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Contents

ORIGINAL ARTICLE

- A Prospective Randomized Double-Blind Study Comparing Intrathecal Dexmedetomidine and Fentanyl as Adjuvants to Bupivacaine in Infra Umbilical Surgeries
Venkanna Pocham, L Giridhar Naik 1
- Comparative Analysis of Anti Versus Probiotic in Patients with Irritable Bowel Syndrome
Vinod Mitla, Surinder Sharma, Syed Arshad Mustafa, Mohd. Ismail 15
- Do Migrants Differ in Knowledge Regarding Mosquito-Borne Diseases and Mosquitoes?
Sankalp Raj Choudhary, Mohmmedirfan H Momin, Anjali Modi 19
- Surgery for Carcinoma of Esophagus Pyloroplasty - Is it a Boon or Bane to the Patient?
Benet Duraisamy, Saravana Boopathy, Siva Shankar, S M Chandramohan, Heber Anandan 24
- Comparison of Sucralfate, Silver Sulfadiazine, and Chlorhexidine Gluconate in Open Versus Close Partial Thickness Burn Dressing: A Comparative Study
MD Shabbirul Islam, Biswajit Mukhopadhyay, Indranil Chatterjee, Ajay Kumar Das, Manoranjan Ghosh, Biswajoy Ray 28
- Effect of High Altitude on Cardiovascular Parameters among Permanent Natives of Ladakh
Anjum Batul 31
- A Study of Duodenal Ulcer Perforation Post-operative Outcome in A Tertiary Center
S Senthil Arumugam, G Parthiban, A Ramprasad, Heber Anandan 38
- Mandibular Ramus: An Indicator for Gender Determination - A Digital Radiographic Study
Neeru Pangotra, Altaf Hussain Chalkoo, Nahida Dar 42

Evaluation of Sexual Dysfunction in Lower Urinary Tract Symptoms/Benign Prostatic Hyperplasia Patients <i>N. Narayanamoorthy, K. Arunprasad</i>	46
Idiopathic Granulomatous Mastitis - Diagnostic and Therapeutic Dilemma <i>S G Subramanyam, H Raja, R Gayatri, Bincy Zacharia</i>	51
Ocular Changes in Pregnancy: An Observational Study <i>Nanda L. Shivkumar, B M Rupakala, Sukriti Agrawal</i>	56
Trabeculectomy: A Follow-up Study of 120 Cases in Terms of Intraocular Pressure <i>Abdul Aziz Makayee, Nilofar Nazir, Maroof Nabi, Nahida Bashir</i>	59
Effects of Perioperative Hyperoxygenation on Surgical Site Infection in Patients with Acute Appendicitis <i>P Harsh, P Vijaya, K Hemanth, K Vijayakumar, R Surekha</i>	63
A Retrospective Study of Clinical Profile of Acute Poisoning in a Tertiary Care Teaching Hospital in Kerala, India, during 2014–2016 <i>Vibha C Santosh, Omana Menon</i>	67
Endometrial Biopsy: Need of Present Time in the Management of Abnormal Uterine Bleeding <i>Preeti Baghel, Vaidehi Tambi, Manju Sharma, Seema Mehta</i>	72
A Study of Modified Alvarado Score and Rovsing's Sign in Diagnosis of Acute Appendicitis <i>Gandla Anil Kumar, B Nagendar</i>	80
Assessment of Nutritional Status of Primary School Children through Anthropometric in Rural Practice Area of IGIMS, Patna: A Cross-Sectional Study <i>Birendra Kumar Rajak, Sanjay Kumar Choudhary, Sanjay Kumar</i>	83
Patterns of Restricted Diffusion within Corpus Callosum in Neonatal Hypoxic-Ischemic Encephalopathy and its Significance in Predicting the Clinical Outcome <i>Alle Praveen Kumar, Nadeem Ahmed, Uzma Afreen</i>	90

Radio-pathological Factors that Predict the Surgical Outcome of Ossification of <i>Ligamentum flavum</i> of Spine – Series of 31 Cases <i>John Christopher, Chockaiah Raja, Heber Anandan</i>	96
A Study to Show Postprandial Hypertriglyceridemia as a Risk Factor for Macrovascular Complications in Type 2 Diabetes Mellitus <i>Srinivas Bingi</i>	102
Study of Lipid Profile in Patients with Chronic Kidney Disease on Conservative Management and Hemodialysis <i>K Rajani Kumari</i>	108
Hyperuricemia as a Prognostic Marker in Acute Ischemic Stroke <i>Bingi Srinivas</i>	114
A Clinical Study of Plasma Fibrinogen Level in Ischemic Stroke <i>B Balaji, B Bingi Srinivas</i>	120
A Study on the Clinical and Laboratory Profile of Patients Having Thrombocytopenia in Pediatrics <i>L Venkatraman, C Baskar, Heber Anandan</i>	126
Behavioral and Emotional Changes among Adolescent Populace <i>Pradeep Rajan Sundara Rajan, Saranya Nagalingam, Balaji Arumugam</i>	131
Perception, Promotion, and Practice of Healthy Eating and Physical Activity among Primary School Teachers in Sokoto, Nigeria <i>Kehinde J Awosan, Usman E Yunusa, Usman M Illo</i>	135
Comparative Study of Unilateral Laminotomy versus Conventional Laminectomy <i>Rohit Thaker, Nishat Goda, Virendra Agrawal, Ram Chaddha</i>	143
Comparative Study of Effectiveness of Short Course versus Long Course Antimicrobial Prophylaxis after Clean Orthopedic Surgery - A Prospective Study of 200 Patients <i>Nishat Manherlal Goda, Dhaval Gordhanbhai Peshivadia</i>	149

Study of Incisional Hernia in Relation to Specific Risk Factors

V. Nagaraju, Goparaju Shanti Kumar, K. Geethanjali

155

Comparative Study of the Effectiveness of Three Techniques of Insertion of Proseal Laryngeal Mask Airway in Adults Posted For Elective Surgery

Poulami Choudhury, Veena Kachhwah, Saikat Sengupta, Subhabrata Pal, Neeraj Narang

159

REVIEW ARTICLE

Demographic Corelation of Fibro-osseous Lesions Prevailing in Uttar Pradesh - A Review

Reshna Roy, Dipanjal Saikia, Jahnobi Dutta, Arpita Kashyap, Bonita Doley

165

CASE REPORT

Aneurysmal Bone Cyst Mimicking Ameloblastoma: A Rare Case Report

Reshna Roy, Jahnobi Dutta, Sherin Nair, Neelutpal Bora

169

A Rare Case of Bilateral Adrenal Hemorrhage

B Divya, K Vengadkrishnan, K Vasanthan, M Sudha

172

Varied Presentations and Management of Symptomatic Meckel's Diverticulum

Noor Mohammad Shawnas Bahnou, H Raja

174

A Prospective Randomized Double-Blind Study Comparing Intrathecal Dexmedetomidine and Fentanyl as Adjuvants to Bupivacaine in Infra Umbilical Surgeries

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Abstract

Background: Regional anesthesia is the preferred technique for most of lower abdominal and lower limb surgeries as it allows the patient to remain awake and minimizes or completely avoids the problem associated with airway management. Hyperbaric bupivacaine 0.5% is extensively used for spinal anesthesia. Fentanyl is a synthetic lipophilic opioid commonly used for post-operative analgesia. Dexmedetomidine, a new highly selective α_2 -agonist, used intrathecally produces prolonged post-operative analgesic effect with hyperbaric bupivacaine in spinal anesthesia with minimal side effects. The present study was designed to evaluate the effects of 5 μ g of dexmedetomidine as an intrathecal adjuvant to compare with the intrathecal 25 μ g of fentanyl with 0.5% bupivacaine (heavy).

Aim of the Study: The present study was designed to evaluate the effects of 5 μ g of dexmedetomidine as an intrathecal adjuvant in comparison with intrathecal 25 μ g of fentanyl along with 3 ml of 0.5% bupivacaine (heavy) in regard to post-operative analgesia and side effects.

Materials and Methods: A prospective randomized double-blind study on 100 patients was conducted by dividing them into two groups Group F: 3 ml of 0.5% hyperbaric bupivacaine and 25 μ g fentanyl and Group D: 3 ml of 0.5% hyperbaric bupivacaine and 5 μ g of dexmedetomidine used intrathecally during spinal anesthesia for sub umbilical surgeries; the patients of ASA I and II Grades. The onset of sensory block, motor blockade, onset of analgesia, and the duration of analgesia between the groups were observed. Parameters such as systolic blood pressure, diastolic blood pressure, heart rate, SpO₂, mean arterial pressure, and development of other side effects were observed. All the data were analyzed using standard statistical methods.

Observations and Results: The patients of both the groups were identical in terms of their age groups, gender incidence, and weight and height parameters. The basal values of systolic pressure, diastolic pressure, mean arterial pressure, and SpO₂ were similar in both the groups. Both group patients were belonging to ASA I and II types. Comparison of onset time (T₁₀), highest sensory level was compared in both the groups and the data were significant statistically with $P < 0.001$ (P significant at < 0.05). Comparison of time of onset of motor blockade were compared in both the groups and was found that the onset of motor blockade was comparable in both the groups, but the duration of the motor blockade was statistically significant with $P < 0.001$. Post-operative analgesia was better in Group D as per the visual analog scale ratings.

Conclusions: 5 μ g dexmedetomidine seems to be an attractive alternative to 25 μ g fentanyl as an adjuvant to spinal bupivacaine in surgical procedures. It provides good quality of intraoperative analgesia, hemodynamically stable conditions, minimal side effects, and excellent quality of post-operative analgesia.

Key words: Adjuvant, Anesthesia, Bupivacaine, Dexmedetomidine, Fentanyl and analgesia, Spinal anesthesia

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INTRODUCTION

The selection of different drug combinations and suitable doses used as adjuvants with local anesthetics is a critical process and signifies the consideration of factors such as the formation and duration of sensory and motor block, the quality, and duration of post-operative analgesia.^[1] Over

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the years, many drugs have been used intrathecally as an adjuvant to local anesthetics to prolong the intraoperative as well as post-operative analgesia with variable effects.^[2] Dexmedetomidine is a new and more selective α_2 receptor agonist with higher sedative and analgesic effects. Dexmedetomidine provides stable hemodynamic conditions, good sedation, and good quality of intraoperative and prolonged post-operative analgesia with minimal side effects.^[3] Korhonen *et al.*,^[4] in 2003, in their double-blind study of 100 patients undergoing knee arthroscopy, received randomly either 4 mg of bupivacaine (B4) or 3 mg of bupivacaine with fentanyl (B3F) intrathecally. They concluded that a combination of local anesthetic and opioid enables the use of less spinal anesthetic and increases the success of anesthesia; addition of small dose of fentanyl does not prolong motor recovery and thus shortens PACU time. A Gupta *et al.*,^[5] in 2003, in their comparative study of intrathecal 6 mg and 7.5 mg of bupivacaine with addition of fentanyl 110 μ g administered to 40 patients undergoing inguinal herniorrhaphy. They found that no difference was seen in spread, duration, and regression of sensory block between the groups. The time to mobilization and discharge were similar, but return of motor block was earlier with low dose group. They concluded that spinal anesthesia with 7.5 mg bupivacaine plus fentanyl 10 μ g offers an alternative to general anesthesia or local anesthesia for ambulatory herniorrhaphy. Kararmaz *et al.*,^[6] 2003, evaluated the effects of low dose bupivacaine plus fentanyl administered intrathecally in elderly patients undergoing transurethral prostatectomy. This study showed that addition of fentanyl to local anesthetic provides adequate analgesia with few side effects. Motor block was higher and duration was prolonged.^[7] Pruritus is a frequent complication of intrathecal fentanyl. Asokumar *et al.*,^[8] 1988, in their study administered intrathecal fentanyl 25 μ g with bupivacaine 2.5 mg in laboring parturient. They found that addition of fentanyl to intrathecal bupivacaine 2.5 mg attenuates the frequency of pruritus on all parts of the body except the face. This combination also resulted in rapid and prolonged duration of labor analgesia compared with either drug alone.^[9] Belzarena,^[10] 1992, assessed the clinical effects of intrathecal fentanyl in patients undergoing cesarean section with varying doses. He concluded that the combination of bupivacaine and low dose fentanyl (25 μ g) provides excellent surgical anesthesia with short lasting post-operative analgesia and few side effects. Kuusniemi *et al.*,^[11] 2000, evaluated the effects of 25 μ g of fentanyl added to varying doses of bupivacaine, on sensory and motor block. Addition of fentanyl 25 μ g to low dose bupivacaine 5 mg resulted in short motor blocks whereas 25 μ g fentanyl with bupivacaine 10 mg increased the intensity and duration of motor block. Singh *et al.*,^[12] investigated the effect of intrathecal fentanyl 25 μ g on the onset and duration of

