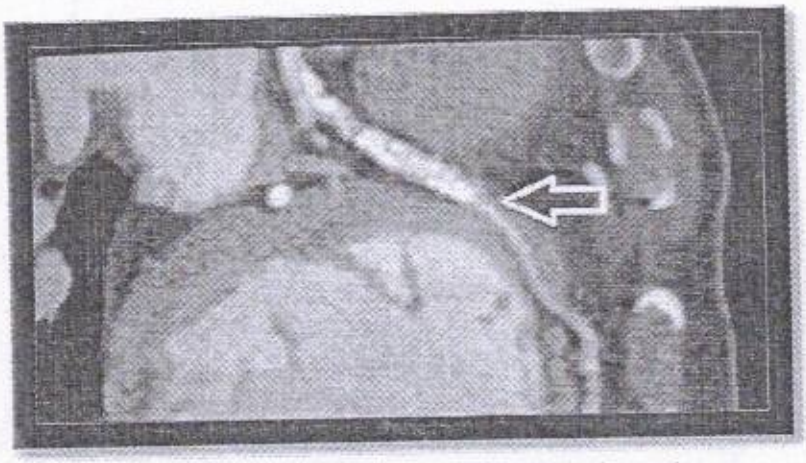

Figure 3 Showing Myocardial bridging (arrow)

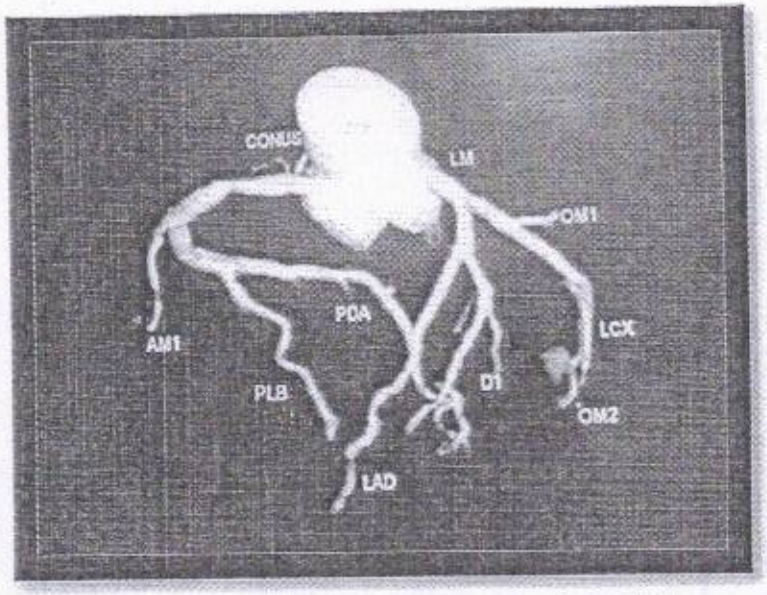

Figure 4 Showing Coronary artery tree in 64 CTA

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FREQUENCY AND CLINICAL SIGNIFICANCE OF THE CONUS ARTERY AS THIRD CORONARY ARTERY ON 64-SLICE COMPUTED TOMOGRAPHY ANGIOGRAPHY (CTA)

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ABSTRACT

Background of the study: Wide information of the anatomy of coronary arteries is useful for a management decisions of the coronary artery disease or for systemic planning of surgery. The objective of this study is to establish variations of Conus coronary arteries which arise directly from aorta and revealing about their frequency .These findings would be of great significance in the interpretation of coronary arteriography, angiography and surgical myocardium revascularization.

Research Methodology: A total number of 111 angiograms were utilized for this study. The coronary angiographic images were evaluated in this study. The study is design to investigate the number by the mean of origin of right conus artery.

Results: The results shows the right conus artery originates from right coronary artery in most of the people 77(69.3%). In this study right conus artery originate from same ostium in 15(13.5%) individuals and from Separate ostium (aortic) origin were seen in 18(16.2%).

Conclusion: A selective Angiography is recommended for conus artery because the frequency of conus artery as the third coronary artery is 29.7% of screened cases of Cat-scan coronary angiography (CTA).

Keywords: Right conus artery (R.Con.A), right coronary artery (RCA), Ostium, pattern of origin,computed tomography Angiography (CTA)

INTRODUCTION

Two coronary arteries, the right and the left one are supplying blood to human heart in general population. Prevalence of Congenital coronary variations is are quite low, which is changing from 0.3% of autopsy reports to 1.3% of angiographic studies.(1,2) Sometimes extra coronary arteries are also present. The right conus artery (R.Con.A) considered as the third coronary artery, because it is originates as a separate artery from the anterior aortic sinus. (3) The right conus artery most frequently arises from the proximal part of the right coronary artery (RCA). The conus artery vascularises to the conus, or outflow tract, of the right ventricle and is usually found to be the first branch of the right coronary artery. (4) Several scientists have suggested that it provides a collateral connection between the right and left coronary arteries. The conus artery variation may be an advantage for the person having it. (5) Computed tomography Angiography (CTA) study facilitates the routine diagnostic workup for the management of Cardiac disorders. In Coronary artery diseases patients, it is also needed to carry out conventional angiography of the third coronary artery (6, 7). An intimate knowledge of the occurrence and distribution of conus coronary arteries is important for correct

understanding of coronary angiograms, assessment of severity and effect of coronary insufficiency, and appropriate preparation and time being myocardium revascularisation (8).The purpose of this study is to establish variations of Conus coronary arteries which arise directly from aorta and its frequency.

MATERIAL AND METHODS

The patients, who had undergone The CT coronary angiograms for various reasons during 3 years at Geetanjali medical college and hospital, Udaipur, were included in this study.

A. Exclusion criteria

Patient with high calcium score >500 were excluded.

B. CT scan and reconstruction parameters:

All examinations were performed with a 64-slice CT scanner (Sensation 64, Siemens, Forcheim, Germany) with the scan protocol described in table no.1.

C. Procedure:

Pre-procedure precautions

The patients were enquired, to rule out the presence of any drug allergy, to avoid the occurrence of any untoward anaphylactic reaction, during the procedure. Patients were advised to avoid tea and coffee a day prior to procedure. Blood urea and creatinine levels were checked before the procedure. The heart rate of patients were stabilised with an oral dose of 40 mg propronalol one hour before the scan, in whom a heart rate were greater than 75 beats/min. Sublingual nitroglycerine was given to the patient just before the scan. A bolus of 100 ml of high iodinated contrast material (350 mg/ml ULTRAVIST German remedies) was injected into an antecubital vein of the right arm with a flow rate of 5 ml/s, followed by a 40-ml saline chaser. A bolus-tracking method was employed for the synchronization between arterial route of contrast material and MSCT-CA. The patient was now shifted to the CT scanner. Adequate counselling of patients were done to reduce anxiety, to preserve the best possible heart rate of 55-60 beats /min. CT angiograms of 110 patients were studied, to see the pattern of origin of right conus artery.

RESULTS

Variation in origin of Right Conus Artery

Out of 111 patients, the right conus artery originates from the right coronary artery in 77(69.3%) patients , common origin from same ostium (right conus artery and right coronary artery) was seen in 15(13.5%) patients and Separate ostium (aortic) origin of right conus artery were seen in 18(16.2%) patients as shown in Table no.2.

DISCUSSION

The variations of number of coronary arteries are relatively common in population suggested by many scientists and could be beneficial for person or could create clinical consequences. Some authors described cases of occurrence of only a single coronary artery come up from the left (9) or the right (10) aortic sinus. This single coronary artery may be associated with cardiac complications like congestive heart failure, myocardial infarction and sudden cardiac death in young athletes (11) Hadžiselimović (12) points out those even three coronary arteries may arise independently from the right aortic sinus. Four coronary arteries were reported by Almira (2008) in one case, where both supernumerary arteries arose from the right aortic sinus.(13)

Usually in most of the cases extra coronary artery begins from the right aortic sinus. Previous studies put forward several terms for classifying this artery: adipose artery, conal artery, arteria of Vieussens, preinfundiblar or supernumerary right coronary artery (12,14,15,16). Usually this coronary artery is a branch of Right coronary artery and called as right conus artery but it has three variations according to its origin. The most appropriate term for this artery when it originate from separate ostium, is the third coronary artery.

Information about incidence of the third coronary artery are varying in different population from1.5% as stated by Lo (17) even to 62% as stated by Hadžiselimović (12).In our study right conus artery as third coronary artery was found in 29.7 % and this result correlated with Kalpana (2003) 24%, Pinar Kosar et al.(2009) 22% and difference with Susan standring (2006) 34% could be due to geographic variation (18,19,20). The other reason for this deference could be due to inability to selectively canulate conus /third coronary artery on conventional angiography.

The common origin of right conus artery with right coronary artery was observed in 13 %.This may be useful while performing conventional coronary arteriography and angiography. Gajbe et al. suggested that a preliminary aortic root injection of dye method was followed to locate the exact number of orifice of the coronary ostia, in order to prevent the fatal outcome (21). An unusual conus artery arising independently from the RCA is mainly at risk for injury from ventriculostomy or other maneuvers carried out during heart surgery (22)

According to Udaya Sankari T et al if right conus artery directly arises from the aorta (third coronary artery) than it creates double collateral circulation for intra-ventricular septum and myocardium of the left ventricle. This prevents the right coronary artery "steal" phenomenon. "Blessed are the people, those who are born with right conus artery with long branches" (23)

In our study, the third coronary artery was found in 29.7% of screened cases what is comparable with the results showed by Yamagishi [30%] (24).In this study, 69.3% of the population had the right conus artery arising from the right coronary artery and in the rest 29.7% of the individual's right conus artery either arose directly from the aorta or in common with right coronary artery. So the present study suggests that 29.7% of population needs care while performing coronary angiography to prevent fatal outcome. The third coronary artery could be very useful collateral in case of proximal RCA stenosis.

CONCLUSION

A non-invasive imaging of small mobile structures, such as coronary arteries has possible with the new advancement in imaging technology, such as multidetector ECG gated CT. Coronary artery diseases have high morbidity, mortality, and socioeconomic burden on society. A non-invasive detection of Right conus artery stenoses is corner stone in management of coronary artery disease with help of 64-slice computed tomography Angiography (CTA).

A selective Angiography is recommended for conus artery because the frequency of conus artery as the third coronary artery is 29.7% of screened cases of CTA. The third coronary artery is appropriate term to categorize extra coronary artery which arises separately from the right aortic sinus. The third coronary artery is an extra artery or god blessing for whom that has it and be very valuable for collateral perfusion.

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Table 1 Scan protocol of 64-slice coronary CT angiography

Scan protocol (Sensation 64, Siemens, Forcheim, Germany)	
Tube current	950 mAs
Tube voltage	120 kV
Tube rotation time	330 ms
Section thickness	0.6 mm
Increment	0.3
Field of view	160-200 mm
ECG gating	Retrospective

Table 2: Variation in origin of Right Conus Artery

pattern of origin Percentage	n (111)	%
From Right coronary artery	77	69.3
Separate ostium	18	16.2
Same ostium	15	13.5
Not identified	1	0.9

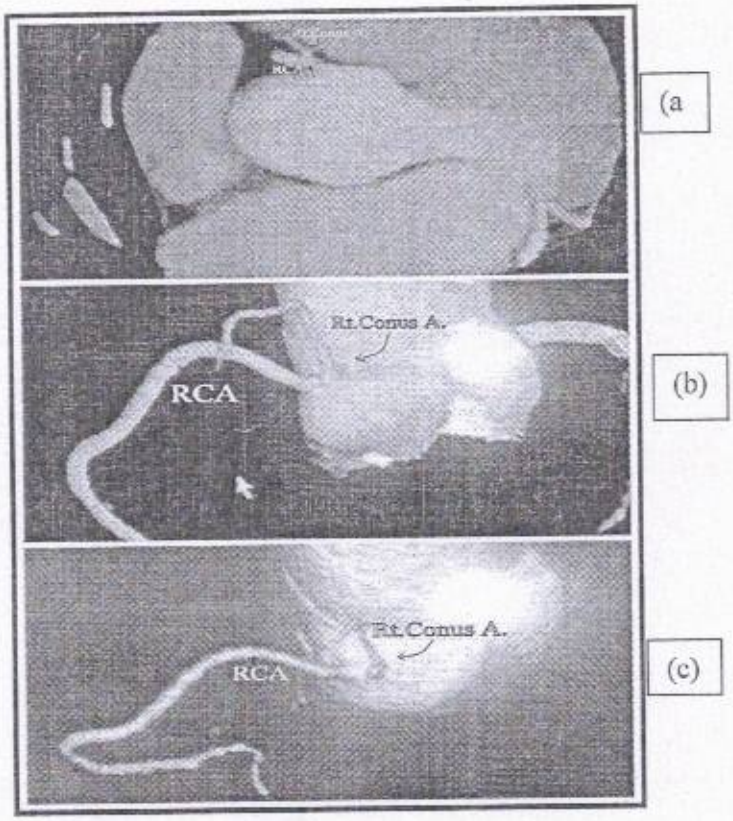

Fig.No.1: The variable origin of the Right conus artery (curved arrow): from Right Coronary Artery (RCA) (straight arrow) (a), in proximity with the ostium (Same ostium) (b), and from aorta (separate ostium) (c).

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Research Article

MRI detected prevalence of abnormalities in patients of knee pain

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ABSTRACT

Background: In patients of knee pain diagnosis has utmost important for treatment and to avoid unnecessary surgery. MRI is a non-invasive procedure in evaluation of knee joint. So this study was planned find out the prevalence of abnormalities detected by MRI in patients of knee pain.
Methods: Fifty patient of knee pain were examined after taking permission from institutional ethics committee by using Siemens Avanto MR machine with a superconducting magnet and field strength of 1.5 tesla using dedicated knee coil (Flex), which were referred from department of Orthopedics & Rheumatology.
Results: In this present study 72% patients were males and 28% patients females and their ages ranging from (11-80) years. Knee pain was found common in age group 31-40 years. Menisci lesions (44%) were more common as compared to ligament lesions (14%) in patients of knee pain. Osteoarthritis was found in 40 % of patients of knee pain. Joint effusion and marrow edema was found with incidence of 74% and 62% respectively. 4% patients were suffering from intraarticular tumors.
Conclusions: Knee pain can occur at any stage of life due to various causative factors. MRI can demonstrate the exact nature and extent of bony as well as soft tissue abnormality. This has increase the use of MRI in evaluation of patients of knee pain.

Keywords: MRI, Knee pain, Menisci, Osteoarthritis

INTRODUCTION

Knee problems may be responsible for much of musculoskeletal disability in elderly persons. The prevalence of abnormalities increased with age, as might be expected. Knee pain is considered as most frequent symptom related to knee problems which brings patient to the hospital. Knee pain and related symptoms may come as a result of damage to one or more of the soft tissue structures that stabilize and cushion the knee joint, including the ligaments, muscles, tendons, and menisci or due to non-traumatic injury like infection, inflammation etc.[1] Presentation of knee pain in a middle-aged or older patient often leads to an x-ray of the knee but MRI is being used in clinical practice to facilitate diagnostic decisions. The potential for MRI to be more sensitive to earlier disease, detecting change, and the capacity of this technology to visualize joint structural changes beyond gross changes in bone and in the joint space, has resulted in great interest in the use of MRI for assessing diagnostic status, disease severity and monitoring progression.[2,3] MRI visualizes most components of the joint, including articular cartilage, menisci, intra-articular ligaments, synovium, bone marrow, subchondral cysts, and other periarticular and intra-articular lesions that are not detectable by radiography.[4] Various studies have reported structural changes in people with knee osteoarthritis by radiographic findings. Very few data are available regarding what structural changes are present in patients of knee pain and also this type of study was not

conducted in our institute. So, this study was planned to find out the prevalence of abnormalities detected by MRI in patients of knee pain which will guide the physician in making treatment strategies according to diagnosis.

METHODS

This prospective study was carried out for a period of six month after taking the permission from institutional ethics committee. A total of 50 patients referred to the department of Radio- diagnosis from department of Orthopedic and Rheumatology with complaints of knee pain were recruited. Patients' socio-demographic data, clinical history and physical examination findings were recorded after taking informed consent to correlate the findings. The patients of knee trauma and who had no complaint of knee pain were not included in this study.

Procedure:

MRI acquisition knees were imaged by using Siemens Avanto MR machine with a superconducting magnet and field strength of 1.5 tesla using dedicated knee coil (Flex).

Each examination consisted of the following: coronal intermediate-weighted (repetition time msec/echo time msec, 2200/20) and T2- weighted (2200/80) dual spin-echo images (number of signals acquired, two; section thickness, 5 mm; intersection gap, 0.5 mm; field of view, 160 mm; acquisition matrix, 205×256; and number of sections, 18), sagittal intermediate-weighted (2200/20) and T2- weighted 4 (2200/80) dual spin-echo images (number of signals acquired, two; section thickness, 4 mm; intersection gap, 0.4 mm; field of view, 160 mm; acquisition matrix, 205×256; and number of sections, 20), sagittal three dimensional T1- weighted spoiled gradient-echo frequency-selective fat suppressed images (46/2.5; one signal acquired; flip angle, 40°; section thickness, 3 mm; section overlap, 1.5 mm; no gap; field of view, 180 mm; acquisition matrix, 205×256; and number of sections, 80), and transverse intermediate weighted (2500/7.1) and T2-weighted (2500/40) turbo spin echo fat-suppressed images (number of signals acquired, two; section thickness, 2 mm; no gap; field of view, 180 mm; acquisition matrix, 205×256; and number of sections, 62). Total acquisition time, which included the initial survey sequence, was 30 minutes. Protocol of examination was in line with European society of musculoskeletal radiology (ESSR). It starts with the patient in supine position and slightly externally rotates the foot by about 10-15 degrees to stretch the anterior cruciate ligament. Pack some cushions around the knee to help it stay motion free. A small cushion under the ankle helps to keep the leg straight. Evaluation of the knee including the patello-femoral joint, medial and lateral compartments as well as related tendons and ligaments and the popliteal fossa is performed with a high resolution proton density sequence acquired in 3 planes: Axial, Sagittal and Coronal. Evaluation of bone marrow for contusion requires a T2 fat saturation sequence in either coronal or sagittal planes. If the patient has a suspicious mass then T1 fat saturation images are helping to determine if the mass is benign or malignant and better delineate its full extent. Obtained MRI images were diagnosed by an experienced musculoskeletal radiologist for the presence of ligament injury, tear, strain and laxity, as well as menisci degeneration and tear, joint effusion, subchondral and bone marrow edema, bony contusion, bursitis, baker cyst and tumor were noted in all patients.

Statistical analysis:

Data were expressed in percentages in comparison tables and graphs. Statistical analysis was performed using Microsoft Excel Software and the standard Statistical Package for the Social Sciences version 15 for windows.

RESULTS

Total 50 patients were recruited with in a study period of six month. MRI of knee was conducted in patients who were complaining knee pain. Of these 50 patients 36 (72%) were male and 14 (28%) were female, with male to female ratio of 2.6:1. Mean age of the patients was 42 years (range 11 to 80 years). They were classified into age groups and out of these groups 12 were found to be in age group between 31-40 years. In this age group 8 were male and 4 were female patients (Table 1).

Table 1: Distribution of patients according to age group and sex.

Age group	Males	Females	Number of patients (Total 50)	Percentage
<10	0	0	0	0
11-20	04	01	05	10
21-30	09	01	10	20
31-40	08	04	12	24
41-50	08	03	11	22
51-60	05	04	09	18
61-70	02	0	02	4
71-80	0	01	01	2

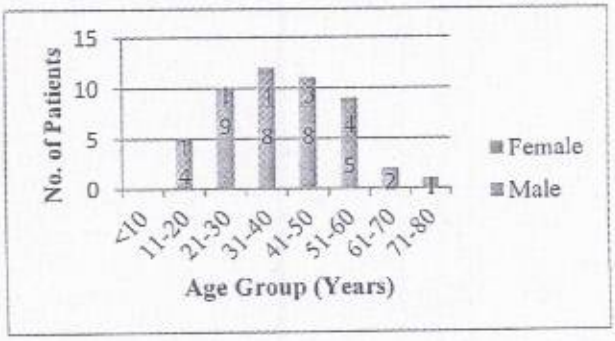

Figure 1: Demographic profile of patients including age & sex (n=50).

Table 2: Most common knee pathologies detected by MRI in patients of knee pain and their distribution with sex.

Knee pathologies	Male	Female	Total patients (50)
Joint effusion	25	12	37 (74%)
Bone marrow edema	22	9	31 (62%)
Meniscal lesions	15	7	22 (44%)
Osteoarthritis	10	10	20 (40%)
Ligament lesions	4	3	7 (14%)
Baker's cyst	4	2	6 (12%)
Ganglion cyst	4	1	5 (10%)
Subchondral edema	1	1	2 (4%)
Tumor	1	1	2 (4%)
Pateller Subluxation	1	1	2(4%)

Table 3: Types of meniscal lesion detected by MRI in patients of knee pain.

Meniscal degeneration (Grade 1)	7
Meniscal degeneration (Grade 2)	15
Total	22

Joint effusion was most frequently found knee pathology constituting 74% in patients of knee pain followed marrow edema (62%), meniscal lesion (44%), and osteoarthritis (40%). Osteomyelitis, simple bone cyst, bone infarct and chondomalacia patellae were least common constituting 2% incidence of each (Table 2). Meniscal injury (44%) was found more common in patients of knee pain as compared to ligament injury. Table 3 shows different grades of meniscal lesions in patients of knee pain.

DISCUSSION

MRI is a valuable tool in the evaluation and management of patients of knee pain and it has been established as an effective, noninvasive test for identifying different knee pathologies.[5] MRI affects the treatment of patients with knee problems because it shows entire lesion in multiple planes so that exact diagnosis and treatment can be planned. Studies have shown that surgery of the knee is less frequently performed after MRI than initially planned before MRI.[6,7]

In this study fifty patients of knee pain were evaluated by MRI. Knee pain was found to be common in males (72%) as compared to females. Similar results were reported in other studies too.[8,9] This could be because of more activities in young males during sports as compared to females and they are also are more prone to accidents. In our study most affected age group was 31-40 years. This supports the reasoning that it is more common in young adult. One study has reported more females as compared to male. We could not find exact reason for that.

Joint effusion was found to be most frequent associated lesion constituting 74%. In another study joint infusion was reported in 63.8%.[8] Higher percentage of joint effusion in our study and other study too could be due to more synovial reactions in patients of knee pain. Bone marrow edema was also found in 62% of patients of knee pain. This much high percentage of marrow edema in patients of knee pain may be due to non-specific finding which is simply fluid accumulation within the bone when there is any insult to bone. A recent systematic review reported that bone marrow lesions and effusion were associated with knee pain.[10]

Menisci lesions were found in 44% patients. Depending on the patient's age, a prevalence of meniscal lesion up to 36% has been reported.[11] In our study most of the menisci lesions was found in males. Similar results have reported by other studies too of higher incidence of menisci injuries in male.[12,13]

Grade I/II injury (signal changes) are common in our study because these are mostly occur with degeneration changes in knee joint and more common in 3rd and 4th decade[14] and in our study most of the patients were in age between 31-50. A meta-analysis based on 22 studies described an overall sensitivity of 88% and specificity of 94% for detecting meniscal lesions with different grades.[15] This would avoid unnecessary arthoscopic examination.[1]

Osteoarthritis was found in 40 % of patients of knee pain with equal prevalence in both male and female. Baker's cyst which is mostly present with osteoarthritis patient was found in 12% in patients. Similar incidence of baker's cyst has been reported by other study conducted by Nasir A.[9] In other studies incidence of osteoarthritis was found more in females and age above 50. The prevalence of osteoarthritis varies greatly depending on the definition used, age, sex and geographical area studied.[16,17]

Difference in our study could be due to more patients in age group 21-50 years. MRI is an excellent tool for diagnosis of intraarticular tumors which in our study shows 4% incidence. MRI is accurate, noninvasive technique for evaluating the structures of the knee, marrow space, synovium and periarticular soft tissue concerning the knee.[18,19]

To conclude, knee pain can occur at any stage of life due to various causative factors. Most of the patients in our study found to be males. MRI gives the noninvasive diagnosis to the patients for their appropriate treatment. This has increase the use of MRI in evaluation of patients of knee pain.

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Original Article

Section Radio diagnosis

An Analytical Study on Prevalence of Knee joint abnormalities assessed by MRI- A Hospital Based Study

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ABSTRACT

Background: *In order to treat the patients suffering from knee joint ailments, diagnosis has plays an essential role for treatment and to avoid unnecessary surgery. MRI is a non-invasive procedure in evaluation of knee joint. So this study was planned find out the prevalence of abnormalities detected by MRI in patients of knee pain.*

Methods: *This prospective study was carried out on n= 62 patients of knee pain. Patients were examined after taking permission from institutional ethics committee by using Siemens Avanto MR Machine with a superconducting magnet and field strength of 1.5 tesla using dedicated knee coil (Flex), which were referred from department of Orthopaedics.*

Results: *In this present study 41 patients were males and 21 patients females and their ages ranging from (20-65) years. Knee pain was found common in age group 46-60 years age group. Joint effusion n=50 were more common followed by Edema n=40, Menisci lesions n=33 were more common as compared to ligament lesions n=7 in patients of knee pain. Osteoarthritis was found in 54.6 % of patients of knee pain.*

Conclusion: *Knee pain can occur at any stage of life due to various causative factors. MRI can demonstrate the exact nature and extent of bony as well as soft tissue abnormality. This has increase the use of MRI in evaluation of patients of knee pain.*

Keywords: *MRI, Knee pain, Menisci, Osteoarthritis*

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INTRODUCTION

Knee pain is considered as most frequent symptom related to knee problems which brings most of the patient to the hospital. Damage to the tissue structures that stabilises Knee joint may cause pain and related symptoms or due to non-traumatic injury like infection, inflammation etc.[1] Many patients with knee pain often leads to an x-ray of the knee but now a days MRI is also being used to facilitate diagnostic decisions. MRI plays an important role in the detection of early disease, detecting change, and the capacity of this technology to visualize joint structural changes beyond gross changes in bone and in the joint space, has resulted in great interest in the use of MRI for assessing diagnostic status, disease severity and monitoring progression.[2,3] Most part of the joint that are not visualised by other radiographic techniques can easily be done by MRI.[4] Previous studies have revealed underlying changes in individuals with knee osteoarthritis with the help of radiographic findings. As few studies have been done in the past regarding what structural changes are present in patients of knee pain, therefore this study was conducted to find out the prevalence of abnormalities detected by MRI in patients of knee pain which will guide the physician in making treatment strategies according to diagnosis.

METHODS

This prospective study was carried out on patients of knee pain attending Orthopaedic. Study was commenced after written informed consent taken from all the patients and with the permission from institutional ethics committee. About 62 patients were enrolled who were referred to the department

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of Radio- diagnosis from department of Orthopaedic with complaints of knee pain. Other findings like demographic data, clinical history and physical examination were recorded after taking informed consent to correlate the findings. The patients of knee trauma and who had no complaint of knee pain were not included in this study.

Statistical analysis:

Data were expressed in percentages in comparison tables and graphs. Statistical analysis was performed using Microsoft Excel Software and the standard Statistical Package for the Social Sciences version 15 for windows.

RESULTS

Total 62 patients were recruited on the basis of inclusion ad exclusion criteria. MRI of knee was conducted in patients who were complaining knee pain. Of these 41 patients were males and 21 patients were females. Knee pain was found more common in 46-60 age group followed by 31-45 years age group and least in <15 years age group.

Joint effusion was most frequently found knee pathology constituting n=50 patients of knee pain followed marrow edema n=40, meniscal lesion n=33, osteoarthritis n=36 and Rheumatoid Arthritis n=12. Simple bone cyst, Ligament lesions, Bakers cyst were least common constituting (Table 1). Meniscal injury was found more common in patients of knee pain as compared to ligament injury. Table 2 shows different grades of meniscal lesions in patients of knee pain.

Table 1: Knee pathologies as detected by MRI in patients suffering from knee pain (n=62)

Knee Pathologies	Male	Female
Joint effusion	30	20
Bone marrow edema	32	8
Meniscal lesions	24	9
Osteoarthritis	20	16
Rheumatoid Arthritis	3	9
Ligament lesions	4	3
Baker's cyst	4	2
Ganglion cyst	4	0
Subchondral edema	1	1
Patellar Subluxation	1	0

Table 2: Meniscal lesion detected by MRI.

Meniscal degeneration	Number
Grade 1	8
Grade 2	15
Total	23

DISCUSSION

MRI plays an important in the assessment and the board of patients of knee torment and it has been set up as a successful, non-intrusive test for distinguishing distinctive knee pathologies.[5] MRI affects the treatment of patients with knee problems because it shows entire lesion in multiple planes so that exact diagnosis and treatment can be planned.

In this study n = 62 patients of knee pain were evaluated by MRI. Knee pain was found to be common in males as compared to females. These findings are in accordance with other studies too.[8,9] [6,7] This could be because of more activities in young males during sports as compared to females and they are also are more prone to accidents. In our study most affected age group was 46-60 years. This finding contradicts other studies showing high prominence in 30-45 age group.

Joint effusion was found to be most frequent associated lesion. In another study joint infusion was reported in 63.8 %.[5] Higher percentage of joint effusion in our study and other study too could be due to more synovial reactions in patients of knee pain. Bone marrow edema was also found in n=40 of patients of knee pain. This much high percentage of marrow edema in patients of knee pain may be due to non-specific finding which is simply fluid accumulation within the bone when there is any insult to bone. A recent systematic review reported that bone marrow lesions and effusion were associated with knee pain.[8]

In our study Menisci lesions were found in 52.8% patients. Depending on the patient's age, a prevalence of meniscal lesion up to 36% has been reported.[9] In our study most of the menisci lesions was found in males. Similar results have reported by other studies too of higher incidence of menisci injuries in male.[10,11]

As most of the patients in our study were found to be in between 31-50 Grade I/II injury (signal changes) are common in our study. A meta-analysis based on 22 studies described an overall sensitivity of 88% and specificity of 94% for detecting meniscal lesions with different grades.[12] This would avoid unnecessary arthoscopic examination.[1]

Cases of Osteoarthritis was found in 54.6 % of patients of knee pain with male and female affected equally. Baker's cyst which is mostly present with osteoarthritis patient was found in 9.6% in patients. Similar incidence of baker's cyst has been reported by other study conducted by Nasir A.[9] In other studies incidence of osteoarthritis was found more in females and age above 50. The prevalence of osteoarthritis varies greatly depending on the definition used, age, sex and geographical area studied.[13,14]

Our study differ from other studies as most of the patients were in age group 21-50 years. MRI is an excellent tool for diagnosis of intraarticular tumors which in our study shows 4% incidence. MRI is accurate, non-invasive technique for evaluating the structures of the knee, marrow space, synovium and periarticular soft tissue concerning the knee.[15,16]

CONCLUSION

It can be concluded from the findings of our study Knee pain can occur at any age due to various causative factors. MRI gives the non-invasive diagnosis to the patients for their appropriate treatment. Therefore, use of MRI in evaluation of patients of knee pain is increased now a days.

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Section: Radio diagnosis

Original Article

A Retrospective Sonological Evaluation of Placental Thickness with Respect to the Gestational Age in a Tertiary Care Hospital in Rajsamand

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ABSTRACT

Background: *Placenta is a source of nutrition for the developing fetus. It can throw light on its health and growth status also. sonography provides the accurate determination of gestational age. It is the most useful information. In estimating GA, growing evidences on the prediction of placental thickness are directing the obstetricians to measure PT as a routine in pregnant woman.*

Methods: *In our study we includes 200 normal antenatal subjects of gestational age ranging from 11 weeks to 40.This study conducted in the Department of Radiology.*

Results: *This result revealed that placental thickness increases with each week of gestation from 11.51mm at 11 weeks to 37.13mm at 40 weeks of gestational age as given in last.*

Conclusions: *It can be concluded that antenatal ultrasound examinations should include measurement of placental thickness, because it helps in quantifying intrauterine environmental adequacy and fetal well-being.*

Keywords: *Placental thickness, Sonography, antenatal cases*

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INTRODUCTION

A normal pregnancy should be happened between 38 and 42 weeks. The delivery of a single baby, with foetal weight of 2.5 kg or more and with no maternal complication is considered as normal pregnancy.[1] Other factors like biochemical test results, evaluation of foetal growth, risk assessment of various foetal anomalies, expanded maternal serum biomarkers, gestational age plays an important role and help the obstetrician to take proper measures that would optimize outcome of foetal.[2] There are major antenatal implications of using ultrasonography. It provides a safe and non-invasive means for the evaluation of the placenta whose normal and abnormal size, appearance and growth pattern can be explained. The placenta is a foetal organ. It provides the physiological link between a pregnant woman and the fetus with important metabolic, endocrine and immunologic functions. Moreover, it is also responsible for nutrition, respiration and excretion for the fetus. As a barrier, it has a role in protecting the fetus from harmful agents.[3] Placental size is a manifestation of health and size of the fetus. The placenta grows from the chorionic villi at the implantation site at about the fifth week of gestation and by the ninth or tenth week, it is clearly visible at sonography as diffuse granular echo texture.[4,5] Scientifically, it would define as the fusion of fetal organs to maternal tissue for the purpose of physiologic exchange. It is usually 2-4 cm thick and weighs around 600 grams.[6] With the new advances in grey scale and Doppler sonography, it is possible to study the placental sonographic appearance and its relationship to uteroplacental blood flow measurement and intrauterine growth. Accurate assessment of gestational age (GA) is very important in assessing the growth of fetus and to plan for delivery. Placenta is a source of nutrition for the developing fetus. It can throw light on its health and growth status also. Studies have revealed that

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during 17-20 weeks, changes in placenta correlate well with the development of the fetus and can predict fetal abnormality. Currently the most effective way to date pregnancy is by the use of ultrasound parameters. Numerous sonographically derived fetal parameters are used to date the pregnancy. According to Campbell S, placental parameters are useful in assessing GA and intra uterine growth retardation that needs early intervention. For estimating gestational age, measurement of placental thickness (PT) can also be used as a new additional parameter. Obstetric sonography provides the accurate determination of gestational age. It is the most useful information. In estimating GA, growing evidences on the prediction of placental thickness are directing the obstetricians to measure PT as a routine in pregnant woman.[7-12]

METHODS

Study Population: - In our study we includes 200 normal antenatal subjects of gestational age ranging from 11 weeks to 40.

Study Area: - This study conducted in the Department of Radiology.

Data collection: - The transabdominal sonography was performed on each subject using Philips Envisor equipment, which has a multifrequency convex transducer with frequency range of 2 to 5MHz. Thickness of placenta was measured from the echogenic chorionic plate to placental myometrial interphase (excluding myometrium and sub placental veins). All these measurements are taken when uterine myometrium is in relaxed phase. Sonologically site of umbilical cord insertion was identified as a 'V' shaped hypo echoic area close to the chorionic plate, where placental thickness was maximum. Calculation of gestational age in 1st trimester was done by measuring CRL (crown-rump length) using had lock tables and for 2nd & 3rd trimesters composite of fetal measurements like biparietal diameter, circumference of head and abdomen taken at appropriate levels and femur length are used.

Data analysis:-Data were analysed by using Microsoft excel.

RESULTS

In our study we were included total 200 cases. Among all cases 146 cases were belongs to 20-25 age group followed by 26-30 (28),<20(16) & >30(10). We observed placental position, out of 200 cases 66 cases of fundal anterior, 58 cases of fundal posterior,24 cases of anterior wall,26 cases of posterior wall & 26 cases of lateral wall position of placenta. This result revealed that placental thickness increases with each week of gestation from 11.51mm at 11 weeks to 37.13mm at 40 weeks of gestational age as given in last.

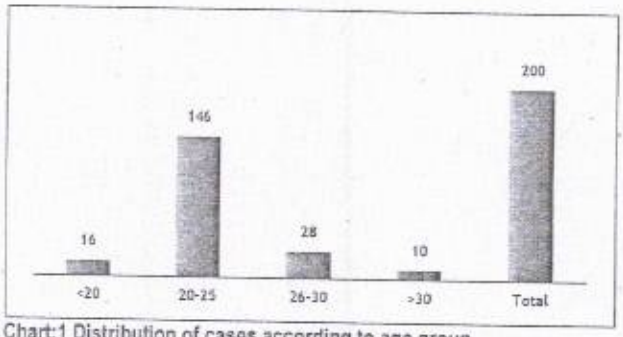

Chart:1 Distribution of cases according to age group

Table 1: Distribution of cases according to Placental position

Placental position	frequency
Fundal anterior	66
Fundal posterior	58
Anterior wall	24
Posterior wall	26
Lateral wall	26
Total	200

Table 2: Distribution of cases according to mean placental in relation of gestation age

Gestation age in weeks	No. of cases	Mean placental thickness
11	4	11.51
12	2	11.86
13	6	12.62
14	4	13.53
15	2	14.98
16	4	15.59
17	6	16.66
18	2	17.53
19	4	18.53
20	6	19.11
21	4	20.66
22	2	21.17
23	8	22.59
24	8	23.61
25	4	24.13
26	6	26.02
27	4	26.53
28	6	23.66
29	8	28.61
30	6	30.33
31	8	31.27
32	18	31.33
33	16	32.39
34	6	32.79
35	16	34.54
36	22	35.46
37	8	36.75
38	6	36.23
39	2	37
40	2	37.13

DISCUSSION

Previously, placenta was evaluated to determine its position or to know any premature separation is present or not. Due to this its role in management of pregnancy is very limited. But now days, with the help of advanced ultrasound equipment and more detailed examination of placenta, it is possible to understand the possible morphological changes

as the placenta matures from first trimester itself. Changes in placental thickness are an indication of normal growth of fetoplacental unit which is measurable on sonography. Altéred placental thickness has been related with several fetal and maternal pathological conditions. Measurement of placental thickness has an important role in screening of pregnancy related complications. Placental thickness must be required for each week of gestation. The abnormalities of fetus can be observed by calculating the placental thickness, as thickness of placenta is changed due to pathological processes.[13] Recognition of posteriorly located placentas is done by acquiring images, where fetal accosting shadowing is least and for anteriorly placed placentas correct positioning of transducer and proper adjustment of gain settings will decrease the near field and reverberation artifacts. Accuracy of placental measurements depends on detailed acquisition and interpretation of images. Error rate can be minimized by taking accurate measurements. For example, imaging obliquely through the placenta leads to images showing increased placental thickening which is incorrect. To reduce these measurement errors, it is necessary to perform the examinations by using the same equipment and also by the same examiner.