bupivacaine 13.5 mg induced spinal block in adult male patients who underwent urological procedures. Addition of fentanyl to local anesthetic prolongs the duration of sensory block and reduces the analgesic requirement in the early post-operative period. Akerman *et al.*,^[13] undertook a study to compare in mice the antinociceptive effect of intrathecal injection of the mixture of morphine with bupivacaine or lidocaine. The results indicate the potentiating effects of local anesthetic on spinal opioids anti-nociception, a finding that has an important clinical implication. Administration of epidural and intraspinal opioids may provide excellent post-operative analgesia, but a minority of patients will suffer from respiratory depression. Etches *et al.* studied shows the effects of respiratory depression following intrathecal opioids administration.^[14] Echevarría *et al.*,^[15] 1995, conducted a study to compare the hemodynamic effects, level of anesthetic block and advantages at a single dose versus continuous intrathecal anesthesia with hyperbaric bupivacaine with or without fentanyl. They concluded that single dose intrathecal anesthesia produces less hemodynamic changes than a continuous intrathecal block. Reuben *et al.*,^[7] 1994, evaluated the dose-response effect of intrathecal fentanyl in elderly patients undergoing lower extremity revascularization procedure. Postoperatively after complete regression of anesthesia, patients received through spinal catheter either 0, 5, 10, 20, 40, or 50 μ g fentanyl. They concluded that 40 μ g of intrathecal fentanyl provided satisfactory analgesia for approximately 5 h in elderly patients with a low incidence of side effects. Rust *et al.*,^[9] conducted a study to examine whether intrathecal opioids such as fentanyl, morphine for labor analgesia offer adequate, and cost-effective alternative to epidural analgesia with minimal side effects. They found this technique offered an excellent and cost-effective alternative to epidural analgesia. Addition of fentanyl to bupivacaine administered for spinal anesthesia for cesarean delivery was evaluated by Hunt *et al.*,^[16] 1989. Analgesia produced by fentanyl in a dose of 6.25 μ g with bupivacaine 10 mg was satisfactory and did not require intraoperative opioids. Increasing the dose of fentanyl above 6.25 μ g did not further increase the duration of complete or effective analgesia. Cascio *et al.*,^[17] proved that intrathecal fentanyl is as effective as labor epidural analgesia in producing pain relief in labor and capable of reducing maternal plasma epinephrine concentration thus reducing maternal distress in the same manner as conventional labor epidural analgesia. In 1996, Fernandez-Galinski *et al.*,^[18] assessed the risk and benefits of the administration of fentanyl during spinal anesthesia in elderly patients undergoing knee or hip replacement surgeries. The study results show that 25 μ g of fentanyl do not modify spinal anesthesia in elderly but induces pruritus and O₂ desaturation. Decrease in post-operative pain intensity and the preservation of cognitive

function would justify the use of spinal fentanyl in the elderly. Respiratory depression may occur following intraspinal administration of opioids. Varrasi *et al.*^[19] observed the ventilatory effects of subarachnoid fentanyl in elderly patients. They recommended 25 µg fentanyl as the only dose which gives significant analgesia without respiratory depression in older patients; fentanyl has been shown to be effective for labour analgesia and often used as part of combined spinal and epidural technique for this purpose, although effective shortcoming of this technique was limited duration of action and occasional side effect like pruritus. Palmer *et al.*^[20] in their study investigated the effect of addition of low dose bupivacaine to intrathecal fentanyl. The results showed that bupivacaine augments intrathecal fentanyl duration and quality of analgesia and speeds onset of analgesia compared with plain intrathecal fentanyl. Ben-David *et al.*^[21] studied 50 patients undergoing ambulatory surgical arthroscopy and found that although small dose bupivacaine alone is inadequate for this procedure the addition of fentanyl makes it reliable. Selective spinal anesthesia is the practice of using minimal doses of intrathecal agents so that only the nerve roots supplying a specific area and the modalities that require to be anesthetized are affected. Valanne *et al.*^[22] used mini dose of bupivacaine 4 mg versus 6 mg for outpatient knee arthroscopy. They hypothesized that mini-dose induces selective spinal anesthesia with faster recovery and allows discharge criteria to be fulfilled significantly faster. In a double-blind study performed by Dahlgren *et al.*^[23] compared the effects of intrathecal sufentanil 2.5 µg and 5 µg of fentanyl and placebo when administered with hyperbaric bupivacaine 0.5% of 12.5 mg for cesarean section. The post-operative analgesia assessed using value-added service (VAS) and umbilical cord blood gases and neonatal Apgar score were same among the groups. Thus, results reveal that small doses of fentanyl and sufentanil added to local anesthetic for spinal anesthesia, reduced need for intraoperative antiemetic medication and increased the duration of analgesia in the early post-operative period, compounded with placebo. Sufentanil had a slight longer duration of action than fentanyl. Liu *et al.*^[24] demonstrated that addition fentanyl improves the quality and duration of lidocaine spinal anesthesia. They administered plain lidocaine 5% in dextrose both with and without 20 µg of fentanyl in a randomized double-blind crossover fashion. They recommended the addition of 20 µg of fentanyl to lidocaine spinal anesthesia as a means to improve duration of sensory anesthesia without prolonging recovery of motor function or time to micturition. Palmer *et al.*^[25] in their study determined the dose-response relation of intrathecal fentanyl 25 µg for labor analgesia and described the onset duration and quality of analgesia when used as sole analgesic. The further increasing the dose of fentanyl beyond 25 µg has little benefit. Sudarshan *et al.*^[26]

investigated the efficacy of intermittent doses of fentanyl intrathecally in 30 patients undergoing thoracotomy. They demonstrated using spinal catheters for analgesia with fentanyl; it is possible to titrate optimum effect required with intermittent doses to provide high-quality analgesia for prolonged period. Jacobson *et al.*^[27] studied the effects on intrathecal fentanyl on relief of persistent post-operative stump and phantom limb pain. In their study shows that neuraxial fentanyl temporarily abolished the pain and apparently produced its effects by segmental spinal action. Kanazi *et al.*^[28] conducted a study on the effect of low dose dexmedetomidine or clonidine on the characteristics of bupivacaine spinal block and found that dexmedetomidine 3 µg or clonidine 30 µg when added to intrathecal bupivacaine, produces a similar prolongation in the duration of the motor and sensory block with preserved hemodynamic stability and lack of sedation. Al-Ghanem *et al.*^[3] compared the effect of adding dexmedetomidine 5 µg versus fentanyl 25 µg to intrathecal bupivacaine on spinal block characteristics in gynecological procedures and found that bupivacaine supplemented with 5 µg dexmedetomidine produced prolonged motor and sensory block compared with 25 µg fentanyl. Hala *et al.*^[29] conducted a study on the dose-related prolongation of hyperbaric bupivacaine spinal anesthesia by dexmedetomidine and concluded that intrathecal dexmedetomidine in doses of 10 µg and 15 µg significantly prolongs the anesthetic and analgesic effects of spinal hyperbaric bupivacaine in a dose-dependent manner. A 15 µg dose may be of benefit for prolonged complex lower limb surgical procedures. Gupta *et al.*^[5] conducted a comparative study of intrathecal dexmedetomidine 5 µg and fentanyl 25 µg as adjuvants to bupivacaine and found that intrathecal dexmedetomidine is associated with prolonged motor and sensory block, hemodynamic stability, and reduced demand for rescue analgesics in 24 h as compared to fentanyl. Dexmedetomidine as an intrathecal adjuvant for post-operative analgesia and found that the addition of 5 µg dexmedetomidine to ropivacaine intrathecally produces prolongation in the duration of motor and sensory block.

Name of the Institute

This study was conducted at the Holdsworth Memorial Hospital, Mandi Mohalla, Mysore.

Type of Study

This was a prospective randomized double-blind study.

Period of Study

This study was from December 2012 to March 2015.

Primary Objectives

The primary objectives of the study were to observe onset and duration of sensory block, onset and duration of motor

blockade, and duration of analgesia and intraoperative sedation.

Secondary Objectives

To also observe perioperative complications such as nausea, vomiting, hypotension, bradycardia shivering, and pruritis are assessed.

MATERIALS AND METHODS: SOURCE OF DATA

The present clinical study was conducted at after obtaining approval from Institutional Ethical Committee; present study was undertaken to compare the efficacy of dexmedetomidine as an adjuvant to 0.5% bupivacaine (heavy) for subarachnoid block in infra-umbilical surgeries including inguinal hernia repair, appendicectomy, hysterectomy, urological, and orthopedic surgeries. It was a prospective randomized control study done on 100 patients undergoing elective lower abdominal surgeries.

Inclusion Criteria

The following criteria were included in the study:

1. Patients satisfying ASA physical status Class I and II and undergoing elective sub umbilical surgeries.
2. Patients with age between 18 and 65 years of either sex.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients undergoing emergency surgeries, deformities of the spine, hypersensitivity to any of the drugs in the study.
2. Patients with contraindications to spinal anesthesia - patient refusal and bleeding diathesis.

Sample Size

The sample size was calculated based on the power analysis performed in a pilot study done in our institution with an $\alpha = 0.05$ and $\beta = 0.90$. A sample size of 45 patients per study group was needed to detect a change of 10% in onset of motor blockade, onset of analgesia, and the duration of analgesia between the groups. However, considering the dropouts, a sample size of 50 patients was considered in each of the groups in our study.

Methodology

After a thorough clinical examination and relevant laboratory investigations of all patients, an informed, valid, and written consent was obtained, both for the conduct of study and administration of spinal anesthesia. All patients were kept nil by mouth from midnight before surgery, and tablet alprazolam (0.01 mg/kg) was administered at bedtime the day before surgery. All the patients were randomly

allocated into two groups of 50 each using computer-generated random numbers by simple randomization technique.

1. Group F: 3 ml of 0.5% hyperbaric bupivacaine and 25 µg fentanyl.
2. Group D: 3 ml of 0.5% hyperbaric bupivacaine and 5 µg of dexmedetomidine.

All the patients were re-examined, assessed and weighed preoperatively on the day of surgery. Intravenous (IV) access was established with 18G IV access, and preloading was done with 15 ml/kg Lactated Ringer's solution 30 min before the procedure. Anesthesia machine and accessories were checked, and drugs, including emergency drugs were kept ready. Furthermore, monitoring equipment such as pulse oximeter, non-invasive blood pressure, and electrocardiogram (ECG) monitors were checked and applied to each patient on arrival to the operating room, and baseline parameters (heart rate [HR], blood pressure, and SpO₂) were recorded. Under strict aseptic conditions, with the patient in the left lateral position, a lumbar puncture was performed at L3-L4 intervertebral space. After ensuring the free flow of CSF, Group 1 patients received 0.5% heavy bupivacaine 3 ml with fentanyl (25 µg) 0.25 ml and Group 2 patients received 0.5% heavy bupivacaine 3 ml with 5 µg dexmedetomidine. After the intrathecal injection patients were returned to supine position. Hemodynamic parameters such as pulse rate, systolic blood pressure (SBP), diastolic blood pressure (DBP), mean arterial blood pressure, and SpO₂ of the patients were recorded. SBP, DBP, and HR were recorded every 2 min up to 15 min and every 5 min up to 30 min then every 15 min up to 90 min irrespective of the duration of surgery. Hypotension was defined as SBP <90 mmHg or >30% fall from the baseline value whichever was low was treated by injection mephentermine 3 mg IV and IV crystalloids. Bradycardia was defined as HR <60 beats/min or >30% decrease from the baseline value whichever was low was treated with IV atropine 0.3 mg increments. Sensory and motor blockade were assessed at following intervals, every 2 min for first 10 min and every 5 min for next 15 min, and every 10 min for next 30 min until the end of the surgery. Postoperatively every 15 min for the first 2 h and every half hourly for the next 4 h and next every hourly for the next 16 h. Sensory block was assessed by pinprick method using a blunt tipped 23 gauge needle, and motor block was assessed by Bromage scale [Table 1].

Definitions: Onset of Sensory Block

Time from completion of intrathecal injection of study drug until the sensory block occurs at T10 level. Time for the maximum sensory block: Time from completion of intrathecal injection of study drug until maximum sensory block occurs. Duration of two segments regression: Time

from maximum sensory block until there is decreased of the sensory block by two segments.

Duration of Analgesia

Time from completion of intrathecal injection of study drug until the patient requires rescue analgesia with VAS of >4 [Table 2 and Figure 1].

Onset of Motor Blockade

Time from completion of intrathecal injection of study drug until the patient develops Bromage Grade II.

Time for Maximum Blockade

Time from completion of intrathecal injection of study drug until the patient develops Grade IV (Bromage).

Duration of Motor Blockade

Time of injection until the patient recovers to Grade I (Bromage). HR, systolic, DBP, and mean arterial pressure were recorded every 2 min for first 10 min, every 10 min for first 30 min, every 30 min till 3 h, and every 60 min till the requirement of rescue analgesia. ECG, SpO_2 , and sedation were monitored continuously. Side effects if any such as nausea, sedation, dry mouth, and bradycardia were recorded during study period.

Duration of analgesia was defined as the time from subarachnoid block to VAS >2 , at that point rescue analgesia was given [Table 2 and Figure 1]. Similarly, sedation score was recorded using sedation score [Table 3].

All the data were collected, tabulated, and analyzed statistically. p value <0.05 is considered statistically significant.

Statistical Methods

Descriptive statistical analysis has been carried out in the present study. Results on continuous measurements are presented on Mean SD (Min-Max), and results on categorical measurements are presented in number (%). The significance is assessed at 5% level of significance. The following assumptions on data are made, Assumption: (1) Dependent variables should be normally distributed, (2) Samples drawn from the population should be random, cases of the samples should be independent. Student's test (two-tailed and independent) has been used to find the significance of study parameters on continuous scale between two groups (intergroup analysis) on metric parameters. Chi-square/Fisher exact test has been used to find the significance of study parameters on a categorical scale between two or more groups.

Study Design

A comparative two-group randomized clinical study with 100 patients with 50 patients in Group F (Fentanyl) and

Table 1: Modified Bromage scale

Grade	Criteria	Degree of block
I	Free movement of legs and feet	None
II	Just able to flex knees with free movement of feet	Partial 33%
III	Unable to flex knees, but with free movement of feet	Partial 66%
IV	Unable to move legs or feet	Complete paralysis

Table 2: Visual analog score

0	None
2	Annoying
4	Uncomfortable
6	Dreadful
8	Horrible
10	Agonizing

Table 3: Sedation score

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

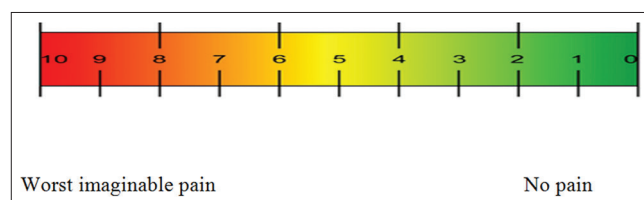


Figure 1: Visual analog scale

50 patients in Group D (Dexmedetomidine) is undertaken to study the changes in hemodynamic and side effects. Statistical analysis was done by applying Chi-square test, ANOVA test, and Student's t -test to analyze the data, P value was determined. $P > 0.05$ is not significant; $P < 0.05$ is significant; and $P < 0.001$ is highly significant.

OBSERVATIONS AND RESULTS

Table 4 shows the age distribution in each group. The patients who took part in this project were in the age group of 18–65 years. On statistical comparison, the two groups were comparable.

Observing the gender distribution in both the groups and on statistical analysis, it was found that the samples were gender-matched with $P=1.000$ [Table 5 and Figure 2].

Comparing the height and weight of two groups, it was found that the data were comparable [Table 6 and Figure 3].

Distribution of ASA grade was statistically similar in two groups with $P=0.419$ [Table 7 and Figure 4].

The distribution of different surgeries undertaken in both the groups was shown in Table 8, Figures 5 and 6.

Comparison of onset time (T10), highest sensory level was compared in both the groups and the data were significant statistically with $P < 0.001$ (P significant at <0.05), [Table 9, Figure 7a and b].

Comparison of time of onset of motor blockade was compared in both the groups and were found that the onset of motor blockade was comparable in both the groups but the duration of the motor blockade was statistically significant with $P < 0.001$ [Table 10, Figure 8a and b].

Comparing the maximum height of sensory blockade achieved in both the groups, it was found that values were comparable and similar in both the groups [Table 11].

Comparison of Maximum Height Wise Distribution of Sensory Blockade in Both Groups ($n = 100$).

The mean values of maximum height of sensory blockade were similar in both the group [Table 12].

In both the groups, the SBP, DBP, mean arterial pressure, HR, respiratory rate, and SpO_2 values were recorded and analyzed in both the groups and their values were found to be comparable and not statistically significant [Tables 13-19, Figures 9-13].

The consumption of mephentermine and atropine in both the groups was compared and found that values were significant [Table 20].

The side effects encountered in both the groups were compared and found to not significant [Figure 13].

The modified Ramsay Sedation Score and Visual Analog Scales of analgesia were compared in both the groups and found that the values were statistically highly significant in this study [Tables 21 and 22, Figures 14 and 15].

DISCUSSION

Lidocaine was regularly being used for intrathecal anesthesia. It had short duration of action and also found to produce transient neurological symptoms.^[30,31] Hence, hyperbaric bupivacaine is the standard local anesthetic that is used for spinal anesthesia for infra-umbilical surgeries. Hyperbaric 0.5% bupivacaine is routinely used in a dose

Table 4: Age distribution of patients studied

Age in years	Group F	Group D
	n (%)	n (%)
18–20	2 (4.0)	0 (0.0)
21–30	3 (6.0)	4 (8.0)
31–40	13 (26.0)	26 (52.0)
41–50	22 (44.0)	14 (28.0)
51–60	8 (16.0)	5 (10.0)
>60	2 (4.0)	1 (2.0)
Total	50 (100.0)	50 (100.0)
Mean±SD	43.76±10.33	40.86±9.27

Table 5: Gender distribution of patients studied

Gender	Group F	Group D
	n (%)	n (%)
Male	25 (50.0)	25 (50.0)
Female	25 (50.0)	25 (50.0)
Total	50 (100.0)	50 (100.0)

Table 6: Comparison of height and weight of two groups

Variables	Group F	Group D	P value
Height (cm)	155.66±5.16	156.10±5.83	0.690
Weight (kg)	58.12±12.35	56.90±10.18	0.591

Table 7: ASA grade in two groups of patients studied

ASA grade	Group F	Group D
	n (%)	n (%)
Grade I	26 (52.0)	31 (62.0)
Grade II	24 (48.0)	19 (38.0)
Total	50 (100.0)	50 (100.0)

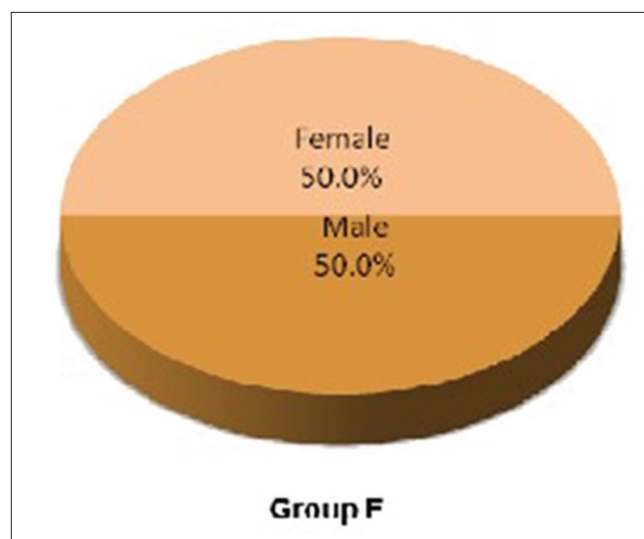


Figure 2: Pie chart showing the gender distribution (n=100)

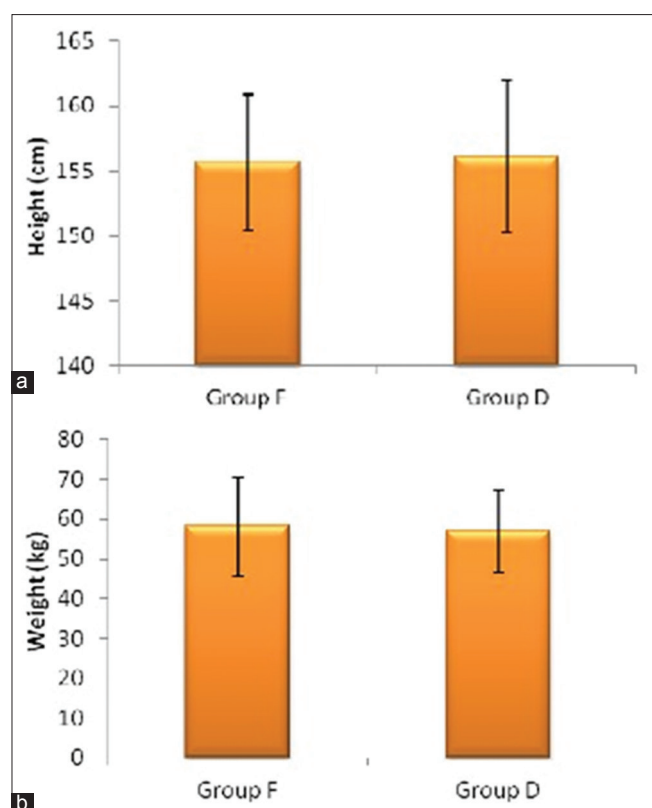


Figure 3: (a and b) Comparison of height and weight in both groups (n=100)

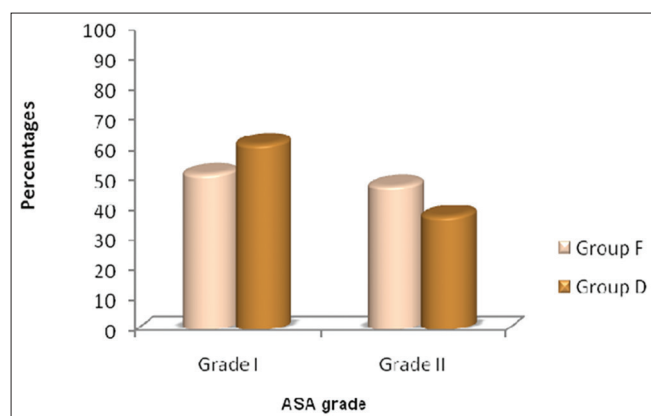


Figure 4: ASA grade distribution in both groups

of 3 ml (15 mg) for infra-umbilical surgeries.^[32-34] In our institution also, hyperbaric 0.5% bupivacaine 3 ml is regularly used for infra-umbilical surgeries. Hence, in our study, 3 ml of 0.5% bupivacaine was selected. Neuraxial opioids are widely used in conjunction with local anesthetics for spinal anesthesia for providing adequate anesthesia and analgesia. The use of opioids in conjunction with local anesthetics prolonged post-operative analgesia and reduced analgesia requirement.^[33,34] Fentanyl is the most commonly used intrathecal opioid adjuvant along with bupivacaine for spinal anesthesia. Various authors have used 25 µg of fentanyl along with hyperbaric bupivacaine.^[35-37] Hence,