It is evident from the above study that sonographic measurement of placental thickness in singleton pregnancies can be used as an additional tool in the assessment of gestational age as its linear correlation with gestational age. An abnormal placental thickness for the respective gestational age should raise the suspicion of any underlying pathological process which may affect the pregnancy outcome. This early identification of abnormalities may help the obstetrician to consider specific antenatal care.

CONCLUSION

It can be concluded that antenatal ultrasound examinations should include measurement of placental thickness, because it helps in quantifying intrauterine environmental adequacy and fetal well-being.

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Section Radio diagnosis

Original Article

An Analytical Study on Prevalence of Knee joint abnormalities assessed by MRI- A Hospital Based Study

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[2]Assistant Professor, Department of Radio diagnosis, AIMS & RC, Rajsamand.

ABSTRACT

Background: *In order to treat the patients suffering from knee joint ailments, diagnosis has plays an essential role for treatment and to avoid unnecessary surgery. MRI is a non-invasive procedure in evaluation of knee joint. So this study was planned find out the prevalence of abnormalities detected by MRI in patients of knee pain.*

Methods: *This prospective study was carried out on n= 62 patients of knee pain. Patients were examined after taking permission from institutional ethics committee by using Siemens Avanto MR Machine with a superconducting magnet and field strength of 1.5 tesla using dedicated knee coil (Flex), which were referred from department of Orthopaedics.*

Results: *In this present study 41 patients were males and 21 patients females and their ages ranging from (20-65) years. Knee pain was found common in age group 46-60 years age group. Joint effusion n=50 were more common followed by Edema n=40, Menisci lesions n=33 were more common as compared to ligament lesions n=7 in patients of knee pain. Osteoarthritis was found in 54.6 % of patients of knee pain.*

Conclusion: *Knee pain can occur at any stage of life due to various causative factors. MRI can demonstrate the exact nature and extent of bony as well as soft tissue abnormality. This has increase the use of MRI in evaluation of patients of knee pain.*

Keywords: *MRI, Knee pain, Menisci, Osteoarthritis*

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INTRODUCTION

Knee pain is considered as most frequent symptom related to knee problems which brings most of the patient to the hospital. Knee pain and related symptoms may come as a result of damage to one or more of the soft tissue structures that stabilize and cushion the knee joint, including the ligaments, muscles, tendons, and menisci or due to non-traumatic injury like infection, inflammation etc.[1] Presentation of knee pain in a middle-aged or older patient often leads to an x-ray of the knee but MRI is being used in clinical practice to facilitate diagnostic decisions. The potential for MRI to be more sensitive to earlier disease, detecting change, and the capacity of this technology to visualize joint structural changes beyond gross changes in bone and in the joint space, has resulted in great interest in the use of MRI for assessing diagnostic status, disease severity and monitoring progression.[2,3] MRI visualizes most components of the joint, including articular cartilage, menisci, intra-articular ligaments, synovium, bone marrow, subchondral cysts, and other periarticular and intra-articular lesions that are not detectable by radiography.[4] Various studies have reported structural changes in people with knee osteoarthritis by radiographic findings. Very few data are available regarding what structural changes are present in patients of knee pain and also this type of study was not conducted in our institute. So, this study was planned to find out the prevalence of abnormalities detected by MRI in patients of knee pain which will guide the physician in making treatment strategies according to diagnosis.

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Source of Support: Nil, **Conflict of Interest:** None

METHODS

This prospective study was carried out on patients of knee pain attending Orthopaedic. Study was commenced after written informed consent taken from all the patients and with the permission from institutional ethics committee. A total of 62 patients referred to the department of Radio- diagnosis from department of Orthopaedic with complaints of knee pain were recruited. Patients' socio-demographic data, clinical history and physical examination findings were recorded after taking informed consent to correlate the findings. The patients of knee trauma and who had no complaint of knee pain were not included in this study.

Statistical analysis:

Data were expressed in percentages in comparison tables and graphs. Statistical analysis was performed using Microsoft Excel Software and the standard Statistical Package for the Social Sciences version 15 for windows.

RESULTS

Total 62 patients were recruited on the basis of inclusion ad exclusion criteria. MRI of knee was conducted in patients who were complaining knee pain. Of these 41 patients were males and 21 patients were females. Knee pain was found more common in 46-60 age group followed by 31-45 years age group and least in <15 years age group.

Joint effusion was most frequently found knee pathology constituting n=50 patients of knee pain followed marrow edema n=40, meniscal lesion n=33, osteoarthritis n=36 and Rheumatoid Arthritis n=12. Simple bone cyst, Ligament lesions, Bakers cyst were least common constituting (Table 1). Meniscal injury was found more common in patients of knee pain as compared to ligament injury. Table 2 shows different grades of meniscal lesions in patients of knee pain.

Table 1: Clinical Presentation of knee pathologies detected by MRI in patients of knee pain (n=62)

Knee Pathologies	Male	Female
Joint effusion	30	20
Bone marrow edema	32	8
Meniscal lesions	24	9
Osteoarthritis	20	16
Rheumatoid Arthritis	3	9
Ligament lesions	4	3
Baker's cyst	4	2
Ganglion cyst	4	0
Subchondral edema	1	1
Patellar Subluxation	1	0

Table 2: Types of meniscal lesion detected by MRI in patients of knee pain.

Meniscal degeneration	Number
Grade 1	8
Grade 2	15
Total	23

DISCUSSION

MRI is a valuable tool in the evaluation and management of patients of knee pain and it has been established as an effective, non-invasive test for identifying different knee pathologies.5 MRI affects the treatment of patients with knee problems because it shows entire lesion in multiple planes so that exact diagnosis and treatment can be planned. Studies have shown that surgery of the knee is less frequently performed after MRI than initially planned before MRI.[6,7]

In this study fifty patients of knee pain were evaluated by MRI. Knee pain was found to be common in males as compared to females. These findings are in accordance with other studies too.[8,9] This could be because of more activities in young males during sports as compared to females and they are also are more prone to accidents. In our study most affected age group was 46-60 years. This finding contradicts other studies showing high prominence in 30-45 age group.

Joint effusion was found to be most frequent associated lesion. In another study joint infusion was reported in 63.8 %.[8] Higher percentage of joint effusion in our study and other study too could be due to more synovial reactions in patients of knee pain. Bone marrow edema was also found in n=40 of patients of knee pain. This much high percentage of marrow edema in patients of knee pain may be due to non-specific finding which is simply fluid accumulation within the bone when there is any insult to bone. A recent systematic review reported that bone marrow lesions and effusion were associated with knee pain.[10]

Menisci lesions were found in 52.8% patients. Depending on the patient's age, a prevalence of meniscal lesion up to 36% has been reported.[11] In our study most of the menisci lesions was found in males. Similar results have reported by other studies too of higher incidence of menisci injuries in male.[12,13]

Grade I/II injury (signal changes) are common in our study because these are mostly occur with degeneration changes in knee joint and more common in 3rd and 4th decade14 and in our study most of the patients were in age between 31-50. A meta-analysis based on 22 studies described an overall sensitivity of 88% and specificity of 94% for detecting meniscal lesions with different grades.[15] This would avoid unnecessary arthoscopic examination.[1]

Osteoarthritis was found in 54.6 % of patients of knee pain with equal prevalence in both male and female. Baker's cyst which is mostly present with osteoarthritis patient was found in 9.6% in patients. Similar incidence of baker's cyst has been reported by other study conducted by Nasir A.[9] In other studies incidence of osteoarthritis was found more in females and age above 50. The prevalence of osteoarthritis varies greatly depending on the definition used, age, sex and geographical area studied.[16,17]

Difference in our study could be due to more patients in age group 21-50 years. MRI is an excellent tool for diagnosis of intraarticular tumors which in our study shows 4% incidence. MRI is accurate, non-invasive technique for evaluating the structures of the knee, marrow space, synovium and periarticular soft tissue concerning the knee.[18,19]

To conclude, knee pain can occur at any stage of life due to various causative factors. Most of the patients in our study found to be males. MRI gives the non-invasive diagnosis to the patients for their appropriate treatment. This has increase the use of MRI in evaluation of patients of knee pain.

CONCLUSION

Knee pain can occur at any stage of life due to various causative factors. Most of the patients in our study found to be males. MRI gives the non-invasive diagnosis to the patients for their appropriate treatment. This has increase the use of MRI in evaluation of patients of knee pain.

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ORIGINAL RESEARCH ARTICLE

Assessment of Temporal Bone Diseases by High Resolution Computed Tomography – Institution based Study

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A B S T R A C T

Introduction: High definition computed tomography is a variation of routine Tomography. It gives a clean visual window of the temporal bone and enables minute structural of anatomy and physiology of temporal bone. The present study was conducted with the aim to assess the role of high resolution computed tomography in diseases of temporal bone and correlating the HRCT image findings with the pathological findings.

Material and Methods: The study was conducted amongst 100 patients who underwent HRCT temporal bone and relevant statistics are drawn from these cases. After local examination, clinical evaluation and consent, C.T scan was performed. Follow up of patients was done for confirmation with operative and/or histopathological findings whenever possible. The findings were noted in a tabulated form and a differential diagnosis were established.

Results: 61 cases were of infective etiology, out of which 16 were of chronic otomastolditis, 4 were of chronic mastoiditis, 38 were of chronic otomastoiditis with cholesteatomas formation and 3 were of otitis externa. Out of 100 cases, 6 were of congenital pathology, 22 were of traumatic, 1 was of dysplasia, 4 were of neoplastic and 6 were normal. Among patients with structures involved due to cholesteatomas, facial nerve was involved in 26 cases, ossicles in 23 cases, tegmen tympaniin 19 cases, sinus plate in 21 cases, intracranial structures in 10 cases and inner ear in 12 cases.

Conclusion: Amongst patients with trauma to temporal bone, HRCT precisely predicts the fracture lines, disruptions of the ossicles and injury to facial nerve. Therefore, it enables the management of most of trauma subjects. A HRCT helps to explain the possible outcomes to the patient as well as assist the otologist to predict disease during the surgery

Keywords: High Resolution Computed Tomography, Mastoid, Temporal Bone, Radiology

INTRODUCTION

Earlier, in majority of the pathologies of temporal bone, diagnosis were established based on clinical evaluation alone. However, with elevation in the incidence of infective diseases of the ear, it was recommended that the present approach to prevent and treat the situation was not adequate. So, primarily in complicated and recurrent situations, imaging carries a crucial role, as imaging results may fundamentally affect the treatment.[1]

High definition computed tomography is a alteration of routine CT. It gives a direct visual window of the temporal bone and enables to visualize minute structural information of both anatomy and physiology of temporal bone. It has the advantage of providing outstanding topographic observations, devoid of superimposition from structures. It enables an accurate evaluation of pathology before surgical exploration with respect to the location, degree and complications of the disorder.[2] In the developing nations like ours, this modality is easily available and inexpensive to the subjects. So, there are chances that the radiologist is likely experience greater frequency of HRCT studies and the knowledge of temporal bone on HRCT will be tremendously beneficial in achieving an accurate diagnosis.[3] The present study was conducted with the aim to evaluate role of this imaging modality in temporal bone disorders and correlating the hrct image based results with both operative and pathological outcomes.

MATERIAL AND METHODS

It was a prospective study done in department of Radiodiagnosis and Imaging in Ananta Institute of Medical Science and Research Center Rajsamand, Rajasthan in collaboration with the deparment of otorhinolaryngology amongst patients with suspected temporal bone disorder. It was conducted for a period of 8 months from June 2018 to February 2019. The study is carried out on 100 patients who underwent HRCT temporal bone and relevant statistics are drawn from these cases. The subjects included were both male and females, in the age group of 1year to 60 year. The subjects referred from OPD or IPD with chief complaints and clinical outcomes relating to temporal bone disorder for examination by high resolution CT were enrolled in the study. Inclusion

criteria was suspected unsafe chronic serous otitis media (CSOM), known or suspected deformities of inner, middle or external ear, suspected temporal bone fracture, suspected tumors of temporal bone evaluation of congenitally deaf child and evaluation of tinnitus or vertigo. Patients aged <1 and >70 years, patient requiring contrast study but were clinically unfit for contrast workup, pregnant women and patients who cannot give a valid consent were excluded from the study. Relevant clinical evaluation was carried out at the presentation. X-ray of mastoid was also reviewed if taken. After relevant examination and informed consent, C.T scan was performed as follows; The examination of patients was done using Brilliance 64 Philips CT scanner and after eliminating all the artefacts from the scanning area. It was done with 0.625 mm thick sections at slice gap of 0.625mm. 140 kV and 300 mAs were used as voltage and current. The cycle duration was 2 seconds. Scanning was done in axial plane. Scan plane was kept parallel to infraorbitomeatal line to prevent radiation to lens. Scanning was done so as to include temporal bone anteroposteriorly on both sides Entire petrous temporal bone was scanned anteroposteriorly in accordance with the topogram. Intravenous contrast was used only in cases that needed assessment of vascular lesions, soft tissue changes and breakdown of blood brain barrier, suspected either clinically or on plain scan. The images were reconstructed and visualized in special bone algorithm. Multiplanar reconstructions were done whenever required in sagittal and coronal planes. Documentation was done on 14 x 17" films. Images were magnified and recognized on separate sheets to enable comparison.

Follow up of patients was done for confirmation with operative and/or histopathological findings whenever possible. All the data thus obtained was recorded in a tabulated form and analysed.

RESULTS

The present study found that among 100 cases of temporal bone diseases (table 1), 61 cases were of infective etiology, out of which 16 were of chronic otomastoiditis, 4 were of

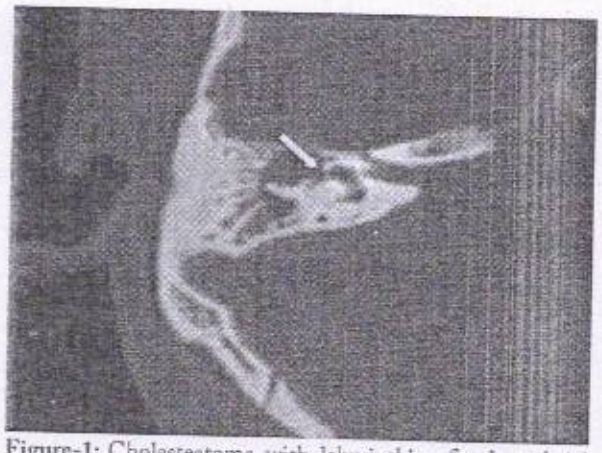

Figure-1: Cholesteatoma with labyrinthine fistula - Axial HRCT image right temporal bone demonstrates soft tissue in middle ear with erosion of bony wall of lateral semicircular canal (arrow).

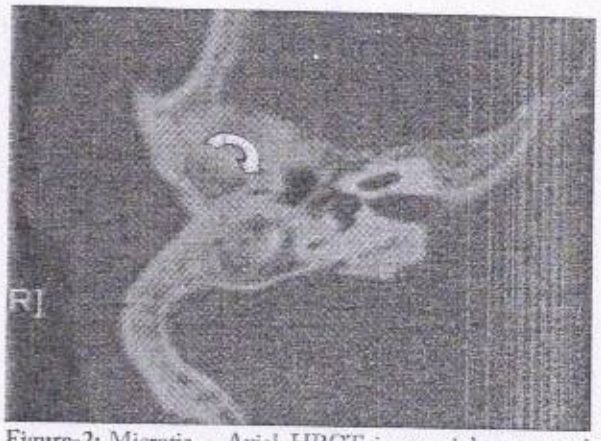

Figure-2: Microtia - Axial HRCT image right temporal bone in another case of microtia with small hypoplastic middle ear cavity, absent external auditory meatus (curved arrow), tympanic membrane and pinna. The innear ear structures appear normal.

Etiology		Number of cases	
Infective	Chronic otomastoiditis	16	61
	Chronic mastoiditis	4	
	Chronic otomastoiditis with cholesteatomas Formation	38	
	Otitis externa	3	
Congenital	Ossicular abnormalities	1	6
	Facial nerve involvement	1	
	Microrotia	2	
	Inner ear dysplasia	1	
	Congenital cholesteatoma	1	
Traumatic (fracture cases)	Transverse	6	22
	Longitudinal	11	
	Mixed	5	
Dysplasia		1	
Neoplastic		4	
Normal		6	
Total		100	

Table-1: Distribution of cases according to the etiology

Structures Involved	No. of cases of cholesteatomas (n=39)
Facial Nerve	26
Ossicles	23
Tegmen Tympani	19
Sinus plate	21
Intracranial structures	10
Inner ear	12

Table-2: Distribution of cases according to structures involved due to cholesteatomas

HRCT finding	No. of cases (n=22)
Hemotympanum	11
Facial nerve involvement	6
Labyrinthine involvement	2
Ossicular involvement	1
Intracranial involvement	5

Table-3: HRCT findings in various trauma cases

chronic mastoiditis, 38 were of chronic otomastoiditis with cholesteatomas formation and 3 were of otitis externa. Out of 100 cases, 6 were of congenital pathology, 22 were of traumatic, 1 was of dysplasia, 4 were of neoplastic and 6 were normal. Among congenital etiology 1 was of ossicular abnormalities, 1 was of facial nerve involvement, 2 were of microrotia, 1 was of inner ear dysplasia and 1 was of congenital cholesteatoma. Among 22 cases of traumatic etiology, 6 cases were of transverse type, 11 were of longitudinal and 5 were of mixed type.

Table 2 shows structures involved due to cholesteatomas, facial nerve was involved in 26 cases, ossicles in 23 cases, tegmen tympaniin 19 cases, sinus plate in 21 cases, intracranial structures in 10 cases and inner ear in 12 cases.

Among trauma cases of temporal bone, HRCT showed hemotympanum involvement in 11 cases, facial nerve involvement in 6 cases, labyrinthine involvementin 2 cases, ossicular involvement in 1 case and intracranial involvement in 5 cases (table 3).

DISCUSSION

The present study found that among 100 cases of temporal bone diseases, 61 cases were of infective etiology, out of which 16 were of chronic otomastoiditis, 4 were of chronic mastoiditis, 38 were of chronic otomastoiditis with cholesteatomas formation and 3 were of otitis externa. Figure 1 shows image of cholesteatoma by high resolution computed tomography The role of X-rays in evaluation of a cholesteatoma is very less. Minute alterations like erosion of ossicules, participation of concealed areas and destruction of facial canal and the LSSC are tremendously difficult to evaluate with X-ray.[4] The aptitude of high-resolution CT to portray the station of structure of temporal bone presents a major advancement in defining pathology before surgical exploration in patients with cholesteatoma.[5] The diagnosis of cholesteatoma is normally made on otological findings in situations where diagnosis is not clear. HRCT temporal bone may show a soft-tissue mass with distinguishing displacement of ossicles and erosion of bone. Cholesteatoma in hidden areas could be revealed by radiological evaluation even if it is not visualized clinically. High-resolution computed tomography scanning of the temporal bone is the imaging modalities of choice to evaluate the extension of cholesteatoma before surgery.[6] Erosion occurs chiefly due to the substances released by mononuclear cells of inflammation and osteoclasts. An expanding cholesteatoma can erode the antrum and mastoid spaces, even additional structures like the bony facial canal, tegmen and the lateral semi-circular canal[4] Out of 26 patients with facial canal involvement that were included in current study, 19 were confirmed by surgery. The results of the present study were in agreement with the study by Fuse T et al[7] who found that in 75% HRCT image based evaluation of facial nerve canal erosion coincided with surgical results. There were 97% subjects HRCT results of semicircular canal fistula concurred with surgical results. As per the study by Thukral CL et al[1] amongst 50 patients with clinically suspected temporal bone or ear pathologies found that the imaging results related to the surgical findings wherever possible. HRCT delivers a good sensitivity of approximately 80.65% in the documentation of variations to the ossicular chain regardless of the presence of soft tissue. Sreedhar S et al[4] compared findings of HRCT scan of 25 patients clinically diagnosed to have CSOM attico-antral type of disease with the intraoperative findings. HRCT scan was found to have a high sensitivity for identification of the disease at most of the sites within the temporal bone except for the sinus tympani and the stapes region. Fritz P et al[8] carried a radiological evaluation of temporal bone diseases and reported that high-resolution CT allows for a clearer diagnosis amongst 80% of cases, conventional radiology enables the same amongst 63%; which is 1.6-times more than the bone information recorded by high-resolution CT, clearly indicating superior features in imaging of cholesteatomas and inflammatory processes and for evaluation of bony destruction. High-resolution CT is the most delicate technique for imaging and classification of the fractures of temporal bone, like labyrinthine injury and ossicular chain damages.

Typical complications occurring from cholesteatoma like ossicular destruction, facial nerve canal, attical wall damage etc can be clearly demonstrated with this technique. As per the study by Koster O et al[9] it was found that the degree of the soft tissue diseased process is clearly shown; however, the differentiation from associated inflammatory alterations is not possible.

In the present study, among cases of congenital etiology, 1 case was of ossicular abnormalities, 1 was of facial nerve involvement, 2 were of microrotia (figure 2), 1 was of inner ear dysplasia and 1 was of congenital cholesteatoma. These findings are in agreement with the findings of Meyer TE et al[10] amongst 184 cases of congenital auricular dysplasia concluded that the extent of the auricular irregularities resembled to the severity of vicissitudes in the external auditory canal.

As regards trauma mechanisms and main complications of each type of temporal fracture, they may be summarized as follows: a) longitudinal fractures generally occur in cases of temporoparietal trauma, commonly affecting the extra labyrinthine segment, and presenting as main complications ossicular lesion and hemotympanum; b) on the other hand,

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transverse fractures generally occur in cases of frontal/ occipital traumas, with translabyrinthine involvement, whose main complication is facial nerve weakness.[11] In the present study, among 22 cases of traumatic etiology, 6 cases were of transverse type, 11 were of longitudinal and 5 were of mixed type. HRCT showed Hemotympanum involvement in 11 cases, Facial nerve involvement in 6 cases, Labyrinthine involvementin 2 cases, Ossicular involvement in 1 case and Intracranial involvement in 5 cases. Twemlow S[12] amongst 205 cases of temporal bone and found that it can precisely diagnose middle ear disease. He also contingent that it delivers efficient usage of resources with low risk to the subjects. The improved contrast and soft tissue definition possible with HRCT produced excellent images of soft tissue in air spaces. Therefore, HRCT seems to be the diagnostic modality of high-quality for cholesteatomas and different soft tissue lesions in ear. HRCT also clearly demonstrates various complications of cholesteatomas and provides a detailed preview of the temporal bone prior to surgery thus enabling the surgeon to operate without any surprises.

CONCLUSION

In patients with temporal bone trauma, HRCT accurately evaluates the fracture lines, ossicular disruptions and facial nerve canal injury. Hence it determines the management of trauma patients. A HRCT helps to explain the possible outcomes to the patient as well as assist the otologist to predict disease during the surgery

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SPECTRUM OF RADIOLOGICAL FINDINGS ON MDCT ABDOMEN AND PELVIS IN PATIENTS OF BLUNT ABDOMINAL TRAUMA

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ABSTRACT

Background: Evaluating patients who have sustained blunt abdominal trauma (BAT) remains one of the most challenging and resource-intensive aspects of acute trauma care. Missed intra-abdominal injuries continue to cause preventable deaths. **Aims & Objective:** To analyse spectrum of MDCT findings in cases of blunt abdominal trauma presenting to the emergency radiology department. **Materials and Methods:** 92 cases of blunt abdominal injury admitted in during the period of June 2018 to Dec 2018 were included in the study after taking written informed consent. All these patients were thoroughly investigated. CT Scan was done for all hemodynamically stable patients. Recorded data included age, sex, type of injuries and scan results. Organ injuries were graded using the OIS (Organ Injury Scale) guidelines. **Results:** The study comprised of 92 patients having blunt abdominal injury. Majority of the patients were in the age group of 21-40 years. Most common organ injured was liver (34.78%), kidney (15.22%), spleen (10.87%), bowel injuries (8.70%) and pancreatic injuries (6.52%). **Conclusion:** In this study CT scan was highly useful in diagnosis of blunt abdominal trauma. OIS (organ injury scale) grading, quantification of hemoperitoneum and anatomical site of organ injury predict the management protocols in the majority of our patients.

KEYWORDS: Blunt Abdominal Trauma; CT Scan; liver; Hemoperitoneum.

INTRODUCTION

The care of trauma patients is demanding and requires speed and efficiency. Blunt Abdominal Trauma usually results from motor vehicle collisions, assaults, recreational accidents, or falls. Men tend to be affected slightly more often than women. Evaluating patients who have sustained blunt abdominal trauma remains one of the most challenging and resource-intensive aspects of acute trauma care. Missed intra-abdominal injuries continue to cause preventable deaths. Neurological impairment due to the traumatic event itself or to concomitant factors such as intoxication markedly limits the usefulness of the clinical examination.

The most commonly injured organs are the liver, kidney, spleen, retroperitoneum, small bowel, bladder, colon, diaphragm, and pancreas. Computed tomography (CT) scan remains the criterion standard for the detection of solid organ injuries. CT scan of the abdomen can reveal other associated injuries, notably vertebral and pelvic fractures and injuries in the thoracic cavity. CT scans, unlike diagnostic peritoneal lavage (DPL) or Focused Assessment with Sonography for Trauma (FAST) examinations, have the capability to determine the source of haemorrhage. Over the last decade, Computed Tomography (CT) has gained widespread clinical acceptance in evaluation of haemodynamically stable patients with blunt abdominal trauma. CT not only allows comprehensive evaluation of presence and extent of injuries to solid organ, retroperitonium, bowel, mesentery and associated haemorrhage but also allows surgeons to reach vital decisions regarding the need of surgery. Accurate diagnosis with CT has played a key role in the increasing trend towards non-operative management of many visceral injuries.

Moreover, routine use of CT has substantially reduced the number of additional radiographic studies as well as the need of Diagnostic peritoneal lavage.[1] CT also plays major role in follow up of the patients with blunt abdominal trauma, determining injury resolution or progression and development of associated complications.[2] The advent of Multi Detector Computed Tomography (MDCT) is a major advancement in evaluation of patients of abdominal trauma by offering decreased scanning time, increased resolution owing to

thinner collimation and reduced partial volume and motion artifacts. MDCT scans rapidly during vascular, parenchymal, excretory phases with optimal contrast enhancement. The volumetric data acquired can be used to obtain high resolution multiplanar reformations (MPR), maximum intensity projection (MIP) and three-dimensional (3-D) reconstruction images. These views help in displaying complex injuries and also increasing diagnostic capability, accuracy and confidence of the radiologist immensely. MDCT has major role on number of patients with solid organ injury and non-operative management.[3]

AIM

To analyse spectrum of MDCT findings in cases of blunt abdominal trauma presenting to the emergency radiology department.

MATERIALS AND METHODS

The prospective study was conducted in Ananta institute of medical science and research centre Udaipur Rajasthan from june 2018 to Dec 2018. Patients reporting to the emergency, with suspected abdominal injuries and evaluated for the same by CT abdomen and pelvis were included in the study.

Inclusion criteria

- Patients with clinically suspected abdominal trauma with uncertain abdominal signs reporting to casualty department.
- Patients with pelvic fractures.
- Hemodynamically unstable patients who later become stable following fluid/blood replacement and other resuscitative measures were also taken up.

Exclusion criteria

- Patients who were haemodynamically unstable and were directly taken up for surgery.
- Patients with penetrating trauma.
- Cases where the intra venous contrast was contraindicated.

Out of 100 patients 92 full filled the inclusion criteria and rest of the 8 patients were excluded from the study.

All the eligible 92 subjects were included in the study, hence no sampling was done. All the patients included in the study underwent CT imaging using 64 slice multidetector (brilliance 64 philips). CT Images were acquired in arterial phase (25 - 30 secs), Porto-venous phase (60-70 secs) following intravenous contrast administration of 80 - 100 ml. Delayed excretory images were acquired at 10 - 15 minutes for evaluation of the urinary tract. Descriptive analysis of various abdominal injuries was presented as frequencies and percentages.

OBSERVATIONS AND RESULTS

Ninety-two (92) hemodynamically stable patients sustaining blunt abdominal trauma referred form the casualty were included in the study. Each patient underwent contrast enhanced MDCT examination of the whole abdomen. The data for this prospective study was collected and was subjected for analysis and clinical correlation. The study group comprised of patients ranging from 10 to 70 years of age. Majority of the patients were in the age group of 21 to 40 years accounting for 54% (50/92) of cases. The mean age in the study was 33.13 ± 14.48 years. Out of 92 patients 74 were males and remaining 18 were females. The male to female ratio in the study group was around 4:1.Pattern of different organ injuries on MDCT is summarized in Table 1.

Hepatic Injury

The liver was the most commonly injured organ accounting for 34.78% (32/92) of injuries. More than 50% of hepatic injuries were grade II and grade III injuries. Hepatic injuries were associated with; injuries to other abdominal organs in 18.75% (6/32) of cases, rib fractures in 50% (16/32) patients more commonly on right side and injury to lungs either in form of lung contusion, pneumothorax, atelectasis or pleural effusion in 31.25% (10/32) patients (Table 2).

Splenic Injury

The spleen was the third most commonly injured organ after liver and kidney accounting for around 10.8% (10/92) of injuries. Grade II injuries constituted around 80 % of splenic injuries.

The splenic injuries were associated with injuries to other intra-abdominal organs in 40% (4/10) of cases, injuries to lungs either in form of lung contusion, atelectasis, or pleural effusion in 20% (2/10) of patients. None of the case was associated with rib fracture (Table 3).

Renal Injury

The kidneys were second most commonly injured solid organ 15.2% (14/92). Cases with right renal injury occurred in 57% (8/14) and left renal injury in remaining 43% (6/14) of patients with renal trauma. Renal injuries were associated with injuries to other intra-abdominal organs in 57% (8/14) of cases, most commonly liver in cases of right renal injury and spleen in cases of left renal injury. Grade III and grade IV injury was seen in 43% and 57% of cases respectively. There was no case with grade I and II injury (Table 4 and 5).

Pancreatic Injury

The pancreatic injuries were observed in around 6.52% (6/92) cases. Sixty six (66%) percent of pancreatic injuries were grade II injuries and 33.3% were grade I. The pancreatic injuries were associated with injuries to; liver in 66.6% (4/6) of cases, injuries to kidneys in 66.6% (4/6) of cases involving right and left kidney

separately and injuries to spleen in 33.3% (2/6) of cases (Table 6).

Bowel and mesenteric injuries

Bowel and mesenteric injuries were seen in around 13.04% (12/92) of cases. Four (8/12) patients had bowel injury, whereas only two (4/12) patients had mesenteric injury. The mesenteric hematomas were associated with hemoperitoneum without solid organ injuries in 100% (4/4) patients. One case was operated and was found to have mesenteric injury preoperatively, which was not detected by MDCT (Table 7).

Table 1: Pattern of organ injuries on MDCT.

Organs involved	No of cases	Percentage%
Solid organs		
Liver	32	34.78
Spleen	10	10.87
Kidneys	14	15.22
Pancreas	6	6.52
Adrenals	6	6.52
Hollow viscera		
Bowel	8	8.70
Urinary bladder	6	6.52
Urethra	4	4.35
Others		
Mesenteric injury	4	4.35
Retroperitoneal hematoma	10	10.87
Parietal wall injury	10	10.87
Multiple organs	16	17.39

Table 2: Hepatic Injury Grading.

Injury grade	No of cases	%
Grade I	2	6.25
Grade II	6	18.75
Grade III	12	37.50
Grade IV	10	31.25
Grade V	2	6.25
Total	32	100

Table 3: Splenic injury grading.

Injury Grade	No of cases	%
Grade I	Nil	0
Grade II	8	80
Grade III	2	20
Grade IV	Nil	0
Total	10	100

Table 4: Renal involvement in blunt trauma abdomen.

Kidney involved	No of cases	%
Left kidney	6	42.86
Right kidney	8	57.14
Total	14	100

Table 5: Renal injury grading.

Injury grade	No of cases	%
Grade I	Nil	0
Grade II	Nil	0
Grade III	6	42.86
Grade IV	8	57.14
Grade V	Nil	0
Total	14	100

Table 6: Pancreatic injury grading.

Injury grade	No of cases	%
Grade I	2	33.33
Grade II	4	66.67
Grade III	Nil	0
Grade IV	Nil	0
Grade V	Nil	0
Total	6	100

Table 7: Type of Bowel involved in blunt trauma.

Bowel	Perforation	%
Small	4	50
Large	2	25
Not known	2	25
Total	8	100

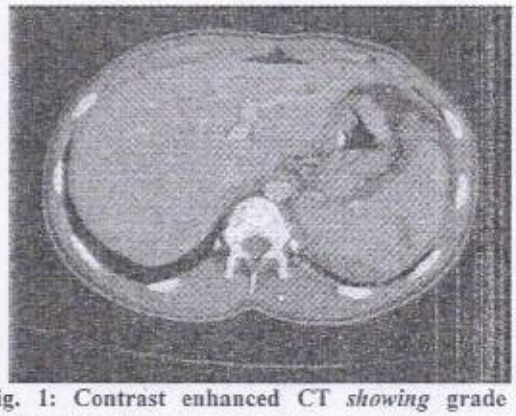

Fig. 1: Contrast enhanced CT *showing* grade II splenic laceration.

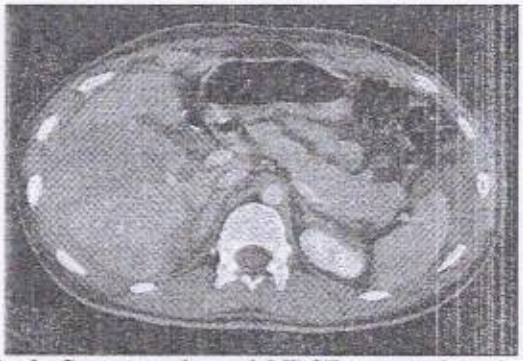

Fig. 2: Contrast enhanced MDCT suggested grade V injury along free fluid in Perihepatic region & pelvis suggesting hemoperitoneum.

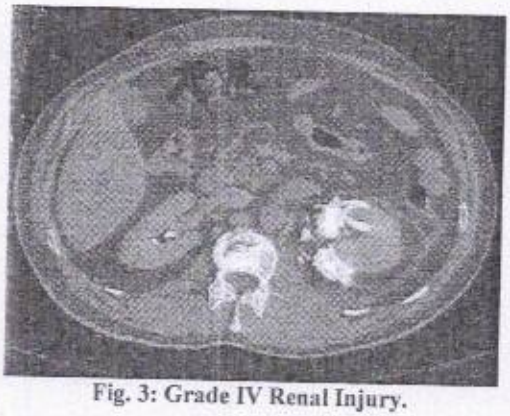

Fig. 3: Grade IV Renal Injury.

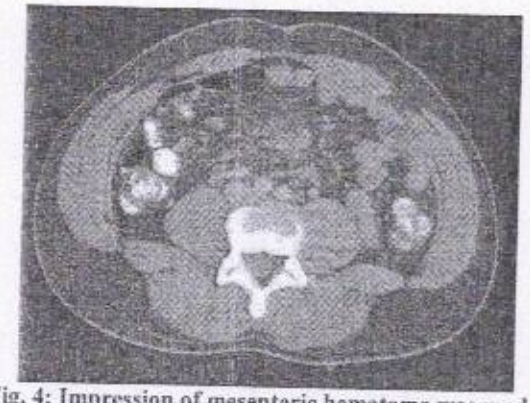

Fig. 4: Impression of mesenteric hematoma was made on basis of MDCT findings.

DISCUSSION

The present study was undertaken to evaluate the role of Multi detector computed tomography (MDCT) in management of clinically stable patients with blunt abdominal trauma by comparing management plan prior to MDCT scan with management plan after MDCT scan and to correlate CT findings with surgical findings in operated cases of blunt abdominal trauma and clinical outcome in conservatively managed cases. In the present study, comprising (92) clinically stable patients with blunt abdominal trauma, more than 54% of the patients were in the age group of 21 to 40 years. The male tonfemale ratio was 4:1. The most common mode of injury was road traffic accident (69.5%) followed by fall from height (17.3%). Bony injuries (including ribs, pelvis and spine) were the most common associated injury (80%) followed by chest injury (atelectasis, pleural effusion, contusion, and pneumothorax) which was seen in 23.9% of cases.

In a study by *Mohapatra et al.*,[4] blunt abdominal trauma accounted for 44% of all abdominal injuries. More than three fourth (3/4th) of the victims were in the first four decades of their lives. Male-Female ratio was 7:1. Road traffic accidents (RTA) were the most common etiology (62%) mostly involving pedestrians or two wheeler riders (combined, 47%). Chest injury was the most common associated extra-abdominal injury (26%) followed by head injury and other bony injuries (21% each).

In the present prospective study, a statistically significant difference (p=0.052) was found between the management plan decided before and after MDCT scan (guided by CT scan findings). The use of MDCT in initial triage of patients with blunt abdominal trauma results in decrease in number of unnecessary laparotomies and helps guiding management plan in virtually every patient with high success rate. In a study by *Wing and associates*[5] evaluating clinical impact of CT for blunt abdominal trauma, it was concluded that the use of computed tomography (CT) had a tremendous impact on the evaluation and management of blunt abdominal trauma. It is non-invasive, easy to perform, and has been shown to be highly sensitive (100%), specific (96.8%), and accurate (97.6%). The use of CT has helped decrease the total number of laparotomies performed for abdominal trauma as well as the number of negative and non-therapeutic laparotomies. In a retrospective study performed by *Udekwu et al.*,[6] to evaluate the use of computed tomography in the initial evaluation of hemodynamically stable blunt trauma patients, the sensitivity of CT for patients with visceral injury was 92.4%, specificity was 99.5%, and overall accuracy was 97.6%. False negative scans occurred in 1.9% of patients, with no deaths or major complications attributable to delay in diagnosis. Non-operative management was possible in 72% of patients with solid organ injuries. In the present study, among (68) patients with solid organ injuries, 76.4% (52/68) were managed conservatively All patients of grade I injury were managed conservatively.

Out of 20 patients with grade II injuries 70% (14/20) were managed conservatively. All patients with grade III injuries were managed conservatively. Out of 18 patients with grade IV injuries 55.5% (10/18) were managed conservatively. 2 patients with grade V injury were operated. *Hackam et al.*,[7] and *Shapiro et al*[8] in their studies regarding correlation between solid organ injury grading and management plan concluded that although useful for epidemiologic studies, CT grading of liver and spleen injuries based on morphology of wounds does not reliably predict the specific outcome in individual cases. In the present study, the liver was the most commonly injured organ accounting for 34.78% (32/92) of injuries, whereas in a study by *Boone et al*,[9] liver was the second most commonly injured organ in the abdomen with damage occurring in 20-30% of blunt trauma overall. More than 50% of hepatihepatic injuries were grade II and grade III injuries. Around 18.75% (6/32) of liver injuries were associated with injuries to other organs, most commonly right kidney 50% (6/12). One patient with liver injury had injury to right adrenal gland. There were associated rib fractures in 50% patients (16/32) with liver injuries, more commonly on right side which was seen in 83.3% cases (10/12). The associated rib fractures have also been reported by *Boone et al* who

found rib fractures in 33% of cases with hepatic injuries.[9] Five out of six i.e. 31.25% patients with liver injury had concomitant injury to chest either in form of lung contusion, atelectasis or pleural effusion. More than 50% of hepatic injuries were grade II and grade III injuries. The spleen was the third most commonly injured organ accounting for around 10.8% (10/92) of injuries whereas in a study by *Mirvis et al*,[10] the spleen was the most frequently injured organ accounting for around 40% of all solid organ injuries. Around 40% (4/10) of splenic injuries were associated with injuries to other organs. There were no associated rib fractures. Associated chest injuries were present in 20% (2/10) of patients, either in form of lung contusion, atelectasis, or pleural effusion. Grade II injuries accounted for around 80 % of splenic injuries. In the present study 60% (6/10) patients with splenic injuries were managed non-operatively. The non-operative management was successful in 100% of patients with blunt splenic trauma i.e. none of the patients who were managed conservatively required delayed laparotomy.

In the present study, multiple organ injuries were seen in around 17.39% (16/92) of cases with liver and right kidney injured simultaneously in 37.5% (6/16) cases. Around 62.5% (10/16) patients with multiple organ injuries were managed conservatively unlike the study performed by *Pieper et al* who found that the patients in whom CT detects multi-organ "package" injuries (e.g. spleen and left kidney; left lobe of the liver; and pancreas) are more likely to undergo surgical intervention.[11]

In the present study, the kidney was second most common injured organ. Renal injuries were seen in 15.2% (14/92) of cases with right renal injury occurring in 57% (8/14) and left renal injury in remaining 43% (6/14). Around 57% (8/14) of renal injuries were associated with injuries to other organs, most commonly liver in cases of right renal injury and spleen in cases of left renal injury. In a study by *Smith et al*,[12] the kidneys were injured in 10% of patients with blunt abdominal trauma and were the most frequent urinary tract organ to suffer injury.

In the present study, grade III and grade IV renal injury was seen in 43% and 57% of cases respectively. There was no case with grade I and II injury. Among the 14 patients with renal injury 71.4% (10/14) were managed conservatively. Out of 8 patients with grade IV injuries 50% (4/8) were managed conservatively. All cases of grade III injury were managed conservatively. With the help of multi detector CT it was possible to accurately characterize the renal injuries and to rule out other associated injuries requiring urgent intervention as a result of which unnecessary laparotomy was avoided in a number of patients sustaining blunt renal trauma. Similar conclusions were drawn in a study by *Quinlan et al*[13] i.e. CT is recommended for detection and characterization of the grade of injury, for qualitative assessment of renal function, and to rule out associated intraabdominal injury that may warrant immediate surgery.

In the present study, pancreatic injuries were observed in around 6.52% (6/92) cases, in contrast to a study by *Wong et al*[14] who found pancreatic injury to be relatively uncommon, occurring in less than 2% of blunt abdominal trauma patients. Sixty six (66%) percent of pancreatic injuries were grade II injuries and 33.3% were grade I. The pancreatic injuries were associated with injuries to liver in 66.6% (4/6) of cases, injuries to kidneys in 66.6% (4/6) of cases involving right and left kidney separately and injuries to spleen in 33.3% (2/6) of cases. In a study by *Bradley et al*[15] it was observed that isolated pancreatic injuries are rare, and associated injuries, especially to the liver, stomach, duodenum, and spleen, occur in over 90% of cases. In the present study, out of 6 patients with pancreatic injuries 66.6% (4/6) were managed conservatively. Out of 4 patients with grade II injuries 50% (2/4) were managed conservatively. Two (2) cases of grade I injury were managed conservatively.

In the present study, bowel and mesenteric injuries were seen in around 13.04% (12/92) of cases. The most common sign of bowel injury in this study was bowel wall thickening, extraluminal air, extravasation of oral contrast, mesenteric thrombosis and evidence of bowel ischemia. Eight (8/12) patients had bowel injury, whereas only four (4/12) patients had mesenteric injury. The mesenteric hematomas were associated with hemoperitoneum without solid organ injuries in 100% (4/4) patients.

CONCLUSION

In this study CT scan was highly useful in diagnosis of blunt abdominal trauma. OIS (organ injury scale) grading, quantification of hemoperitoneum and anatomical site of organ injury predict the management protocols in the majority of our patients. Result of this study shows that CT scan is a superior diagnostic modality in the diagnosis and management of blunt abdominal trauma. The use of multi detector CT in initial triage of clinically stable patients with blunt abdominal trauma results in reduction in number of unnecessary laparotomies and helps guiding initial management in emergency department in virtually every patient with high success rate.

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Role of diffusion weighted magnetic resonance imaging of intra and extra axial intracranial lesions

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ABSTRACT

Background: Diffusion weighted imaging (DWI) has a wide range of applications in the evaluation of intracranial pathological conditions. It provides a specific diagnosis in few situations, and adds to the information provided by conventional sequence in many others.
Methods: The present study was conducted in the Department of Radiology, Dr. S. N. Medical College, Jodhpur, Rajasthan. Participants after understanding the study protocol and procedure, were asked to give their written consent for the study.
Results: In the study group of 115 patients (41%) were females and (59%) males. Infarcts comprised 45.2% of the total cases out of these acute infarcts constituted 30 cases (57.7%); 18 (34.6%) chronic infarcts and 4 (7.6%) were subacute infarcts. All cases of acute infarcts and 50% of subacute infarcts showed diffusion restriction. None of the chronic infarcts showed true restriction of diffusion. Among intra axial tumours true restriction was noted in 6 cases. 40% of glioblastoma multiforme showed true diffusion restriction. None of the low-grade gliomas or anaplastic astrocytomas showed diffusion restriction. 75% of medulloblastomas and 50% of lymphomas showed diffusion restriction. All cases of intracerebral abscesses showed true diffusion restriction. The cystic or necrotic component of none of the brain tumours included in this study showed diffusion restriction. All cases of arachnoid cysts seen in this study had low signal on DWI. 33% of meningiomas showed restricted diffusion in this study likely reflecting their high cellularity. All cases of HII showed true diffusion restriction. 25% of these cases showed no signal change on T2WI. Also, the extent of abnormality was noted to be more on DWI than on T2WI. Two cases of extradural empyema seen in this study showed restricted diffusion similar to abscesses. Hypertensive encephalopathy and demyelination did not show restricted diffusion reflecting absence of cytotoxic oedema in these conditions.
Conclusions: DW MRI helps in differentiating and characterizing intracranial lesions.

Keywords: ADC (Apparent diffusion coefficient), DWI, Intracranial lesions, MRI (Magnetic resonance imaging), T1W (T1 weighted), T2W (T2 weighted)

INTRODUCTION

Diffusion weighted imaging (DWI) is a technique that assesses local environment at the cellular level to determine changes in the random movement of water protons. Whereas DWI is most often used to identify acute arterial ischemia, other processes that interfere with or restrict the movement of water can cause notable changes on DWI, including neoplastic lesions, encephalitis, pyogenic abscesses and occasional

demyelinating diseases. Reduced diffusion can be seen in highly cellular tumors such as lymphoma, meningioma and glioblastoma. Several reports have suggested an inverse correlation between ADC value and glioma grade 2 to grade 4 astrocytoma.[1]

The signal intensity of gliomas on DWI is variable (hyper, iso or hypo intense), and a subtle hyper intensity is a common nonspecific finding. Tumor cellularity is probably a major determinant of ADC values of brain tumors, although probably not the only one. ADC values cannot be used in individual cases to differentiate glioma types reliably (the ADC values of patients with grade 2 astrocytoma and glioblastoma overlap). The ADC values of solid gliomas, metastasis and meningioma were in the same range. In cases of lymphomas, however there was a good contrast with the white matter, with strongly reduced ADC values. Further studies are needed to define clearly the ability of DWI to help differentiate various brain tumors and to help grade gliomas.[2]

DWI is useful in providing a greater degree of confidence in distinguishing brain abscesses from cystic or necrotic brain tumors than conventional MRI.[3] Thus, it may increase the diagnostic accuracy when combined with other sequences. Likewise, in Creutzfeldt-Jakob disease, DW imaging helps differentiate from infarct by showing persistent restricted diffusion.[4]

Thus, diffusion weighted imaging (DWI) has a wide range of applications in the evaluation of intracranial pathological conditions. It provides a specific diagnosis in few situations, and adds to the information provided by conventional sequence in many others.

METHODS

The study was conducted in the Department of Radio diagnosis, Dr. S. N. Medical College and associated group of hospitals, Jodhpur. Imaging was done with Philips 1.5 tesla magnetic resonance imaging equipment for one year from 2013 to 2014.

Inclusion criteria

All patients with diffusion weighted magnetic resonance imaging reference for infarction, hypoxic ischemic injury, infective condition, tumors, demyelination, metabolic and toxic insult to brain, Degenerative disorder irrespective of age and sex were included in the study.

Exclusion criteria

Patients who are detected to have intracranial bleed were excluded from the study.

Patients underwent the examination after contraindications for MRI were excluded and consent was taken. All the MRI scans in this study were performed using 1.5T MRI scanner. MRI Protocol consisted of the following:

- A head coil was used
- Axial diffusion weighted images of the brain
- Sagittal T1W images of the brain
- Axial T2W FLAIR images of the brain
- ADC images were reconstructed from the diffusion weighted images.

Table 1: MRI protocols.

	DWI	T2-FLAIR axial	T1-FLAIR sagittal
TE	5000	8002	2060
TE	80	86	20
TI		2000	650
Matrix	128*192	256*320	224*384
No. of excitations	2	1	1
Thickness	5 mm	5 mm	5 mm
Section spacing	1.5 mm	1.5 mm	1.5 mm
FOV	24*30	24*24	24*24
Imaging time	45 sec	1min 25 sec	1 min. 25 sec

Data evaluation

The observations of these patients were compiled and analyzed. All statistical analyses were conducted using the SPSS statistical package (version 16.0).

RESULTS

The present study was carried out to describe imaging characteristics of various intracranial lesions on DWI and to compare them with ADC and T2 FLAIR images.

Age wise distribution of patients

The age of the patients with intra cranial lesions ranged from 3 days to 78 years with a mean of 43.97±2.04. The patients involved in the study were divided into 7 age groups viz. 0-10 years, 11-20 years, 21-30 years, 31-40 years, 41-50 years, 51-60 years and 61-70 years. There were nine patients (7.8%) in 1-10-year age group, ten (8.6%) in 11-20-year age group, ten (8.6%) in 21-30-year age group, sixteen (13.9%) in 31-40-year age group, sixteen (13.9%) in 41-50 year age group, twenty three (20%) in 51-60 year age group, twenty five (21.7%) in 61-70 year age group, six (5.2%) in 71-80 year age group as given in Table 2.

In the present study 31 (41%) were females and 84 (59%) males. The mean age among females was 50 years and in males was 44 years. In the present study, majority were infarcts which constituted 52 cases (45.2%), 4 cases of hypoxic ischemic encephalopathy (3.4%) were also included. The other cases were tumors (31.3%) of which 19 (52.8%) were intra axial and 17 (47.2%) were extra

axial tumors, 15 infective conditions (13%), 4 cases of demyelination (3.4%) and 4 other miscellaneous conditions (3.4%). These included 1 case of adrenoleucodystrophy, 1 periventricular leukomalacia, and 2 posterior reversible encephalopathy syndrome (PRES) cases.

Table 2: Age wise distribution.

Intra cranial lesion	Age (years) range								Total
	0-10	11-20	21-30	31-40	41-50	51-60	61-70	71-80	
Abscess		1	1	1					3
ADEM	1								1
Acute infarct					4	11	14	1	30
Adrenoleucodystropy	1								1
Anaplastic astrocytomas				1	1				2
Arachnoid cyst		2	2	1					5
Chronic infarct					1	5	7	5	18
Demyelination toxic				1					1
Epidermoid cyst				1					1
Extradural empyema			1	1					2
GBM						2	3		5
Hemangioblastoma					1				1
HSV encephalitis			1						1
Low grade glioma		1		3					4
Lymphoma						1	1		2
Medulloblastoma		4							4
Meningioma			1	2	5	1			9
Multiple sclerosis				1	1				2
NCC granuloma			1	2					3
PVL	1								1
Pilocytic astrocytoma	1								1
PRES		1	1						2
Preterm HII	3								3
Profound term HII	1								1
Schwannoma				1		1			2
Subacute infarct					2	2			4
TB granuloma	1	1	2	1	1				6
TOTAL	9	10	10	16	16	23	25	6	115

In present cohort, 82 cases (71.2%) showed hyper intensity on DWI of which true restriction (hyper intense on DWI and hypo intense on ADC) was noted in 52 patients (45.2%). This constituted 63.4% of the cases showing diffusion restriction. T2 shine through was noted in 30 patients (26%). This constituted 36.6% of the cases showing diffusion restriction. 52 cases (45.2%) showed hypo intensity on ADC images. All of these were hyper intense on DW images. 13 patients (11.3%) showed T2 washout (hyper intense on T2WI and isointense on DWI). 5 patients (0.43%) showed no signal change on DWI or ADC images. 51 patients (44.3%) had lesions that showed increased diffusivity (hyper intense signal on ADC image). Of these 15 (13%) were hypo intense on DWI. This constituted 29.4% of the cases showing increased diffusivity. 13 of these showed T2 washout, and 23 showed T2 shine through.

Infarcts constituted 52 cases (45.2%) of the total cases in this study. Of this 30 (57.7%) were acute infarcts, 18 (34.6%) were chronic infarcts and 4 (7.6%) were subacute infarcts. The age group of patients with infarcts ranged from 43 to 78 years with a mean age of 60 years. There were 13 (25%) females and 39 (75%) males among these cases. In 30 cases (58%) the infarcts were in MCA territory, in 4 cases (8%) they were in ACA territory, in 11 cases (21%) the infarcts were in PCA territory and in 7 cases (13%) they were in basilar artery and vertebral artery territory. All 30 cases (100%) of acute infarcts showed true diffusion restriction with hyper intensity on DWI and hypo intensity on ADC images. Of these, 26 cases (86.66%) showed hyper intensity on T2W images. The remaining 4 cases (13%) showed no signal change on T2W images.

Of the 18 cases of chronic infarcts, ADC signal was increased in all, suggesting increased water diffusivity. In 8 cases (44.44%), there was hypo intensity on DWI and T2 FLAIR images with hyper intensity on ADC images indicating encephalomalacia. T2 shine through was noted in 10 cases (55.55%). None of the cases showed T2 washout. Out of 4 cases of subacute infarcts, 2 (50%) showed true restriction and 2 (50%) showed T2 shine through.

Four cases of hypoxic ischemic injury were included in this study, age range of 3 days to 15 days. Three cases were preterm neonates and one was a term neonate. All four cases showed true diffusion restriction. 3 of four cases (75%) showed hyper intensity on T2 FLAIR images, and 1 (25%) did not show any change on T2 FLAIR images. The extent of abnormality was noted to be more on DW and ADC images than on T2 FLAIR images.

In study major, infective conditions (15 in total) were tubercular granulomas 6 (40%), Neurocysticercosis (NCC) granulomas 3 (20%), abscesses 3 (20%), extradural empyemas 2 (13.3%) and HSV encephalitis 1 (6.7%). True restriction of diffusion was noted in 7 (46.66%) cases. This included 2 tubercular granulomas 3 abscesses and 2 extradural empyemas. Thus 33.33% of tubercular granulomas, 100% of abscesses and 100% of extradural empyemas showed true diffusion restriction. T2 washout was seen in all 3 cases (100%) of NCC granulomas and 3 cases (50%) of tubercular granulomas. T2 shine through was seen in 1 case of tubercular granuloma and one case of HSV encephalitis.

There were 19 cases of intra axial tumors with age ranging from 10 to 68 years with 5 females and 14 males. This included 2 cases of anaplastic astrocytoma, 5 cases of glioblastoma multiforme, 1 hemangioblastoma, 4 low grade gliomas, 4 medulloblastomas, 1 pilocytic astrocytoma, and two cases of lymphomas. 6 cases (31.6%) showed true diffusion restriction. Of these 2 were GBM, 3 were medulloblastomas, and one was lymphoma. Thus 40% of GBM, 75% of medulloblastomas, and 50% of lymphomas showed true restriction of diffusion.

T2 shine through was noted in 8 cases (42.1%). This included all 2 cases of anaplastic astrocytomas, 3 cases (60%) of GBM, 2 cases (50%) of low grade gliomas and 1 (50%) case of lymphoma. T2 washout was seen in one case of hemangioblastoma and 2 cases (50%) of low grade gliomas.

17 cases of extra axial tumors with an age range of 14 to 52 years, mean 36 years were included in this study. Of these 6 were females and 11 were males. These were 5 cases of arachnoid cysts, 1 epidermoid cyst, 9 cases of meningiomas and 2 cases of schwannomas. True restricted diffusion was noted in 4 cases (23.52%). This included the single case of epidermoid cyst and 3 cases (33.3%) of meningiomas. In one case of meningioma, T2 shine through was noted. In 6 (66.6%) cases of meningiomas, T2 FLAIR showed iso to hypo intense signal probably due to high cellularity and presence of calcification. 1 case (50%) of schwannoma showed T2 washout.

Out of four cases of demyelination, two (50%) were multiple sclerosis, one was a case of toxic demyelination and one was a case of ADEM. All the lesions showed hyper intensity on T2 FLAIR images. True restriction of diffusion was not noted in any of the cases. T2 washout was seen in one case of multiple sclerosis (50%) and in toxic demyelination. No change was noted on DWI or ADC images in one case (50%) of multiple sclerosis and in ADEM.

Miscellaneous other lesions like 1 case of adrenoleucodystrophy, 1 case of periventricular leukomalacia and 2 cases of posterior reversible encephalopathy syndrome were detected. All the lesions showed hyper intensity on T2 FLAIR images. True restriction of diffusion was not noted in any of the cases. T2 washout was seen in one case of PRES. No change was noted on DWI or ADC images in one case of PRES. T2 shine through was noted in adrenoleucodystrophy.

DISCUSSION

Diffusion weighted MRI provides image contrast that is different from that provided by conventional MRI sequences. It provides a technique for mapping proton contrast that reflects the microvascular environment. This imaging technique is sensitive to early ischemic insult. DWI is performed with a pulse sequence capable of measuring water translation over short distances. This water diffusion is much slower in certain pathological conditions as compared with normal brain.[5] In this study, 115 patients with intracranial lesions detected on DW MRI of the brain were included.

The sensitivity and specificity of DWI in the detection of acute ischemia is 100%. The difference in sensitivity of DWI and conventional MRI sequences is more in the initial time period and decreases as time progresses. Results of our study are similar with a study done by Gonzalez et al who concluded that DWI is superior to conventional MRI in the diagnosis and characterization of acute infarct.[6] In 13% of acute infarcts, no change was noted on T2WI. Thus, DWI was noted to be superior to T2WI in detection of acute infarcts. In subacute infarcts and chronic infarcts, abnormal signal was noted on T2WI and on DWI in all patients.

Thus, there was no difference in their sensitivity for later stages of infarcts. Rima K et al showed that restricted diffusion is present in all patients on DWMR studies obtained within 24 hours of the onset of symptoms, and in 94% of patients scanned after 2 weeks after ictus.[5] In this study, subacute infarcts were defined as patients in

whom imaging was performed between 2 and 14 days after symptom onset. Schwartz R et al, true diffusion restriction was noted in 50% of patients with subacute infarcts. The other 50% showed T2 shine through. In this study, 58% of infarcts were noted to be in MCA territory, 21% in PCA territory, 8% in ACA territory and 13% in vertebral artery and basilar artery territory. This is comparable to a study done by Zwan VD et al, which showed that MCA territory is the most common site for infarcts and ACA territory is the least common among major arterial territories.[8]

In chronic infarcts, the signal on DWI and ADC images is variable and depends on a combination of T2 signal and increased ADC values. The T2 signal is also affected by the onset of cystic encephalomalacia Schaefer PW et al.[9] In the present study T2 shine through was noted in 55.5% of chronic infarcts and cystic encephalomalacia was noted in 44.4%.

Hypoxic ischemic injury

Fu JH et al, compared conventional MRI sequences to DWI in the evaluation of HII and found that DWI showed abnormal high signal intensity in the brain in patients in whom the conventional MR sequences were initially normal.[10] Schaefer et al, concluded that HII lesions not seen on routine MR images are identified on DW MR Images.[9] When lesions are identified on conventional images, lesion conspicuity is increased and lesion extent is seen to be larger on DW MR Images. All cases of neonatal HII included in this study showed true diffusion restriction. In 25% of cases there was no abnormality on T2 FLAIR images. The extent of abnormal signal was much more in the remaining 75% of cases on DWI, than that showed by T2W images.

Infections

Chang et al, have showed that abscess cavity shows high signal intensity on DWI and a low signal on ADC image. This is not seen in the necrotic component of brain tumors. They concluded that DWI may enable one to distinguish brain tumors from necrotic tumors. Also, it helps in the evaluation of partially treated abscesses and to look for their recurrence. In the present study 100% of cases of abscess showed true diffusion restriction. The cystic or necrotic component of none of the tumors included in this study showed restricted diffusion. In 33.3% of the tubercular granulomas observed in this study, diffusion restriction was noted, probably denoting presence of necrosis. 50% of tubercular granulomas and 100% of NCC granulomas could not be detected on DWI alone and needed ADC and T2W images for lesion detection probably due to the poor spatial resolution of diffusion weighted imaging. All two cases (100%) of extradural empyemas noted in this study showed true diffusion restriction. The thick nature of this collection causes reduced water diffusivity similar to abscesses.

Tumors

Intra axial tumors

In the present study, 40% of GBM, 75% of medulloblastomas and 50% of lymphomas showed true diffusion restriction. None of the low-grade gliomas or anaplastic astrocytomas showed restricted diffusion. The single case of hemangioblastoma seen in this study showed high signal on ADC images in its solid component suggesting high water diffusivity. DWI can differentiate between tumor and infection and can provide information about the cellularity of tumors thereby helping in characterization and grading of tumors. Cruz CH et al, showed that highly cellular tumors such as high-grade gliomas and lymphomas can have low ADC values and show restricted diffusion.[11] It was also shown that medulloblastomas may be differentiated from other pediatric brain tumors by presence of diffusion restriction. The solid portion of hemangioblastomas has high ADC values due to their rich vascular spaces. The findings of this study were similar.

Extra axial tumors

Schaefer et al, showed that conventional MR cannot be reliably used to differentiate these two lesions as both have CSF like signal intensity on conventional MR sequences.[9] This was also demonstrated in a study by Cruz et al, in which epidermoid cysts had ADC values similar to brain parenchyma while arachnoid cysts had ADC values similar to CSF.[11] In the present study all 5 cases of arachnoid cysts had signal similar to CSF on DWI and ADC images. The single case of epidermoid cyst noted in this study had restricted diffusion. Tadeusz et al and Cruz et al concluded that most meningiomas are isointense on DWI.[11,12] Only few may show restricted diffusion depending on their cellularity. In their study 23% of meningiomas showed restricted diffusion. This study had similar results with 33% of meningiomas showing true diffusion restriction. Schwannomas show high signal on ADC images with no restricted diffusion reflecting lack of high cellularity.

Demyelination

Four cases of demyelination seen in this study did not show restricted diffusion and had increased signal on T2 FLAIR images. Studies done by Christiansen P et al and Larsson H et al, have shown that most foci of demyelination do not show restricted diffusion.[13-14]

Others

Schwartz et al, showed that the edema of hypertensive encephalopathy is of vasogenic type.[7] The results of this study are similar. None of the cases of PRES seen in this study had features of restricted diffusion. No signal change was noted in periventricular leukomalacia seen in

this study, while the single case of adrenoleucodystrophy showed features of vasogenic edema.

CONCLUSION

Diffusion weighted MRI is a valuable technique that provides unique information about the physiological state of brain tissue. By using a combination of various MR sequences coupled with DWI and ADC images a valuable diagnosis may be provided to the clinicians. In this study the signal characteristics of various lesions on DWI, ADC, T2FLAIR and T1W images were studied. Diffusion weighted MRI has been proven to be of excellent use in the characterization of infarcts and in the detection of acute infarcts. It is especially useful in the initial few hours of the ischemic insult when conventional MR sequences may be inconclusive and may not detect the infarct. Thus, DW MRI helps in differentiating and characterizing various intracranial lesions.

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Original Article

Early and late onsetpsoriasis: A clinical study

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Abstract

Background: It has been postulated that two clinical subtypes of psoriasis, namely the "early onset" and the "late onset" can be characterized based upon the age of onset. However precise data to differentiate the two clinical subtypes of psoriasis are not available. **Objective:** To investigate the clinical characteristics of early and late onset psoriasis in the Mauritian patient. **Methodology**: A cross-sectional study of consecutive 55 patients of psoriasis was carried out at the Skin Outpatient department of a regional hospital in Mauritius. The Case study method was used to collect the clinical data and was recorded in a comprehensive Case Record Form. The data was statistically analyzed using SPSS 22 (Statistical Package for the Social Sciences) software. **Results:** A bimodal distribution of onset of psoriasis was observed with peak between 20-30 years age in 12 (21.8%) of patients, and between 49-59 years age in 24 (43.6%); 27 (49.1%) patients had onset < 40 years ; 28(50.9%) patients had onset ≥ 40 years. In Early onset psoriasis co-morbidities were present in 22/27 (66.7%) of which was significant. In Late onset psoriasis 22/28 (78.6%) were male and nail involvement was seen in 26 (78.8%) male patients as compared to 7(21.2%) female patients, which was statistically significantly. Total Body Surface Area larger than 10% was observed in 12 (44.4%) in early onset as compared to 6 (21.4%)in late onset psoriasis but this was statistically not significant. **Conclusions:** The psoriasis had a bimodal distribution of onset. The psoriasis of Late onset showed a male preponderance, frequent nail involvement and psoriatic arthritis of axial joints. The clinical features validated existence of two clinical subtypes of the disease separated by the age of onset.
Key words: Clinical subtypes, age of onset, Total Body Surface Area (TBSA), psoriatic arthritis.

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INTRODUCTION

Worldwide prevalence rates of psoriasis range from 0.6 to 4.8%.[1, 2]The disease tends to have a bimodal distribution of onsetwith major peak occurring at age of 20-30 years, and later a smaller peak occurring at age of 50-60 years.[3, 4]Two sub-populations of patients of psoriasis, early onset and late onset type, with distinct clinical and immuno-genetic characteristics have been identified. The two types show different evolutionary features.[5] Patients with early age onset of psoriasis are more likely to have a family history of psoriasis and more unstable with frequent remissions and relapses. The disease tends to be more severe as measured by involvement of Total Body Surface Area (TBSA) and is more resistant to treatment.[3, 4]. There is a higher incidence of obesity, diabetes, dyslipidaemia, hypertension and major cardiovascular events (MACE). HLA Cw6, B13 and B17 are the specific markers of the early onset type of psoriasis.[6, 7]

Late onset typepsoriasis involves less TBSA, is a milder disease and is more likely to be associated with psoriatic arthritis, nail involvement and palmoplantarpustular involvement.[3, 4]Family history is less frequent and HLAB27, Cw2, B44 and Cw5 seem to be associated with the late onset type of psoriasis.[6, 7] The purpose of our study was to study the clinical features of early age and late onset psoriasis in the Mauritian patient.

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MATERIALS AND METHODS

The study was carried out at the Skin outpatient department of a regional hospital in Mauritius from February 2011 to October 2012. A cross-sectional study of consecutive 55 patients of psoriasis of either sex was carried out. The permission of the Regional Health Director of the Hospital and an informed consent of the patient were obtained for the study. A clinicaldiagnosis of 'psoriasis vulgaris' was made, when typical well circumscribed, erythematous, scaly, chronic plaques were observed on the scalp and the extensors, 'guttate psoriasis' if there was an abrupt eruption of typical psoriatic lesions of papular type, 'pustular psoriasis' if tiny sterile pustules were found on the surface of a psoriatic plaque and 'psoriatic erythroderma' if extensive erythema and superficial scaling of more than 90% of the body surface occurred in a known case of psoriasis.[8, 9] Patient in remission of skin lesions of psoriasis or guttate psoriasis found to be serologically positive for VDRL or TPHA test were excluded from the study. The Case study method was used to collect the clinical data like age of onset, clinical type of psoriasis, the Body sites and the TBSA affected, involvement of the nail and the joints and presence of co-morbidities like obesity, hypertension, diabetes mellitus and cardiovascular diseases. Severity of the disease was assessed, by using percentage of the TBSA affected due to psoriasis. As per Finlay's concept of 'Rule of Tens', area covering more than 10 hand prints, indicating BSA more than 10%, was considered as severe psoriasis.[10] All the data was recorded in a comprehensive Case Record Form (CRF). The data collected was statistically analyzed using SPSS 22 software (Statistical Package for the Social Sciences). The continuous data was described as mean and standard deviation. The categorical data was expressed as frequencies and percentages. Analysis of categorical data was done by chi-square test or Fisher's Exact test. A p value of <0.05 was considered as statistically significant.

RESULT

Out of 55 patients registered in the study, men accounted for 36 (65.5%) and women 19 (34.5%). Male to female ratio was approximately 2:1.The age of patient varied from 20 to 76 years with mean age being 48.85 years, ± SD 13.49. Majority of patients, 51 (92.7%) were of age 30 years and above; 19 (34.5%) of patients were in their sixth decade. Least number of patient, 2 (3.6%) and 4 (7.3%), were recorded in the two extreme age groups (70-79 and 20-29 years, respectively). The number of patients with family history of psoriasis were 23(41.8%) out of which19 (34.7%) patients reported a first degree relative with psoriasis, 2 patients had a second degree relative and in 2 cases third degree relatives were suffering from psoriasis.

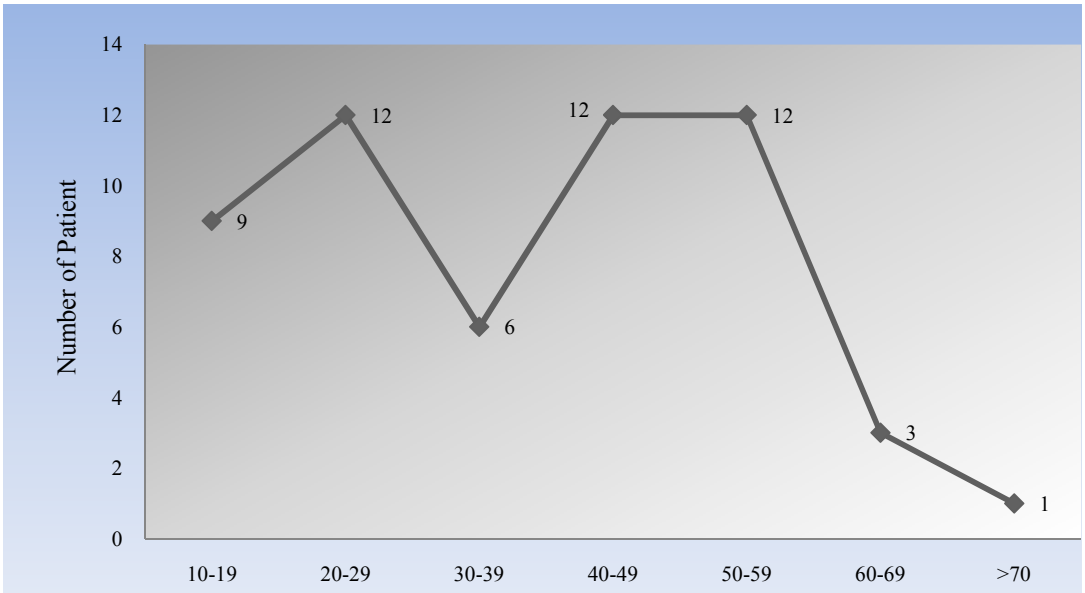

Figure 1: Bimodaldistribution

The age at onset of psoriasis of the skin was12 to70 years; mean being 37.7 years ± SD 16.0. Two peaks were observed, first during the third decade in 12(21.8%) patients, second during the fifth and sixth decades in 24(43.6%) subjects;27(49.1%) patients had onset of psoriasis below 40 years (early onset);28(50.9%) patients reported onset of psoriasis ≥ 40 years (late onset).

Table 1: Gender distribution, family history and TBSA**in 2 subtypes ofpsoriasis.

Variables		Psoriasis		p value
		Early onset (n=27)	Late onset (n=28)	
Gender	Male	14 (51.9%)	22 (78.6%)	p = 0.037*
	Female	13 (48.1%)	6 (21.4%)	
Family History	Yes	11 (40.7%)	12 (42.9%)	p = 0.874
	No	16 (59.3%)	16 (57.1%)	
Co-morbidities	Yes	22 (66.7%)	11 (33.3%)	p = 0.002*
	No	5 (22.7%)	17 (77.3%)	
TBSA	<10%	15 (55.6%)	22 (78.6%)	p = 0.069
	>10%	12 (44.4%)	6 (21.4%)	

*Statistically significant **Total Body Surface Area

Gender distribution in Early onset psoriasisis almost equal, butin Late onset psoriasis a male preponderance, almost 4: 1, was observed. Co-morbidities were present in 22/27 (66.7%) of Early onset psoriasis. Total Body Surface Area (TBSA) involvement larger than 10% was observed inalmost twice the number of patients in Early onsetas compared toLate onset psoriasis.Chi-square test was performed, and there is statistically significant association between gender and co-morbidities withsubtype of psoriasis; but no significant association was found between family history and disease severity (BSA). Late onset psoriasis was found more in male patients. Nail psoriasis was more common in Late onset psoriasis, 19 (67.9%) patients as compared to 14 (51.9%) patients in Early age onsetpsoriasis. In contrast, Joint involvementwas more frequent in patients of Early age onset, 9 (29.6%) as compared to Late onset psoriasis5 (14.3%) patients.Differences between the two groups having nail or joint involvement were statistically not significant.

Table 2: Nail involvement as per gender and type of psoriasis.

Variables		Nail involvement	p value
Gender	Male	26 (78.8%)	p = 0.000*
	Female	7 (21.2%)	
Psoriasis	Early onset	14 (42.4%)	p = 0.298
	Late onset	19 (57.6%)	

*Statistical significance

Nail involvement was more among male patients, 26 (78.8%) patients compared to female patients, 7(21.2%). Male to female ratio was approximately, 4:1. Proportion of male patients with nail involvement was significantly more ($p < 0.05$). No statistical significance was found in the Early and Late onset psoriasis patients.

Table 3: Joint involvement as per gender, subtype of psoriasis and family history.

Variables		Joint involvement	p value
Gender	Male	4(28.6%)	p = 0.085
	Female	10(71.4%)	
Psoriasis	Early onset	9(64.3%)	p = 0.254
	Late onset	5(35.7%)	
Family History	Positive	5(35.7%)	p = 0.254
	No	9(64.3%)	

Joint involvement was predominantly within the female population 10(71.4%), compared to males 4(28.6%). Male to female ratio was 2:5.On performing the z-test (Standard error of difference between two proportions) this finding was statistically not significant ($p > 0.05$).Majority of patients, 9(64.3%) with joint involvement had early age onset disease; From among patients with joint involvement 5/14(35.7%) had a positive family history of skin psoriasis; but this is not statistically significant.

Table 4: Type of joints involvedas pertype of psoriasis and family history

Variable		Types of joint involved in psoriasis		P value
		Non Axial joints	Axial joints	
Psoriasis	Early onset	6(75.0%)	3(50.0%)	P = 0.580
	Late onset	2(25.0%)	3(50.0%)	
Family History	Yes	4(50.0%)	1(16.7%)	P = 0.3
	No	4(50.0%)	5(83.3%)	

Non axial joints were mostly involved in Early onset psoriasis. Majority of patients 5(83.3%) with axial joints involvement did not have a positive family history. Associations of axial and non-axial joints to the Early or Late onset and family history were not statistically significant.

DISCUSSION

Plaque psoriasis was the predominant clinical type in this study. Relation of Early onset and Late onset psoriasis to gender,involvement of Total Body Surface Area (TBSA), nail and the joints were studied. A bimodal age of onset was observed with first peak during 20-30 years and second peak between 49-59 years of age was observed confirming the observations of Ferrándiz C *et al*[3] and Henseler T *et al*.[4] Early onset psoriasis revealed co-morbidities in 22/27 (66.7%) which was significant. A larger percentage of patients with family history and TBSA involvement was seen in almost twice the number of patients as compared to the Late onset psoriasis but the figures were statistically not significant to confirm similar findings of Ferrándiz C *et al*[3]and Youn JI *et al*.[11] In Late

onset psoriasis a significant male preponderance, almost 4: 1, was observed. There was also a significant association ofLate onset psoriasis and nail involvement. Joint involvement was predominantly in the female with more frequent involvement of axial joints. The study revealed a bimodal age of distribution of onset of psoriasis, higher co-morbidities in the Early onset psoriasis and male preponderance with a higher incidence of nail involvement in the Late onset psoriasis.