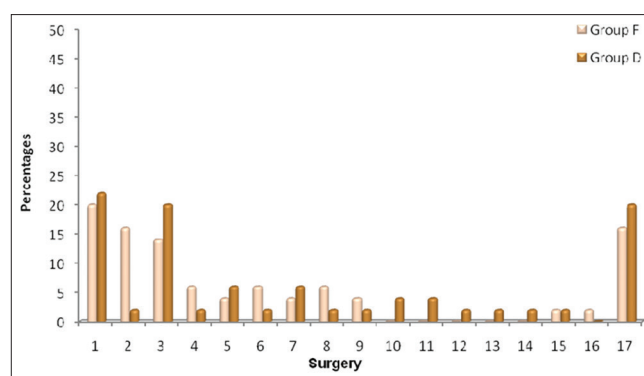


Figure 5: Types of surgeries in both groups

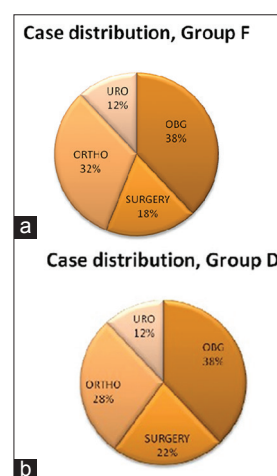


Figure 6: Types of surgeries in both groups

in our study, we have selected fentanyl 25 mcg as the adjuvant along with 0.5% bupivacaine heavy. Fentanyl has limitations as an adjuvant due to: (1) Its duration of action is short - being highly lipid soluble does not stay in the central neuraxial for a long period, and (2) being an opioid, produces a lot of side effects, such as post-operative nausea and vomiting, pruritis, and respiratory depression.^[36,37] Hence, other adjuvants like alpha-2 agonists became popular because they do not have the side effects of the opioids. Intrathecal α_2 receptor agonists have antinociceptive action for both somatic and visceral pain. Dexmedetomidine shows more specificity toward α_2 -receptor (α_2/α_1 1600:1) compared with clonidine (α_2/α_1 200:1). Several studies have shown that α_2 -receptor agonists, when administered intrathecally, will enhance the analgesia provided by subtherapeutic doses of local anesthetics like bupivacaine due to synergistic effects with minimal hemodynamic effects.^[32-34] Alpha-2 agonist clonidine has been used as an adjuvant to bupivacaine in higher doses of 55–75 mcg but it was found to have side effects of severe bradycardia and hypotension.^[32,38] It was hypothesized that intrathecal dexmedetomidine being more specific to alpha-2 receptors may produce prolonged post-operative analgesia without producing any side effects

Table 8: Surgery in two groups of patients studied

Surgery	Group F (n=50)	Group D (n=50)
	n(%)	n(%)
Vaginal hysterectomy	10 (20.0)	11 (22.0)
Abdominal hysterectomy	8 (16.0)	1 (2.0)
ORIF	7 (4.0)	10 (20.0)
TURP	3 (6.0)	1 (2.0)
URS	2 (4.0)	3 (6.0)
Mesh Repair	3 (6.0)	1 (2.0)
Below knee procedure	2 (4.0)	3 (6.0)
Stripping and ligation	3 (6.0)	1 (2.0)
Tension band wiring	2 (4.0)	1 (2.0)
Implant removal	0 (0.0)	2 (4.0)
Interval appendicectomy	0 (0.0)	2 (4.0)
Fistula repair	0 (0.0)	1 (2.0)
Screw fixation	0 (0.0)	1 (2.0)
Skin grafting	0 (0.0)	1 (2.0)
Internal urethrotomy	1 (2.0)	1 (2.0)
DHS	1 (2.0)	0 (0.0)
Others	8 (16.0)	10 (20.0)

TURP: Transurethral resection of prostate, URS: Ureter lithotomy

Table 9: Comparison of onset time (T10), highest sensory level (n=100)

Variables	Group F	Group D	P value
Onset time of sensory block (min)	3.38±0.83	2.62±0.56	<0.001
Time from injection to highest sensory level (minutes)	11.47±1.23	11.72±1.23	0.314
Duration of analgesia	240±0.83	360±0.83	<0.001

Table 10: Comparison of time of onset of motor blockade (mean±SD) in both Groups (n=100)

Variables	Group F	Group D	P value
Onset of motor block	10.38±1.08	10.59±1.00	0.317
Duration of motor block	252.90±8.31	419.70±16.85	<0.001

Table 11: Highest sensory level of patients studied

Maximum height of sensory blockade (segments)	Group 1 (n=50)	Group 2 (n=50)
T4	2	1
T6	12	13
T8	13	14
T10	3	2

such as hypotension and bradycardia. Dexmedetomidine has been used in the dose of 5 µg with 0.5% hyperbaric bupivacaine intrathecally as an adjuvant by various authors.^[38,39] Dexmedetomidine has been introduced very recently in India and fentanyl was regularly being used as an intrathecal adjuvant in our hospital it was decided to compare 25 µg of fentanyl with 5 µg of dexmedetomidine as adjuvants to 0.5% bupivacaine heavy for infra-umbilical surgeries. 100 adult patients posted for elective infra-umbilical surgeries were randomly divided using computer-

Table 12: Comparison of mean of maximum height of sensory blockade in both Groups (n=100)

Maximum height of sensory blockade	Group F (n=50)	Group D (n=50)
Mean of maximum height of sensory blockade (segments)	T6-T8	T6-T8

Table 13: Comparison of systolic blood pressure (mmHg) in two groups of patients studied

SBP (mmHg)	Group F	Group D	P value
Pre-operative	128.60±11.70	126.20±9.54	0.264
2 min	125.12±12.11	119.40±10.65	0.014
4 min	119.10±11.34	114.84±10.85	0.058
6 min	115.24±9.77	112.76±10.84	0.233
8 min	112.42±9.04	110.92±10.86	0.455
10 min	110.22±9.87	110.50±10.50	0.891
20 min	109.46±9.70	109.38±10.77	0.969
30 min	107.66±9.49	108.34±10.57	0.736
40 min	106.64±9.98	107.32±10.20	0.737
50 min	106.82±10.18	107.12±9.75	0.881
60 min	108.98±9.74	107.82±9.20	0.542
75 min	111.24±9.57	108.60±8.88	0.156
90 min	114.58±8.32	110.56±8.55	0.019

Table 14: Comparison of diastolic blood pressure (mmHg) in two groups of patients studied

DBP (mmHg)	Group F	Group D	P value
Pre-operative	80.10±8.58	80.78±7.81	0.679
2 min	77.38±9.68	74.18±9.22	0.094
4 min	72.46±8.56	71.06±9.48	0.440
6 min	69.04±8.65	69.44±9.56	0.827
8 min	65.76±7.87	67.74±10.31	0.283
10 min	62.30±8.39	66.68±10.31	0.022
20 min	60.92±9.23	65.12±9.96	0.031
30 min	61.36±7.40	64.80±9.66	0.048
40 min	60.90±8.25	64.94±9.62	0.026
50 min	61.28±8.50	64.76±9.28	0.053
60 min	62.98±8.79	65.16±8.90	0.221
75 min	65.75±7.53	65.62±8.30	0.933
90 min	69.00±7.54	67.18±8.42	0.258

generated numbers into two equal groups. Patients in Group F were administered spinal anesthesia using 25 mcg fentanyl and 3 ml of hyperbaric bupivacaine. Patients in Group D were administered 5 mcg dexmedetomidine and 3 ml of 0.5% hyperbaric bupivacaine. There was no statistically significant difference in the age, height, weight, and gender of the patients in both the groups. There was no statistically significant difference in both the groups regarding the type of surgeries and duration of surgeries.

Sensory Block

Onset of sensory block

In our study, we found highly significant difference regarding the onset of sensory block between the two Groups D and F. There was an early onset of sensory

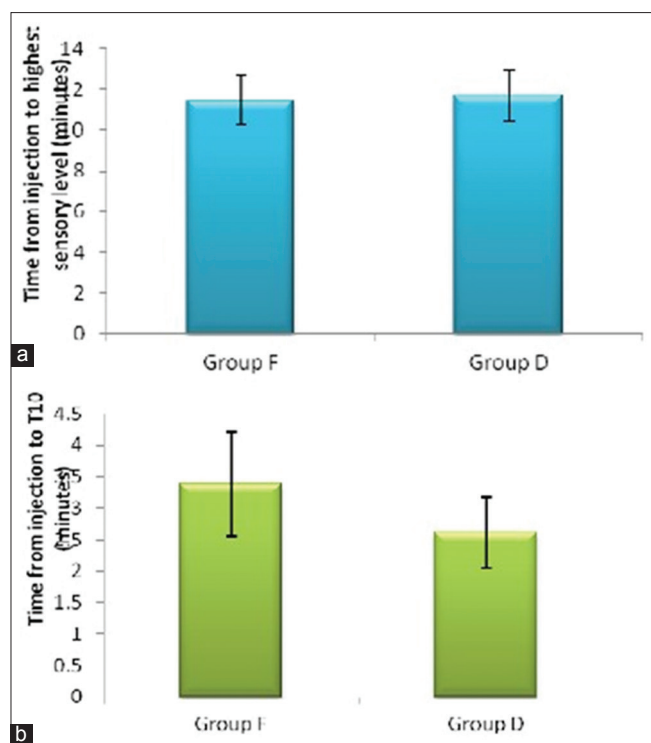


Figure 7: (a) Time from injection to highest sensory level, (b) time from injection to T10 level

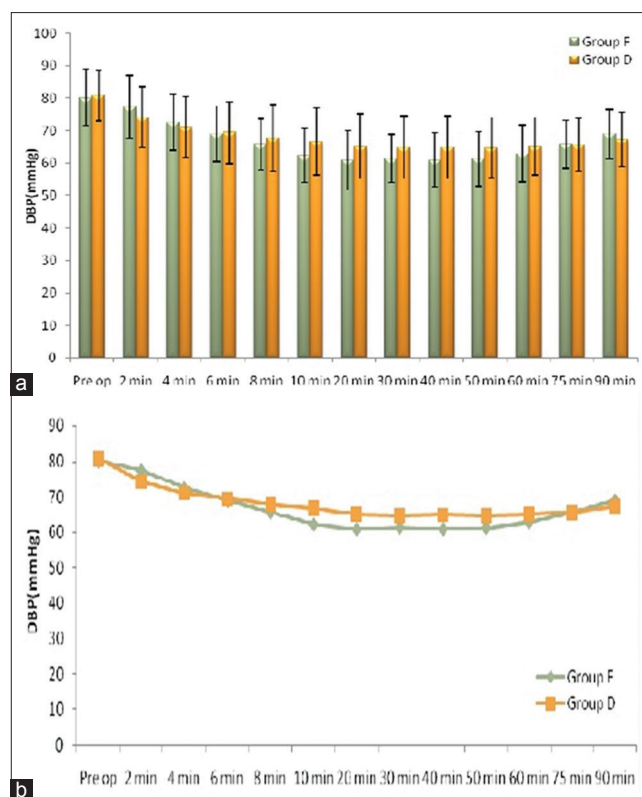


Figure 9: (a and b) Comparison of diastolic blood pressure changes in both groups

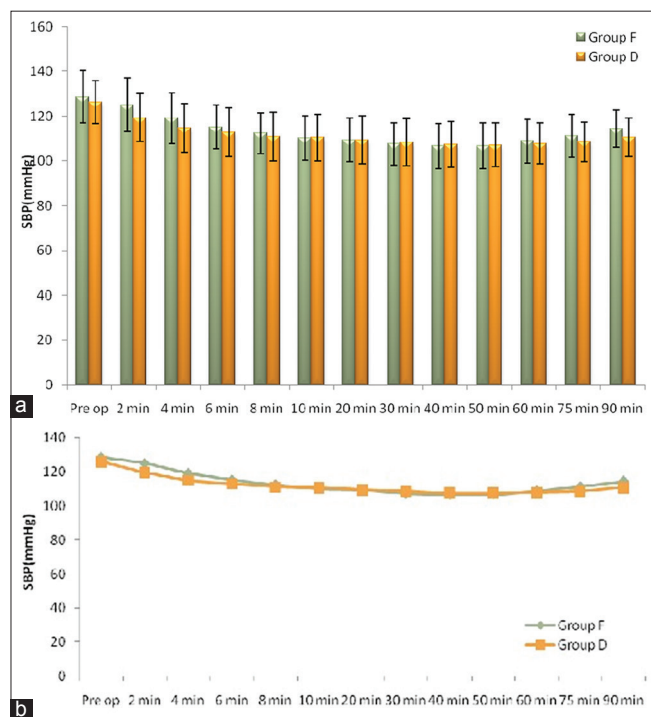


Figure 8: (a and b) Comparison of systolic blood pressure changes in both groups

block with dexmedetomidine group (2.6 ± 0.056 min) compared to the fentanyl group (3.38 ± 0.83 min) in our study. This does not compare with the study conducted by Al-Ghanem *et al.*^[3] The authors have not found any