CONCLUSION

The Early onset psoriasis revealed significantly higher co-morbidities. The late onset psoriasisshowed a male preponderance, frequent nail involvement and psoriatic arthritis involving axial joints.The clinical features of psoriasis studied confirmed the existence of two clinical subtypes of psoriasis however a more extensive study is required.

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Original Article

Determinants of quality of life in psoriasis

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Abstract

Background: The impact of psoriasis on QOL of the individual may vary considerably depending on various factors such as gender, age of onset and the type of disease. However no study of the same had been carried out in Mauritius. **Objective:** Aim was to study the impact of clinical and epidemiological features of psoriasis on the Quality of Life of the psoriatic patient. **Methodology:** The study was carried out in the Outpatient department of a regional general government hospital in Mauritius. It was a cross sectional study of consecutive 55 patients of psoriasis using the case study method. The clinical features of psoriasis were correlated to the impact of psoriasis on the Quality of Life of the patient. The data was analyzed using SPSS 22 software. **Results:** Out of a total of 55 patients of psoriasis 36 (65.5%) patients were men and 19 (34.5%) women; Association between gender and the PDI score was a statistically significant (p value=0.024). Larger percentage of female patients was seen with greater PDI score. PDI was significantly dependent on stress (p value = 0.003). The patients with stress had a PDI score > 20. Involvement of the Body surface area less than 10% was observed in 37 (67.3%) and >10% BSA in 18 (32.7 %); 16 (83.3%) patients with involvement of Body surface area >10% had PDI score >20. Psoriatic arthritis was observed in 14/55 (24.5%) patients and 13/14 (92.8%) patients of psoriatic arthritis had PDI score > 20. **Conclusion:** There was a significant association between the gender, stress, severity of the disease, psoriatic arthritis and the total PDI score. The disability due to psoriasis was more in females, when a larger Body surface area was affected and in cases of joint involvement.

Key words: Quality of Life, Psoriasis Disability Index (PDI) score, Psoriatic arthritis, Body surface area.

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INTRODUCTION

Psoriasis is a recurrent and chronic systemic inflammatory disease with a wide spectrum of clinical patterns of skin, nail and joint involvement.[1,2] It is the most prevalent autoimmune disease in the United States, affecting approximately 7.5 million, or 2.2%, of the US population.[3] The most common type of psoriasis is Psoriasis vulgaris or plaque psoriasis. Symptoms of plaque psoriasis include erythematous plaques with silvery, micaceous scales. In most cases, the symptoms are mild and cover less than 3% of the body. However, for a small subset of individuals (8% of psoriasis patients), psoriasis can cover over 10% of the skin and is classified as severe.[4] Severe psoriasis can have a major impact on quality of life (QOL) of the patient. The impact of psoriasis on QOL of the individual may vary considerably depending on gender, the age, clinical type, the severity of the disease and involvement of the joints. Psoriasis is reported to have a greater impact on the quality of life of patients in the age 18 years to 45 years, with men subjected to a greater work-related stress as compared to women.[5] QOL was observed to be significantly more impaired in the older age group, particularly women, in another study.[6]

Symptoms, particularly itching, and severity of the disease as indicated by the total Body surface area (BSA) are reported to have negative impact on the QOL.[7] Psoriatic arthritis has a marked negative impact on the

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QOL and is an indication for treatment with immunosuppressant and or the Biologicals.[8] Various co-morbidities such as obesity, hypertension and cardiovascular disease may also influence the QOL of the psoriatic.

The chronic nature and course of the disease contribute to a lifelong burden.[9] Aim was to study various factors of the disease determining Quality of Life in psoriasis.

MATERIALS AND METHODS

It was an exploratory cross sectional study of consecutive 55 patients of psoriasis in the Skin Outpatient department of a regional government hospital in Mauritius. The study was carried out using the case study method. A permission of the Regional Health Director of the Hospital and an informed written consent of patient were obtained for the study. Only classical cases of psoriasis were included in the study. A clinical diagnosis of 'psoriasis vulgaris' was made when typical, well circumscribed, erythematous, scaly, chronic plaques were observed on the scalp and the extensors, and that of 'guttate psoriasis' was made when abrupt eruption of typical psoriatic lesions of papular type were observed. The diagnosis of 'pustular psoriasis' was made if tiny sterile pustules were found on the surface of a psoriatic plaque and with extensive erythema and superficial scaling of more than 90% of the body surface in a known case of psoriasis the diagnosis of 'psoriatic erythroderma' was made.[1,2] Patient of psoriasis who were in remission of skin lesions of psoriasis or those found to be serologically positive for VDRL or TPHA test were excluded from the study. The clinical data such as gender, age, duration of the disease, clinical type of psoriasis, the body sites and the Body surface area (BSA) affected, involvement of joints and presence of co-morbidities like obesity, hypertension, diabetes mellitus and cardiovascular diseases were recorded in a comprehensive Case Record Form (CRF). Severity of psoriasis was assessed by percentage of the total BSA affected due to the disease. As per Finlay's concept of 'Rule of Tens', area covering more than 10 hand prints, indicating BSA more than 10%, was considered as severe psoriasis.[10] A quantitative assessment of impact of psoriasis on QOL was done by the Psoriasis Disability Index (PDI) Questionnaire of A Y Finlay designed 30 years ago.[11] Since its introduction the PDI has been used widely as a tool for assessment of quality of life in psoriasis. It has been translated into at least 16 languages and has been used in published research in 20 countries.[12] A written permission for the use of PDI Questionnaire was obtained from Prof. A Y Finlay.

The PDI Questionnaire contained a total of fifteen questions, covering difficulties encountered under five different sections such as 'daily activities', 'at work', 'personal relationships', 'leisure activities' and 'treatment'. The patient assessed the impact of psoriasis on his QOL by selecting one answer from the choice of four answers; the answer 'very much' (scored 3), 'a lot' (scored 2), 'a little' (scored 1), 'not at all' or no answer (scored 0). The maximum score for the whole questionnaire could be 45 and minimum 0. The total PDI scores were put in two categories: patients with total PDI score of less than (<) 20 and patients with total PDI score of greater than or equal to (≥) 20.

The data collected was statistically analyzed using SPSS 22 software (Statistical Package for the Social Sciences). The continuous data was described as mean and standard deviation. The categorical data was expressed as frequencies and percentages. Analysis of contingency tables was done by Fisher's Exact test. The categorical data was analyzed by Chi-squared test. A p value of < 0.05 was considered as statistically significant.

RESULT

A total of 55 patients of psoriasis were studied. Age of patients ranged from 20 to 76 years with a mean age 48.85 years, ± SD 13.49; 36 (65.5%) patients were men and 19 (34.5%) women; 25 (45.5%) were employed and 18 (32.7%) unemployed.

Pruritus was noted in 32 (58.2%) patients. No statistically significant association between pruritus, episodes of exacerbation, disease severity (as indicated by BSA) and total Psoriasis Disability Index scores could be established.

Episodes of exacerbation of lesions within a year were observed in all 55 patients; 23 (41.8%) patients reported 1 to 2 exacerbation, 12 (21.8%) patients had more than 2 episodes of exacerbations of the disease.

Co-morbidities were present in 12 (40%) patients. They were Overweight (38.2%), Diabetes Mellitus Type II (32.7%), Hypertension (25.4%), Obesity (16.4%) and Cardiovascular disorders (12.7%).

Table 1: PDI (Psoriasis Disability Index) score as per gender, age of onset and stress

Variable	Number of Patients	PDI score groups		p value
		< = 20	> 20	
Gender				
Male	36	21 (58.30%)	15 (41.70%)	0.024
Female	19	5 (26.30%)	14 (73.70%)	
Age of onset				
< 40 years	27	9 (36.0%)	18 (60.0%)	NS
> 40 years	28	16 (64.0%)	12 (40.0%)	
Stress				
"No"	15	12 (80.00%)	3 (20.00%)	0.003
"Yes"	40	14 (35.00%)	26 (65.00%)	

NS: Not Significant Statistically

The gender and the PDI score were associated significantly (p value=0.024). A larger percentage of female patients were seen with greater PDI score. PDI was significantly dependent on stress (p value = 0.003). The patients with stress had a larger (>20) PDI score. Morphologically 53 (96.4%) patients were of Psoriasis vulgaris and1(1.8%) patient had Guttate psoriasis.

Table 2: PDI score as per Body site involved

Body site involved	Total Psoriasis Disability Index scores			p value
	≤20	>20	Total	
Limbs	25 (47.2%)	28 (52.8%)	53	NS
Trunk	16 (37.2%)	27 (62.8%)	43	0.02
Scalp	10 (40.0%)	15 (60.0%)	25	NS
Face	2 (28.6%)	5 (71.4%)	7	NS
Flexures	4 (26.7%)	11 (73.3%)	15	NS
Palms and soles	2 (50.0%)	2 (50.0%)	4	NS

NS: Not Significant statistically

A larger number of patients with psoriasis on the trunk had total PDI scores >20 which was statistically significant. Areas like the flexures, face and the scalp had more patients with high total PDI scores (>20) but were statistically not significant.

Table 3: PDI score as per Body surface area (BSA) and psoriatic arthritis

	Total number of patients	PDI groups		p value
		< = 20	> 20	
BSA				
< 10%	37	24 (64.90%)	13 (35.10%)	0.001
> 10%	18	2 (16.70%)	16 (83.30%)	
Psoriatic arthritis	14	1 (4.0%)	13 (92.8%)	0.001

16 (53.3%) patients with total body surface area (BSA) > 10% had a total PDI score o > 20 while 2 (8.0%) patients had total PDI score < 20, ($p<0.05$). A significant correlation was established between disease severity (BSA) and the total PDI scores. A significant proportion of variance of the PDI, was found to be dependent on BSA (23.1%) on performing a regression analysis.

Most of the patients 13 (43.3%) with joint involvement had higher total PDI score except for one patients who had a total PDI score of less than 20. On performing the Fisher's Exact test, a statistical significant association was found between the total PDI scores and Joint involvement ($p < 0.05$).

DISCUSSION

The study examined the relation of age, gender, pruritus, body site affected, clinical type and the severity of psoriasis to the total Psoriasis disability index (PDI) score. The PDI score is a quantitative measure of the impact on QOL.

Gupta MA *et al* has reported that Psoriasis has a greater impact upon the quality of life of patients in the range of age 18 years to 45 years, with men facing a greater work-related stress.[5] Samogna F *et al* reported that elderly people specially women were more adversely affected.[6] In this study also the female gender was associated with a larger PDI score. A larger percentage of female patients were seen with greater PDI score but age did not seem to have a significant negative impact on the QOL.

Patient-reported symptoms particularly itching, pain and scaling are reported to negatively affect work productivity.[7] No significant association between pruritus and total Psoriasis Disability Index scores could be established in this study. Stress had a negative impact on QOL.

Patients in the study were predominantly those of Psoriasis vulgaris. Most of the patients had lesions on limbs and the trunk. A larger number of patients with psoriasis on the trunk had high total PDI score. Areas like the flexures, the face and the scalp had more patients with a high total PDI score but were statistically not significant.

BSA involvement larger than 10% was considered to be a severe disease. This study noted an association between BSA and the total PDI score. BSA greater than 10% was observed in 18 (32.7%) patients; 16/18 patients had a PDI total score greater than 20. Horn *et al* also found a negative impact on QOL in moderate-to-severe psoriasis.[13] In contrast, a study from Kwa Zulu Natal, South Africa, reported a weak correlation of Psoriasis area severity index (PASI) with PDI.[14] The authors found that body sites like face, groin or genitalia when involved resulted in higher PDI score and these areas consisted of a smaller percentage of BSA.[14]

Almost all patients with joint involvement had higher total PDI score. Literature reports that patients with PsA have more bodily pain, decreased mental health, social functioning and a poorer quality of life compared to those with psoriasis alone.[15,16]

CONCLUSION

There was a significant association between the gender, stress, severity of the disease, psoriatic arthritis and the total PDI score. The disability due to psoriasis was more in females, at the time of stress and exacerbations, when a larger Body surface area was affected and in cases of associated Psoriatic arhritis. Areas like the flexures, the face and the scalp had more patients with a high total PDI score but were statistically not significant.

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Original Article

Psoriasis with psoriatic arthritis: A clinical study

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Abstract

Background: Psoriasis may be associated with Psoriatic arthritis in 6% to 42% of cases. Psoriatic arthritis can cause serious disability. No data about incidence of Psoriatic arthritis in patients of Psoriasis was available in Mauritius. **Objective:** To determine the prevalence of Psoriatic arthritis and its clinical types in Mauritian patients of psoriasis. **Methodology**: A cross-sectional study of consecutive 55 patients of Psoriasis was carried out by the case study method at a tertiary medical centre in Mauritius. The diagnostic criteria of Moll and Wright were used for the diagnosis and the classification of Psoriatic arthritis. The data collected was statistically analysed using SPSS16 (Statistical Package for the Social Sciences) software. A p value of < 0.05 was considered as statistically significant. **Results:** Psoriatic arthritis was observed in 14 (25.4%) of patients of Psoriasis. Female to Male ratio was 5:2. Clinical types of Psoriatic arthritis observed were Polyarthritis in 5 (35 %), a Combination of Spondylitis and Symmetric polyarthritis in 3 (29%), Oligoarthritis in 3 (29%) and Classical Isolated Distal interphalangeal joint involvement in 1 (7%) patient. The Proximal interphalangeal joints of the fingers were involved in 10 (71%), followed by the knee joint in 7 (50%) and the ankle joint in 7 (50%) of patients. **Conclusion:** Psoriatic arthritis affected female more frequently than male and the Polyarthritis type of psoriatic arthritis was predominant. The proximal-inter-phalangeal joints were most frequently involved.
Key words: Psoriatic arthritis, polyarthritis, spondylitis, oligoarthritis.

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INTRODUCTION

Psoriasis is a recurrent and chronic systemic inflammatory condition predominantly involving the skin, the nails and the joints.[1,2] Worldwide prevalence rates of psoriasis range from 0.6 to 4.8%[3,4] out of which 6% to 42% are reported to develop psoriatic arthritis[5], a painful and potentially debilitating type of arthritis. Patients with moderate to severe psoriatic arthritis are candidates for systemic treatment with immunosuppressant and biologicals.[6] However prevalence of psoriatic arthritis in Mauritian patients of psoriasis is not known.

Psoriatic arthritis (PsA) is the inflammation of the joints and the musculoskeletal system, in a patient of psoriasis with negative serology for rheumatoid factor.[1,2] No universally accepted gold standard exists for diagnosing PsA.[7] The criteria first proposed by Moll and Wright are currently the most frequently used, and includes an inflammatory arthritis, the presence of psoriasis and negative serology for rheumatoid factor.[8] Moll and Wright criteria for the diagnosis of Psoriatic arthritis does not include radiological findings. Using the criteria, PsA has been subdivided into five types, including oligoarticular, spondylitic, asymmetric polyarticular, distal interphalangeal and arthritis mutilans.

MATERIALS AND METHODS

An exploratory clinical research was carried out at the Skin Outpatient Department of a tertiary medical centre in Mauritius. A cross-sectional study of consecutive 55 patients of psoriasis of either sex was carried out by the

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case study method from February 2011 to October 2012. A convenience sample of patients of psoriasis attending Skin Outpatient Department was taken, as source list of patients in the region, was not available.

Only patients of classical psoriasis of the skin were included in the study and the diagnosis of psoriasis was made on the following clinical criteria: 'Psoriasis vulgaris' if there was a typical clinical picture of well circumscribed, erythematous, scaly, chronic plaques on the scalp and the extensors, the 'Guttate psoriasis' if there was an abrupt eruption of typical psoriatic lesions of papular type; the 'Pustular psoriasis' if tiny sterile pustules were found on the surface of psoriatic plaques and the 'Psoriatic erythroderma' if extensive erythema and superficial scaling of more than 90% of the body surface occurred in a known case of psoriasis.[1,2]

The diagnostic criteria of Moll and Wright were used for the diagnosis of Psoriatic arthritis[8] which include the presence of inflammatory arthritis with psoriasis and with negative serological tests for rheumatoid factor. Joint swelling, redness, and deformity with restriction of movement of the joint, were recorded. Joints were categorized as distal interphalangeal joint (DIP), small joints of the hands, small joints of the feet, large joints and axial joints. Clinical types of psoriatic arthritis were divided in to five clinical types, as per the classification of Moll and Wright[8] : Isolated Distal interphalangeal joint (DIP) without any other peripheral joint involvement, Asymmetrical oligoarthritis (four or less joints involved), Polyarthritis (more than four joints involved), Spondylitis and Arthritis mutilans.

Patient of psoriasis in remission of skin lesions of psoriasis or a patient with isolated nail psoriasis or a patient of guttate psoriasis found to be serologically positive for VDRL or TPHA test were excluded from the study.

Following a detailed medical history and a clinical examination of each patient, the data was recorded in a comprehensive Case Record Form (CRF). Clinical photographs of selected cases and X-rays of hands, wrists, feet, cervical spine and lumbosacral spine were taken as per complaint of the patient and clinical findings.

The data collected was statistically analysed using SPSS16.0 (Statistical Package for the Social Sciences) software. The continuous data was described as mean and standard deviation. The categorical data was expressed as frequencies and percentages. Analysis of contingency tables was done by Fisher's Exact test. The categorical data was analyzed by Chi-squared test. A p value of < 0.05 was considered as statistically significant.

OBSERVATIONS AND RESULTS

A total of 55 patients were studied. Ethnically 52 (94.6%) patients were Mauritians of Indian origin and 3 (5.4%) patients were Mauritians of African origin. The age of patient ranged from 20 to 76 years and mean age was 48.9 years, SD is 13.5. Men were 36 (65.5%) and women 19 (34.5%). Male to female ratio was approximately 2:1.

A total of 14/55 (25.4%) patients of psoriasis were diagnosed to have Psoriatic arthritis.

Table 1: Gender and Psoriatic arthritis

Gender	Psoriatic arthritis	p value
Male	4 (28.6%)	p =0.002*
Female	10 (71.4%)	

* p< 0.05, Significant statistically

Psoriatic arthritis affected male to female in the ratio of 2:5. On performing the Fisher's Exact test, this finding was statistically significant ($p < 0.05$). Patients with scalp psoriasis were 22 (40%), flexural psoriasis 15 (27.2%), palmo-plantar psoriasis 4 (7.3%), nail psoriasis, 33 (60.0%) and psoriatic arthritis 14 (40.0%). Psoriasis vulgaris 53 (96.4%) and Guttate psoriasis 1 (1.8%). Limbs and the trunk were the commonest involved sites. Palms and soles were the least affected body sites. The duration of the skin psoriasis was 1-43 years, mean duration being 11.2 years ±SD 10.4. The duration of joint complaints was 1-25 years, mean duration being 7.3 years ±SD 7.1.

Table 2: Duration of Psoriasis of skin and that of joint involvement

	Duration of psoriasis of the skin				
	0-5 years	5-10 years	>10 years	TOTAL	p value
Psoriasis of skin	19 (34.5%)	14 (25.5%)	22 (40.0%)	55 (100.0%)	NS
Psoriatic arthritis	\3 (15.8%)	4 (28.6%)	7 (31.8%)	14 (25.5%)	NS

NS: Not Significant statistically

On comparing duration of psoriasis of the skin and joint involvement equal number of patients, 7 (50%) had joint involvement within 10 years or after 10 years duration of psoriasis of the skin.

Table 3: Clinical types of psoriatic arthritis. (n=14)

Type of Psoriatic arthritis	Patients
Symmetric Polyarthritis	3 (21%)
Asymmetric Polyarthritis	2 (14%)
Combination of Spondylitis and symmetric polyarthritis	4 (29%)
Oligoarthritis	4 (29%)
Classical Isolated distal inter-phalangeal joint of fingers	1 (7%)

Polyarthritis type of psoriatic arthritis occurred most frequently while Isolated Distal-inter-phalangeal joint type of Psoriatic arthritis was least frequent.

Table 4: Joints involved in Psoriatic Arthritis. (n=14)

Type of joints	Upper Limb	Lower Limb
Small Joints	(%)	(%)
▪ Distal inter-phalangeal	35.7	14.2
▪ Proximal inter-phalangeal	71	-
▪ Metacarpo-phalangeal and Metatarso-phalangeal jnts.	21.4	-
Large Joints		
▪ Wrist/Ankle	28.5	50
▪ Elbow/Knee	42.8	50
▪ Shoulder/Hip	35.7	7.1

Small joints of the upper limb were involved most frequently.

DISCUSSION

The estimated prevalence of psoriatic arthritis among psoriasis patients in the world literature ranges from 6% to 42%.[3,4] In this study the incidence of psoriatic arthritis among patients of psoriasis at a tertiary medical centre in Mauritius was observed to be 18.2%.

Table 5: Percentage of patients with Psoriatic arthritis in various studies

	This study	Bedi[9]	Saeed *et al.*[10]	Prasad *et al.*[11]
Number of patients	55	530	104	472
Joint involvement	18.2%	10.3 %	35%	8.5%

This wide range of prevalence of psoriatic arthritis could be due to influence of several factors such as environment, ethnicity, absence of standardized validated criteria and methodology in the studies.

In this study the Polyarthritis type of PsA was predominant, followed by Oligoarthritis and Spondilytis in equal frequency. The least frequent joint involvement was isolated DIP. Polyarthritis was also reported to be the commonest type of psoriatic arthritis, in an Indian study by Rajendran *et al*[12], and an Iranian study by Shariati *et al*.[13] Sadek *et al* from Egypt observed Spondylitis (64.4%) as being the most common type.[14] The Malaysian Annual report recorded more frequently the Oligoarthritis type.[15] Moll and Wright's paper also identified the Oligoarthritis type of joint pattern, as the commonest type.[8] Gladman *et al* inferred that more joints became involved as psoriasis progressed, hence polyarthritis pattern was more prominent.[16]

Half of patients in this study developed psoriatic arthritis within 10 years, and the remaining half, after more than 10 years of skin lesions. The association of psoriatic arthritis and duration of psoriasis of skin was statistically not significant. Psoriatic arthritis has been reported to occur within 10 years of duration of skin psoriasis.[8] One of the patients enrolled in the study had concurrent onset of joint involvement and skin lesions, while another patient reported having joint involvement 4 years prior to onset of skin lesions. Psoriasis arthritis can precede or appear simultaneously with skin psoriasis.[1]

The proximal-inter-phalangeal joints (PIP) of the fingers (71%) were observed to be most frequently involved, followed by the knee (50%) and the ankle joint (50%) in the study (Table 4). The report of joint most commonly affected by psoriatic arthritis differs: Rajendran *et al* reported the knee joint, Baker *et al*, the shoulder joint and Robert *et al*, the metatarsophalangeal joint (MTP).[11]

CONCLUSION

Among patients of psoriasis, Psoriatic arthritis was observed in about 1 out of 5 patients. It predominantly affected the female population as compared to males. The Polyarthritis type of Psoriatic arthritis was predominant. The proximal-inter-phalangeal joints (PIP) of the fingers were most frequently involved.

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IMPACT OF PSORIASIS ON THE QUALITY OF LIFE

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ABSTRACT

Background: The Quality of Life of a patient of psoriasis is similar to or worse than a patient of chronic diseases like ischemic heart disease, hypertension, diabetes and cancer, however no assessment of the same was available in Mauritius. Aim was to do a quantitative study of impact of psoriasis on the Quality of Life of the psoriatic.

Methods: A cross-sectional study of consecutive 55 patients of psoriasis was carried out at the Skin Outpatient department of a regional hospital in Mauritius. An assessment of impact of psoriasis on the Quality of Life of each patient of psoriasis was carried out using the Psoriasis Disability Index Questionnaire of A Y Finlay.

Results: Out of total 55 patients of psoriasis 30 (54.6%) had PDI score ≥ 20 and 25 (45.4%) patients < 20; 14/19 (73.70%) women had PDI score >20. (p value=0.024). The impact of psoriasis on the 'daily activities' of the psoriatic scored highest with (62.3%), followed by 'leisure' (39.2%), 'at work' (33.3%), 'treatment' (29.3%) and 'personal relationships' (8.1%).

Conclusions: The majority of the psoriatic had a severe negative impact on their Quality of Life which was most obvious in their 'daily activities' and in women.

Key words: Impact, Quality of Life, Psoriasis Disability Index, 'daily activities', women.

INTRODUCTION

Psoriasis is a disease characterized by systemic chronic inflammation with prominent involvement of skin, joints and the skeletal system. Emerging evidences demonstrate association of psoriasis with obesity, dyslipidaemia, hypertension, Diabetes mellitus Type 2, cardiovascular disease and the stroke.[1-4]

A psoriatic is also at an increased risk of psychiatric illness. National Psoriasis Foundation patient-membership survey of 6,194 patients with severe psoriasis revealed that 79% considered psoriasis had a negative impact on their quality of life.[5] The severity of the negative impact on QOL can be gauged from another study of 138 patients in which 7.2% reported thoughts of suicidal ideation.[6]

Quality of Life (QOL) is the term used to describe a person's emotional, social and physical well-being.[7] Among psoriatic, QOL is found to be similar to or worse than chronic diseases like ischemic heart disease, hypertension, diabetes and cancer.[8,9] During the past decade, dermatologists have taken much

interest in quantification of Quality of Life among skin patients to the benefit of patients, clinicians and ultimately decision makers.

Psoriasis affects the individual in all spheres of his life. For a psoriatic 'daily activities' like sleeping, walking, sitting and doing household chores or shopping might become difficult.[10,11] A psoriatic may dress differently to conceal the lesions of psoriasis, may change dress and bathe more frequently.[10] A psoriatic may be denied use of public facilities like swimming pools, health clubs and hair salons.[12]

The disabling nature of the disease restricts a psoriatic from practicing sports[10] and in selection of the career.[13] The work life and career of a psoriatic is affected as one has to take leave due to the disease and its treatment; earning capacity and productivity of the individual may also be reduced.[13]

Disease perception by spouse, family members, relatives and friends could make a psoriatic feel embarrassed or humiliated affecting the relationships and this may lead to depression and suicidal ideation.[6,8]

Psoriasis Area and Severity Index, is a measure of severity of psoriasis and is not directly related to the QOL. The Psoriasis Disability Index (PDI) and the Dermatology Life Quality Index Questionnaire are commonly used quantitative measures of impact on QOL of a psoriatic.[14] The PDI has been used in 20 different countries during the past two decades and is composed of 15 questions covering the disability in 'daily activities', 'at work', 'personal relationship', 'leisure' and 'treatment'.[15]

Aim was to make a quantitative study of the impact of psoriasis on Quality of life of the psoriatic.

METHODS

A cross-sectional study of consecutive 55 patients of psoriasis was carried out at the Skin outpatient department of a Regional Hospital in Mauritius from February 2011 to October 2012. An approval of the Regional director of the hospital and an informed consent of the patient were obtained for the study. A convenience sample of patients of psoriasis attending Skin Outpatient Department was taken as source list of patients in the region was not available.

A clinical diagnosis of 'psoriasis vulgaris' was made on the basis of a typical clinical picture of well circumscribed, erythematous, scaly, chronic plaques on the scalp and the extensors. A diagnosis of the 'guttate psoriasis' was made in case of abrupt eruptions of typical psoriatic lesions of papular type, 'pustular psoriasis' if tiny sterile pustules were found on the surface of a psoriatic plaque and 'psoriatic erythroderma' if extensive erythema and superficial scaling of more than 90% of the body surface occurred in a known case of psoriasis.[16,17] The clinical data about psoriasis and co-morbidities like obesity, hypertension, diabetes mellitus and cardiovascular diseases were collected.

Patient of psoriasis in remission of skin lesions of psoriasis or with isolated nail psoriasis or the guttate psoriasis found to be serologically positive for VDRL or TPHA test were excluded from the study.

The impact of psoriasis on Quality of Life of the psoriatic was studied using a disease specific 'Psoriasis Disability Index (PDI) Questionnaire' of A.Y.Finlay[15]. A written permission for the use of the said 'Psoriasis Disability Index questionnaire (PDI)' was obtained from Prof. A.Y. Finlay. A tick box system was used in the questionnaire for simplicity and clarity in the scoring.[10,15]

The questionnaire contained a total of fifteen questions, covering difficulty encountered under five different subsections during the previous 4 weeks. The five subsections were: daily activities, at work, personal relationships, leisure activities and treatment. A score from 0 to 3 was given in response to every question. The choice for each question was 'very much' (scored 3), 'a lot' (scored 2), 'a little' (scored 1), 'not at all' or no answer (scored 0).

The 'daily activities' section had 5 questions with a maximum score of 15, 'at work' 3 questions with a maximum score of 9, 'at leisure' 4 questions with a maximum score of 12, 'personal relationship' 2 questions with a maximum score of 6 and 'treatment' 1 question with a maximum score of 3. The maximum score for the whole questionnaire could be 45 and minimum 0. The total PDI scores were put in two categories: patients with total PDI score of < 20 and patients with total PDI score of ≥ 20.

Data Analysis: The data obtained was recorded in a comprehensive Case Record Form (CRF) and statistically analysed using SPSS 22 (Statistical Package for the Social Sciences) software. The continuous data was described as mean and standard deviation. The categorical data was expressed as frequencies and percentages. Analysis of contingency tables was done by Fisher's Exact test. The categorical data was analyzed by Chi-squared test. A p value of < 0.05 was considered as statistically significant.

RESULTS

A total of 55 patients of psoriasis were subjected to the 'Psoriasis Disability Index' Questionnaire. The age of patients of psoriasis ranged from 20 to 76 years and the mean age was 48.85 years, ± SD 13.49;

36 (65.5%) patients were men and 19 (34.5%) patients women; 34 (61.8%) married, 11(20%) single, 7 (12.7%) widowed and 3 (5.5%) divorced; 25 (45.5%) employed and 18 (32.7%) patients unemployed. A total of 14 (25.4%) patients had psoriatic arthritis.

The minimum Psoriasis Disability Index (PDI) score recorded was 0 and maximum 39, the mean PDI score was 21.25 ± SD 10.5.

The PDI score was greater than or equal to 20 in 30 (54.6%) patients and less than 20 in 25 (45.4%) patients.

PDI score and the gender were associated significantly. (p value=0.024) Larger percentage of Female patients was seen with greater PDI score.

The highest PDI score (indicating the greatest disability) was recorded in 'Daily activities', followed by 'Leisure activities', 'At work' and 'Treatment'. "Personal relationship" scored the least. The maximum score in the 'Daily activities' subsection in the PDI questionnaire was 15/15 and minimum 0. The mean score was was 9.35 with SD 4.4. The maximum score in 'At work' subsection was 9/9 and minimum 0. The mean score was 3.95 with SD 3.6. No significant statistical association was found between patients who were unemployed and those who had a job.

Table 1: PDI* score and frequency

PDI score	Patients (%)
<10	8 (14.5)
10 -19	17 (30.9)
20 - 29	14 (25.5)
>=30	16 (29.1)
Total	55 (100)

*Psoriasis Disability Index

Table 2: PDI score in male and female.

Gender	PDI score groups		Total
	< = 20	> 20	
Male	21 (58.30)	15 (41.70)	36 (100)
Female	5 (26.30)	14 (73.70)	19 (100)
Total	26 (47.30)	29 (52.70)	55 (100)

Table 3: Total score in each subsection of the PDI questionnaire

PDI score	Patients (%)
Daily activities	62.3
At work	33.3
Personal Relationship	8.1
Leisure	39.2
Treatment	29.3

*Psoriasis Disability Index

Table 4: Details of responses to questions pertaining to the impact on 'Daily activities', 'Work' and 'Leisure activities' subsections of the PDI Questionnaire

	No answer	Very much	A lot	A little	Not at all	Total
Daily Activities						
Work around the house or garden	0 (0)	27 (49.1)	8 (14.5)	6 (10.9)	14 (25.5)	55 (100)
Types or colors of clothes	0 (0)	45 (81.8)	1 (1.8)	4 (7.3)	5 (9.1)	55 (100)
Change or wash clothes	0 (0)	39 (70.9)	3 (5.5)	3 (5.5)	10 (18.2)	55 (100)
Problem at hairdresser	4 (7.3)	18 (32.7)	2 (3.6)	5 (9.1)	26 (47.3)	55 (100)
More Baths	0 (0)	29 (52.7)	4 (7.3)	4 (7.3)	18 (32.7)	55 (100)
At work						
Time off work	0 (0)	22 (40)	4 (7.3)	5 (9.1)	24 (43.6)	55 (100)
Problem at work	0 (0)	24 (43.6)	5 (9.1)	3 (5.5)	23 (41.8)	55 (100)
Career affected	0 (0)	19 (34.5)	2 (3.6)	0 (0)	34 (61.8)	55 (100)
Leisure activities						
Stopped going out socially	1 (1.8)	22 (40)	6 (10.9)	6 (10.9)	20 (36.4)	55 (100)
Difficulty in doing sports	1 (1.8)	14 (25.5)	5 (9.1)	5 (9.1)	30 (54.5)	55 (100)
Stopped using communal facilities	5 (9.1)	28 (50.9)	3 (5.5)	4 (7.3)	15 (27.3)	55 (100)
Smoking and Drinking alcohol	3 (5.5)	7 (12.7)	1 (1.8)	0 (0)	44 (80)	55 (100)

Figure in parenthesis indicate percentage

The maximum score in 'Leisure activities' subsection in the PDI questionnaire was 12/12 and minimum 0. The mean score was 4.7 with SD 3.5. Only 8 (22.2%) male patients had reported that they were not at all affected by psoriasis; rest of the male patients and all the female patients were affected (that is answered as either 'very much', 'a lot' or 'a little').

The maximum score in the 'personal relationships' subsection in the PDI questionnaire was 6/6 and minimum 0. The mean score was 0.56 with SD 1.1. This subset had the least scores. Only 7% of patient had responded to 'very much' for the two questions; 24 % of patient did not respond to the question on sexual difficulties. No statistical significant association could be seen between divorced, single patients with patients who were married.

The maximum score in 'Problem with Treatment' section in the PDI questionnaire was 3/3 and minimum 0.The mean score was 2.25 with SD 1.1; 34 patients (61.8%) were very much affected by the treatments and about 10 patients (18.5%) marked the 'a lot' tick box.

In this study among male patients 20/36 (55.6%) had PDI scores ≤ 20, and among female patients 14/19 (73.6%) had PDI scores > 20. The association between PDI and gender was statistically significant. (p value 0.024). The complaint of pruritus was present in 32 (58.2%). No statistically significant association between pruritus and episodes of exacerbation, severity of disease (BSA) and total PDI score could be established.

The most frequent co-morbidities reported were Obesity 28 (54.6%), Diabetes Mellitus Type II 18 (32.7%) followed by Hypertension 14 (25.4%), and Cardiovascular disorders 7 (12.7%). Following diseases were reported in 41 (74.5%) patients. They were Vitiligo, Bronchial asthma, Hepatitis C, Diabetes mellitus Type I, Transient ischaemic accident, Adenocarcinoma of colon and Depression. Limbs and the trunk were the commonest involved body sites. Psoriasis vulgaris was the clinical type observed in 53 (96.4%), guttate psoriasis in 1 (1.8%) and psoriatic arthritis in 14 (40.0%).

DISCUSSION

The mean PDI (Psoriasis disability index) score of a patient of psoriasis in the study, was 20.84 ± SD 10.4 with a maximum 39. The score in this study was twice than that of an Indian study and a European-survey.[18,19] In a cluster analysis of 50 patients in India, the authors recorded a mean total PDI score of 9.38 with a maximum score of 48.[18] A modified scoring was adopted by the author and the questionnaire had 16 questions with a maximum score of 48.[18]

The impact on QOL in this study, was highest in subset "daily activities" (score 62.3%), followed by "leisure activities", "at work", "treatment" and least in the "personal relationship".

A study in Kerala observed that QOL was most affected in the subset "daily activities" (90.6%), followed by work (84.4%), leisure (71.9%), problems with treatment (68.7%) and the personal relations (62.5%).[20] According to the EUROPSO survey, 48% of reported problems were related to activities of 'daily living' and less disability was reported in employment, personal relationships, and behaviour (smoking or drinking).[19]

Patients paid particular importance to the type and colour of clothing to conceal psoriatic lesions, 81.8% patients had responded as affected "very much" to this question. Patients reported wearing long sleeved clothes and preferred trousers or long dresses or skirts while going out. The psoriatic patients also reported using pale colours, as the scales were more prominent on dark coloured clothes. Rakhesh et al[21] and the EUROPSO survey[19] also reported a high response rate for the questions on clothes and baths. It was observed that questions pertaining to the impact on choice of clothing and need for frequent change or washing were mostly answered by 'a lot' or 'very much' like other studies and surveys.[11,20,21] Problems at the hair dresser scored least in this study. Patients reported that they usually did not visit the hairdresser but preferred to do the haircut themselves at their home.

The impact on the QOL of the psoriatic in the "daily activities" is unanimously confirmed.[11,18,20,21]

In this study, 45.5% of patients were employed. Nearly half of the patients found psoriasis to be a problem 'at work' and lost time off work, 38% of patient reported their career to be affected. Few patients had to change their jobs due to the disease. They opted for careers where they were not in direct contact with the public; 32.7% of psoriasis patients were unemployed and they related psoriasis as the cause of unemployment, this was statistically not significant. Manjula et al[20] reported that 84.4 % of patients psoriasis were affected 'at work'. The career seemed to be less affected as per Dubertret et al and Rakhesh et al.[19, 21]

It should be noted that 24% of patients did not respond to the question on 'sexual difficulties', hence scored 0 for the unanswered question. Cultural reluctance to answer this question or merely the fact that 42.7% of patients were single, widowed or divorced could be the reason for the poor response rate to this question. The survey carried out in European countries has reported that more than a quarter of respondents were significantly affected within sexual relationships.[19]

In the Mauritian context, the communal facilities commonly used are the public beaches. More than half of the patients responded to the question pertaining to it by answering affected "very much". Few reported going to beaches early morning when the visitors would be scarce. More than half of the patients avoided social events; 40% had responded by answering affected "very much" and 10.9% "a lot". Similar findings were noted by Rakhesh et al.[21]

In this study 25.5% of the patients found it "very much" difficult to practice any sports mainly due to pain and disability due to the disease. In contrast, Rakhesh et al reported a much lower impact on sports activities and related their findings to the cultural differences and the life style.[21]

Majority of the patients in the study (61%), found the treatment very messy; consistent with findings by Manjula et al. from Kerala.[20]

CONCLUSION

Psoriasis caused a severe negative impact on the Quality of Life in majority of the patients. The majority of women had a severe disability unlike men. The negative impact due to psoriasis was greatest on "daily activities', followed by "leisure activities", "at work", and the "personal relationship" of the patient. Majority of the patients of psoriasis had "problems with treatment" as it was "very messy."

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Section Skin & VD

Original Article

A Prospective Study on Bacteriological Profile of Skin and Soft Tissue Infections with it`s Antimicrobial Sensitivity Pattern in a Tertiary Care Hospital

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ABSTRACT

Background: *SSTIs are the most common cause of morbidity in community and hospital.1 the most common examples of SSTIs are cellulitis, abscesses, impetigo, folliculitis, furuncle, carbuncle, necrotizing fasciitis , diabetic foot infections and surgical site infections .*
Methods: *In this study we were included 207 cases of skin & soft tissue infection. Among all 134 cases have positive bacterial growth which we were considered. This study conducted in Department of skin with collaboration of Department of Microbiology.*
Results: *We seen 47.1% growth of Staphylococcus aureus followed by Enterococcus spp. While in gram negative bacteria we seen 24.6% growth of Klebseilla followed by Pseudomonas aeruginosa & Escherichia coli.*
Conclusions*: Local antibiotic policy can be adopted which will prevent resistance among organisms and help in early recovery from infection.*
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Keywords: *Antimicrobial susceptibility test, Organisms, skin and soft tissue infection*

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INTRODUCTION

It is well known that skin and soft tissue infections (SSTIs) are a common type of infection. It may contribute to longer hospital stays, increase the cost of medical care. It also plays an important role in development of antimicrobial resistance. SSTIs are the most common cause of morbidity in community and hospital.1 the most common examples of SSTIs are cellulitis, abscesses, impetigo, folliculitis, furuncle, carbuncle, necrotizing fasciitis, diabetic foot infections and surgical site infections. Some infections can be treated by oral antibiotics. Complicated SSTI may require hospitalization, intravenous antibiotic and or surgery. An SSTI is categorized as complicated if the infection has spread to the deeper soft tissue, if surgical intervention is necessary or if the patient has comorbid conditions hindering treatment response.[1,2] SSTIs may be caused by many pathogens. Staphylococcus aureus is salvaged from maximum number of SSTIs. Other organisms recovered are Pseudomonas aeruginosa, Escherichia coli, Enterococcus, Klebsiella and Enterobacter species.[2,3-6] It is crucial to monitor the changing trends in bacterial infection and their antimicrobial susceptibility pattern to provide adequate antimicrobial therapy for controlling infection, preventing morbidity and improve the quality of life.

Though, the most common organism causing wound infections was Staphylococcus aureus followed by other Gram-negative bacilli,[7] but in India Gram negative bacilli was predominantly isolated compared to Gram-positive pathogens.[8,9] These infections are difficult to treat due to increasing antibiotic resistance.[8] The arbitrary use of

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antibiotics has also lead to the increase in multidrug resistant organisms (MDRO).[9] Now a days, infections are the leading cause of morbidity in patients of surgery, trauma etc.[10] For proper management of the patients, it is important to know the pathogens causing the infections and its antibiotic susceptibility.[11]

Previous studies provided very limited data on soft tissue infection, mortality rate and antibiotic susceptibility of Gram negative bacilli in our hospital settings. Therefore, the present study was undertaken to determine the aerobic bacteriological profile from various type of wound infections and the susceptibility pattern of the isolates.

METHODS

Study population:- In this study we were included 207 cases of skin & soft tissue infection. Among all 134 cases have positive bacterial growth which we were considered.

Study area:-This study conducted in Department of skin with collaboration of Department of Microbiology.

Study duration:- The duration of this study was over a period of one year.

Data collection:- First samples were inoculated on to Blood agar and MacConkey agar . Then samples were subjected to gram stain of direct smear to examine for the presence of pus cells and any bacteria. Culture plates were incubated at 37degree Celsius for 24hrs to 48hrs in aerobic condition. If there was no growth it was considered sterile. After incubation ,identification of bacterium from positive cultures was done with a standard microbiological technique which includes motility testing by hanging drop preparation ,gram staining and biochemical reactions such as catalase, coagulase, indole, methylred, Voges-Proskauer, citrate, urease, Phenyl pyruvic acid test and oxidase test(6).Further biochemical tests done were carbohydrate fermentation test using Lactose, sucrose, mannitol & Maltose, Triple sugar Iron test, Nitrate reduction test, Arginine dihydrolase production, lysine and ornithine decarboxylase test, Hugh and leifson test. The antimicrobial susceptibility testing was done by Kirby Bauer Disk Diffusion method and interpreted as per Clinical Laboratory Standard Institution (CLSI) guidelines

Data analysis:-Data were analysed by using Microsoft excel.

RESULTS

In this study we were screened 207 cases. Among all cases 134 cases have got positive culture & rest were no growth. In our study we found that 50.7% growth of gram-positive bacteria & 49.3% growth of gram negative. Among gram positive growth we seen 47.1% growth of Staphylococcus aureus followed by Enterococcus spp. While in gram negative bacteria we seen 24.6% growth of *Klebseilla* followed by Pseudomonas aeruginosa & Escherichia coli. Antimicrobial susceptibility pattern we also observed in this study which showed in chart:1,2,3,4.

Table 1: Distribution of cases according to culture growth

Culture growth	No. of cases	Percentage
Negative	73	35.2
Positive	134	64.8
Total	207	100

Table:-2 Distribution of cases according to bacteria

BACTERIA	No. of cases	Percentage
Gram positive	68	50.7
Gram negative	66	49.3
Total	134	100

Table:- 3 Distribution of cases according to isolates

ISOLATES	No. of cases	Percentage
Staphylococcus aureus	63	47.1
Klebsiella spp.	33	24.6
Pseudomonas aeruginosa	18	13.4
Escherichia coli	12	8.9
Enterococcus spp	5	3.7
Proteus spp.	3	2.2

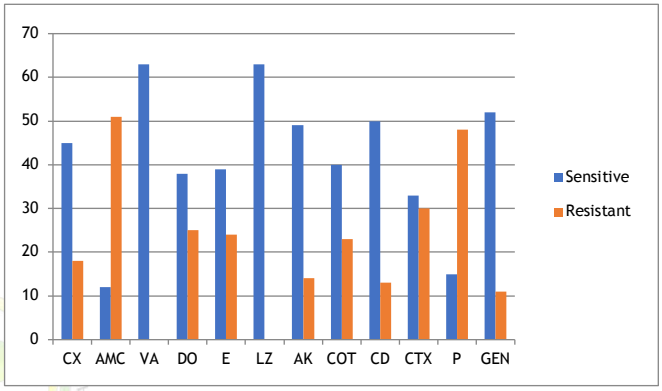

Chart:-1 Sensitivity pattern of Staphylococcus aureus

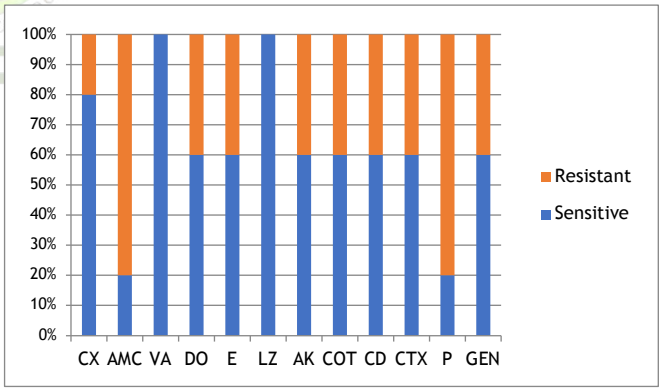

Chart:-2 Sensitivity pattern of Enterococcus spp.

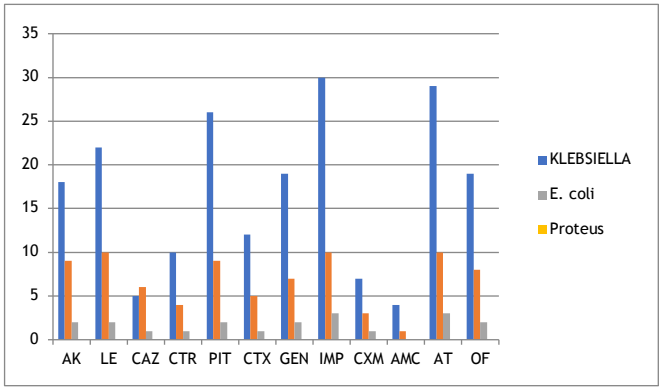

Chart:-3 Sensitivity pattern of E. *coli, Klebsiella, Proteus*

DISCUSSION

In the present study, the prevalence of culture positive samples is 64.73%. Similar results were found by Hanumanthappa P et al[12] and Sah P et al.[13] This study observed the domination of Gram-positive organisms which comprises 50.75%. These findings were supported by Sah P et al.[13] Though studies done by Afroz Z et al,[14] Najotra K et al,[15] Madhavi S et al[16] showed domination of Gram-negative isolate. The most common organism isolated in our study is Staphylococcus aureus. Similar findings were found by Najotra K et al,[15] Hanumanthappa P et al[12], Sah P et al[13] and Madhavi S et al.[16] Results also showed that among the Gram-negative organisms, the most common isolate is Klebsiella species. Hanumanthappa P et al[12] also reported the similar findings. However, in Afroz Z et al[14], Najotra K et al.[15]

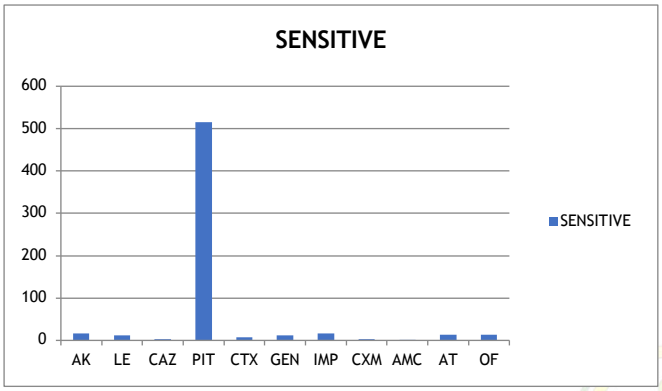

Chart:-4 Sensitivity pattern of Pseudomonas aeruginosa

Mishra D et al[17] studies, the most common isolate is Pseudomonas and in Sah P et al the most common isolate is Escherichia coli.

Staphylococcus aureus is 100% sensitive to Vancomycin and Linezolid in this study. Similar finding was found in Mishra D et al**,** Najotra K et al**.** While Sah P et al found only 5.56% Vancomycin resistance in their study. Staphylococcus aureus is least sensitive to Amoxycillin/ Clavulanic acid in our study. In contrary, a study conducted by Madhavi S et al[16] Staphylococcus aureus showed maximum resistance towards Ampicillin. The prevalence of MRSA is 28.57% in this study. Similar finding was found by Mishra D et al. However, Rani S et al,[18] Shetty J et al[19] showed low prevalence of MRSA in their study.

In the present study, the most common organism among Gram negative isolates is Klebsiella species. Klebsiella showed highest susceptibility towards Imipenem and maximum resistance towards Amoxyclav. Mohanty S et al[20] found Klebsiella has the maximum sensitivity towards Piperacillin/ Tazobactum and maximum resistance towards Piperacillin. While Sah P et al observed Klebsiella has maximum susceptibility towards Ciprofloxacin and maximum resistance towards Cefepime and Amoxycillin. Therefore, the antibiotic susceptibility pattern of Klebsiella changed in different studies.

It can be concluded that the most common organism causing skin and soft tissue infections is Staphylococcus aureus followed by Klebsiella.

The study also observes a rise in prevalence of MRSA. Though, a changing pattern were observed among the organisms isolated as well as their antibiotic sensitivity pattern in several studies from different geographical locations.

CONCLUSION

This study concludes that it is important to conduct repeated monitoring of antibiotic susceptibility pattern to reduce the increasing trend of antimicrobial resistance. Additionally, a local antibiotic policy can be adopted which will prevent resistance among organisms and help in early recovery from infection. The study stresses on appropriate and judicious use of antibiotics.

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Section Dermatology | Original Article

A Prospective Study on Dermatological Manifestations in Type 2 Diabetes Mellitus Patients

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ABSTRACT

Background: *Diabetes mellitus is a major health problem with increasing numbers. Globally, it has been estimated that the prevalence of DM among all age groups is about 2.8% in the year 2000 and will reach up to 4.4% by the year 2030. In developing and underdeveloped countries, the prevalence will rise from 4.2% to 5.6%.*
Methods*: Total 200 cases were included in this study. Among all 118 cases were infective and rest were non-infective. This study was conducted in Department of Dermatology. The duration of study was over of period of one year.*
Results*: Among 200 cases 56% cases were male rest were female. Out of 200 cases 118 cases are infective and 82 cases are non-infective. In this study we studied 61.1% cases of fungal infection followed by 30.5% bacterial cases, 6.7% of viral cases & 1.6% cases of parasitic infection.*
Conclusions*: The manifestations should be actively sought in all diabetic patients because early diagnosis and management can reduce morbidity.*

Key words*: Diabetes mellitus, Bacterial infection, fungal infection*

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INTRODUCTION

Diabetes mellitus is a metabolic disease. It is characterized by hyperglycaemia. It occurs due to defects in insulin secretion or insulin action or a combination of both.[1] Infections occur frequently in diabetes mellitus patients and their presence can trigger acute metabolic complications.[2] The long-term complications of diabetes mellitus have adverse effects on both the cellular and humoral immune systems. For example, the chemotactic function of polymorphonuclear leucocytes is weakened in patients with diabetes.[3] In diabetic patients, many abnormalities might contribute to the higher susceptibility and severity of infections for example, reduced mastocyte function, lower neutrophil chemotactic activity, reduced leucocyte numbers in inflammatory lesions, low oxidant molecule production, decreased lymph node retention capacity and reduced cytokine release.[4-7] Diabetes mellitus is a major health problem with increasing numbers. Globally, it has been estimated that the prevalence of DM among all age groups is about 2.8% in the year 2000 and will reach up to 4.4% by the year 2030. In developing and underdeveloped countries, the prevalence will rise from 4.2% to 5.6%.1 Skin being the largest organ of the body also gets badly affected by both acute metabolic derangements and chronic degenerative complication of DM.[8,9] Several factors are involved in manifestation of dermatological signs of DM. Derangement

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in carbohydrate metabolism, changes metabolic pathways in the patients which leads to display of the disease in various forms involving all the systems of the body. The incidence of cutaneous disorders is mostly observed than the manifestations of the disease in other systems of the body. Dermatological signs of DM are generally seen once the disease develops; at times they may precede the development of the disease and can give a clue of the impending metabolic disorder. Some skin manifestations are caused by direct metabolic changes arising due to hyperglycaemia and lipid abnormalities. Whereas several other complications are caused by vasculopathies, neuropathy or immunological.[10,11] most of the subjects had a history of DM of over 10 years, and all these subjects had dermatological manifestations. It can be assumed that with increasing duration of illness the complications tend to rise. It is due to the development of advanced glycated products that are formed no enzymatically causing cutaneous damage.[12,13]

METHODS

Study population:- Total 200 cases were included in this study. Among all 118 cases were infective and rest were non-infective.

Study area:- This study was conducted in Department of Dermatology.

Study duration:- The duration of study was over of period of one year.

Data collection:- Informed consent was obtained. A detailed history was elicited with particular reference to cutaneous complaints and including details regarding duration, history of evolution, progression and treatment modalities. Clinical examination included general physical examination followed by a meticulous examination of the lesion done to make a diagnosis and investigations such as 10% KOH smear where required. Control of Diabetes was assessed by available HbA1c levels, FBS, PPBS levels.

Data analysis:- Data were analysed by using Microsoft excel.

RESULTS

In this study we were involved 200 cases. Among 200 cases 56% cases were male rest were female. Out of 200 cases 118 cases are infective and 82 cases are non-infective. In this study we studied 61.1% cases of fungal infection followed by 30.5% bacterial cases, 6.7% of viral cases & 1.6% cases of parasitic infection. In the fungal cases 46 cases of candida infection and rest were dematophytic infection found. Among the camndidal infection 65.2% were found of intertrigo ,26.6% cases of Candidal Balanophosthitis and 8.6% of Vulvovaginal Candidiasis. While in dematotophytic cases we found 30.7% cases of Tinea corporis followed by other cases. In 44.5% cases of Furunculosis we seen while 22.3% cases of Folliculitis & abscess, 5.5% cases of Carbuncle & Cellulitis were found.

Table 1: Distribution of cases according to gender

Gender	No. of cases	Percentage
Male	88	44%
Female	112	56%
Total	200	100%

Table 2: Distribution of cases according to infective cases

Diabetic cases	No. of cases	Percentage
Infective	118	59
Non-infective	82	41
Total	200	100

Table 3: Distribution of cases according to type of infection

Infection	No. of cases	Percentage
Fungal	72	61.1
Bacterial	36	30.5
Parasitical	2	1.6
Viral	8	6.7
Total	118	100

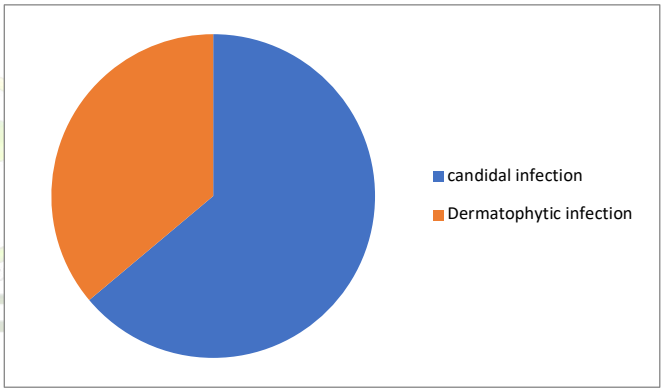

Chart:-1 Distribution of cases according to type of fungal infection

Table 4: Distribution of cases according to type of infection

Fungal infection	No. of cases	Percentage
Candidal infection		
Intertrigo	30	65.2
Vulvovaginal Candidiasis	4	8.6
Candidal Balanophosthitis	12	26.2
Dermatophytic infections		
Onychomycosis	4	15.3
Tinea pedis	2	7.6
Tinea corporis	8	30.7
Tinea incognito	6	23.1
Tinea cruris	6	23.1

DISCUSSION

In the present study, the most common age group of diabetic patients with cutaneous manifestations is between 46-55 years. While in Mashkoor ahmed et al study the age group

was 51- 60 years.[14,15] The female predominance was found in our study. Similar findings were found by Mashkoor ahmed et al Mahajan et al and Romano et al.[16,17] Ahmed et al also showed that skin diseases 19 were more common in women than in men. In contrast Binkley[18] and Danowsky et al observed a higher incidence of cutaneous diseases among male diabetics. Sargodha also conducted a study and found skin disorders more in men than women.[19]

Results of this study also showed that cutaneous infections were the most common cutaneous manifestations in 59% of the cases, Similarly, Nigam and Pande and Ahmed et al[16] found cutaneous infections to be the most common dermatoses in their studies. The reason behind higher incidence of cutaneous infections in diabetes may be related to abnormal microcirculation, hypohidrosis, peripheral vascular disease, diabetic neuropathy, decreased phagocytosis, impaired leukocyte adherence, and delayed chemotaxis.[20,21] This study also found the cutaneous fungal infections as the most common infection. It was observed in 61.01% of the cases[22], followed by bacterial infections in 30.5%[17] and viral 6.77%[23] and parasitic 25 1.69%.[24] These findings were supported by Dependra et al. Among the non-infective dermatosis Pruritus and xerosis were the second most common manifestation. It was seen in 17.07% patients. Generalized pruritus is not precisely related with diabetes mellitus, though pruritus vulvae and[21] balanitis may be the presenting symptoms of diabetes . In elderly diabetics, itching could be a manifestation of xerosis. Pruritus[15] was also the second most common finding in Mahajan et al's[25] study. Rao and Pai also showed that pruritus was the main presenting symptom and was seen in 60.23% patients in their series. Diabetic patients can present with array of cutaneous disorders. Cutaneous infections formed the largest group of dermatoses in our study. Higher incidence of cutaneous infections mainly fungal and bacterial was observed in majority of the uncontrolled diabetics, this condition emphasizes the need for more aggressive management of diabetes mellitus. Among infective dermatoses, fungal infections were the most common than dermatophytosis. Other commonly observed dermatoses were pruritus without any skin lesions, xerosis, prurigo, achrochordon, acanthosis nigricans, granuloma annulare, seborrhoic keratosis. There are multiple factors for cutaneous manifestations of diabetes mellitus. These are abnormal carbohydrate metabolism, microangiopathy, atherosclerosis, neuron degeneration and impaired host defense mechanisms.

Table 5: Distribution of cases according to bacterial infection

Bacterial infection	No. of cases	Percentage
Folliculitis	8	22.3
Furunculosis	16	44.5
Abscess	8	22.3
Carbuncle	2	5.5
Cellulitis	2	5.5

CONCLUSION

The manifestations should be actively sought in all diabetic patients because early diagnosis and management can reduce morbidity.

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Original Research Article

Clinical profile of acne vulgaris in semiurban patients

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ABSTRACT

Background: Acne is a chronic inflammatory disease of the pilosebaceous unit, mainly affecting face and frequently followed by scarring. It is the most common skin disease in an urban dermatology clinic in India. Adult acne is more common in women and may be a marker of hyperandrogenism. The present study was carried out to study the clinical profile of acne vulgaris in semiurban patients.
Methods: The study was conducted for 1 year on all eligible patients of acne vulgaris attending dermatology OPD of a hospital catering to semiurban patients. Data including grade of acne, markers of androgenicity and post-acne scarring was collected. Statistical analysis was done using SPSS 15 software.
Results: Frequency of acne vulgaris patients in the dermatology OPD was 2.8% with 429 acne patients out of 15,322 new patients. Female to male ratio was 1.44:1. The mean age of onset in males was 16.24 and in females, 14.84 years. Grade 2 acne (66%) was commonest followed by grade 3 (5.1%) and grade 4 (3.7%). Associated conditions seen were seborrhea (60.8%), alopecia (18.9%), acanthosis (4.9%) and PCOD (2.3%). Markers of androgenicity were more frequently seen in grade 2 acne which was statistically significant. Atrophic scars were commonest including icepick scars (80.2%), rolling scars (67.4%) and box scars (57.8%).
Conclusions: In our study females had an earlier onset and closed comedones were the most common acne lesion. Grade 2 acne vulgaris formed majority of patients. Grade 4 acne vulgaris was more common in males.

Keywords: Acne vulgaris, Semiurban, Clinical profile, Markers of androgenicity, Scarring

INTRODUCTION

Acne is a chronic inflammatory disease of the pilosebaceous units; it is characterized by seborrhoea, the formation of open and closed comedones, erythematous papules and pustules and in more severe cases nodules, deep pustules and pseudocysts. Inflammatory lesions are followed by scarring.[1] It is stated that 90% of individuals, male and female, between puberty and age of 30 years, experience some degree of acne and is reported by Kubba et al to be the most common skin disease, in an urban dermatology clinic in India. There are estimated 200-300 million acne sufferers in the country.[2]

Acne vulgaris develops earlier in females than in males. Occasionally, it may start at age 7 or 8 years (adrenarche) and when it does, it portends severe acne. Less commonly, acne may make its first appearance in mature adults- after 25 years of age (adult acne). Adult acne is more common in women and is often, a part of cutaneous hyperandrogenism. Acne waxes and wanes through adolescent years and early adult life, rarely it may persist

well into the fifth and the sixth decade (persistent acne). The most severe forms of acne vulgaris occur more frequently in males, but the disease tends to be more persistent in females. Severity of the disease varies markedly from one individual to the other depending upon the interplay of various factors involved in the development of acne vulgaris.[1-4]

Acne may ruin beauty and it may result in scars for life. Sufferers often have significantly impaired psychological development. The patient develops reduced self- esteem, and reduced career prospects caused by perceived disfigurement. These effects can be less related to the severity of the disease than to the patient's own perception.[2,5]

The present study on acne vulgaris was carried out to study age of onset, gender predilection, body site involved, severity, association of seborrhea, alopecia, and markers of androgenicity in females.

METHODS

A cross sectional, observational study on acne vulgaris was conducted between January 2011 to December 2011 in the dermatology outpatient department of a medical college hospital at Lucknow, after obtaining permission of Institutional Ethics Committee. A total of 429 consecutive, eligible patients of either gender were included as subjects. Acneiform eruptions, drug and cosmetic induced acne were excluded.

The data was collected in a predesigned case record form which included age, gender, marital status, age of onset, duration of acne, body site involved, number and severity of acne lesions, relation to menstrual cycle, markers of androgenicity, post-acne hyperpigmentation and scarring. The severity of acne vulgaris was graded into four grades using a simple grading system, taking into account the predominant lesion.[6]

- Grade 1: Comedones, occasional papules
- Grade 2: Papules, comedones, few pustules
- Grade 3: Predominant pustules, nodules, abscesses
- Grade 4: Mainly cysts, abscesses, widespread scarring

Statistical analysis was done using SPSS 15 software (SPSS, Chicago, IL, USA).

RESULTS

A total of 15,322 new patients attended the dermatology OPD, during the study period of one year, 429 patients presented for acne vulgaris, giving a frequency of 2.8%.

A total of 253 (59%) were females and 176 (41%) were males, giving female to male ratio of 1.44:1. Mean age of male patient was 19.20 (±3.16) years and female 21.68 (±4.29) years (Table 1). All male and 90.9% of female patients were unmarried.

Table 1: Age wise distribution.

Age in years	Male	Female
	No.	**No.**
10-15	21	16
16-20	101	100
21-25	47	85
26-30	7	47
>30	0	5
Total	176	253

X^2=33.1; p<0.001

Table 2: Age of onset of acne vulgaris.

Age onset	Male (n=176) (%)	Female (n=253) (%)
10-15	64 (36.4)	176 (69.6)
16-20	105 (59.6)	76 (30.0)
21-25	7 (4.0)	1 (0.4)
Mean±SD	16.24±2.05	14.84±1.58

X^2=49.18; p<0.0001.

Age of onset in 240 (55.9%) patients was between 10 to 15 years of age, with a mean of 15.41 (±1) years. Age of onset in males 105 (59.6%) was between 16 to 20 years of age, with a mean of 16.24 (±2.05) years; age of onset in females was 176 (69.6%) between 10-15 years of age, at the mean age of 14.84 (±1.58) years (Table 2). Family history of acne was observed in 225 (52.5%) patients.

In a majority (40.3%) of patients, the total duration of acne, was more than 60 months. The duration of acne ranged from 1 week to 24 years, with an average duration of 39.81 months. Out of a total of 286 (66.7%) patients, 186 (43.4%) patients complained of itching and post inflammatory hyper pigmentation. A total of 204 (80.6%) female patients gave history of habitual picking of acne, as compared to 122 (69.3%) male.

The mean age of menarche was 13.99 (±1.80) years. Menstrual cycle was regular in 73 (28.9%) patients. History of premenstrual flare was present in 159 (37.2%) patients.

Table 3: Body site affected.

Site of acne lesions	No (n=429) (%)
Face	429 (100)
Arms	83 (19.3)
Back	110 (25.6)
Chest	75 (17.5)
Neck	32 (7.5)

A total of 288 (67.1%) patients presented with acne of 'face alone.' As such face was involved in all (100%) patients, followed by back 110 (25.6%), arms in 83

(19.3%), chest 75 (17.5%) and neck in 32 (7.5%) patients (Table 3).

Table 4: Morphology of lesions.

Types of lesions	No (n=429) (%)
Open comedones	223 (52)
Closed comedones	416 (97)
Papules	321 (74.8)
Pustules	112 (26.1)
Nodules	38 (8.9)
Abscesses	29 (6.8)
Pseudocyst	16 (3.7)

Closed comedones were observed in 416 (97%) patients had, followed by papules in 321 (74.8%), open comedones in 223 (52%), pustules in 112 (26.1%), nodules in 38 (8.9%), abscesses in 29 (6.8%) and pseudocyst in 16 (3.7%) (Table 4).

Table 5: Grade of acne vulgaris.

Acne grade	Male (n=176) (%)	Female (n=253) (%)	No. (n=429) (%)
1	27 (15.3)	81(32)	108 (25.2)
2	122 (69.4)	161(63.6)	283 (66)
3	15 (8.5)	7 (2.8)	22 (5.1)
4	12 (6.8)	4 (1.6)	16 (3.7)

X^2=26.31; p<0.0001.

Grade 2 acne was observed in 283 (66%) patients, followed by grade 1 in 108 (25.2%) patients, grade 3 in 22 (5.1%) patients and grade 4 in 16 (3.7%) patients (Table 5). Male 122 (69.4%) patients and female 161 (63.6%) patients had grade 2 acne vulgaris (Table 5). In our study, patients having acne more than 60 months duration had grade 3 or grade 4 acne.

Table 6: Markers of androgenicity in the female (n=253).

Marker	Present (%)	Absent (%)
Hirsutism	67 (26.5)	186 (73.5)
Acanthosis nigricans	13 (5.1)	240 (94.9)
Seborrhea	95 (37.5)	158(62.5)
Increased muscle mass	0	0
Deepening of voice	0	0

In the study, seborrhea was observed in 95 (37.5%) female patients, followed by hirsutism in 67 (26.5%) and acanthosis nigricans in 13 (5.1%). None of the patient had increased muscle mass or deepening of voice. In female subjects, markers of androgenicity – such as hirsutism, acanthosis nigricans and seborrhea were more frequently seen in grade 2 acne and the association between them was statistically significant (p=0.045, p<0.0001, p value<0.0001 respectively) (Table 6).

Table 7: Associated cutaneous and systemic conditions.

	No (n=429)	%
Seborrhoea	261	60.8
Alopecia	81	18.9
Folliculitis	32	7.5
Acanthosis nigricans	21	4.9
PCOD	10	2.3

Seborrhoea was the most common dermatological association as seen in 261 (60.8%) followed by folliculitis in 32 (7.5%), acanthosis nigricans in 21 (4.9%), melasma in 9 (2.1%) and alopecia in 81 (18.9%). Polycystic ovarian disease (PCOD) was seen in 10 (2.3%) patients. According to BMI, 8 out of 10 PCOD patients were overweight, and 2 were obese. USG findings in all 10 patients were suggestive of PCOD. Seven patients of PCOD had diabetes mellitus and none of them gave a positive family history of PCOD. Clinical findings were irregular menses and hirsutism in 10 patients, Seborrhea in 6 patients and acanthosis nigricans in 8 patients (Table 7).

Table 8: Types of acne scars.

Types of acne scars	No (n=429) (%)
Atropic scars	
Icepick	344 (80.2)
Rolling	289 (67.4)
Boxscar	248 (57.8)
Hypertrophic	5 (1.2)
Keloid	1 (0.23)

Atrophic scars were commonest: icepick scars in 344 (80.2%), rolling scars in 289 (67.4%) and boxcar scar in 248 (57.8%) patients. Hypertrophic scar were present in 5 (1.2%) and keloids in 1 (0.23%) patient (Table 8).

DISCUSSION

The present study was done to study the clinical profile of patients of acne vulgaris in the Dermatology OPD of a medical college hospital and a possible correlation between acne vulgaris and markers of androgenicity in females. Acne vulgaris constituted 2.8% of all new patients attending Dermatology OPD. Other hospital based studies done in Asian population have reported acne vulgaris patients to be 1.06% to 19.6%.[7,8] The mean age of a patient of acne vulgaris was 20.66 (±4.05) years confirming acne vulgaris to be a primarily, a problem of the adolescent.

In the present study, female patients (59%) outnumbered male (41%) in the ratio of 1.44:1 with a mean age 21.68 (±4.29) years, a marriageable age group. The majority (90.9%) female patients were unmarried. These observations confirm the report of Al-Ameer et al and Tallab.[8,9] However Adityan et al have reported a larger

number of male patients in their study.[7] Similar finding were observed by Kane et al indicating the greater concern of facial appearance in female patients, of younger and marriageable age group.[10]

In the present study the mean age of onset in was 15.41 (±1.92) years, confirming observations of Adityan et al.[7] The age of onset in female was about 1.5 years earlier than in males and the difference was statistically significant ($p<0.0001$). Association between age of onset and age of puberty in our study was significant ($p<0.0001$). The observations confirm reports that acne develop earlier in females as compared to males due to an earlier onset of puberty.[1,11,12]

In the present study, the average mean duration of acne vulgaris was 39.81 months and severe acne were associated with a longer duration. Adityan et al had reported mean duration of acne as 45.55 months and patients with longer duration of the disease had more severe acne vulgaris.[7]

History of itching was noted in 186 (43.4%) patients and post inflammatory hyperpigmentation (PIH) in 286 (66.7%) of patients. Reich et al in their study reported itching in 50% and Lim et al in 70% of their patients.[13,14] Post-inflammatory hyperpigmentation is a common sequel in acne patients.[15] History of picking was noted in 326 (76%) patients and it was more common in female 204 (80.6%) as compared to male 122 (69.3%) patients. On the contrary, Pandey observed picking of acne to be more common in males as compared to females.[16]

In our study, face was involved in all the patients of acne vulgaris (100%), back in 25.6%, arms in 19.3%, chest in 17.5% and neck 7.5%, whereas only face involvement was seen in 67.1%. These observations are in accordance with data from earlier literature.[1,7] The primary and the pathognomonic lesion of acne vulgaris is a comedone, which may be open or closed.[1,4,17] In the present study, closed comedones were observed in 97% of our patients whereas open comedones were seen in 52% of our patients. Similar results were noted by Adityan et al.[7]

Acne vulgaris is a disease with polymorphic eruptions.[1] In our study, the severity of acne vulgaris was graded using a simple and quick system of classification of four-grade system.[6] Grade 2 acne was seen in 283 (66%) patients followed by grade 1 in 108 (25.2%), grade 3 in 22 (5.1%) and grade 4 in 16 (3.7%) patients. Patients with grade 2 acne vulgaris outnumbered patients with more severe inflammatory forms of the disease. Similar findings were noticed by Kane et al.[10] However, Adityan et al observed grade 1 acne vulgaris to be 60.2% of patients.[7] In the present study, grade 4 acne vulgaris was observed in 6.8% male patient as compared to 1.6% female patients ($p<0.0001$). This observation is in accordance to studies of Tallab and Adityan et al.[7,9]

Although acne is not an inherited condition, there is an inherited predisposition.[18,19] We observed family history of acne in 52.5% of our patients; 62.5% patients of grade 4 acne vulgaris had a positive family history of acne. Cunliffe and Gollnick reported family history in 40% and Kubota et al in 56.8% of their patients of acne vulgaris.[20,21]

In our study, acne scarring was seen in 80.2% patients. Incidence of post acne scarring is observed to vary from 5.9% to 40.2%.[4,7,10,22] We observed that patients with longer duration of disease were more likely to have post-acne scarring and the association between them was statistically significant ($p<0.0001$) and this finding is in accordance with earlier studies.[7,23]

Whereas, ice-pick scar was the most common type of post-acne scar and it was universally present in all patients of post acne scaring. Similar findings were noticed by Layton et al.[23] However, we observed a higher percentage of post acne scarring as this may be a phenomenon in the North Indian race or may be due to longer duration of disease which was present in majority of patients and habit of picking might have played its important role.

In our study, premenstrual flare was noticed in 62.8% of female patients. Incidence of premenstrual flare is reported to vary from 39.1% to 57.7% by Adityan et al, Stoll et al, Ikaraoha et al, and Kubota et al.[7,24-26] In the present study, irregular menses was noted in 28.9% of female patients. Similarly, irregular menses noted in earlier studies varied from 10.2% to 48%.[7,27]

Markers of androgenicity in female patients such as hirsutism was observed in 26.5% of patients. Similarly, in earlier studies it varied from 0% to 21%.[7,27] Seborrhea was observed in 37.5% of female patients followed by acanthosis nigricans in 5.1% female patients. Seborrhea plays a central role in the pathogenesis of the disease.[7] In the present study, seborrhoea was observed in 60.8% of patient and it was associated with severe grades of acne ($p<0.0001$). Similar results were seen in Pandey study.[16]

Other associated conditions, seen in our study, were alopecia in 18.9% of patients, folliculitis in 7.5% of patients, acanthosis nigricans in 4.9% and melasma in 2.1% of patients. Most of the patients, having alopecia had traction alopecia and androgenic alopecia. Folliculitis is a known association of acne vulgaris. More over in our study, many of the patients were using hair oil which may be the underlying factor. Acanthosis nigricans was seen commonly in obese patients and polycystic ovarian disease patients. The only associated systemic disease was polycystic ovarian disease. Similarly, Adityan et al found polycystic ovarian disease as associated condition in 17 patients in their study.[7]

In our study, 10 patients were of PCOD, confirmed by USG of lower abdomen. However, 60% patients had

elevated luteinizing hormone (LH) level, 30% had normal and 10% had below normal level; 30% patients had elevated follicle stimulating hormone, 70% had normal; 90% patients had altered LH/FSH (that is above 2) and 10% patients had below 2; 40% patients had elevated testosterone level and 60% had normal level. Hormonal investigations were done as close to menses as possible. There may be some patients haven't had the exact idea of timing of their menses. Hence there may be slight variation in percentage as reported in earlier available literature.[28]

CONCLUSION

Female patients of acne vulgaris outnumbered male in the ratio of 1.44:1 and belonged to the age group 16 to 25 years. Mean age of onset of acne was 15.41 (±1.92) years with onset earlier in females. The average total duration of acne vulgaris was 39.81 months and those with longer duration of the disease had more severe form. Post-inflammatory hyperpigmentation was common and habitual picking is more frequent in females.