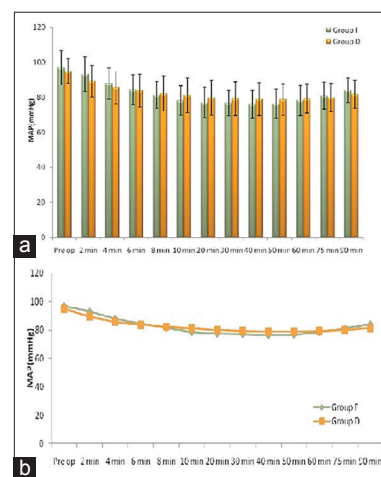


Figure 10: (a and b) Comparison of mean arterial pressure changes in both groups

difference between the two groups regarding the onset of sensory block - dexmedetomidine (7.5 ± 7.4 min) and group fentanyl (7.4 ± 7.4 min). These results do not compare with our study probably because, in their study, the position used for the spinal block was sitting position compared to the lateral position used in our study. In their study, they have not specified how much time was used to place the patient from sitting to supine posture and then to lithotomy posture and also when, how frequently the

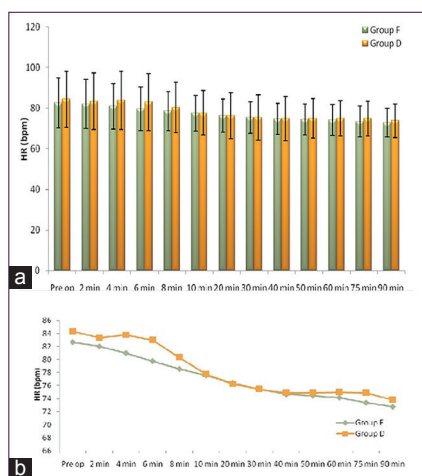


Figure 11: (a and b) Comparison of heart rate in both groups

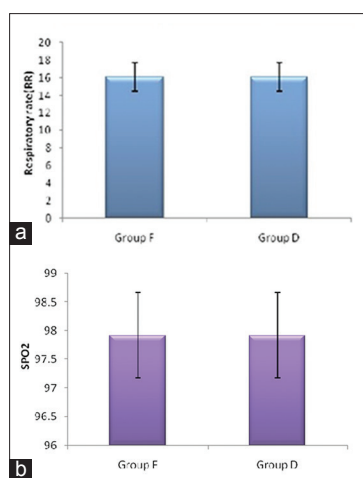


Figure 12: (a and b) Comparison of respiratory rate and SpO₂

sensory block was checked. Sensory block was checked, which may be probably the reason for higher onset of time in their study when compared to this study. Our study also does not compare with the study conducted by Hala *et al.*,^[29] where in the onset time for sensory block in dexmedetomidine (8.7 ± 3.3) min group was longer than in our study (2.6 ± 0.056) min. This probably because the height of the patients selected was 170 cm in comparison with our study which is 155 cm. The authors have also not mentioned what was the position adopted for administering spinal anesthesia. Our study also compares with the study conducted by Singh *et al.*^[12] regarding fentanyl 25 mcg as the adjuvant, in which the onset time was (2.72 ± 1.51) minutes as compared to our study with fentanyl being (3.78 ± 2.8) min which was significant.

Time to achieve maximum sensory block

In our study, we did not find any statistically significant difference in the time to achieve maximum sensory block between the groups dexmedetomidine (11.72 ± 1.23 minutes) and fentanyl (11.47 ± 1.23) min. Our study

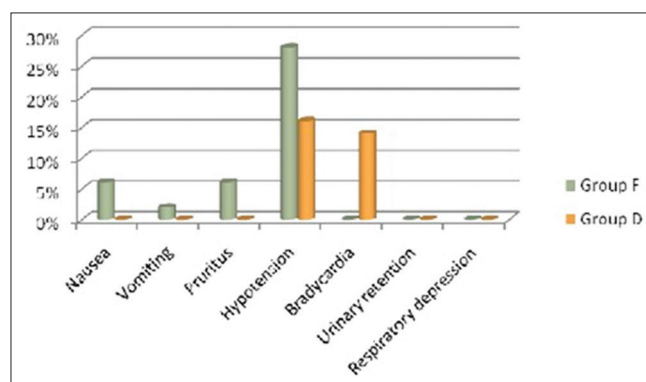


Figure 13: Side effects in both groups

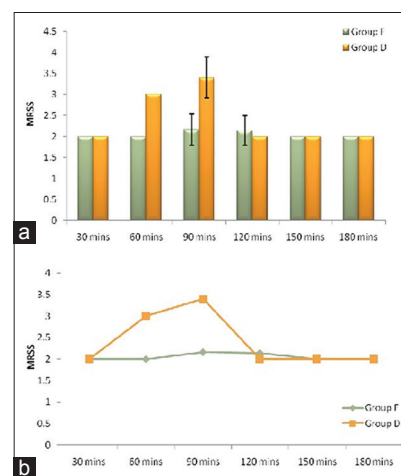


Figure 14: Modified Ramsay Sedation Score in the groups

compares with the study conducted by Gupta *et al.*^[5] where they have not found statistically significant difference between dexmedetomidine (12.3 ± 1.8) min and fentanyl (12.1 ± 1.17) min. Our study also compares with the study conducted by Al-Ghanem *et al.*^[3] where they also did not find any statistically significant difference between the two groups, but in their study, the time to achieve maximum sensory block was longer in both the groups dexmedetomidine (19.34 ± 2.87) min and fentanyl (18.39 ± 2.46) min. This is probably because the spinal anesthesia was given in sitting posture and also they have not specified how long patients were kept in sitting posture before bringing to supine position.

Duration of Analgesia

In our study, we have found highly significant difference regarding the duration of analgesia with dexmedetomidine group having (360 ± 0.83) min compared to the fentanyl group (240 ± 0.83) min. Our study compares with the study conducted by Al-Ghanem *et al.*,^[3] (274 ± 73) min in Group D and (179 ± 47) min in Group F and also with the study conducted by Tarbeeh *et al.*,^[38] the fentanyl group was (280 ± 62) min and the dexmedetomidine group was (450 ± 75) min and with the study conducted by Gupta

Table 15: Comparison of MAP (mmHg) in two groups of patients studied

MAP (mmHg)	Group F	Group D	P value
Pre-operative	97.02±9.99	94.98±7.02	0.238
2 min	93.29±10.02	89.25±8.97	0.036
4 min	88.00±8.86	85.65±9.27	0.198
6 min	84.44±8.48	83.88±9.50	0.757
8 min	81.31±7.67	82.13±10.08	0.648
10 min	78.27±8.37	81.28±9.98	0.105
20 min	77.10±8.63	79.87±9.84	0.138
30 min	76.79±7.38	79.31±9.50	0.142
40 min	76.14±8.15	79.06±9.35	0.099+
50 min	76.46±8.49	78.88±8.95	0.169
60 min	78.31±8.62	79.38±8.41	0.533
75 min	80.91±7.65	79.94±7.98	0.541
90 min	84.19±7.14	81.64±8.02	0.096+

Table 16: Comparison of HeartRate (beats per min) in two groups of patients studied

HR (bpm)	Group F	Group D	P value
Pre-operative	82.68±12.42	84.36±13.71	0.522
2 min	82.04±12.16	83.36±13.94	0.615
4 min	81.02±11.16	83.82±14.32	0.278
6 min	79.78±10.72	83.02±14.03	0.198
8 min	78.58±9.67	80.34±12.51	0.433
10 min	77.60±8.79	77.75±10.80	0.938
20 min	76.42±8.14	76.26±11.38	0.936
30 min	75.46±7.70	75.48±11.20	0.992
40 min	74.68±7.67	74.92±10.87	0.899
50 min	74.48±7.70	74.92±9.70	0.802
60 min	74.18±7.57	74.98±8.64	0.624
75 min	73.40±7.57	74.90±8.54	0.355
90 min	72.78±7.11	73.84±8.22	0.492

Table 17: Comparison of RR and SpO₂ of two groups

Variables	Group F	Group D	P value
RR	16.10±1.61	16.10±1.61	1.000
SpO ₂	97.92±0.75	97.92±0.75	1.000

RR: Respiratory rate

et al.,^[5] (251 ± 21) min in Group D and fentanyl was (168 ± 18) min, wherein there was highly significant difference between dexmedetomidine and fentanyl groups with prolonged duration with the dexmedetomidine group.

Comparison of VAS Score

In our study, patients in the dexmedetomidine group had lower VAS score which was highly significant during the 24 h of the study. Most of the patients, in the Group D had $<3.5 \pm 0.51$ VAS score before 12 h compared to 5.9 ± 0.97 VAS score in the fentanyl group which is highly significant. Our study compares with the study conducted by Tarbeeh *et al.*^[38] who also has found highly significant difference in the VAS scoring between the groups.

Table 18: The comparison of respiratory rate values

Side effects	Group F (n=50) n (%)	Group D (n=50) n (%)	P value
Nausea	3 (6.0)	0 (0.0)	<0.05
Vomiting	1 (2.0)	0 (0.0)	>0.05
Pruritus	3 (6.0)	0 (0.0)	<0.05
Urinary retention	0 (0.0)	0 (0.0)	--
Respiratory depression	0 (0.0)	0 (0.0)	--

Table 19: Comparison of the hypotension and bradycardia

No of patients	Group F	Group D	P value
Hypotension	8 (16)	14 (28)	<0.001
Bradycardia	0	7 (14)	<0.001
No of patients treated	8	21 (14+7)	

Table 20: Consumption of Mephentermine and Atropine

Group	Mephentermine	Atropine
Fentanyl Group F	48 g	
Dexmedetomidine-Group D	84 g	2.8 g

Table 21: Comparison of modified Ramsay Sedation Score of two groups

MRSS	Group F	Group D	P value
30 min	2.00±0.00	2.00±0.00	1.000
60 min	2.00±0.00	3.00±0.00	<0.001
90 min	2.16±0.37	3.40±0.49	<0.001
120 min	2.14±0.35	2.00±0.00	0.006
150 min	2.00±0.00	2.00±0.00	1.000
180 min	2.00±0.00	2.00±0.00	1.000

MRSS: Modified Ramsay Sedation Score

Table 22: Comparison of visual analog scale of two group

VAS	Group F	Group D	P value
6 h	3.50±0.51	0.00±0.00	<0.001
12 h	5.90±0.97	3.50±0.51	<0.001
18 h	7.28±0.95	5.52±0.51	<0.001
24 h	7.24±0.96	3.62±0.69	<0.001

VAS: Value-added service

Highest Sensory Level

Most of the patients in both the groups developed a sensory block between T6 and T8 in our study. Our study does not compare with the study conducted by Tarbeeh *et al.*^[38] in which most of the patients reached maximum sensory block below T8. This is probably because 2.5 ml of bupivacaine has been used in their study with a total volume 3 ml including the adjuvant when compared to our

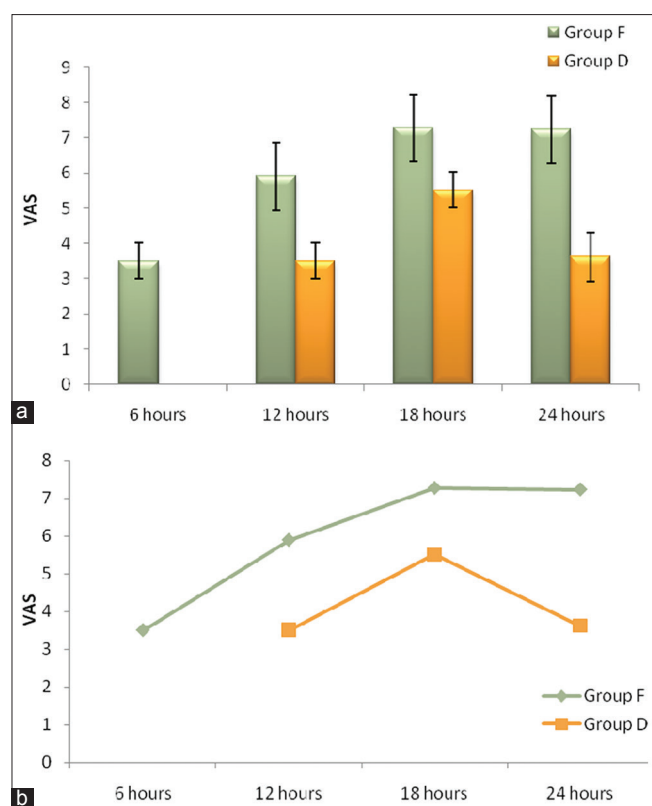


Figure 15: (a and b) Visual analog scales cores in both groups

study where local anesthetic 3 ml bupivacaine and total volume 3.5 ml with an adjuvant. Another reason probably because, the spinal anesthesia in their study was given in sitting position and they have not mentioned how long the patient was kept in sitting position, compared to our study where spinal anesthesia given in lateral position [Graph 1].

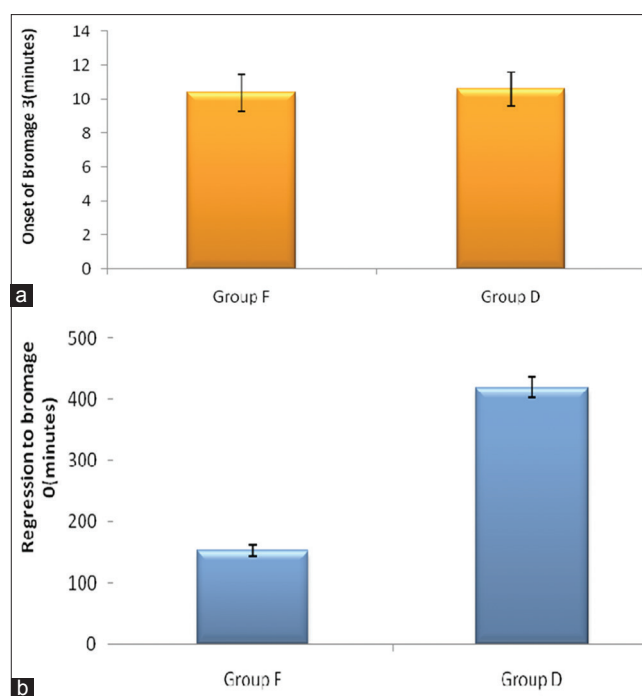
Motor Blockade

Onset of motor blockade

In our study, onset of motor blockade was (10.38 ± 1.08) min for the dexmedetomidine and (10.59 ± 1.0) min for fentanyl group, respectively, which is statistically not significant. Our study compares with the study conducted by Al-Ghanem *et al.*^[3] where group fentanyl was (14.4 ± 6.7) min and for group dexmedetomidine was (14.3 ± 5.7) min and also with the study conducted by Gupta *et al.*^[5] where group fentanyl was (14.4 ± 6.7) min and the group dexmedetomidine was (14.3 ± 5.7) min, who also did not find any significant difference between the two groups.

Duration of motor blockade

In our study, there was a highly significant difference in the duration of motor blockade between the two groups fentanyl (252.90 ± 8.31) min and the dexmedetomidine group (419.70 ± 16.85). Our study compares with the study conducted by Gupta *et al.*^[5] where the dexmedetomidine group was 421 ± 21 min and the fentanyl group was 149.3 ± 18.2 min, respectively, where it was highly significant. Our



Graph 1: (a) Onset of motor blockade (in min), (b) duration of motor blockade (in min)

study also compares with the study conducted by Tarbeeh *et al.*^[38] where in, group fentanyl was 149 ± 62 min and the group dexmedetomidine was 175 ± 75 min, respectively, which was found to be highly significant. In their study, the duration of motor block was less when compared to our study as they had used 2.5 ml of bupivacaine compared to our study wherein we have used 3 ml of bupivacaine. Furthermore, the patients in their study were taller (175 cm) compared to the patients in our study (155 cm) and as such the level of block was below T8 in their study. Our study also compares with the study conducted by Al-Ghanem *et al.*^[3] where the findings were, group dexmedetomidine was 240 ± 64 min and the group fentanyl F was 155 ± 46 min, respectively, which was highly significant. The duration of motor block in their study was less compared to our study as isobaric bupivacaine 10 mg was used in their study compared to 15 mg of hyperbaric bupivacaine used in our study.

Hemodynamic Parameters

There was no statistical difference regarding the SBP, DBP, and mean arterial pressure at various time interval in our study between the two groups. Our study compares with the study conducted by Tarbeeh *et al.* and with the study of Al-Ghanem *et al.*^[3] where they also have not noticed any significant difference between the two groups. In our study, 8 patients of the dexmedetomidine group had hypotension peroperatively in comparison with the fentanyl group it was 14 patients which was statistically highly significant. All the patients who have developed hypotension in the

both the groups had T4 level of sensory block and since more number of patients in fentanyl group had T4 level of sensory block compared to the dexmedetomidine group, there was increase in the number of patients in the fentanyl group to develop hypotension. Our study compares with the study conducted by Al-Ghanem *et al.*^[3] who also found more number of patients developing hypotension in fentanyl group (9 patients) compared with dexmedetomidine group (4 patients) and no explanation has been given in their study for the same. Our study does not compare with the study conducted by Tarbeeh *et al.*^[38] as all the patients in their study had sensory block achieved below T8 level and hence minimal incidence of hypotension (3 patients in both the groups). It may be because 2.5 ml of bupivacaine heavy was used in their study unlike 3 ml of bupivacaine heavy in the present study. The mean height of patients in their study (175 cm) was also much higher compared to our study (155 cm).

HR

Regarding HR, there was significant bradycardia incidence in the dexmedetomidine group (7) patients compared to the fentanyl group (0) patients in our study. Our study does not compare with the studies conducted by Tarbeeh *et al.*^[38] and Al-Ghanem *et al.*^[3] where in all the patients developed sensory block below T8 in their study.

Sedation

In our study, at first 1 h and 1½ h interval, there was an increased grade of sedation with dexmedetomidine group compared to fentanyl group, which was highly significant. However, later from 2 h onward there was no statistically significant difference in the sedation grading between the two groups. We could not compare with the studies conducted by Gupta *et al.*, Tarbeeh *et al.*,^[38] and Al-Ghanem *et al.*^[3] where there was no mention of sedation scoring in the results in their studies. There was no respiratory depression in both the groups in our study. Pruritus after intrathecal fentanyl is known but it was not statistically significant in the present study. The α -2 adrenergic agents also have anti-shivering property as observed by Talke *et al.*^[40] and Maroof *et al.*^[41] We too did not find any incidence of shivering.

CONCLUSIONS

Addition of 5 µg dexmedetomidine with hyperbaric bupivacaine significantly prolongs both sensory and motor block. Intraoperatively, there was less incidence of side effects with intrathecal dexmedetomidine when compared to intrathecal fentanyl. The post-operative 24 h analgesic requirements was significantly less in the dexmedetomidine group than group fentanyl 1.5 µg dexmedetomidine

seems to be an attractive alternative to 25 µg fentanyl as an adjuvant to spinal bupivacaine in surgical procedures. It provides good quality of intraoperative analgesia, hemodynamically stable conditions, minimal side effects, and excellent quality of post-operative analgesia. Hence, dexmedetomidine seems to be a better choice as intrathecal adjuvant with bupivacaine when compared with fentanyl.

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Comparative Analysis of Anti Versus Probiotic in Patients with Irritable Bowel Syndrome

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Abstract

Background: Irritable bowel syndrome (IBS) is a functional gastrointestinal disorder with high prevalence. It imposes a significant economic burden to the health-care system worldwide. Earlier IBS was thought to be a disease hard to categorize, difficult to diagnose and impossible to treat, but over the years, the pathophysiology and clinical paradigm of IBS have been well elucidated so are the therapeutic options and diagnostic strategies.

Objective: In our study, we tried to analyze the efficacy of antibiotic (rifaximin) versus probiotic (VSL#3) in alleviating symptoms of IBS.

Materials and Methods: Comparative efficacy of anti-biotic versus pro-biotic was assessed in 220 IBS patients with regard to improvement in global IBS symptoms. The study was conducted in the postgraduate Department of Medicine, Government Medical College, Srinagar, from February 2012 to September 2013 and all the enrolled patients had given informed consent before conducting this study.

Results: There was a significant improvement in global IBS symptoms in both the groups even after switchover of drugs in both the cohorts. The safety profile of both drugs was the same.

Key words: Irritable bowel syndrome, Rifaximin, VSL#3

INTRODUCTION

Irritable bowel syndrome (IBS) is a chronic gut disorder characterized by recurring symptoms of abdominal pain, bloating, and altered bowel function in the absence of any organic abnormality.^[1] The prevalence of non-GI symptoms such as lethargy, poor sleep, backache,

nocturia, sense of incomplete bladder emptying, and early satiety is also seen more in patients of IBS.^[2] IBS is seen to be slightly more prevalent in females,^[3] whereas age and race do not seem to have any consistent effect on the symptoms.

The exact cause of IBS is not yet known, but factors likely implicated in its etiology include genetic influences, food intake habits, endocrine disturbances, malabsorption, post-operative changes, and stress.^[4,5]

Disorders in gut motility have been observed in the stomach, small intestine, colon, and rectum of IBS patients.^[6] Studies have pointed to a disturbance in cyclic pattern of gut motility involving greater frequency of the high frequency of high amplitude prolonged contractions and greater pre-prandial colonic motility.^[7] Small bowel bacterial overgrowth has emerged as a possible cause of IBS.^[8] In an analysis of 202 patients with IBS, around 78% of the patients were found to have bacterial overgrowth.^[9]

Role of antibiotics has emerged in recent years due to good response of these drugs in symptom improvement and normalization of abnormal breath testing.^[10] Patients with IBS are supposedly have an alteration in intestinal microbiota.^[11] Hence, various antibiotics have been

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incriminated in the treatment of IBS including neomycin and rifaximin albeit with mixed results.^[10,12]

Manipulation of intestinal microflora by probiotics has shown some symptomatic improvement in some studies^[13] lending support to the evidence that intestinal microflora of IBS patients is different from that of healthy individuals.^[14] This study was undertaken to evaluate the efficacy of rifaximin (a broad spectrum poorly absorbed antibiotic) with VSL#3 (Probiotic) in reducing symptoms in patients with IBS without constipation.

MATERIALS AND METHODS

This study was conducted in the Department of Internal Medicine Government Medical college, Srinagar, from February 2012 to September 2013. It was a monocentric, prospective, randomized study involving 220 patients. All the patients' fulfilling diagnostic criterion for IBS (ROME II CRITERIA) Table 1 were enrolled after obtaining proper informed consent. Eligible patients were rated for their abdominal pain on a 7 point Likert scoring system (with 0 indicating no pain at all; 1, hardly; 2, somewhat; 3, moderate; 4, a good deal; 5, a great deal; and 6, a very great deal) and for average daily consistency of their stools on a 5 point scale (1 indicating very hard stool; 2, hard; 3, formed; 4, loose; and 5 watery) over the course of at least 07 days.

Patients with constipation-predominant IBS were excluded from the study as were patients with inflammatory bowel disease, diabetes, uncontrolled thyroid disease, previous surgery, HIV infection, uncontrolled hepatic and renal disease, patients on antispasmodics, tegaserod, antipsychotics, pre-probiotics, and rifaximin.

Patients were randomized into two groups of "A" and "B" comprising 116 and 104 patients, respectively. The study was carried out in two phases whence in Phase 1, Group A received VSL#3 once daily for 2 weeks, and Group B rifaximin twice a day for 2 weeks. Patients were weekly monitored for 10 weeks for symptom improvement. After completion of Phase 1, Phase 2 study was carried out after a washout period of 4 weeks to eliminate the residual effect of Phase 1 drugs before starting Phase 2, crossover was done between two groups. Group A now received rifaximin and Group B received VSL#3.

Table 1: Rome II criteria

A	Continuous or recurrent abdominal pain	>12 weeks
B	>2 of the following	Relief with defecation Change in stool frequency Change in stool form
C	Onset of clinical symptoms	>1 year before diagnosis

The primary endpoint in both the groups was relief of IBS symptoms.

OBSERVATIONS AND RESULTS

None of the demographic parameters with respect to age, sex, and symptomatology were significant statistically [Table 2].

Majority of the patients (57%) in this study were in the age group of 21–40 years, as consistent with world literature [Table 3].^[15]

Neither the difference in the number of patients in the two groups nor the duration of symptoms in two phases was statistically significant [Table 4].

In the Phase-1, there were 60 patients in the probiotic group and 32 patients in the rifaximin group who did not respond to treatment. Of the responders, there were 56 in the probiotic group while as 72 in rifaximin group [Table 5].

The response was sustained in 33 patients in the probiotic group and 46 patients in rifaximin group until the end of the study which was significant statistically.