Face is the most common site and closed comedone the most common acne lesion (97%) followed by open comedone (52%). Patients with grade 2 acne vulgaris form the majority of patients. Grade 4 acne vulgaris is more common in males (6.8%) as compared to females (1.6%). Premenstrual flare of acne was seen in majority (62.8%) of female patients.

Seborrhoea (60.8% of patients) was the most common association followed by alopecia (18.9%), folliculitis (7.5% of patients) and acanthosis nigricans (4.9% of patients). Polycystic ovarian disease (2.3%) was the most common associated systemic disease. Common clinical markers of androgenicity in female patients; were hirsutism in (26.5%), acanthosis nigricans in (5.1%), seborrhea (37.5%). In female patients associated with PCOD, FSH, LH and testosterone level levels were normal but FSH-LH ratio was altered.

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Original Article

Diagonal Earlobe Crease: Prevalence and Association with Medical Ailments

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Abstract

Context: It has been hypothesized that diagonal earlobe crease (DELC), "Frank's sign" is indicative of coronary artery disease (CAD) and/or diabetes mellitus (DM). Several studies have confirmed an association between DELC and cardiac morbidity, mortality, and hypertension (HTN). However, some studies have not found any significant association. **Aims:** This study aims to find out the prevalence of DELC and its association with CAD, DM, and HTN. **Settings and Design:** Sangli-Miraj-Kupwad Corporation area. This was a cross-sectional analytical study. **Subjects and Methods:** Study participants: Adults from 18 to 60 years age. Inclusion criteria: willing to participate in the study Exclusion criteria: Wearing heavy ear rings and excessive normal generalized wrinkling of the skin. Sample size: Sample size 6310, determined after a pilot study revealing DELC in 1.5%. Sampling technique: Two-stage cluster sampling. Duration of study: 6 months. Study tools: Predesigned, pilot tested pro forma. **Statistical Analysis:** Statistical analysis was done by using SPSS 22 software. Prevalence and percentages were calculated, and Chi-square test was applied. **Results:** Out of 6638 participants, 179 had DELC. The prevalence of bilateral DELC was 2.7%. The prevalence was significantly high among males (4.13%) and in the 51–60 years age group (5.29%). The prevalence of Grade 3 DELC was high and 91% of young adults had Grade 3 DELC. There were 408 (6.15%) participants who gave a history of CAD, 827 (12.46%) of DM, and 670 (10.09%) HTN. Significantly high association observed between DELC and CAD, DM, and HTN. CAD, DM, and HTN were significantly associated with Grade 3. **Conclusions:** The prevalence of bilateral DELC was 2.7% and is significantly associated with CAD, DM, and HTN.

Keywords: *Coronary artery disease, diabetes mellitus, diagonal earlobe crease, hypertension*

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Introduction

Bilateral diagonal earlobe crease (DELC), also called "Frank's sign," was first reported to be associated with risk factors for coronary artery disease (CAD) by Frank.[1]

Several reports thereafter have confirmed an association between earlobe crease and CAD.[2-8] It has been reported that DELC is associated with increased cardiac morbidity and mortality.[9] An association between DELC and systolic hypertension (HTN) is also reported.[10] However, some studies have not found any significant association between DELC and CAD.[10] Agouridis *et al*. mention that even though it is evident that there is an association between DELC and CAD, there are some limitations to say so.[11]

The pathophysiological link between DELC and CAD can be explained as both the earlobe and heart are supplied by "end arteries" without the possibility for collateral circulation.[9] The microvascular disease results into loss of elastin and elastic fibers in the earlobe causing DELC. The presence of DELC may reflect the presence of a similar microvascular disease in the coronary circulation in the individual.[9] Hence, DELC may be used as a sign for prediction of CAD.

The prevalence of DELC in general population is not available as all available studies are hospital based. Indians as a community are more prone to CAD, Diabetes Mellitus (DM), and HTN and at a much younger age. Hence, this study was planned to find out the prevalence of DELC and its association in known patients with CAD, DM, and HTN.

Subjects and Methods

A cross-sectional study was conducted in Sangli-Miraj-Kupwad Corporation (SM and KC) area, Maharashtra, India. Study participants were adults of both sexes and with age ranging from 18 to 60 years. Study participants wearing heavy ear rings or with excessive generalized wrinkling of the skin were

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excluded. Sample size was calculated by using prevalence of DELC (1.5%) as obtained from a pilot study. Calculated sample size was 6310 (α = 5%, zα = 1.96, P = 1.5%, d = error 20%). Two-stage cluster sampling technique was used for selection of study participants. There are total 71 wards in SM and KC area. One ward from each area (Sangli, Miraj and Kupwad) was selected. House-to-house visit was paid to identify study participants. All participants willing to participate in the study were included till the desired sample size was achieved. All available and eligible participants from a house were included.

A well-designed questionnaire as per the need of study was developed to collect and record the data of the participant. The questionnaire was pretested and used for pilot study also. Four interns were identified and were trained by investigator with the help of power point presentation for identification, grading of DELC, and for data collection by using the questionnaire. Trained interns were provided with the photograph of DELC to help them in explaining about the study to participants.

The study participants were asked about history of three medical ailments – CAD, DM, and HTN, and the answer was recorded.

Definition and grading of the diagonal earlobe crease

The DELC is an earlobe crease extending diagonally from the tragus across the lobule to the rear edge of the auricle.[1] In the study, the participant is diagnosed to have DELC only when the said crease is bilateral. The severity of DELC is graded as follows:[12] Grade 1: A small amount of wrinkling on the earlobe [Figure 1], Grade 2a: Creased more than halfway across the earlobe [Figure 2], Grade 2b: A superficial crease across the earlobe [Figure 3], and Grade 3: A deep crease across the whole of the earlobe [Figure 4].

Statistical analysis

Statistical analysis was done by using SPSS 22 software (IBM Corp, Armonk, New York, USA). Prevalence and percentages were calculated. Chi-square test was applied to find out the association between DELC and diseases, namely, CAD, DM, and HTN.

Results

Total participants interviewed during survey were 6638, out of which 3035 were females and 3602 were males. Age of the participants ranged from 18 to 70 years, mean age being 43.80 years standard deviation (SD) ±13.51.

Out of 6638 individuals, 179 had bilateral DELC. Grade-wise distribution of DELC was as follows: Grade 1: 51 (28.49%), Grade 2a: 38 (21.23%), Grade 2b: 26 (14.53%), and Grade 3: 64 (35.75%).

The prevalence of bilateral DELC was 2.7%. The prevalence of Bilateral DELC in males was 4.13% (149) and in females, it was 0.99% (30). The prevalence of DELC was significantly more common in males (χ =37.32, P = 0.00) [Table 1].

Mean age of participants without bilateral DELC was 43.52 years with SD ± 13.42. In contrast, mean age of persons with bilateral DELC was 53.43 years with SD ± 13.47 (z = 9.71, P = 0.00). The prevalence of bilateral DELC was significantly high in the 51–60 years age group (5.29%, χ^2 = 94.73, P = 0.00). Interestingly, 91% of

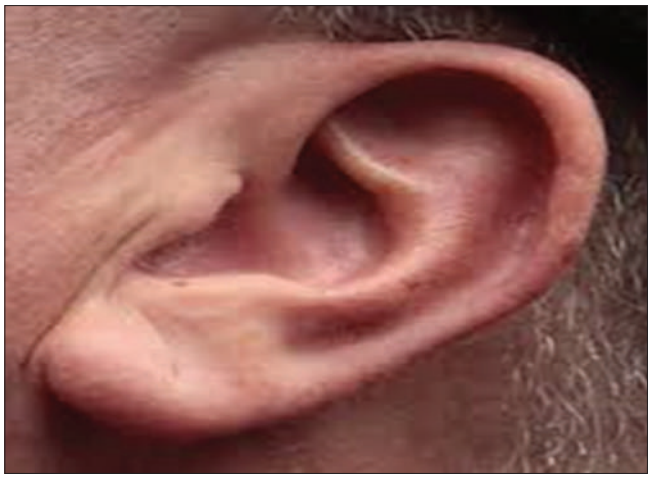

Figure 1: Grade 1 – A small amount of wrinkling on the earlobe

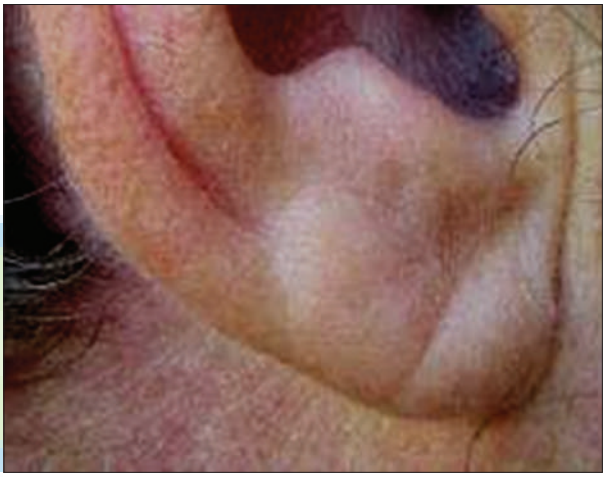

Figure 2: Grade 2a – Creased more than halfway across the earlobe

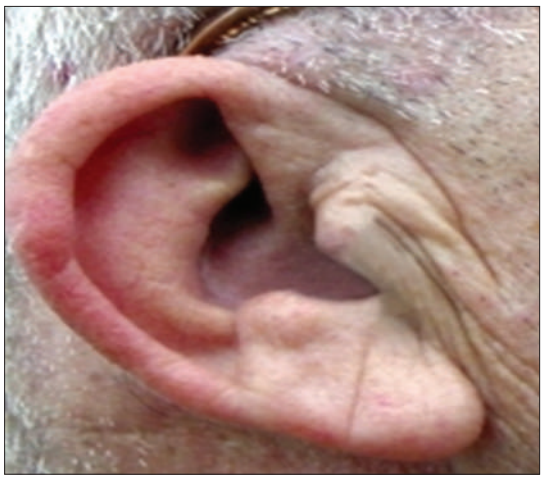

Figure 3: Grade 2b – A superficial crease across the earlobe

young adults of age between 18 and 35 years having DELC had DELC of Grade3 [Table 2].

History of CAD was present in 408 (6.15%) participants, history of DM in 827 (12.46%), and history of HTN in 670 (10.09%).

Out of 179 persons with DELC, 36 (20.1%) had history of CAD (χ^2 = 62.19, P = 0.00), 34 (19%) had DM (χ^2 = 7.20, P = 0.00), and 42 (23.5%) had HTN (χ^2 = 36.23, P = 0.00) [Table 3].

Maximum study participants with CAD had DELC of Grade 3 and 2a. DM was present mainly in participants with Grade 2b and Grade 3 DELC. Maximum study participants with HTN had Grade 3 DELC. Significant association was observed between grades of bilateral DELC and DM (χ^2 = 38.43, P = 0.00) and HTN (χ^2 = 16.18, P = 0.001).

Discussion

DELC has been suggested as a marker of generalized atherosclerosis. It has been already stated that both earlobes and heart are supplied by "end arteries" where possibility for development of collateral circulation is low. Histopathology studies of biopsies from earlobe in cases of DELC have reported loss of elastin fibers indicating a generalized microvascular disease and hinting at possibility of similar changes in coronary arteries in the affected individuals.[2]

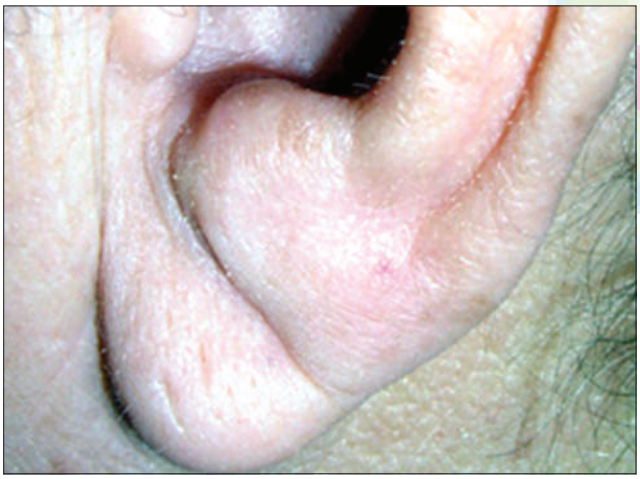

Figure 4: Grade 3 – A deep crease across the whole of the earlobe

Majority of clinical, angiographic, and postmortem study reports support the proposition that DELC may be associated with CAD and can be used as a valuable indicator which can be observed/identified easily clinically.[2,3,4,13-17] Ramos *et al*. have studied and concluded that ear creases are independently associated with peripheral arterial disease and may be an external marker for risk identification.[18] In addition, Kang and Kang found association between earlobe crease and the metabolic syndrome.[19] Elliot and Karrison conducted a prospective cohort study and found a positive association between DELC and all cause morbidity and mortality including cardiac cause.[9] In another study, Elliot and Powell found earlobe creases to be associated in a graded fashion, with a higher rate of cardiac events.[20]

In "a review of the medical literature and dental implications," authors conclude that even though more research is needed in this area, it is advisable for a dentist to use DELC as a vital sign along with the medical history and other signs for risk assessment and medical evaluation.[21] A positive association between DELC and CAD was observed in the present study.

Most studies of "prevalence" of DELC are actually hospital-based studies while ours is a community-based study. The prevalence of DELC was found to be significantly higher in males. This finding of male preponderance is also noted by other studies, even though the studies were hospital based.[2,4] It was observed that prevalence of DELC was mainly present in the older age and similar findings are noted by other investigators.[2]

DELC was also observed to be significantly associated with DM and HTN in our study. DM and HTN are independent risk factors for CAD, and patients with DM and HTN are vulnerable to atherosclerosis. This fact may explain a significant association between DELC, DM, and HTN.

Telomeres shorten during the replication of somatic cells, leading to attrition in the length of telomere indicating progressing biological age. Telomere length in leukocytes reflects the cumulative burden of oxidative stress and inflammation in the circulation during an individual's lifetime and has been reported to be a useful marker of biological aging of the cardiovascular system.[22] Atherosclerosis, essential HTN, and noninsulin-dependent DM are age-related disorders, and telomere length is one of a number of biologic

Table 1: Age-wise distribution of persons with diagonal earlobe crease

DELC	Age groups			Total	Significance
	18-35, *n* (%)	36-50, *n* (%)	51-60, *n* (%)		
Yes	23 (1.09)	31 (1.43)	125 (5.29)	179 (2.70)	χ^2=94.73
No	2093 (98.91)	2130 (98.57)	2236 (94.71)	6459 (97.3)	P=0.00
Total	2116 (100)	2161 (100)	2361 (100)	6638 (100)	
Grade- and age-wise distribution of persons with DELC					
Grade 1	2 (8.70)	8 (25.81)	41 (32.80)	51 (28.49)	
Grade 2a	0	20 (64.52)	18 (14.40)	38 (21.23)	
Grade 2b	0	3 (9.68)	23 (18.40)	26 (14.53)	
Grade 3	21 (91.30)	0	43 (34.40)	64 (35.75)	
Total	23 (100)	31 (100)	125 (100)	179 (100)	

DELC=Diagonal earlobe crease

Table 2: Gender distribution of diagonal earlobe crease

DELC	Sex		Total	Significance
	Female, *n* (%)	Male, *n* (%)		
Yes	30 (0.99)	149 (4.14)	179 (2.70)	χ^2=37.32
No	3006 (99.01)	3453 (95.86)	6459 (97.30)	*P*=0.00
Total	3035 (100.00)	3602 (100.00)	6638 (100.00)	
Grade of DELC				
Grade 1	10 (33.33)	41 (27.52)	51 (28.49)	
Grade 2a	2 (6.67)	36 (24.16)	38 (21.23)	
Grade 2b	14 (46.67)	12 (8.05)	26 (14.53)	
Grade 3	4 (13.33)	60 (40.27)	64 (35.75)	
Total	30 (100)	149 (100)	179 (100)	

DELC=Diagonal earlobe crease

Table 3: Association between diagonal earlobe crease and medical ailments

Association between DELC and CAD				
DELC	CAD		Total	Significance
	Yes, *n* (%)	No, *n* (%)		
Yes	36 (8.82)	143 (2.30)	179 (2.70)	χ^2=62.19
No	372 (91.18)	6087 (97.70)	6459 (97.30)	*P*=0.00
Total	408 (100.00)	6230 (100.00)	6638 (100.00)	
Association between DELC and DM				
DELC	DM		Total	Significance
	Yes, *n* (%)	No, *n* (%)		
Yes	34 (4.11)	145 (2.50)	179 (2.70)	χ^2=7.20
No	793 (95.89)	5666 (97.50)	6459 (97.30)	*P*=0.00
Total	827 (100.00)	5811 (100.00)	6638 (100.00)	
Association between DELC and HTN				
DELC	HTN		Total	Significance
	Yes, *n* (%)	No, *n* (%)		
Yes	42 (6.27)	137 (2.30)	179 (2.70)	χ^2=36.23
No	628 (93.73)	5831 (97.70)	6459 (97.30)	*P*=0.00
Total	670 (100.00)	5968 (100.00)	6638 (100.00)	

DELC=Diagonal earlobe crease, DM=Diabetes mellitus, HTN=Hypertension, CAD=Coronary artery disease

indicators that may serve to assess the progression of biologic aging in humans.

A study conducted on male Japanese patients with metabolic syndrome found association between DELC with a shorter telomere. Hence, the researchers concluded that DELC might be a useful indirect marker of high-risk patients.[22]

Pasternac and Sami concluded in their study that "the ear-crease sign" could identify patients who are aging earlier than usual and are thus at risk of CAD prematurely and whose prognosis might be improved by early preventive measures.[23]

In the present study, only self-reported cases of CAD, DM, and HTN were considered. Therefore, many of the undiagnosed cases may have been missed. In spite of this limitation, on the basis of statistical results and results reported by several other studies, we can say that there is an association between DELC with CAD, DM, and HTN. Considering the pathophysiology of DELC, DELC may be said to be the external presentation of atherosclerosis. This atherosclerosis could be because of aging or accentuated by DM and HTN leading to CAD.

At present, the association between the time of onset of DELC and that of atherosclerosis is not known. Thus, considering all these aspects, we can conclude that whenever there is DELC, we should plan to evaluate the individual for CAD, DM, or HTN.

Conclusions

The prevalence of bilateral DELC was 2.7% and was significantly associated with CAD, DM, and HTN. Therefore, bilateral DELC, a visual cutaneous clinical marker, can be used as a screening tool for early diagnosis and prevention of CAD and other related diseases.

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Conflicts of interest

There are no conflicts of interest.

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Original Research Article

The efficacy of intralesional triamcinolone acetonide (20mg/ml) in the treatment of keloid

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ABSTRACT

Background: Management of keloid is difficult as well as challenging. Intralesional triamcinolone acetonide (TAC) injections have remained a gold standard in non-surgical management of keloid. TAC is generally used in the concentration of 40mg/ml, which causes adverse effects such as local dermal atrophy and hypopigmentation. Aim was to study efficacy and adverse effects of TAC in treatment of keloid, in a lesser concentration of 20mg/ml.
Methods: An open label study was conducted from November 2015 to May 2017 on 25 subjects of either gender, in the age group 11-55 years, at a medical college hospital. Intralesional injection TAC 20 was administered in the keloid at an interval of 3 weeks, for a total of 6 sessions, over a period of 18 weeks. Vancouver scar scale (VSS) was used to assess the improvement and SPSS 21 for statistical analysis.
Results: Mean age of keloid subjects was 30.72 years and median duration of keloid was 8 months. The mean VSS score before treatment was 8.36 which reduced to 3.20 after treatment. Mean percentage change in VSS score was 62.79%, which was very highly significant ($p < 0.001$). Physician's assessment was 'Very Good' in 52.0% and 'Excellent' in 5 (20%). Adverse effect of atrophy was seen in 3 (12%), hypopigmentation in 11 (44%) and telangiectasia in 4 (16%).
Conclusions: Intralesional injection triamcinolone acetonide 20mg/ml gives very good to excellent improvement in the majority of patients of keloid. Local adverse effects seen were hypopigmentation, atrophy and telengiectasia.

Keywords: Adverse effects, Efficacy, Keloid, Triamcinolone (20mg/ml), Vancouver scar scale

INTRODUCTION

Keloids are characterized by firm, mildly tender, bosselated nodules or plaques occurring more frequently on shoulders, chest, neck, upper arms and face.[1] They are benign overgrowth of fibrous tissue that usually develops after healing of a skin injury and extends beyond the original defect.[2] The uncontrolled growth of keloid continues progressively, and the patients experience itch and pain. The fibrous keloid progresses to gain a larger size, leads to cosmetic disfigurement, functional impairment, and affects the quality of life adversely.[3]

It is supposed that corticosteroids owing to their anti-inflammatory properties are helpful in suppressing hypertrophic scars and the keloid.[4] The corticosteroids diminish collagen and glycosaminoglycan synthesis, inhibit fibroblast growth and enhance collagen and fibroblast degeneration.[5,6]

Triamcinolone acetonide (TAC) is the most commonly used intralesional corticosteroid for the treatment of keloids and is considered to be the first line therapy for the treatment of keloids.[7] TAC is used in different concentrations ranging from 10 to 40mg/ml. Different studies recommend different intervals between successive injections and the number of injections may vary from four to eight.[8]

Intralesional injection TAC 40mg/ml is more commonly used, as the concentration of 40mg/ml is very effective in controlling keloid. However Local side effects such as dermal atrophy, telengiectasia, hypopigmentation and pain at the site of injection due to TAC 40mg/ml are common. Pain can be avoided by use of topical anesthesia and/or regional injections of local anesthetic around the scars.[9] Hypopigmentation is not a problem in non-pigmented western skin but is significant in pigmented skin.

Aim was to study the efficacy and the adverse effect of intralesional injection triamcinolone acetonide in treatment of keloid, in concentration of 20mg/ml.

METHODS

The study was carried out on 25 patients in Dermatology OPD of a medical college hospital in North India from November 2015 to May 2017 (one year and six months). Patients of keloid of either gender, in the age group 11 to 55 years, were included in the study. Patients with local infection, immune-compromise, pregnancy or lactation and those who had received treatment for keloid during previous 6 months were excluded. Sample size was calculated on the basis of decrease in volume of the keloid.[10]

Injection Triamcinolone acetonide 20mg/ml (TAC 20) was injected intralesionally at an interval of 3 weeks, for a total of 6 sittings over a period of 18 weeks. Injection Triamcinolone acetonide 40mg/ml was diluted using lignocaine with adrenaline, in equal proportions, to get a final concentration of 20mg/ml. The lesion was infiltrated with the drug suspension, using a disposable insulin syringe and 26-gauge needle, till complete and uniform blanching of the lesion, was achieved. The subject was not administered any sedation or analgesia prior to the injection.

The details of the subject including the Fitzpatrick skin type, duration, site, number and parameters such as height, pliability, vascularity and pigmentation of the keloid assessed on Vancouver Scar Scale (VSS), were recorded in a predesigned "Case record form." VSS was assessed before treatment and three weeks after completion of the treatment.

VSS is a validated and widely used tool to document a change in appearance of the scar, in clinical practice and research.[11-13] Parameters of the keloid such as vascularity, pliability, pigmentation and height are assessed, in order to determine the score. The score allotted for pliability is from 0 to 5, score for height and vascularity from 0 to 3 and for pigmentation from 0 to 2, to give a maximum possible score of 13. The decreasing mean value of the total score indicates clinical improvement, in the scar.

Scar height was measured with calipers, and scar pliability assessed by palpation; scar vascularity rated by visual inspection, and the rate of refill, after blanching it. Blanching was achieved by a transparent plastic sheet with VSS score sheet, pasted on it. Scar pigmentation was assessed after blanching and comparing the scar color with the surrounding skin.[13] The percentage reduction in VSS was graded according to the Quartile score with ≤25% reduction in VSS graded as Poor, 26-50% reduction as Good, 51-75% reduction Very good and >75% reduction as Excellent response.

Data was analyzed using Statistical Package for Social Sciences (SPSS) version 21.0. Wilcoxon signed rank was used to assess the outcome and 'p' value less than 0.05 was considered to be a statistically significant change.

RESULTS

A total of 25 subjects of keloid of either gender, were treated with intralesional injection of triamcinolone acetonide 20mg/ml (TAC-20). All the 25 subjects completed the study. Male were 52%, female 48% and the mean age was 31.76±13.08 years. Family history of keloids was present in 4 (16.0%). The majority (60.0%) of the subjects had Fitzpatrick Skin type IV. Duration of keloid ranged from 1 to 36 months with a median duration of 7 months.

Table 1: Demographic data.

Keloid patients		Value
Gender	Male	13 (52%)
	Female	12 (48%)
Age (year)	11 to 55	Mean 31.76±13.08
Family history	Positive	4 (16.0%)
	Negative	21 (84%)
Skin Photo-type	Type IV	15 (60.0%)
	Type V	10 (40.0%)
Duration (months)	1 to 36	Median 7

The majority (92%) had one or two keloids and 2 (8%) of the subjects had more than three keloids.

Table 2: Number of keloids.

Patients	Number of Keloids
18 (72%)	1
5 (20%)	2
0 (0%)	3
1 (4%)	4
1 (4%)	5

The majority (90%) of keloids were either on the chest or shoulders.

Table 3: Location of keloids.

Location on the body	No. of keloids (30)
Chest	16 (52 %)
Shoulder and arm	11 (38 %)
Face and ear	3 (10 %)
Back	0 (%)
Thigh and leg	0 (%)

An assessment of Vancouver Scar Scale (VSS) score was carried out at the baseline i.e. before the treatment, and at 3 weeks after the last (sixth) injection, i.e. at 18 weeks from the first injection: Before starting the treatment, at the baseline, mean VSS score was 8.36±1.60 (Median 8.0), which reduced to 3.20±1.92 (Median 3.00) at final follow up, thus showing a mean change of -5.16±1.63 (62.79%). On evaluating the data, it was found to be statistically significant ($p<0.001$).

Table 4: VSS score following treatment with intralesional injection of triamcinolone acetonide.

VSS score (n=25)	Median	Mean	SD
At baseline	8.00	8.36	1.60
4.5 months (final follow up)	3.00	3.20	1.92

Mean±SD -5.16±1.63 % change -62.79%; z=4.401; $p<0.001$

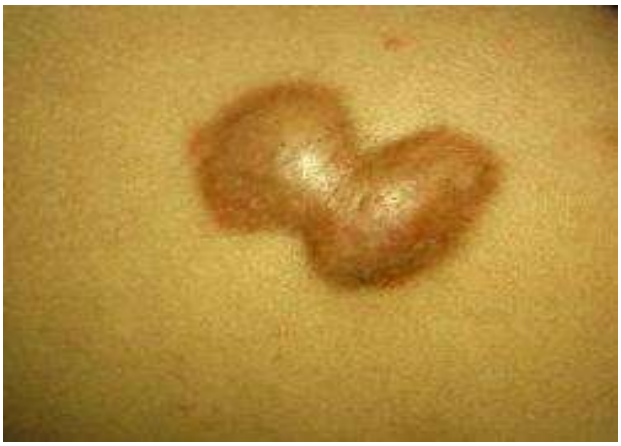

Figure 1: Pretreatment photograph of keloid on back of shoulder.

Physician rated outcome was 'Very good' to 'Excellent' in 18 (72%) and 'Good' in 5 (20%) subjects. There were 2 (8%) cases in which outcome was evaluated as 'Poor'.

Table 5: Physician rated outcome.

Assessment	n = 25
Poor	2 (8%)
Good	5 (20%)
Very good	13 (52%)
Excellent	5 (20%)

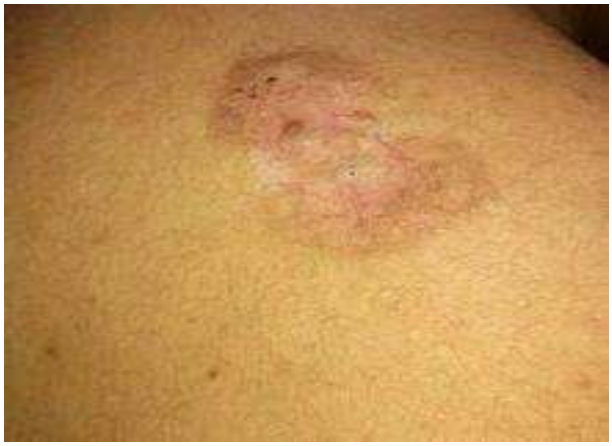

Figure 2: Post-treatment photograph after TAC-20 (excellent response).

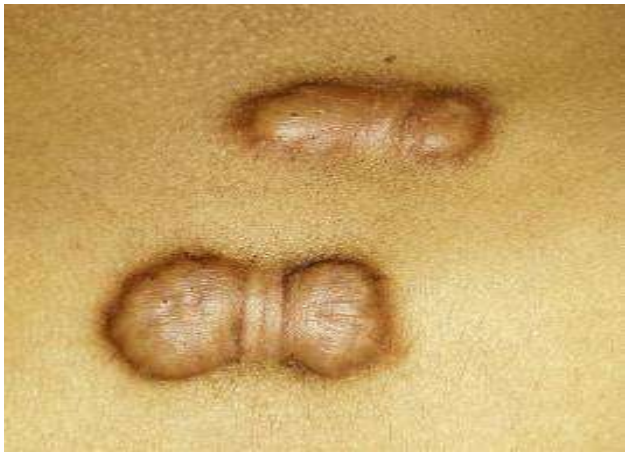

Figure 3: Pretreatment photograph of keloid.

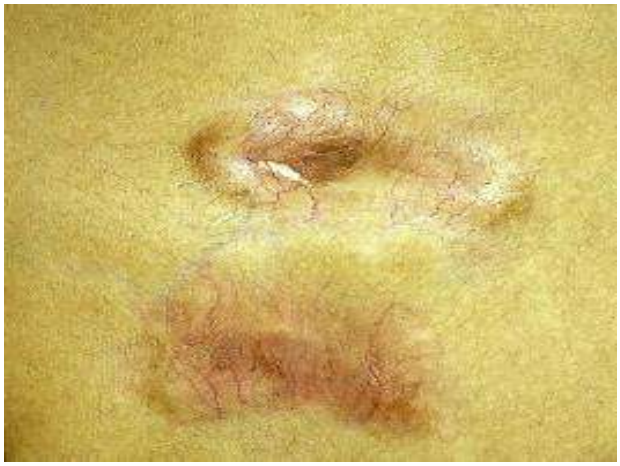

Figure 4: Post-treatment photograph of keloid after TAC20 (very good response but with atrophy and telengiectasia).

Pain was the most common adverse effect as reported by 21 (84%) patients. Hypopigmentation was observed in 11 (44%), telengiectasia in 4 (16%), and dermal atrophy in 3 (12%) of the subjects (Table 6).

Table 6: Adverse effects.

Adverse Effects	n = 25
Pain	21(84%)
Hypopigmentation	11 (44%)
Telangiectasia	4 (16%)
Dermal atrophy	3 (12%)

DISCUSSION

Pathogenesis of the keloid is still not well understood.[14] A variety of treatment modalities such as silicone gel sheeting, intralesional injections, cryotherapy, surgical manipulation, laser and radiotherapy are used, but no particular treatment is suitable or effective in all cases and keloid it tends to recur, irrespective of the treatment used.[8] Drugs like bleomycin, interferon, 5-fluorouracil when used intralesionally, have a better efficacy, but are costly and cause severe drug reactions. Surgery and laser therapy have limitations and radiotherapy causes malignancy.[15]

Corticosteroids seem to be effective as they diminish collagen and glycosaminoglycan synthesis, inhibit fibroblast growth, enhance collagen and fibroblast degeneration and have powerful anti-inflammatory effect.[4-6] The anti-inflammatory effect of TAC in addition to inhibition of collagen and glycosaminoglycan synthesis, and degeneration of fibroblast/collagen might be giving it an edge, however the drug causes local adverse effects such as dermal atrophy, telengiectasia and hypopigmentation in large number of patients.

Inability to measure amount of drug used with respect to area as well as thickness of keloid, has been a major limitation in this study as in most other studies. Consequently, complete blanching of the keloid, was considered to be the end point, for the dose of the drug injected intralesionally.

TAC is cost effective and practical and has become first-line treatment for keloid, in spite of many limitations. Studies have reported that lower dose of TAC, i.e. 20mg/ml reduces the side effects of TAC without jeopardizing the efficacy.[16-18]

In this study, majority of the subjects were in the age group <30 years; males being slightly more than females. Uzair et al and Ahuja et al also observed predominance of keloid in the younger age group.[19,20] The duration of keloids in majority of subjects was less than 12 months. The majority showed a very good to excellent response conforming observations from studies.[21,22] The Keloid were found to be most common on the chest (60%), followed by shoulder (20%), arm (18%) and face (10%) similar to observations.[23]

In the present study following intralesional TAC 20, a majority (62.79%) of patients of keloids showed significant mean reduction in VSS. The observations were in conformity with that of Uzair et al.[19] The improvement observed was comparable to TAC 40mg/ml used by Chatterjee A and Shanthi M et al.[15,20] The improvement in keloid with TAC 20 mg/ml was observed to be similar to TAC 40mg/ml used in other studies.[15,19,20,23,24]

Immediate pain at the site of injection was the commonest side effect with TAC 20 as reported by 84% of the subjects. However, the pain was mild, transitory and resolved within few hours, which is attributed to dilution with lignocaine and adrenaline which causes a sustained hypoesthesia and therapeutic effect at the site, locally. Hypopigmentation was observed in 44%, atrophy in 12% and telengiectasia in 16% of the subjects treated by TAC 20; this was comparable to other studies.[25-27] Manuskiatti et al and Jannati et al using TAC-20, reported hypopigmentation in 20%, atrophy in 10% and telengiectasia in 20% of patients.[23,28] Bilal et al using TAC 40mg/ml reported hypopigmentation (29%), atrophy (4%) and telengiectasia (25%).[29] An occurrence of atrophy in 18% of cases was from studies.[20]

In the present study with TAC 20, hypopigmentation was observed in 44 % of the subjects. The incidence of hypopigmentation in the study was much higher as compared to other studies probably because all subjects in this study, were of Fitzpatrick skin type IV and V. Most other studies do not mention the skin phototype of the subjects.

Limitations of the study includes therapeutic effect of injection TAC was studied over a period of only 18 weeks for a patient, which may be inadequate. Post treatment follow up of patient should be of a longer period to judge the recurrence.

CONCLUSION

TAC 20mg/ml gives very good to excellent response in a majority of patients and the improvement is comparable to the result with TAC 40mg/ml as reported by other workers. TAC 20 also causes adverse effects such as hypopigmentation, telengiectasia and atrophy. However adverse effects with TAC 20 are less compared to TAC 40. Immediate postoperative pain occurs but is mild and transitory.

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Original Research Article

A study of verapamil in treatment of keloid

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ABSTRACT

Background: Keloid is a common presentation in clinical practice. Symptoms due to keloid are mild, but disfigurement and functional impairment can be severe. It is difficult to treat. Intralesional, injection triamcinolone acetonide, has limited efficacy, causes adverse effects such as local dermal atrophy, telengiectasia and hypopigmentation. Injection verapamil is reported to have similar efficacy, but lesser side effects, and is cheaper. Aim was to study efficacy and adverse effects of intralesional verapamil in treatment of keloid.
Methods: An open label study on 25 patients of keloid, either gender, age 11 to 55 years at a medical college hospital. Injection verapamil 2.5 mg/ml was administered intralesionally, at an interval of 3 weeks, for a total of 6 sittings, over a period of 18 weeks. Vancouver scar scale (VSS) was used to assess the improvement. The statistical analysis was done using SPSS version 21.0.
Results: Median duration of keloids was 8 months. The mean VSS score before treatment was 7.68 which reduced to 4.28 after treatment. Mean percentage change in VSS score was 46.21%, very highly significant ($p<0.001$). Physician's assessment was 'very good' in 32.0% and 'excellent' in 8.0%. The complaint of post-procedure pain was present in almost all.
Conclusions: Intralesional injection verapamil, gives very good to excellent improvement in 40% of patients of keloid. Post injection pain persists for more than 24 hours. Drug does not cause local dermal atrophy or hypopigmentation.

Keywords: Keloids, Intralesional, Verapamil, Efficacy, Vancouver scar scale

INTRODUCTION

Keloid is an area of benign overgrowth of fibrous tissue that usually develops after healing of a skin injury, and extends beyond the original defect.[1] Keloids clinically manifest as raised, hyper-pigmented, erythematous nodules or plaques, with an irregular border, making them visible and distinct from the surrounding skin.[2] Patients with darker skin have a higher prevalence for keloid than lighter skin.[3] It is the fifth most common skin disease in adult black patients, in the United Kingdom.[4]

Symptoms of itch and pain due to keloid are mild, but the disfigurement and functional impairment can be severe. It leads to aesthetic and physical complaints, causing psychogenic turmoil and severe depression in affected individuals.[5-7] Intralesional triamcinolone acetonide (TAC) is considered to be the first line of treatment, however it is effective only against younger keloids, response rate varies from 50% to 100%, and a recurrence rate of 9% to 50% is reported.[8] Local side effects due to TAC include dermal atrophy, telengiectasia and pain at the site of injection.

Verapamil, a calcium channel blocker, and an antiarrhythmic agent, has emerged as a useful treatment modality in treatment of keloids.[9] It is reported to decrease IL-6 and vascular endothelial growth factor in the central keloid fibroblasts, reducing cell proliferation, increasing apoptosis and expression of decorin, thus inhibiting fibroblast proliferation and migration and reducing keloid.[10] It is reported that VPL has lesser side effects as compared to TAC, is cheaper and could be a suitable alternative to TAC.[11] Aim was to study efficacy and adverse effects of intralesional verapamil in treatment of keloids, by assessing clinical improvement using Vancouver scar scale (VSS).