Sustained response during the 3rd month was seen in 21 patients in the probiotic group while it was seen in 44 patients in rifaximin group in Phase 2. This finding was statistically significant. In this phase, 36 patients in the rifaximin group and 58 patients in the probiotic group did not respond to treatment [Table 6].

DISCUSSION

IBS with a prevalence of 10–20% of the general population globally^[16] and 24.9% in the Kashmir valley^[17] reduces the quality of life and imposes a significant economic burden to the health-care system.

Specific peripheral mechanisms like intraluminal intestinal irritants such as maldigested carbohydrates or fats, excess of bile acids, gluten intolerance, alterations in the microbiome, and genetic susceptibility to inflammation are thought to result in symptoms of IBS.^[18] Other pathophysiological mechanisms that are considered in IBS are abnormalities intrinsic to the smooth muscle of the gut, visceral hypersensitivity, and central nervous system hypervigilance.^[19-21] To reestablish the balance of nature within the intestinal flora to correct the disruption caused by antibiotic treatment, physicians in the past had done fecal microbiota transplantation in the patients with fulminant, life-threatening pseudomembranous colitis

Table 2: Baseline patient characteristics

Demographic parameters	Rifaximin	VSL3#	Remarks
No. of patients	104	116	NS
Age	39±13.559	39.22±11.248	NS
Age group (%)			
<50	83 (79.8)	97 (83.6)	NS
>50	21 (20.2)	19 (16.4)	
Sex (%)			
M	65 (62.5)	66 (56.9)	NS
F	39 (37.5)	50 (43.1)	
Average daily score			
Global IBS score	3.5±0.6	3.4±0.7	NS
IBS related bloating	3.4±0.7	3.4±0.8	NS
IBS related pain	3.3±0.7	3.2±0.8	NS
Stool consistency	3.9±0.3	3.8±0.8	NS
Average daily bowel movement	3.0±1.2	3.0±1.5	NS
Days with stool urgency (%)	81±22.5	81.9±22.6	NS
Duration of IBS symptoms	6.16±4.56	5.28±2.89	NS

IBS: Irritable bowel syndrome

Table 3: Distribution of patients in two groups in two phases of the study

Phase of study	Group		Total	Remarks
	Probiotic	Rifaximin		
	n (%)	n (%)	n (%)	
Phase-1	116 (52.7)	104 (47.3)	220 (100)	NS
Phase-2	96 (49.2)	99 (50.8)	195 (100)	
Total	212 (51.1)	203 (48.9)	415 (100)	
	100	100	100	

NS: Not significant; Chi-square - 0.159; P value - 0.695

Table 4: Distribution of duration of symptoms (years) in patients in two groups

Group	No. of pts	Mean±SD	Minimum age	Maximum age	remarks
Probiotic	116	5.28±2.89	1.0	15.0	NS
Rifaximin	104	6.16±4.56	1.5	30.0	NS

NS: Not significant; P Value - 0.085; SD: Standard deviation

caused by *Clostridium difficile* and reported dramatic responses.^[22] Rifaximin; a minimally absorbed antibiotic and probiotics are currently being used to restore the balance in the gut flora in patients of IBS. This study was conducted to evaluate the efficacy of two frontline modalities of treatment of IBS, i.e., antibiotic (rifaximin) versus probiotic (vsl3#). Functional gut disorders have predominantly been seen to be prevalent in the younger age group and female sex,^[23] but in our study the majority of the patients (59.5%) were males.

Although diarrhea-predominant IBS has been seen to be more in men than in women,^[24] in our study the observation

Table 5: Durability of relief of global IBS symptoms during the entire study period in the two groups in Phase-1

Months	Global IBS Symptom response		Total
	Probiotic n (%)	Rifaximin n (%)	
No response	60 (51.7)	32 (30.8)	92 (41.8)
1	56 (48.3)	72 (69.23)	128 (58.18)
2	44 (37.9)	58 (55.7)	102 (46.36)
3	33 (28.4)	46 (44.2)	79 (35.9)

Chi-square -14.043; P value 0.003. IBS: Irritable bowel syndrome

Table 6: Durability of relief of global IBS symptoms during the entire study period in the two groups in Phase-2

Months	Global IBS symptoms response		Total
	Rifaximin n (%)	Probiotic n (%)	
No response	36 (36.4)	58 (60.4)	94 (48.2)
1	63 (63.6)	38 (39.6)	101 (51.8)
2	51 (51.5)	27 (28.1)	78 (40.0)
3	44 (44.4)	21 (21.9)	65 (33.3)

Chi-square - 19.899; P value<0.0001. IBS: Irritable bowel syndrome

of association of constipation and gender in IBS was extended to indicate the female to male ratio significantly increases according to the severity of constipation

relative to the severity of diarrhea. As far as smoking is concerned, it has not been seen to be a factor implicated in IBS,^[25] as is consistent in our analysis too. IBS comes with frequent relapses which could be managed by a short course of rifaximin as reported by studies that more patients in the rifaximin group had statistically significant ($P < 0.001$) relief of global IBS symptoms as compared to placebo in case of relapses.^[26] In the VSL#3 group proportion of patients having satisfactory relief of IBS symptoms compared to placebo is not statistically significant.^[27] The key secondary endpoint - adequate relief of IBS related bloating for at least 2 of the first 4 weeks after treatment was achieved in 47.1% of rifaximin group and 29.3% of the probiotic group in Phase 1 and 51.5% of rifaximin group and 34.4% of probiotic group in Phase 2 (after crossover).

Hence, rifaximin proved superior to probiotic in achieving both primary and secondary endpoints with sustained response at 12 weeks in a significant proportion of patients (nearly 49%).

Studies conducted by Pimentel and Kim have concluded that rifaximin and probiotic have significantly reduced bloating symptoms as compared to placebo ($P < 0.001$).^[26,27]

No comparative study is available between rifaximin and probiotic vis a vis bloating is concerned. In daily global IBS symptoms 11.5% and 11.1% of the patients in the

rifaximin group and 9.5% and 7.3% patients in the VSL#3 group, hardly had any response to treatment in Phase 1 and Phase 2 (after crossover), respectively. However, 38.5% and 41.4% of patients in the rifaximin group and 23.3% and 27.1% of patients in the VSL#3 group reported their response to treatment as somewhat in Phase 1 and Phase 2, respectively. This was statistically significant.

In a worldwide analysis pertaining to the durability of response to rifaximin, it was concluded that the response was more over a course of 3 months on the basis of daily assessments.^[26]

CONCLUSION

The primary endpoint was attained in 51% and 49.5% of the patients in rifaximin group and 37.1% and 34.4% in the VSL#3 group in Phase 1 and 2, respectively, with $P = 0.04$ in both the phases. The key secondary endpoint was attained in 47.1% and 51.5% of patients in the rifaximin group and 29.3% and 34.4% of patients in the VSL#3 group in Phase 1 and 2, respectively. The respective p values in Phase 1 and 2 were 0.008 and 0.021, respectively.

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Do Migrants Differ in Knowledge Regarding Mosquito-Borne Diseases and Mosquitoes?

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Abstract

Introduction: Mosquito-borne diseases (MBDs) are one among the major public health problem in India. Surat city being endemic for MBDs and catering large proportion of migrants along with the non-migrants motivated us to conduct this research to study and compare the knowledge about MBDs and mosquitoes among migrants and non-migrants.

Methods: A community-based cross-sectional study conducted among migrant and non-migrant families of Surat city by employing a stratified sampling technique and using a pretested semi-structured questionnaire between July 2015 and October 2016.

Results: Equal number of migrant and non-migrant families were studied (200 each) of which majority of migrant families were from Uttar Pradesh and Bihar (46%) with lower middle socioeconomic class (38.5%) while the majority of non-migrants were from upper middle socioeconomic class (39%). The ability to name at least one MBD was less among migrants (67%) as compared to non-migrants (73.5%). Significantly higher number of non-migrants (52.5%) named dengue as MBD as compared to migrants (39.5%) ($P = 0.01$). Similarly, significant higher number of non-migrants (51.5%) mentioned fever with chills as the symptom of malaria as compared to migrants (41%) ($P = 0.04$). Around 48% non-migrants and 38% migrants knew that different types of mosquito exist. Around 62% non-migrants and 55% migrants knew that mosquito lay eggs and among them more than half replied water as the breeding place for mosquitoes. It was observed that breeding places in ($P = 0.04$) and around ($P = 0.03$) the houses of migrants were significantly higher as compared to non-migrants.

Conclusion: Study findings clearly shows that overall non-migrant respondents had higher knowledge about MBDs and mosquitoes in comparison to migrant respondents and thus emphasizes the need for generating the awareness regarding MBDs and mosquitoes especially in areas dominated by migrant population.

Key words: Knowledge, Migrants, Mosquito-borne diseases, Mosquitoes, Non-migrants

INTRODUCTION

Vector-borne diseases (VBDs) are an important group of infectious diseases. Over half of the world's population is at risk from VBDs. They account for 17% of the estimated global burden of all infectious diseases.^[1] Among VBDs, mosquito-borne diseases (MBDs) are an important public health problem in countries of South East Asia Region (SEAR) including India. Malaria,

Dengue, and Filariasis are the prevalent MBDs in India and are also responsible for considerable morbidity and mortality.^[2]

Migration plays a very important role in the spread of MBDs. Migrants may have a lot of difference in their housing conditions, environment, knowledge, and practices. As a result, their health status is also different. A study has also documented that these differences are seen even in health behavior.^[3]

Surat city being endemic for MBDs such as malaria, dengue, and filariasis due to its favorable climatic condition and also a city with highest migrant population provided us an excellent opportunity to study how migrants were different as compared to non-migrants in their knowledge regarding MBDs and mosquitoes.^[4,5]

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MATERIALS AND METHODS

This was a community-based cross-sectional study, conducted among migrant and non-migrant families between July 2015 and October 2016, in Godadara area of South-east zone of Surat city.

For the purpose of the study, we defined Migrant family as a family which has migrated to Surat (particularly in Godadara area) from any other city of Gujarat or India and has stayed for a period of <10 years and non-migrant family as a family which has been living in Surat (particularly in Godadara area) for 10 years or more. Near about 400 families were studied, out of which 200 were migratory and 200 were non-migratory families. Stratified sampling technique was employed. The whole study population was divided into migrant, and non-migrant population and the migrant population was divided into 5 strata based on their native place (4 states and 1 other districts of Gujarat). A total of 400 adult individuals (200 each from migrant and non-migrant families) were interviewed. A pre-tested semi-structured questionnaire was used to collect data which was entered into Microsoft Excel and analyzed using IBM SPSS v 19 software. The χ^2 -test was used for the group comparisons.

RESULTS

Sociodemographic information as depicted in Table 1 shows that majority of migrants belonged to Uttar Pradesh and Bihar and were in age group of 31–40 years. Most of the migrants studied up to secondary and non-migrants up to higher secondary school. Higher number of migrants belonged to lower middle class, and non-migrants belonged to upper middle class. Almost half of the non-migrants had outdoor sleeping habits [Table 1].

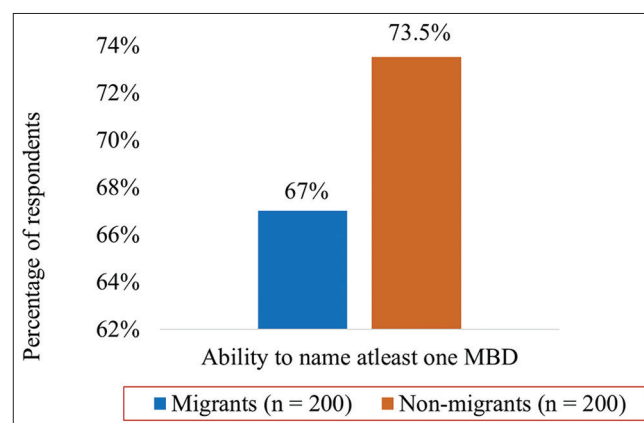
Ability to name at least one MBD was less among migrants 134 (67%) as compared to non-migrants 147 (73.5%) [Graph 1]. About 138 (69%) non-migrant and 125 (62.5%) migrant respondents named Malaria while significantly higher number of non-migrants 105 (52.5%) named dengue as MBD as compared to migrants 79 (39.5%) ($\chi^2 = 6.80$, $df = 1$, $P = 0.01$).