METHODS

The study was carried out on 25 patients in Dermatology OPD of a medical college and hospital, Uttar Pradesh, India, over a period of one year and six months, with due permission of Institutional Ethics Committee. Keloid patients of either gender, in the age group 11 to 55 years, were included in the study. Patients with immuno-compromised status, local infection, pregnant or lactating mothers and those who had received any specific treatment for keloid within previous 6 months were excluded. Sample size was calculated on the basis of decrease in volume of keloid.[12]

Injection verapamil (VPL) 2.5 mg/ml was administered intralesionally at an interval of 3 weeks, for a total of 6 sittings, over a period of 18 weeks (4.5 months). Injection Verapamil needs no dilution as it is available in the required concentration of 2.5 mg/ml (vial: 5 mg/2 ml). The lesion was infiltrated with the drug solution, until complete and uniform blanching of the lesion was achieved, using a disposable insulin syringe, and 26 gauge needle. No sedation/analgesia was used prior to the injection.

The details of the subject were recorded in a predesigned "case record form" which included the Fitzpatrick skin type, duration, site, number and various other parameters of the keloid. Height, pliability, vascularity, pigmentation and size of the keloid were assessed on VSS. VSS was assessed before treatment with Injection VPL, and after completion of the treatment at 18 weeks.

VSS is a validated tool to document a change in appearance of the scar and is widely used in clinical practice and research.[13-15] It was first described by Sullivan in 1990.[16] Vascularity, pliability, pigmentation, and height of the scar are the parameters assessed to determine the score, in VSS. The score for pliability ranges from 0 to 5, height and vascularity from 0 to 3 and pigmentation from 0 to 2, to give a maximum score of 13. The decreasing mean value of the score indicates clinical improvement in the scar.

Scar height was measured with calipers, scar pliability subjectively assessed by palpation, scar vascularity was rated on visual inspection, and the rate of refill after blanching the keloid. Blanching was achieved by a transparent plastic sheet with VSS score sheet pasted on it, as suggested by Baryza and Baryza.[15] Scar pigmentation was assessed after blanching, and comparing the scar color with the surrounding skin.

The percentage reduction in VSS was graded according to the quartile score with ≤25% reduction in VSS, graded as poor, 26-50% reduction as good, 51-75% reduction very good and >75% as excellent response.

Statistical analysis

Data was analyzed using Statistical Package for Social Sciences (SPSS), version 21.0. Wilcoxon signed rank was used to assess the outcome. A 'p' value less than 0.05, indicated a statistically significant change.

RESULTS

A total of 25 patients of keloid, were treated with intralesional injection verapamil 2.5 mg/ml. All 25 patients completed the study. Male patients were 14 (56%) and female 11 (44%). Age of the patients varied from 12 years to 49 years, mean age was 30.72 (±11.23) years (Table 1). Family history of Keloid was present in 3 (12.0%) patients. The majority (64.0%) had Fitzpatrick skin type IV. Duration of Keloids ranged from 1 to 36 months with a median duration of 8 months (Table 1). The majority (92%) had one or two keloids; none of the patient had more than three keloids (Table 2). The majority (92%) of keloids were either on the chest or shoulders (Table 3).

Table 1: Demographic data.

Demographic characteistics		
Gender	Male 14 (56%), Female 11 (44%)	
	Ratio M:F- 1.27:1	
Age in years	12-49	Mean 30.72±11.23 yrs
Family history	+ve 3 (12.0%)	-ve 22 (88%)
Fitzpatrick skin type	Type IV (64.0%)	Type V skin (36.0%)
Duration	1 to 36 months	Median- 8 months

Table 2: Number of keloids.

Patients	Number of Keloids
15 (60%)	One
8 (32%)	Two
2 (8%)	Three

An assessment of VSS score was done at baseline and at 3 weeks, after the last injection, i.e. at 18 weeks from the first injection. At baseline, mean VSS score was 7.68±1.89 (median 8), which reduced to 4.28±2.21

(median 5) at final follow up, showing a mean change of 3.40±1.44 (46.21%). On evaluating the data statistically, it was found to be significant (p<0.001) (Table 4). Physician rated outcome was 'very good' to 'excellent' in 10 (40%) and 'good' in 11 (44%) cases. There were 4 (16%) cases in which outcome was evaluated as poor (Table 5).

Table 3: Location of keloids.

Location on the body	Number of keloids (%)
Chest	14 (56)
Shoulder and upper arm	9 (36)
Face and ear	4 (16)
Back	3 (12)
Thigh and leg	2 (8)

Table 4: Vancouver scar scale (VSS) score.

VSS score (n=25)	Median	Mean	SD
At baseline	8.00	7.68	1.89
At 4.5 months (final follow up)	5.00	4.28	2.21
Mean change±SD (% change)	3.40±1.44 (46.21%)		
Significance of change (Wilcoxon signed rank test)	z=4.401; p<0.001		

Table 5: Physician rated outcome.

Assessment	N=25 (%)
Poor	4 (16)
Good	11 (44)
Very good	8 (32)
Excellent	2 (8)

Table 6: Side effects.

Adverse effects	N=25 (%)
Pain	24 (96)
Hypopigmentation	0 (0)
Telangiectasia	0 (0)
Dermal atrophy	0 (0)

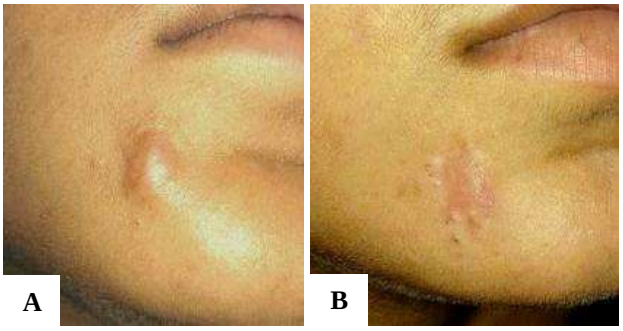

Figure 1: A= Before treatment; B= After 18 weeks of treatment (excellent improvement).

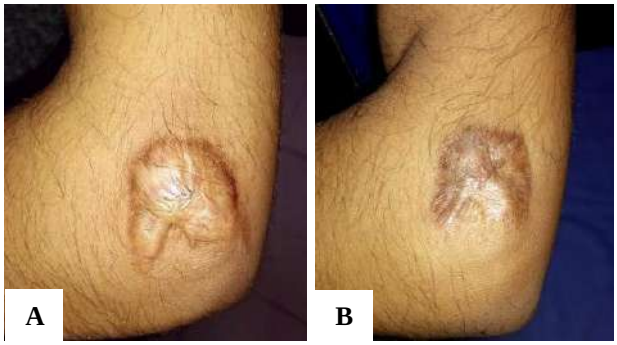

Figure 2: A= Before treatment; B= After 18 weeks of treatment (poor response).

Pain was the most common side effect as reported by 24 (96%) patients. None of the patients showed hypopigmentation, telengiectasia or atrophy (Table 6).

DISCUSSION

Keloids cause cosmetic disfigurement, functional impairment and a significant morbidity.[6,7] A variety of treatment such as pressure therapy, silicone gel sheeting, intralesional bleomycin or interferon or corticosteroid injections, cryotherapy, surgical manipulation, laser and radiotherapy are being used. No particular treatment is suitable or effective in all the cases of keloid.[17] Intralesional corticosteroids seem to be more effective, however they cause local adverse effects such as hypopigmentation, dermal atrophy and menstrual irregularities.

Among the emerging therapies, verapamil (VPL) is reported to be effective, relatively safer and much cheaper than TAC.[9] Verapamil inhibits the synthesis and secretion of extracellular matrix molecules, including collagen, glycosaminoglycans, fibronectin and increases collagenase by inducing procollagenase expression.[18] This study was done to evaluate efficacy of VPL in treatment of the keloid, in skin phototype IV and V. The drug VPL was used in the concentration of 2.5 mg/ml intralesionally, and VSS was used for assessment of the improvement.[19-21]

The actual amount of dose of the drug being injected, with respect to area and thickness of the keloid, cannot be measured as thickness of the keloid varies from lesion to lesion, and also within the lesion. Consequently in this study, complete blanching of the keloid at the time of intralesional injection, was considered to be the end point of the dose.

Majority of patients in this study, were in the age group ≤30 years; males being slightly more than females. Kant et al, Uzair et al, and Ahuja et al also observed predominance of keloid in the younger age group.[11,20,22] The presentation of the patient in the younger is more probably due to a greater esthetic concern in the young. The duration of keloids, in the majority of subjects was

less than 12 months. Keloids were observed to be commonest on the chest (60%), followed by shoulder (20%), arm (18%) and face (10%), similar to the findings of Jannati et al.[23]

In the present study, a mean reduction of 46.21% in all the parameters of the VSS, was observed at the end of 18 weeks. Uzair et al observed 36.75% reduction in VSS score, which was less than the improvement in the present study, however he had used only 3 injections of verapamil, one each at monthly interval.[20] In the present study, a total of 6 injections of VPL were administered, one each at 3 weeks interval, over a period of 18 weeks. Shanthi et al observed reduction in mean height of keloid from 4.33 mm to 0.15 mm, indicating an almost complete flattening, and maintenance of the improvement at 52 weeks.[19] Results obtained by Shanthi et al are markedly higher than the present study, but she used a total of 8 injections of VPL over a period of 6 months.

Danielsen et al compared efficacy of intralesional verapamil and triamcinolone acetonide (TAC) after surgical excision, to prevent recurrence of the keloid. They observed a recurrence of 20% in the verapamil group but none in TAC group.[21]

The commonest adverse effect was persistent pain at the injection site. The pain persisted for 24 to 48 hours and some required analgesics for relief. Hypopigmentation, dermal atrophy, profuse sweating and menstrual irregularities, which are common adverse effects due to administration of corticosteroids, were absent following intralesional VPL.[23-25]

Limitations of the study

Therapeutic effect of injection verapamil was observed over a period of only 18 weeks (4.5 months); ideal period of observation could be about 1 to 2 years.

CONCLUSION

Intralesional verapamil gives very good to excellent improvement in a large number of patients. The drug is available as a thin solution, and is easy to inject, using a fine gauge needle. It does not cause adverse effects such as local dermal atrophy or hypopigmentation, and is relatively safe. Pain following verapamil is severe and analgesics may be required.

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TUBERCULOSIS AND HIV COINFECTION AT ANANTA INSTITUTE OF MEDICAL SCIENCES AND RESEARCH CENTER

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Conflicts of Interest: Nil

ABSTRACT:

INTRODUCTION: About 60 per cent of TB cases and deaths occur among males, but the disease burden is also high among women also. In 2015 nearly 500,000 women died from TB, and among them, 28 per cent had human immunodeficiency virus (HIV) co-infection. Tuberculosis (TB) is a bacterial disease caused by *Mycobacterium tuberculosis (M. tuberculosis*), which mostly manifests as pulmonary TB but it can affect other organs called as extra-pulmonary Tuberculosis (ETB). TB is expanding public health issue amongst the developing countries, due to HIV pandemic, poverty, movement of displaced people and emergence of multidrug-resistant strains and it is evidenced that, in most of the developing countries, HIV pandemics, diabetes, malnutrition, alcoholism, smoking cigarette, active TB contact, extreme poverty, and homelessness are common identified risk factors pertaining to tuberculosis. **MATERIAL AND METHODS**: Patients who presented with cough lasting for 2 weeks, evening rise of temperature, weight loss or more were clinically suspected of having TB. Laboratory and radiological investigations were carried out. Laboratory investigation for TB was by sputum smear for acid-fast bacilli (AFB) and who had at least one smear positive for AFB were categorized as smear-positive pulmonary TB (PTB). Chest X-ray was done to detect radiological changes of PTB. Extra-pulmonary tuberculosis included tuberculosis of organs other than the lungs, such as the abdomen, genitourinary tract, lymph nodes, skin, bones, joints, and meninges. A diagnosis of extra pulmonary tuberculosis (EPTB) was made based on clinical findings suggestive of TB, radiology, cytology, and tissue histology. **RESULTS**: A total of 100 TB patients were included in the study. Age range was 15 to 59 years with mean age 37 ±15.9 years. HIV coinfection was found in 15 patients age range was 24 to 49 years with mean age 35 ±12.9 years. More than a half (*n*=10; 54.3%) of participants had CD4 count ranged between 200-500/µl and 21.6% (*n*=63) of respondents had CD4 count <200/µl. In addition, the study also showed that 29.2% (*n*=85) and 3.7% (*n*=11) . Of the 15 HIV positive diagnosed cases 5 were relapse case (33.33%) of which 2 were female and 3 were male . 10 cases (66.67%) were new cases of which 3 were female and 7 were male.MDR TB (multidrug resistant TB) was seen in 10 cases of HIV co infected patients as compared to HIV negative it was 15 cases. **CONCLUSION**: Drug-resistant TB is becoming a significant challenge to the control of the infection in the world especially in HIV-positive patients. Treatment should be targeted at treating the immune suppression associated with HIV which promotes development of active TB. Previous history of TB, CD4 count less than 200/µl were the possible risk factors.

KEYWORDS: TB, HIV, CD4 and ETB.

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Introduction

Tuberculosis (TB) is a bacterial disease caused by *Mycobacterium tuberculosis (M. tuberculosis*), which mostly manifests as pulmonary TB but it can affect other organs called as extra-pulmonary Tuberculosis (ETB)[i]. Tuberculosis is a major health problem globally which affects millions of people every year. It has been ranked as the second leading cause of death from an infectious disease worldwide. The World Health Organization (WHO) estimated that there are over 9 million new active cases of tuberculosis resulting in 1.5 million TB deaths per year[ii]. Some epidemiological studies evinced that, co-infection with HIV can elevate the risk of latent TB reactivation by 20-fold and is the most potent risk factor known for the advancement of *M. tuberculosis* infection to active disease[iii]. TB is expanding public health issue amongst the developing countries, due to HIV pandemic, poverty, movement of displaced people and emergence of multidrug-resistant strains and it is evidenced that, in most of the developing countries, HIV pandemics, diabetes, malnutrition, alcoholism, smoking cigarette, active TB contact, extreme poverty, and homelessness are common identified risk factors pertaining to tuberculosis[iv] . The depressed immune system associated with HIV increases the risk of reactivation of latent tuberculosis and rapid progression to active infection. Therefore, areas with high HIV prevalence also have high TB incidence rate[v]. Generally pulmonary tuberculosis is the commonest TB manifestation and those who are HIV positive are more likely to have extra pulmonary TB. Extra pulmonary TB is seen in 40–80% of TB–HIV infection but in only 10–20% of patients without coinfection [vi],[vii]. Therefore HIV-related TB impacts negatively on the efforts to control tuberculosis. This study was carried out to determine the prevalence of TB–HIV coinfection among those being treated for TB, to compare the pattern of TB in HIV-infected and non-HIV-infected individuals.

MATERIAL AND METHODS

The present study was carried out in the Dept. of Pulmonary Medicine at Ananta Institute of Medical Sciences and Research centre, Rajsamand.

Patients who presented with cough lasting for 2 weeks, evening rise of temperature, weight loss or more were clinically suspected of having TB. Laboratory and radiological investigations were carried out. Laboratory investigation for TB was by sputum smear for acid-fast bacilli (AFB) and who had at least one smear positive for AFB were categorized as smear-positive pulmonary TB (PTB). Chest X-ray was done to detect radiological changes of PTB. Extra-pulmonary tuberculosis included tuberculosis of organs other than the lungs, such as the abdomen, genitourinary tract, lymph nodes, skin, bones, joints, and meanings. A diagnosis of extra pulmonary tuberculosis (EPTB) was made based on clinical findings suggestive of TB, radiology, cytology, and tissue histology. Patients with EPTB were treated using the directly observed treatment short course (DOTS) regimen of at least 6 months of anti-TB drugs which consists of 2 months of rifampicin, isoniazid, pyrazinamide, and ethambutol followed by 4 months of rifampicin and isoniazid.

After proper counselling and permission all patients were tested for HIV by an initial rapid test screening and confirmed by ELISA. Demographic and clinical information were retrieved from patients' records using a standardized questionnaire.

Data analysis was performed using the SPSS software. The Chi-squared test was used to test for association between categorical tables. The level of significance was set at $p \leq 0.05$.All data was entered on the EXCVEL sheet of Windows 2013.

Written informed consent was obtained from all the patients.

OBSERVATIONS AND RESULTS

A total of 100 TB patients were included in the study. Age range was 15 to 59 years with mean age 37 ±15.9 years. HIV coinfection was found in 15 patients age range was 24 to 49 years with mean age 35 ±12.9 years

Table 1: HIV and TB coinfection

	HIV positive	HIV negative	Total
Total	15	85	100
Male	10	42	52
Female	5	43	48

In the present study, more than a half (*n*=10; 54.3%) of participants had CD4 count ranged between 200-500/µl and 21.6% (*n*=63) of respondents had CD4 count <200/µl. In addition, the study also showed that 29.2% (*n*=85) and 3.7% (*n*=11)

Of the 15 HIV positive diagnosed cases 5 were relapse case (33.33%) of which 2 were female and 3 were male . 10 cases (66.67%) were new cases of which 3 were female and 7 were male.

MDR TB (multidrug resistant TB) was seen in 10 cases of HIV co infected patients as compared to HIV negative it was 15 cases

Table 2: New and relapse cases

Sex	Male	Female
New cases	7	3
Relapse or old case	3	2
Total	10	5

Out of 15 diagnosed cases of HIV 3 were on ART while 12 were not taking any drugs. 1 case (male) was having CD4 count less than 200 while 5 cases were having count 200 to 500

DISCUSSION AND CONCLUSION

WHO Tuberculosis report shows that prevalence of tuberculosis has been declining globally; we are far away from achieving TB free world even in 2050[viii]. Also people living with HIV are most prone to contracting active TB because of the deficiency of immune response. It is envisaged that TB can affect young people in a disproportionate manner[ix].

In our study the age distribution showed the mean age of TB–HIV infection to be of 35 ±12.9 years. This is in accordance to findings of several other studies where the peak age of coinfection ranged from 31–40 to 41–50[x,xi]. In Thanh et al. study in Vietnam[xii] lower age group was reported,

The WHO global report shows that more TB cases and deaths occur among men compared to women. [xiii]in our study same results were found in which 5 female (33.33%) were having co infection as compared to men having 10 (66.67%). Atypical presentations like extra pulmonary TB and sputum smear-negative TB and atypical radiologic manifestations have been said to hamper the diagnosis of TB, thus, affecting the prompt treatment and control of the infection. Suchindran S reported high multidrug resistant TB in HIV patients [xiv].MDR TB (multidrug resistant TB) was seen in 10 cases of HIV co infected patients as compared to HIV negative it was 15 cases. One study reports a similar contrasting picture in which, even though the prevalence of extra pulmonary TB was 11–38%, it was higher in areas with the lowest HIV prevalence [xv].

Drug-resistant TB is becoming a significant challenge to the control of the infection in the world especially in HIV-positive patients[xvi].Treatment should be targeted at treating the immune suppression associated with HIV which promotes development of active TB. Previous history of TB, CD4 count less than 200/µl were the possible risk factors. Large-scale studies on the trends in TB/HIV co-infection and associated factors should also be implemented across the country.

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SPUTUM NEUTROPHILS AS A BIOMARKER IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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ABSTRACT

Introduction: COPD is a common, preventable and treatable disease with increased disease burden accounting for significant mortality. A hallmark feature of COPD is the increased numbers of pulmonary neutrophils that can secrete a wide range of pro-inflammatory cytokines and chemokines as well as proteases that play role in the development of emphysema. We aimed to find out a simple, accessible and economical biomarker to prevent morbidity & mortality associated with COPD. Induced sputum is a non-invasive method that allows evaluation of neutrophil numbers in the airway lumen. **Methods:** A longitudinal comparative study involving 50 COPD patients with age, sex, race matched individuals were categorized into treatment group (Group1) and control group (Group2) underwent sputum induction and analysis to look for sputum neutrophil and its relation to COPD exacerbation and management. Response to treatment was measured using spirometry (FEV1, FEV1/FVC). **Observation:** We found out that 76% of the COPD patients had >70 Sputum Neutrophil count which persisted among 28% of the COPD patients despite treatment with macrolide. Most of the group 1 patients improved with macrolide treatment in addition to usual bronchodilators as shown by improvement in pre and post FEV1(p=0.001); compared to group 2 patients where there was no significant changes in pre and post FEV1(p=0.516). Sputum Neutrophil was significantly associated with improvement in CAT Score (p=0.009) and reduction in exacerbation(p=0.002). **Conclusion:** The author strongly concludes that sputum neutrophil count could prove to be one of the Significant biomarker to predict and manage the exacerbation of COPD.

KEYWORDS: COPD, FEV1, FEV1/FVC.

INTRODUCTION

COPD is currently the fourth leading cause of death in the world but is projected to be the 3rd leading cause of death by 2020. More than 3 million people died of COPD in 2012 (up from 2.4 million deaths in 1990) accounting for 6% of all death globally. COPD affects 329 million people or nearly 5 percent of the global population. It typically occurs in people over the age of 40. More than 90% of these deaths occur in the developing world. The number of deaths is projected to increase further because of higher smoking rates and an aging population in many countries. In the European Union, the total direct costs of Respiratory diseases are estimated to be about 6% of the total health care budget, with COPD accounting for 56% (38.6 billion Euros) of the cost of respiratory diseases. In the United States, the estimated direct costs of COPD are $32billion and the indirect costs $20.4 billion. It resulted in an estimated economic cost of $2.1 trillion in 2010. d treatable. COPD is a major cause of chronic morbidity and mortality throughout the world. Many people suffer from this disease for years, and die prematurely from it or its complications. COPD develops slowly.

Spirometry is used to confirm the diagnosis. Spirometry measures the amount of airflow obstruction present and is generally carried out after the use of a bronchodilator, a medication to open up the airways. Two main components are measured to make the diagnosis: the forced expiratory volume in one second (FEV_1), which is the greatest volume of air that can be breathed out in the first second of a breath, and the forced vital capacity (FVC), which is the greatest volume of air that can be breathed out in a single large breath. Normally, 75–80% of the FVC comes out in the first second and a FEV_1/FVC ratio of less than 70% in someone with symptoms of COPD defines a person as having the disease. Based on these measurements, spirometry would lead to over-diagnosis of COPD in the elderly. The Excellence criteria additionally require a FEV_1 of less than 80% of predicted.

However, there is a need for biomarkers that are reflective of the inflammatory mechanisms involved in disease pathogenesis. Such biomarkers may be useful for monitoring disease progression, evaluating the effects of therapeutic interventions or identifying disease sub-phenotypes with different clinical characteristics.

A hallmark feature of COPD is the increased numbers of pulmonary neutrophils that can secrete a wide range of pro-inflammatory cytokines and chemokines as well as proteases that play a role in the development of emphysema. Induced sputum is a non-invasive method that allows evaluation of neutrophil numbers in the airway lumen. The measurement of induced sputum neutrophils fulfils some of the ideal characteristics of a biomarker in COPD; neutrophils are thought to be mechanistically involved in disease pathophysiology, can be easily measured in the target organ using a non-invasive method, and are increased in patients with COPD compared to controls. There is a need to conduct large cohort studies to further explore the potential utility of this biomarker in COPD patients.

The use of sputum in research has improved our understanding of airway diseases in many ways because it is noninvasive (in the case of spontaneous sputum) or relatively noninvasive (with induced sputum), and cell counts in sputum have the qualities of excellent and highly reproducible measurements that are accurate and sensitive and identify the presence, type, and severity of airway inflammation. These measurements can be obtained repeatedly and in exacerbations, as well as in all severities of disease. Induced sputum, in particular, has been shown to be a highly effective method for determining the inflammatory processes in the airways (Gibson et al 1989; Pizzichini et al 1996; Pizzichini et al 1997; Jayaram et al 2000). Increasingly, sputum induction has been used in clinical and research settings to study airway inflammation in both asthma and COPD (Fahy et al 1993; Keatings and Barnes 1997; Wielders and Dekhuijzen 1997; Rutgers et al 2001).

Sputum analysis can also be used to determine the inflammatory response to inhaled glucocorticosteroids. Indeed, a single large dose (2400 μg) of inhaled budesonide was shown to result in a reduction in sputum eosinophil numbers 6 hours after administration (Gibson et al 2001).

In COPD, the most common sputum change is neutrophilia and increased products of neutrophil activation, including proteases, myeloperoxidase, and elastase (Chung 2001; Williams and Jose 2001; Kim and Nadel 2004; O'Donnell RA et al 2004). In cigarette smokers with COPD, the degree of neutrophilia is loosely related to the degree of chronic airway obstruction (Stanescu et al 1996). This suggests that sputum neutrophils or their products may be used as early markers of the manifestation of COPD.

AIMS AND OBJECTIVES

Objectives

1. To study prevalence of Sputum Eosinophilia and Neutrophilia in Chronic Obstructive Pulmonary Disease (COPD)
2. To study prevalence of Sputum Eosinophilia and Neutrophilia in Different COPD GOLD groups
3. To study prevalence of Sputum Eosinophilia and Neutrophilia in Response to COPD Treatment

MATERIALS AND METHOD

Patient Selection

We performed a longitudinal comparative study to evaluate sputum analysis in all diagnosed COPD patients who attended the Department of TB and respiratory diseases, SS Hospital, IMS, BHU.

If not previously documented/tested, all such patients were documented for COPD with post bronchodilator pulmonary function test confirmation (FEV1 / FVC < 0.7) with irreversible airway obstruction and were screened for other causes of breathlessness like exacerbation of Bronchial Asthma, Interstitial lung diseases, worsening of Dyspnea due to heart failure etc., by channeling through detailed history, thorough physical examination and a battery of relevant investigations. Data on demographic characteristics, sleep, medical history, medication use, and habits were obtained with the use of a modified standardized questionnaire.

Inclusion criteria

- Patients with COPD.
- Age 41 to 85 year.
- Patients as well as attendants willing to give informed consent.
- Patients ready to undergo necessary investigation.

Exclusion criteria

- Patients with multiple organ failure.
- Clinical features and spirometry suggestive of disease other than COPD.
- Haemodynamic instability.
- Those patients who are not giving consent.
- Women who are pregnant or currently lactating.
- Mixed and restrictive pattern of lung function in spirometry.
- Could not perform spirometry correctly.

The institutional ethics committee was asked to approve the protocol, informed consent was obtained from the participants.

Study Size

We did Sputum analysis of 50 COPD patients which were attend outdoor or indoor of our department. All patients included in study underwent evaluation as per pre-standardized protocol**.**

RESULTS AND OBSERVATION

A total of 50 COPD patients with age, sex, race, BMI matched were enrolled into the study, between 40 to 85 years of age group which were chosen from the OPD and ward of TB & Respiratory Diseases of Sir Sunderlal Hospital, BHU Varanasi**.**

In our study, out of 50 subjects in group I, 6 (24%) had Eosinophilia and 18 (72%) had Neutrophilia and in group II, 5 (20%) had Eosiniphilia and 20 (80%) had Neutrophilia. Earlier studies by Singh et al. (2010), total 359 subjects produced an evaluable sample at baseline, and 297 subjects after 1 year.

The researcher also found out that most of the patient in Group 1 fell into GOLD 3(n=12) and GOLD 2 (n=6) prior to initiation of treatment with macrolide compared to post treatment in GOLD 3 (n=10) and GOLD 2(n=15). However in Group 2, most of the patient fell into GOLD 3(n=11) and GOLD 2 (n=10) compared to post treatment in GOLD 3 (n=7) and GOLD 2 (n=13). Our findings were similar to Singh et al. where half of the subjects were GOLD stage 2, with the remaining subjects being GOLD stage 3 or 4. Another study conducted by Stanescu et al. (1996) suggested In cigarette smokers with COPD, the degree of neutrophilia is loosely related to the degree of chronic airway obstruction. This suggests that **sputum neutrophils or their products may be used as early markers of the manifestation of COPD**

The researcher also showed that 22% (n=11 out of 50) of the COPD patients had ≥ 3% Sputum eosinophil count and 78% (n=39 out of 50) had < 3% sputum Eosinophil. The lower sputum eosinophil may be due to treatment with ICS/oral steroid.

The researcher found out that 22% of the participants had sputum Eosinophil ≥ 3% compared to most literatures which states that 40% of patients with COPD have eosinophilic airway inflammation.

The researcher also found out that **76% of the COPD patients had neutrophilic airway inflammation with sputum Neutrophil > 70**%. According to **Hoenderdos**, and **Condliffe** et al. Neutrophilic inflammation predominates in the COPD airway wall and lumen, but, despite the presence of abundant innate immune cells, the progressive clinical course of the disease is punctuated by recurrent infection-driven exacerbations.

The Researcher also found out that increased sputum Neutrophil was associated with decline in lung function (FEV1) which is similar to the finding by Singh et al, who concluded that Sputum neutrophil measurements in COPD are associated weakly with FEV_1 % predicted and health status.

Table 4-1a: Prevalence of Sputum Eosinophil in COPD Patients Prior to Treatment.

Eosinophil (PRE)	No. of patients	Percentage
≥3%	**11**	**22**
< 3%	**39**	**78**
Total	**50**	**100**

Table 4-1a, showed that 22% (n=11 out of 50) of the COPD patients had ≥ 3% Sputum eosinophil count and 78% (n=39 out of 50) had < 3% sputum Eosinophil. The lower sputum eosinophil may be due to treatment with ICS/oral steroid.

Table 4-1b: Prevalence of Sputum Neutrophil in COPD Patients Prior to Treatment.

Neutrophil (PRE)	No. of patients	Percentage
>70	**38**	**76**
≤70	**12**	**24**
Total	**50**	**100**

Table 4-1b, showed that 76% (n=38 out of 50) of the COPD patients had > 70 Sputum Neutrophil count and 24% (n=12 out of 50) had ≤ 70 sputum Neutrophil.

Table 4-2a: Prevalence of Sputum Neutrophil in COPD Patients Prior to Treatment.

Gold Stage Pre	No. of patients	Percentage
≥80	**3**	**6**
50-79	**16**	**32**
30-49	**23**	**46**
<30	**8**	**16**
Total	**50**	**100**

Table 4-2B: Prevalence of Sputum Neutrophil in COPD Patients Post Treatment.

Gold Stage Post	No. of patients	Percentage
≥80	**1**	**2**
50-79	**28**	**56**
30-49	**17**	**34**
<30	**4**	**8**
Total	**50**	**100**

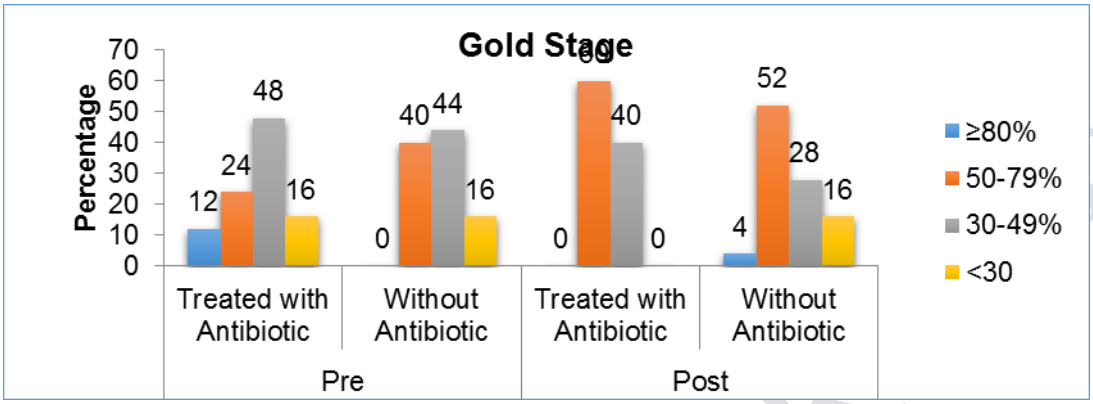

Figure 4-2a: Prevalence of Sputum Neutrophil in COPD Patients Pre and post Treatment.

Table 4-2a/4-2b and figure 4-2 showed maximum number of COPD patients in GOLD 3 (n=23 in pre treatment Vs n=17 aftertreatment) followed by G0LD 2(n=16 prior to treatment vs n=28 after treatment), followed by GOLD 4 (n=8 in pre treatment vs n=4 post treatment).

Table 4-3a: Prevalence of Sputum Eosinophil in COPD Patients after Treatment.

Eosinophil Post	No. of patients	Percentage
≥3%	**7**	**14**
< 3%	**43**	**86**
Total	**50**	**100**

Table 4-3a, showed that 14% (n=7 out of 50) of the COPD patients had ≥ 3% Sputum eosinophil count and 86% (n=43 out of 50) had < 3% sputum Eosinophil. The further decline in sputum eosinophil may be due to treatment with ICS/oral steroid.

Table 4-3b: Prevalence of Sputum Neutrophil in COPD Patients after Treatment.

Neutrophil Post	No. of patients	Percentage
>70	**14**	**28**
≤70	**36**	**72**
Total	**50**	**100**

Table 4-3b, showed that 28% (n=14 out of 50) of the COPD patients had > 70 Sputum Neutrophil count and 36% (n=36 out of 50) had ≤ 70 sputum Neutrophil. There is a significant decrease in Neutrophil count after treatment with Macrolide.

Table 4-4: Comparison of Severity of COPD in Group 1 Vs Group 2.

Gold Stage	Group 1		Group 2	
	Treated with Antibiotic Pre	Treated with Antibiotic Post	Without Antibiotic Pre	Without Antibiotic Post
	No. (%)	No. (%)	No. (%)	No. (%)
≥80%	3 (12.0)	0 (0.0)	0 (0.0)	1 (4.0)
50-79%	6 (24.0)	15 (60.0)	10 (40.0)	13 (52.0)
30-49%	12 (48.0)	10 (40.0)	11 (44.0)	7 (28.0)
<30	4 (16.0)	0 (0.0)	4 (16.0)	4 (16.0)
Total	25 (100.0)	25 (100.0)	25 (100.0)	25 (100.0)
P-value	0.001		0.516	

Table 5-3: Summary of all findings of current study.

Variables	Mean±SD		p-value
	Treated with Antibiotic	Without Antibiotic	
Age	62.64±11.060	58.92±11.354	0.246
TLC	1.25E4±3860.928	2.00E4±43709.112	0.400
Neuter	82.24±9.697	78.44±10.697	0.194
Lymphocytes	10.12±5.925	15.36±12.278	0.061
Hb	12.216±2.2433	12.308±1.4323	0.864
FVC	2.405±1.0110	2.433±0.7789	0.913
FEV1 Pre	50.00±17.357	46.64±13.976	0.455
FEV1 Post	56.04±12.371	52.68±16.030	0.411
FVC1 FVC ratio	58.80±7.751	58.84±7.069	0.985
BMI	24.136±4.4631	22.616±4.8470	0.254
PaO2	96.96±66.977	98.72±42.651	0.912
PaCO2	65.648±22.1778	60.852±19.4685	0.420
PH	7.381±0.0752	7.367±0.0837	0.544
HCo 3	32.012±9.5260	30.704±7.0409	0.583
Neutro Pre	77.68±7.920	78.80±7.643	0.613
Neutro Post	57.36±8.010	68.20±9.862	0.000
Eosinophil Pre	1.88±2.489	1.60±2.784	0.709
Eosinophil post	2.00±0.645	1.92±0.759	0.690
CAT Pre	25.32±6.336	25.12±7.126	0.917
CAT Post	12.96±2.835	15.88±6.194	0.037

SUMMARY AND CONCLUSION

1. The author strongly concludes that sputum neutrophil count could prove to be one of the Significant biomarker to predict and manage the exacerbation of COPD.
2. The researcher found out that most of the patients with COPD (76%) had increased Sputum Neutrophil count.
3. COPD patients with increased Sputum Neutrophil count was associated with worsening of lung function and as well as CAT Score. Neutrophilic airways were less responsive to steroid compared to eosinophilic airway diseases.
4. After Treatment with macrolide in addition to LABA+LAMA+ICS, there was an improvement in lung function and sign and symptoms as revealed from CAT Score.
5. Sputum Neutrophil may be used as a biomarker for predicting future worsening and deteriorating lung function.
6. Sputum Eosinophil was increased in 22% of COPD patients and it could also be used as one of the biomarker for COPD progression, exacerbation.
7. The researcher also found out that number of exacerbation was significantly increased in patients with increased sputum Neutrophil and eosinophil count.
8. However, eosinophilic airway disease as evident from our study was associated with better lung function and improved responsiveness to therapy (ICS).
9. The Researcher also found positive correlation of Sputum Neutrophil with CAT Score in patients with COPD i.e. CAT score improved with improvement in Sputum Neutrophil count.

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Section Microbiology

Original Article

A Comparative Evaluation of Rapid Card Test with Enzyme- Linked Immunosorbent Assay for the Detection of HBsAg Among Pregnant Women in a Tertiary Care Hospital

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ABSTRACT

Background: *Hepatitis B virus infection is an important health problem and a leading cause of death worldwide. The most important marker for HBV infection is HBsAg. A proper identification of kit is required for proper diagnosis of infection, as well as disease management and prevention.* ***Aims& Objective****: - The aim of the present study was to compare rapid HBsAg detection ICT kits for the screening of HBV infection with gold standard ELISA method.*
Methods: *The study comprised 500 blood samples of pregnant women. These samples were tested with ICT kits of (Hepa Card Company) and ELISA (HEPLISA by J. Mitra.).* ***Results:*** *In present study we found 100% sensitivity, 99.59% specificity, 81.81% positive predictive value ,100%Negative predictive value and 99.60% diagnostic efficiency of rapid card test with comparison to ELISA for HBsAg detection.* ***Conclusion****: The present study concluded that the overall performance of the rapid ICT kit for HBsAg was equally sensitive to ELISA and yet they were cheap and quicker. It can be recommended that ELISA comparable rapid devices may be allowed to be used for preliminary screening of HBsAg especially in remote areas or where cost is an issue.*

Keywords: *HBsAg, Immunochromatographic kit ICT, ELISA, comparison for effectiveness.*

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INTRODUCTION

Hepatitis B virus (HBV) infection has been one of the leading causes of hepatocellular carcinoma not only globally but in India also. India has an intermediate prevalence of Hepatitis B with a 4% to 5.4% HBsAg positive population.[1] In order to prevention of HBV transmission the Global Advisory Group to the world Health Organization (WHO) recommended that all countries integrate the Hepatitis B vaccine into national immunization programs. With respect to it the Hepatitis B vaccine has been introduced into national Immunization program in India. India has introduced the Hepatitis B vaccine into the routine childhood vaccination schedule. A recent report of Dwivedi et al[1] in India, suggested that there may be a significant role of vertical transmission in Hepatitis B infection.[2] Screening of HBV infection by detecting Hepatitis B virus surface antigen (HBsAg) in every pregnant woman has been practiced in India to prevent perinatal transmission. Also screening for HBsAg before vaccination and blood transmission has been practiced in India. It has been estimated that 350 million people worldwide are chronic carriers of Hepatitis B virus.[3] High risk of death form livers cirrhosis and hepatocellular carcinoma occur in these chronic carriers of Hepatitis B.[4,5] HBV infection is spreading rapidly in developing countries due to lack of health education, illiteracy, poverty, lack of awareness of the need of HBV vaccination.[6] It is therefore important for individuals to

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undergo screening for HBV before blood donation, in pregnancy, high risk infants for ensuring prompt treatment and avoidance of transmission. Early and accurate detection of HBV infection using sensitive and specific methods allow investigators to evaluate the status of HBV infection and develop strategies to prevent transmission. Also, a highly infectious virus like HBV which causes silent infection, accurate detection of the virus marker is essential for controlling the transmission of the virus that is why it is required to validate detection methods prior to allowing their use in diagnostic laboratories. HBsAg rapid card test is a rapid screening test for the qualitative detection of HBsAg in whole blood, serum or plasma specimen. The test utilizes a combination of monoclonal and polyclonal antibodies to selectively detect elevated levels of HBsAg in whole blood, serum or plasma.[7] While ELISA is an enzymatic immunoassay technique of the "sandwich" type for the detection of HBV in human serum or plasma. The test uses monoclonal antibodies selected for their ability to bind themselves to the various subtypes of HBsAg now recognized by the World Health Organization (WHO)[8] and the most part of variant HBV strains.[9]

Different methods are used for the diagnosis of Hepatitis including ICT, ELISA, EIA and PCR. ELISA, EIA and PCR methods are expensive and are used in well equipped laboratories and major tertiary care hospitals. Rapid diagnostic kits are a good choice as they are less expensive and do not need high technical manpower or infrastructure[10]. In India, they are found useful in resource limited setting and as a point of screening tests, making them widely popular for HBsAg detection. The rapid card test is known to have less sensitivity and specificity than ELISA but some have sensitivity and specificity comparable to ELISA.[11] Ideal rapid screening tests should have a high degree of sensitivity and a reasonable level of specificity to minimize false positive and false negative results. The aim of present study is to check the sensitivity and specificity of rapid card test of HBsAg which are frequently used in different laboratories and hospitals, nursing homes, camps and to compare with gold standard method ELISA. Goal of this study is to recommend a reliable and cost effective test for diagnosis of HBV in a developing country like India where advance diagnostic facilities are not available everywhere.

METHODS

Collection of specimen- A prospective study was conducted from August 2015- Jan 2016 in a tertiary Care hospital at Udaipur, Rajasthan, India. A total of 500 pregnant women blood samples were collected after obtaining an informed consent and were tested for HBsAg in department of Microbiology at Hospital. Sample Processing- Each blood sample was tested for HBsAg using both rapid card test (Hepacard Diagnostic enterprises) and ELISA by Hepalisa-J.Mitra & Co. Pvt. Ltd method.)

Rapid card Test process

Hepacard is one step immunoassay based on antigen capture or sandwich principle. The method uses monoclonal antibodies conjugated to colloidal gold and polyclonal antibodies immobilized on a nitrocellulose strip in a thin line. The test sample is introduced to and flows laterally through an absorbent pad where it mixes with the signal reagents. If the sample contains HBsAg, the colloidal gold-antibody conjugate binds to the antigen, forming an antigen-antibody-colloidal gold complex. The complex then migrates through the nitrocellulose strip by capillary action. When the complex meets the line of immobilized antibody (test line) 'T', complex is trapped forming an antigen-antibody colloidal gold complex. This forms a pink band indicating the sample is reactive for HBsAg. To serve as a procedural control, an additional line of antimouse antibody (control line)'C', has been immobilised at a distance from the test line on the strip. If the test is performed from the test line on the strip then the test is performed correctly, this will result in the formation of a pink band upon contact with the conjugate.[12]

ELISA Method

Hepalisa is a solid phase enzyme linked immunosorbent Assay based on the direct sandwich ELISA principle. The microwells are coated with monoclonal antibodies with high reactivity for HBsAg. The samples are added in the wells followed by addition of enzyme conjugate (polyclonal antibodies) linked to horseradish peroxide (HRPO). A sandwich complex is formed in the well where in HBsAg (from serum complex is formed in the well wherein HBsAg (from serum sample) is "trapped" or "sandwich" between the antibody and antibody HRPO conjugate. Unbound conjugate is washed off with wash buffer. The amount of bound peroxidise is proportional to the concentration of HBsAg present in the samples. Upon addition of the substrate buffer and chromogen, a blue colour develops. The intensity of developed blue colour is proportional to the concentration of HBsAg in sample. To limit the enzyme –substrate reaction stop solution is added and a yellow colour develops which is finally read at 450nm spectrophotometrically.

RESULTS

Out of 500 blood samples tested on rapid card tests, 9 samples were positive, and 491 were negative for HBsAg by rapid card test. On further testing with ELISA, 2 false positive were detected. Using ELISA as a gold standard confirmatory method sensitivity of rapid card was 100%, specificity was 99.59%, positive predictive value was 81.81%, negative predictive value was 100%, and diagnostic accuracy was 99.60%.

Table 1: Comparison of rapid card test with ELISA, (n=500)

	Rapid card	ELISA
Positive	9	7
False Positive	2	0
Negative	489	493
False Negative	0	0

Table-2 Evaluation of Rapid test kits with ELISA

HBsAg test	Sensitivity	Specificity	Positive Predictive value	Negative Predictive value	Diagnostic efficiency
Rapid Card Test	100%	99.59%	81.81%	100%	99.60%
ELISA	100%	100%	100%	100%	100%

DISCUSSION

In the present study rapid kits were compared with gold standard ELISA for screening of HBsAg. ELISA and rapid test kits are equally sensitive yet rapid kits are cheaper than the prior one. Rapid tests enable early detection at sites

where laboratory facilities or trained manpower are not available. The high laboratory cost for screening of HBsAg among the poor population is also sought as the rapid card tests are cheaper in diagnosis of HBsAg. Ideally rapid devices should have a high degree of sensitivity and a reasonable specificity so as to minimize false positive and false negative results.

In our study, the sensitivity of rapid test kit was 100% and specificity was 99.56%. Yogendra K.Tiwari et al[13] reported sensitivity of rapid kit test as 95.12% and specificity 99.82%. Another study by Kaur et al[14] reported 100% specificity and 94.4% sensitivity of ELISA to pick up all false negative. A study by Akhtar et al [15] showed 100% sensitivity of rapid card test kit with specificity of 91.7% for HBsAg. Ansari et al[16] showed that rapid assays with strip or devices had sensitivity between 97.5% and 99.2% and specificity between 97.25% and 99.2%. A study conducted by Lin et al[17] by using two ICTs the sensitivity and specificity was 100% respectively. A study from Karachi, Pakistan showed comparable sensitivity and specificity of ICT kit and ELISA techniques[18], followed by another study from Seoul[19] showed 97% sensitivity and 100% specificity for detecting HBsAg. Few variance results were seen in a study conducted by Khanet al[20] found sensitivity 53% and specificity was 100% for HBsAg rapid card. Ideally rapid devices should have a high degree of sensitivity and a reasonable specificity to minimize false positive and false negative results. False positive in our study was 18.19% and false negative as nil. Tiwari et al[13] came with a result of 4.88% as false positive and 0.18% as false negative similar to Gul et al.[21] Rapid ICT kits giving more false positive result are better for diagnosis than those that give more false negative results.[22] A positive result can be followed by more accurate and advance method to confirm the infection presence unlike a negative result. Hence choosing a test with high sensitivity and Negative predictive value is more important than choosing a test with high specificity and positive predictive value for routine use. In a study conducted in India by Maity et al[23], a comparative study, 3 different HBsAg ICT kits Hepacard, Crystal and SD bioline, were evaluated, all of them showing 100% sensitivity and 100% specificity. Immunochromatography based rapid assays used for HBsAg detection may not have the same accuracy indices in every region due to the differences in the prevalence of HBV infection in a given population. The prevalent subtype of HBV infecting a population can be different. Some ICT kits may not detect certain subtype of HBV giving false negative results.[24,25.] ICT for HBsAg detection must be validated before being used in resource limited settings. Further failure of rapid test kit to detect HBV reactive samples may be due to inadequate coating of the antigen, different nature of antigen used and genetic heterogeneity of the virus prevalent in that area.

CONCLUSION

The present study demonstrate that ICT based rapid test devices are suitable to be used as a screening test for Hepatitis B surface antigen as at a point of care test and should be recommended only in resource limited poor settings, remote areas and peripheral health facilities for screening purpose. But threat of silent transmission and spreading of diseases among people create an urge for more accurate diagnostic method such as ELISA.

Ethical Approval: Obtained

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Section Microbiology

Original Article

Seroprevalence & Risk Factors of Hepatitis B Surface Antigen among Pregnant Women Attending a Tertiary Care Hospital of Southern Rajasthan, India

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ABSTRACT

Background: *Hepatitis B virus infection is a major global health problem and India accounts for 10-15%of the entire pool of HBV carriers of the world. Prevalence of Hepatitis B in pregnant women worldwide is 2.5 to 1.5%, whereas in India it is 2 to 7%. Hepatitis B virus is a double stranded DNA virus. The study was undertaken to determine the seroprevalence of Hepatitis B among the pregnant women in southern part of Rajasthan at a rural based tertiary care teaching hospital.* ***Methods:*** *This is a prospective study conducted at a tertiary care hospital, Udaipur, Rajasthan, from August 2015 to December 2017.Blood samples were collected from 1011 pregnant women with age ranging from 15-45 years. Screening of HBsAg was done by RPHA method and positive HBsAg tests were confirmed by ELISA. The data of those , who were found to be positive for HBsAg was statistically analyzed with the chi square tests, and results were considered significant if the p value was <0.05.*

Results: *The overall HBsAg seroprevalence rate was 1.28%, among the total 1011 pregnant women included in this study. HBsAg seroprevalence was highest, (1.64%) in 15-25 years of age group, and 1.71% in the second trimester of pregnancy. The correlations of seroprevalence rate of HBsAg among selected age groups and according to second trimester of pregnancy were not found statistically significant. (p value>0.05)*

Conclusion*: In this study the seroprevalence of Hepatitis B surface antigen was 1.28%. To prevent vertical transmission in the pregnant women, they should be screened for HBsAg at the first antenatal visit for appropriate management.*

Keywords: *Hepatitis B surface antigen, pregnant women, Vertical Transmission*

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INTRODUCTION

Hepatitis B Virus (HBV) infection is one of the most common public health problems. India has over 40 million hepatitis B virus carriers accounting for 10-15% of the entire pool of HBV carriers of the world.[1,2] However, the epidemiology and pattern and consequence of HBV infection varies greatly from one part of the world to another also changes with time. Hepatitis B is caused by double stranded DNA virus belonging to hepadnaviridae family. It leads to acute hepatitis and may also have serious complications like acute and chronic hepatitis, cirrhosis and hepatocellular carcinoma.[3-5] Hepatitis B Virus infection during pregnancy, is associated with a high risk of maternal complications. Prevalence of hepatitis B in pregnant women worldwide is 2.5 to 1.5%, whereas in India is 0.2 to 7.7%[6] Ten percent of infants born to women with acute HBV infection during the first trimester of pregnancy are HBsAg positive at birth, and 80 to 90% of neonates become HBsAg positive without prophylactic therapy, if acute maternal infection develops during the third trimester of pregnancy.[7,8] Screening and evaluation of hepatitis during the pregnancy is much more important to prevent mortality of mother and child. However there is a scarcity of systematic information on the prevalence of HBV infection among pregnant women in India including the study area. This will be useful to address the current prevalence status of hepatitis B during pregnancy, the present study aimed to determine the seroprevalence of hepatitis B surface antigen among pregnant women. The risk factors of Hepatitis B infection like IV drugs, previous Blood transfusion history, previous surgeries, tattooing, piercing etc were also

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evaluated, which would provide information to institutional and public measures to reduce the transmission of infection.

METHODS

The present study was undertaken over a period of one and half year from August 2015 to December 2017, approved by the institutional Ethics Committee. The present study was conducted at a rural based tertiary care teaching hospital at Udaipur district of Rajasthan. A population of 1011 pregnant women age ranging from 15-45 years attending Antenatal clinic was involved in the study. Individuals were interviewed by structured questionnaire including data regarding obstetric history, previous HBV vaccination, HBsAg status of self and spouse and the associated risk factors of infection were also asked.

Laboratory Assay: About 2 ml of venous blood was collected from each individual after obtaining a written consent under strict aseptic precautions. Rapid immunochromatography test (HEPA card) was employed to detect the presence of HBsAg. For confirmation, blood samples tested positive for HBsAg were subjected to commercially available fourth generation ELISA (Enzyme Linked Immunosorbent Assay) Kit Hepalisa by J. Mitra & Co. Pvt. Ltd with antigen sensitivity 0.1ng/ml was used. Manufacturer's instructions were followed during the entire test procedure.

RESULTS

A total of 1011 pregnant women attending antenatal clinic in a tertiary care hospital, were studied. All the women were asymptomatic and were unaware of Hepatitis B status. The subject age ranges from 15-45 years. The seroprevalence of HBsAg positivity in this current study was 1.28% among 1011 participants 13 women tested positive for HBsAg. Age distribution and HBsAg screening tests were given in Table1. In statistical analysis, the p-value obtained was >0.05 (statistically insignificant). The distribution of trimester of pregnancy and HBsAg screening results were given in Table 2. The p value obtained was >0.05 which is statistically insignificant. Analysis of age distribution of HBsAg positive women revealed a high prevalence (1.71%) among 15-25 years majority of them were primigravidae in second trimester of pregnancy. Associated risk factors distribution among HBsAg positive women was shown in Table 3.

Table 1:- Age wise distribution and HBsAg status (n=1011)

Age	Number tested	HBsAg positive	HBsAg negative
15-25	364	6(1.64%)	358 (98.35%)
26-30	384	4 (1.04%)	380 (98.95%)
31-35	208	3(1.44%)	205 (1.44%)
36-40	47	0	47(100%)
41-45	8	0	8(100%)
Total	1011	13	998

Table 2:- HBsAg seropositivity in different trimesters of pregnancy (n=1011)

Trimesters	No of Pregnant women	HBsAg positive (%)
First	243	3 (1.23%)
Second	467	8(1.71%)
Third	301	2 (0.66%)

Table-3 Risk Factors observed in HBsAg Positive women (n=13)

Risk Factors	No of ANC
History of Blood Transfusion	3(23.07%)
Previous Surgeries	2 (15.38%)
HIV status	0
Tattooing	4 (30.76%)
Piercing	13(100%)

DISCUSSION

The prevalence of HBsAg varies widely in different parts of the India. The variety of socioeconomic status of the population studied, genetic factors, and other risk factors contribute to the variance of seroprevalence rate. The prevalence of HBsAg positivity in pregnant women has been reported to range from 2.61-6.3% in various studies.[9-12] In our study, the overall seroprevalence of HBsAg positivity in pregnant women 1.28%, was in accordance with a seroprevalence of 1.1% reported by Pande et al[13] and also comparable to the seroprevalence 1.15% by Ambade et al.[14] Dwivedi et al[15] study shows the declining seroprevalence of HBsAg 0.91. Few other studies from India by Chatterjee et al[16] (0.82%) and Shazia Parveen S. et al[17](0.61%), the seroprevalence rate reported were lower than the present study. Other studies from India as carried out by Mittal et al,[18] Gill et al,[19] Nayak et al,[20] and Khakhkhar Vipul et al,[21] reported higher seroprevalence rate of 6.3%, 5%, 3.7% and 3.07% respectively in comparison of our study. Also, the seroprevalence of HBsAg among pregnant women in our study can also be comparable with 1.6%, 1.47% and 1.37% as reported in some countries respectively like Saudi Arabia,[22] Turkey[23] and Pakistan.[24] Regarding age, in the present study, high HBsAg seropositivity rate in pregnant women was found in age group of 15-25 years (1.64%) in agreement with Ambade et al, Dwivedi M et al and Khakhkhar Vipul et al, and smita Thakkarwad et al.[25] In our study highest seroprevalence of HBsAg positivity was found in second trimester 1.71%. This was with comparable studies of Padmavati Palange et al[23] and Mehta et al[26] and variance with the findings from similar works, Dwivedi M et al and Khakhkhar Vipul et al, and smita Thakkarwad et al.[25]

CONCLUSION

This study provides necessary information to detect the risk factors to formulate necessary preventive measures. The HBsAg seropositivity rate of 1.28% in pregnant women in this study recommends and supports an appropriate antenatal screening, so that the vertical transmission of Hepatitis B virus infection can be avoided. Public health policies should include routine universal screening of HBV infection and immunization of risk infants immediately after birth.

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Original Article

Antimicrobial Resistance Pattern of Bacterial Isolates from Endotracheal Aspirate of Ventilated Patients at a Tertiary Care Hospital

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ABSTRACT

Background: *Respiratory infections among critically ill Patient are associated with high morbidity and mortality. Mechanically ventilated patients are at a high risk of acquiring respiratory infections due to complex interplay between the endotracheal tube, host immunity and virulence of invading bacteria. Irrational use of antibiotics increases the emergence of drug – resistant bacteria.* ***Objectives:*** *The aim of study was to investigate the bacterial isolates in the endotracheal aspirates of mechanically ventilated patients in ICU and see the antimicrobial resistance pattern of bacterial isolates.*

Methods: *Analysis of E.T aspirates of 459 patients over a period of 1 year (Aug 14 to Aug 15) was done. Aspirates were cultured on Blood and MacConkey agar isolation and identification was done using conventional techniques and biochemical reactions. Antibiotic sensitivity testing was done by Kirby-Bauer disc diffusion method as per CLSI guidelines.* ***Results:*** *Out of 459 Samples 365 was found to be positive. Acinetobacter sp (44.65%) was the most common isolate followed by Klebsiella sp (18.63%), Pseudomonas sp (11.23%), Candida (10.46%), Escherichia Coli (7.94%), COPS (3.28%), CONS (2.46%), Enterococci (0.82%), and Citrobacter (0.54%). The gram-negative bacilli were mostly sensitive to Tigecycline, Colistin, Imipenem, Meropenem, Amikacin and Piperacillin/Tazobactam. Gram positive Cocci were mostly sensitive to Vancomycin, Linezolid and Gentamicin.*

Conclusion*: The isolation and antimicrobial resistance pattern of the microorganisms is necessary for their effective management. Endotracheal intubation is one of the major risk factors in causing iatrogenic infections to patients. A local antibiogram for each hospital, based on bacteriological patterns and susceptibility is essential to initiate empirical therapy.*

Keywords: *Endotracheal aspirates, ventilated patients, antibiogram of bacterial isolate*

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INTRODUCTION

Mechanical ventilation is a life-saving procedure for many patients in intensive care unit. Patients who are intubated and mechanically ventilated are further at a high risk of acquiring respiratory infections due to complex interplay between the endotracheal tube, host immunity and virulence of invading bacteria which may lead to ventilator associated pneumonia (VAP).Tracheal colonization of different bacteria may be responsible for added or super infections and at the same time, increases the risk of mortality[1]. The etiological agents may vary according to the population of patients in ICU, duration of hospital stay, pre-existing and prior antimicrobial therapy.

To add to the trouble, the statistical data and evidences from research prove that multi drug resistance bacteria are rapidly emerging across the world and pose a big challenge to health care system. Extensive and non-specific use of broad-spectrum antibiotics in hospitalized patients has led to both increased carriage and the development of multi drug resistant strains.[2] Multi drug resistance bacteria cause serious nosocomial and community acquired infections that are hard to eradicate. One must use existing antibiotics skillfully and more judiciously. It is difficult to manage these infections effectively unless we are armed with adequate and good quality data about the antibiotics susceptibility pattern of organisms causing respiratory infections among mechanically ventilated patients in intensive care unit. To be more effective this data has to be region specific and also

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has to be updated regularly as bacterial susceptibility varies with time and space. Unfortunately, such data is scanty, and this has led to a wide spread of mortality and morbidity due to respiratory infections. Therefore, updated knowledge of local epidemiology and susceptibility profile is recommended for guiding the clinicians regarding empirical choice of antibiotics and should become mandatory along with adequate clinical diagnosis and bacterial confirmation.[3]

Hence, the study was planned to identify pattern of bacterial isolates responsible for respiratory tract infections among mechanically ventilated patients at intensive care unit and to make their antimicrobial resistance pattern.

Aims & Objectives:

1. To study the microorganism's profile in the ICU during the study period in endotracheal tube culture.
2. To study the antibiotics to which these microorganisms are susceptible.
3. To propose a proper empirical antibiotic therapy in intubated patients according to prevalence of microbiological organisms in ICUs.

METHODS

The prospective study was carried out with the samples of endotracheal aspirates and endotracheal tube tip received from ICUs in the microbiology laboratory over a period of one year (Aug-2014 – Aug-2015). Samples were collected under sterile conditions from patients admitted in both medical and surgical intensive care unit who were ventilated for at least 48 hrs.

Collection of Specimen:

Endotracheal Aspirate: Sampling was done by introducing a catheter aseptically through the endotracheal tube and secretions aspirated into a sterile syringe.

Endo-tracheal tube tip: The endo-tracheal tube tip was cut aseptically into a sterile container and sent to the Microbiology laboratory.

Processing of Specimen:

Endotracheal Aspirate*:*

Both 10µl of the specimen and 1 µl of the specimen was inoculated in blood agar and MacConkey agar.

Endotracheal tube tip: The lumen of endotracheal tube tip was rinsed with 0.5 ml of sterile normal saline. 10µl of the fluid was inoculated on blood agar and MacConkey agar. A gram's stain of the endotracheal secretions / endotracheal tube tip fluid was done to assess the number of pus cells and the presence of bacteria. A semi quantitative method was followed, and plates were incubated overnight at 37°C.13. The organisms isolated were identified based on colony characteristics on Blood agar and MacConkey agar, Gram's stain, Biochemical reactions by using standard microbiological techniques. Isolates identified as commensals or contaminants were excluded from further process. A Kirby-Bauer method was used to test the susceptibility of organisms to various antibiotics. As per Clinical and Laboratory Standards guideline (2014).[4]

Antibiotics used:

Ampicillin/Sulbactam (AS-10/10µg), Cefuroxime (CXM-30µg), Cefoxitin (CX-30 µg), Ceftriaxone(CTR-30µg),Vancomycin (VA-30µg), Linezolid (LZ-30µg), Piperacillin/Tazobactam (PIT-100/10µg), Ceftazidime/Clavulanic acid (CAC-30µg/10µg), Cefotaxime/Sulbactam (CFS-5/30µg), Cefepime (CPM-5µg), Ceftriaxone (CTR-30µg),Gentamicin (GEN-10µg), Amikacin (AK-30µg), Aztreonam (AT-30µg),Azithromycin- AZM-15 µg), Ciprofloxacin (CIP-5µg), Levofloxacin-(LE5µg), Amoxicillin/Sulbactam (A/S-30µg), Imipenem (IMP-10µg), Colistin (CL-10µg), Meropenem (MRP- 10µg), Polymyxin B (PB-300U), Tigecycline (E- strip).Zone diameter was measured and interpreted as per the Clinical and Laboratory Standards Institute(CLSI) guidelines (2014)[4].

RESULTS

A total of 459 samples were collected from 459 patients during the study period of one year. Out of 459, 94 samples were either sterile or were polymicrobial growth which were not processed further for the study. Among 365, 184 samples (50.4%) were of male and rest were of female181 (49.58%). The organism isolated were *Acinetobacter sp*. 163 (44.65%), *Klebsiella sp* 68 (18.63%), *Pseudomonas sp* 41 (11.23%), *Escherichia Coli* 29 (7.94%), *Candida* 38 (10.41%), *Coagulase Positive staphylococcus aureus* (COPS)12 (3.28%), *Coagulase Negative Staphylococcus aureus* (COPS) 9 (2.46%), *Enterococci* (0.82%), and *Citrobacter* 02 (0.54%)

Acinetobacter was the most resistant of all other isolates. It was sensitive to Tigecycline (98.15%), Colistin (96.9%0, Meropenem (94.4%), Imipenem (92.02%), followed by Amikacin 36.80%, Levofloxacin 30.6%, Piperacillin/Tazobactam (25.7%), Ciprofloxacin 25.15%. (table-2).

Table 1: Micro-organisms isolated and percentage (n=459)

Micro-organisms	%
Acinetobacter sp	163(44.65%)
Klebsiella sp	68(18.63%)
Pseudomonas sp	41(11.23%)
Candida	38(10.46%)
Escherichia Coli	29(7.94%)
Citrobacter	2(0.54%)
Coagulase Negative Staphylococci (CONS)	9(2.46%)
Coagulase Positive Staphylococci (COPS)	12(3.28%)
Enterococci	3(0.82%)
No growth	94
Total	459

All isolates of Pseudomonas sp were sensitive to Imipenem 100%, Meropenem 100%, Tigecycline 100%, Colistin 100%, Polymyxin-B 100%, followed by Amikacin 68.2%, Piperacillin/ Tazobactam 68.2, Levofloxacin 56.09%. (table-2).

All Klebsiella sp were 100% sensitive to Tigecycline and Colistin followed by Imipenem 86.76%, Meropenem 88.2%, Levofloxacin 23.5%, Amikacin 35.29%, Piperacillin/Tazobactam 19.11, Ciprofloxacin 11 (16.17%). Other drugs were 7.3% sensitive were highly resistant with sensitivity of 7.3% (Ceftazidime/ C.A, Cefotaxime/ Sulbactam, Cefepime, Ceftriaxone) (table-2).

Similarly, all strains of Escherichia Coli were 100% sensitive to Tigecycline and Colistin only. Followed by Imipenem

89.6%, and Meropenem 89.6%, followed by Amikacin 79.3%, Piperacillin/ Tazobactam 68.9%, Levofloxacin 41.3%, Ciprofloxacin 34.4% (table-2.)

Only two isolates of *Citrobacter* were found which were 100% sensitive towards Amikacin, Piperacillin/Tazobactam, Imipenem, Tigecycline, Colistin, Meropenem.

In case of Gram positive bacteria all 12 (3.28%) COPS were 100% sensitive towards Vancomycin and Linezolid, followed by Gentamicin 78%, Fluoroquinolones as 41.6%, followed by Amoxicillin/Clavulanic acid and Ampicillin / Sulbactam and Cotrimoxazole 33.3%,each , other cephalosporins , (Cefuroxime, ceftizoxime, ceftriaxone, cefixime and cefoxitin) as 25% sensitive only.(Table-3)

CONS isolates were 100% sensitive towards Vancomycin and Linezolid, followed by Gentamicin 77.7%, Levofloxacin 55.5% Cotrimoxazole 33.3%) followed by other cephalosporins and Ciprofloxacin as 22.2% sensitive. (Table-3)

Enterococci show 100% sensitivity towards Vancomycin, Amoxicillin/ C.A, Ampicillin/ Sulbactam and linezolid and Gentamicin.

Table- 2 Antibiotic Sensitivity pattern of Gram-negative Clinical isolates

Organism/Antibiotics	Klebsiella sp n = 68	Acinetobacter sp n = 163	Pseudomonas sp n = 41	Escherichia Coli n = 29	Citrobacter n = 2
Amikacin	24(35.29%)	60(36.80%)	28(68.2%)	23(79.3%)	2(100%)
Piperacillin/Tazobactam	13(19.11%)	42(25.7%)	28(68.2%)	20(68.(%)	2(100%)
Ciprofloxacin	11(16.17%)	41(25.15%)	20(48.7%)	10(34.4%)	0
Levofloxacin	16(23.5%)	50(30.6%)	23(56.09%)	12(41.3%)	0
Imipenem	59(86.76%)	150(92.02%)	41(100%)	26(89.6%)	2(100%)
Tigecycline	68(100%)	160(98.15%)	41(100%)	29(100%)	2(100%)
Colistin	68(100%)	158(96.9%)	41(100%)	29(100%)	2(100%)
Meropenem	60(88.2%)	154(94.4%)	41(100%)	26(89.6%)	2(100%)
Ceftazidime/Clavulanic acid	5(7.3%)	0	18(43.9%)	9(31.03%)	0
Cefotaxime/Sulbactam	5(7.3%)	0	18(43.9%)	9(31.03%)	0
Cefepime	5(7.3%)	0	18(43.9%)	9(31.03%)	0
Ceftriaxone	5(7.3%)	0	18(43.9%)	7(24.13%)	0
Polymixin-B	ND	ND	41(100%)	ND	ND
Ampicillin/ Sulbactam	ND	ND	ND	11(37.9%)	ND

DISCUSSION

To prevent or combat respiratory failure, life- saving procedures are done on emerging or elective basis such as endotracheal intubation and mechanical ventilation. Many clinical conditions warrant need for ventilated support like life threatening infections, sepsis in acute respiratory distress syndrome, neurological dysfunction due to poisoning drug toxicity, cerebrovascular accidents, traumas and others. Mechanical Ventilation helps to prevent deaths due to respiratory failure but on the other hand it possess great threat, by host immune response and infectious organisms that lead to life threatening lung infection.[5] Mechanically ventilated and tracheotraumatized patients are colonized with bacteria of either endogenous or exogenous origin which might end up in Vat or VAP.[6] Healthcare associated infections continue to be a major cause of patient morbidity and mortality in ICUs.

The various organisms were isolated and cultured from these samples and their susceptibility testing was done according to clinical and Laboratory standard Institute guidelines (CLSI)[4] with the intention of assessing the discriminative prevalence of various common bacteria and to identify the local prevalent antibiotic response against the detected pathogens.

Table-3 Antibiotic susceptibility pattern of Gram-positive clinical isolates

Antibiotics	COPS	CONS	Enterococci
Total Strains	n = 12	n = 9	n = 3
Gentamicin	9(78%)	7 (77.77%)	3(100%)
Cefuroxime	3(25%)	2(22.2%)	0
Ceftozoxime	3(25%)	2(22.2%)	0
Ceftriaxone	3(25%)	2(22.2%)	0
Cefixime	3(25%)	2(22.2%)	0
Vancomycin	12(100%)	9(100%)	3(100%)
Azithromycin	3(25%)	2(22.2%)	0
Amoxcillin +Calvulanic Acid	4(33.3%)	2(22.2%)	3 (100%)
Ampicillin/Sulbactam	4(33.3%)	2(22.2%)	3 (100%)
Ciprofloxacin	5(41.6%)	2(22.2%)	0
Levofloxacin	5(41.6%)	5(55.5%)	0
Cotrimoxazole	4(33.3%)	3(33.3%)	0
Linezolid	12(100%)	9(100%)	3(100%)
Cefoxitin	3(25%)	2(22.2%)	0
Penicillin	2(22.2%)	5(55.5%)	0

Our study showed 80% growth from endotracheal aspirates which are concurrent with the study of Bhaskar Thakuria et al[7]. who has reported 85% growth and V.R. Rathod et al[8] who also has also reported 85% of endotracheal aspirate growth. Another study of Santosh Khanal et al[9] Ada Siler Junior et al.[10] and Koirala et al[11]have variable growth rate of (78-92%). Another Study by Kartik S.L. et. al.[12] gave a lower growth rate of 70.07%.

As far as the bacterial profile is concerned out of 365 isolates, 303 (83.47%) were gram negative bacterial isolates (GNB) and only 22 (6.06%) were GPC, similar findings has been quoted by V.S. Rathod et al[8] in which 80% were GNB, 20% were GPC. Our study correlates with many studies and particularly as shown in one systemic review article by Yaseena Arabi et al[13] were GNB range from 41 to 92%, GPC between 6-58%. In our study 38 (10.41%) isolates were fungus whose DST was not followed as our aim of study was to chart out antibiotic susceptibility profile of the bacterial isolates only.

In our study bacterial isolates identified are *Acinetobacter sp.* 44.65%, *Klebsiella sp* 18.63%, *Pseudomonas sp.* 11.23%, *Escherichia Coli* 7.94%, *Citrobacter* 0.54%,. Similar findings were reported by Priya Santharam et. al.[14] Acinetobacter followed *Pseudomonas, klebsiella pneumonia*. Non fermenter gram negative bacilli, Escherichia Coli and then *Citrbacter*. Our study also coincides with study conducted by N. Shanmuga vadivoo et. al.[15] that *Acinetobacter* has over taken the pathogenic role in ventilated patients.

V.S. rathod et al[8] quoted *Klebsiella pneumonia* as the most common isolate followed by *pseudomonas aeriginosa* and *Acinetocabter baumannii*, in his study which coincides with vadivoo et al[15] which reported *Klebsiella* followed by *Acinetobacter* and *Pseudomonas*. Also, Shilpi Dhakar et. al.[16] detected *Klebsiella* as most common pathogen followed by *Pseudomonas, staphylococcus*, *Acinetobacter* and *Escherichia Coli* with small number of *enterobacter*, and *streptococcus.* Such contrast can be due to discriminative prevalence due to the change in the demographic region of all studies conducted.

Among GPC, in our study 3.28% were COPS, 2.46% CONS and 0.821% were Enterococci isolates which is in similarity to the findings of V.S. Rathod et al [8] were GPC contributed to 6% among micro-organisms isolates. Priya Santharam et al[14] figured out 8% *Staphylococcus aureus* and were as Dipti Chandra et. al.[17] also reported 8.82% of *Staphylococcus aureus.*

In our study *Acinetobacter* was found to be the most predominant bacteria which shows high resistance towards penicillin, cephalosporins (ceftazidime and cefepime), intermediate sensitivity for aminoglycoside (Amikacin as 36.80%) followed by fluoroquinolones (Ciprofloxacin and Levofloxacin). *Acinetobacter sp* were highly sensitive towards carbapenems (Imipenem 92.02%, Meropenem 94.4%) followed by Colistin 96.9% and Tigecycline 98.15%. 40 (24.53%) strains of *Acinetobacter sp* was multidrug resistant.

Sensitivity pattern of *Klebsiella sp.* shows high resistance towards cephalosporins. Intermediate sensitivity towards Amikacin 35.29%, 23.5% for levofloxacin and 16.17% for Ciprofloxacin. Carbapenems shows 88.2% sensitivity. Most sensitive drugs against *Klebsiella sp* were Tigecycline and Colistin as 100% each. 44(64.70%) strains of *Klebsiella sp* were multi drug resistant[18]

In our study *Pseudomonas sp* shows high sensitivity pattern towards Tigecycline 100%, Colistin 100%, Meropenem 100%, Imipenem 100%, Polymixin B 100%, followed by Amikacin 68.2%, and combination Piperacillin/ Tazobactam 68.2%. Cephalosporins gave 43.9% sensitivity for pseudomonas. Flouroquinolones were also intermediate sensitive for Pseudomonas (Levofloxacin 56.09% and Ciprofloxacin 48.70 %.)

Tigecycline and Colistin were 100% sensitive for *Eschericha Coli* followed by Carbapenems (Imipenem and Meropenem 89.6% each). Amikacin has also significant sensitivity pattern for *Escherichia Coli* 79.3% followed by combination of Piperacillin/Tazobactam. Levofloxacin has lesser senstivity 41.3% and Ciprofloxacin 34.4%. All specimens show a great resistance towards cephalosporins with a sensitivity pattern of 24.13%.

Few species of *Citrobacter* were isolated which were highly sensitive towards Amikacin, Piperacillin /Tazobactam, Imipenem, Meropenem, Colistin, Tigecycline as 100% sensitive. But all were resistant towards flouroquinolones and cephalosporins.

In case of *COPS, CONS* and *Enterococci* all isolates were found 100% sensitive towards Vancomycin and Linizolid followed by Gentamicin,(78%) Flouroquinolones 41.6%, combination of Amoxicillin/C.A 33.3% /22.2% respectively and Ampicillin /Sulbactam 33.2%/ 22.2% respectively. 9 (75%) strains were identified as Methicillin resistant *Staphylococcus aureus*. Gram positive organisms of E.T. aspirates in our ICU set up were mostly resistant to penicillin derivatives and cephalosporins.

CONCLUSION

The study reveals that the antibiotic susceptibility pattern varies across region and timeline and hence studies examining the local susceptibility pattern should be carried out at every centre. Endotracheal Intubation is a major risk factor in causing iatrogenic infections to patient which leads to an increase in the morbidity and mortality. Our study reported a high percentage resistance among gram negative bacilli to cephalosporins. Aminoglycosides (Amikacin), and a combination of Piperacillin/Tazobactam were found to be moderately effective. Carbapenems, Colistin and Tigecycline were found to be most effective drug of choice.

For gram positive bacterial isolates shows significantly high resistance for penicillin and cephalosporin. 75% MRSA strains were also indentified. Vancomycin and linezolid were found to be most sensitive followed by Aminoglycoside (Gentamicin).

From present study we have concluded that analyzing the E.T aspirate was important as the sensitivity to the antibiotic obtained, is an alarming factor for efficacious and judicious use for antibiotics. This study will help us in implementing different antibiotics prophylactically with regard to the commonly obtained sensitivity pattern.

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