Significantly, higher number of migrants 56 (28%) mentioned fever ($\chi^2 = 4.51$, $df = 1$, $P = 0.03$) while significantly higher number of non-migrants 103 (51.5%) mentioned fever with chills as the symptom of malaria ($\chi^2 = 4.44$, $df = 1$, $P = 0.04$) [Graph 2].

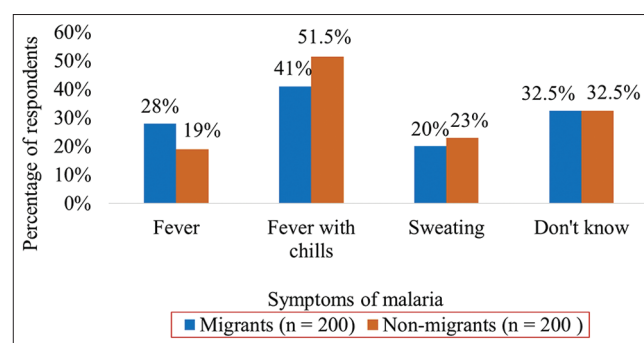
There was no significant difference in the knowledge about symptoms of dengue among migrants and non-migrants [Graph 3].

Around 76 (38%) migrants and 96 (48%) non-migrants knew that different types of mosquito exist. Among them, higher number of migrants knew the correct vector of malaria 34 (44.7%) and its biting time 35 (46.1%) [Graph 4].

Higher number of non-migrants 59 (61.5%) knew that aedes mosquito is the vector for dengue as compared to migrants 39 (51.3%); similarly the knowledge regarding



Graph 1: Ability to name at least one mosquito-borne disease

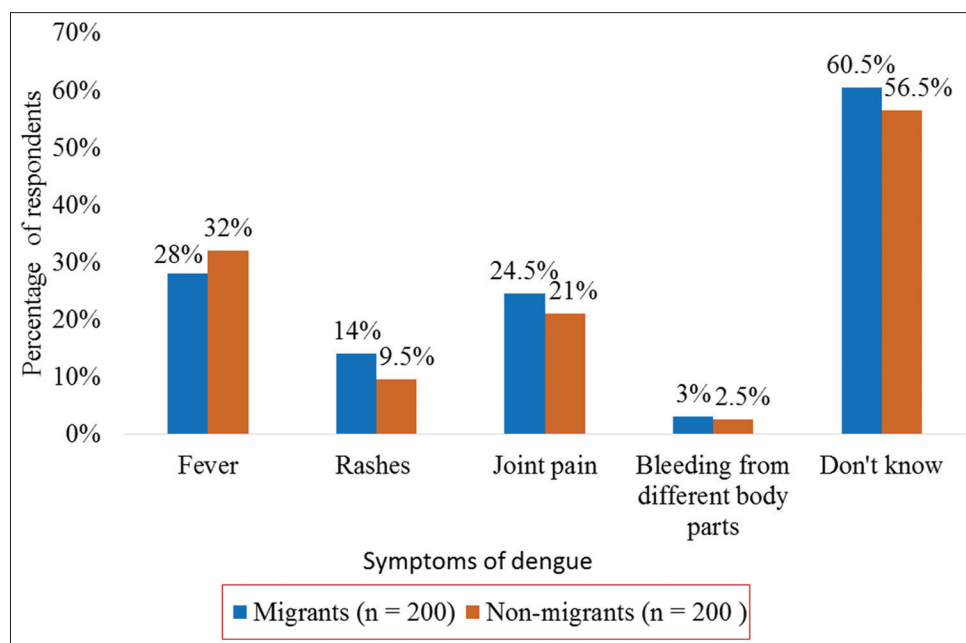


Graph 2: Knowledge about symptoms of malaria

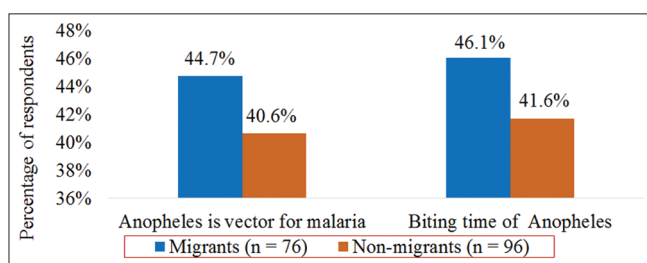
Table 1: Sociodemographic information

Variables	Migrants 200 (100%)	Non-migrants 200 (100%)
State	Uttar Pradesh and Bihar 92 (46%)	Surat 200 (100%)
Age group (in completed years)	31–40 years 81 (40.5%)	31–40 years 72 (36%)
Education*	Secondary 55 (27.5%)	Higher secondary 42 (21%)
Socioeconomic status**	Lower middle 77 (38.5%)	Upper middle 78 (39%)
Outdoor sleeping habits	79 (39.5%)	99 (49.5%)

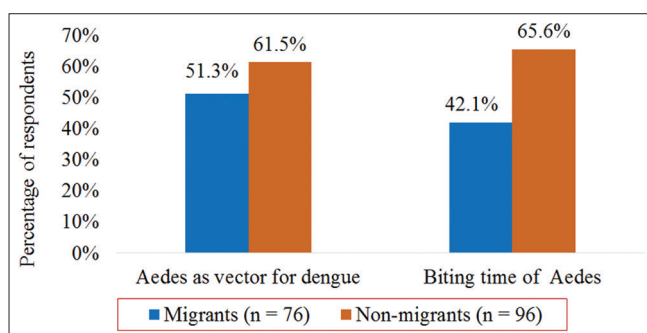
*Education - Secondary school: 9th and 10th standard, higher secondary school: 11th and 12th standard, **Socioeconomic status based on modified prasad's classification (February 2015 AICPI = 1171)



Graph 3: Knowledge about symptoms of dengue



Graph 4: Knowledge about malaria vector and its biting time



Graph 5: Knowledge about dengue vector and its biting time

correct biting time of the aedes mosquito was also more among non-migrants 63 (65.6%) as compared to migrants 32 (42.1%) [Graph 5]. Higher proportion of non-migrants knew that Culex is a vector for filariasis 26 (27.1%) and also knew its biting time 36 (37.5%) [Graph 6].

Around 110 (55%) migrants and 123 (61.5%) non-migrants knew that mosquito lay eggs. Among them, more than half replied water as breeding place (61 [55.5%] migrants and 64 [52%] non-migrants, respectively). Among them, a higher

proportion of migrants had knowledge about the breeding habit of Anopheles 33 (54%), and a higher proportion of non-migrants had knowledge about the breeding place of Aedes 35 (54.7%) and Culex 52 (81.3%) [Graph 7].

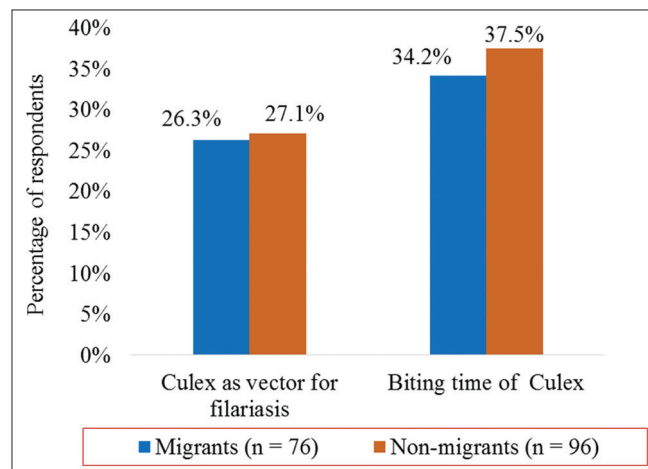
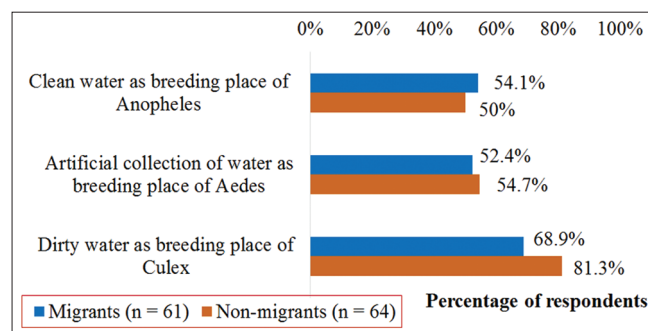
It was observed that breeding places in and around the houses of migrants were significantly higher as compared to non-migrants [Table 2].

DISCUSSION

The present community-based cross-sectional study was conducted to know the knowledge regarding MBDs and mosquitoes among migrants and non-migrants of Surat city. In the present study, the majority (46%) of migrants belonged to Uttar Pradesh and Bihar. Majority of migrants (40%) and non-migrants (36%) were in the age group of 31–40 years. These findings were similar to a study which was done in Delhi.^[6] Another study of Delhi conducted by Kohli *et al.* reported lesser proportion (28.6%) of participants between 30 and 39 years of age.^[7] Most of the migrants (27.5%) studied up to secondary and non-migrants (21%) up to higher secondary school. In a study conducted in Delhi, majority (24%) of the participants were illiterates.^[7] Another study conducted in Lhasa (Tibet) also reported that majority (34.9%) of the participants had completed their primary school education.^[8] Higher number of migrants (38.5%) belonged to lower middle class and non-migrants (39%) belonged to upper middle class. Higher number of non-migrants (49.5%) had outdoor sleeping habits as compared to migrants (39.5%).

Table 2: Observatory findings

Variables	Migrants 200 (100%)	Non-migrants 200 (100%)	χ^2 , P value (df = 1)
Breeding places of mosquitoes observed in the house	41 (20.5%)	26 (13%)	4.03, 0.04
Breeding places of mosquitoes observed around the house	39 (19.5%)	24 (12%)	4.23, 0.03
Adult mosquitoes seen in the house	23 (11.5%)	12 (6%)	3.78, 0.05

**Graph 6: Knowledge about filariasis vector and its biting time****Graph 7: Knowledge about breeding places of vectors**

In the present study more than two-third of the participants, i.e., 67% among migrants and 73.5% among non-migrants were able to name at least one MBD. More than three-fifth of the respondents named malaria while knowledge about dengue being a MBD was found to be significantly higher among non-migrants as compared to migrants ($P = 0.01$). These findings can be compared with another study conducted by Patel *et al.* in Rajkot where it was found that more than three-fifth (62%) of the participants had knowledge that malaria is transmitted by mosquitoes.^[9] The reason for higher awareness about malaria, dengue in the present study may be endemicity of the diseases in Surat and awareness campaigns conducted by Government and municipal authorities. Significantly, higher number of non-migrants was aware of “fever with chills/rigor” as compared to migrants ($P = 0.04$), while as a symptom of malaria “fever” was mentioned by significantly higher number (28%) of migrants as compared to non-

migrants (19%) ($P = 0.03$). As compared to the present study, higher awareness about the symptoms of malaria among the participants was seen in a study conducted in Ethiopia where fever and chills were most frequently mentioned symptoms reported by 94.4% and 93.3% of the participants, respectively.^[10] When asked about the symptoms of dengue, there was no significant difference in the knowledge among migrants and non-migrants.

Present study findings report that a higher proportion of participants knew that malaria and dengue are MBDs as compared to people having knowledge about symptoms of respective diseases. This could be because people are not fully aware about MBDs except that mosquito cause them.

The present study reports that a higher proportion of non-migrants (48%) knew that different types of mosquito exist as compared to migrants (38%). Among them higher number of migrants knew the correct vector of malaria (migrants [44.7%] and non-migrants [40.6%]) and its biting time (migrants [46.1%] and non-migrants [41.6%]), while higher proportion of non-migrants had knowledge that Aedes is vector for dengue (non-migrants [61.5%], and migrants [51.3%]) and also knew its biting time (non-migrants [65.6%] and migrants [42.1%]). Higher proportion of non-migrants knew that Culex is vector for filariasis (non-migrants [27.1%] and migrants [26.3%]) and also knew its biting time (non-migrants [37.5%] and migrants [34.2%]). Studies conducted in Ethiopia and Pakistan have reported a higher proportion of participants as compared to present study which mentioned mosquito bite as the cause of malaria and dengue, respectively, while a study from South India reported the lesser proportion of participants who mentioned mosquito bite as the cause of filariasis as compared to the present study.^[10-12] None of the other studies conducted explored the knowledge of mosquito type among study participants. The reasons for the majority of the participants being unaware of the existence of different types of mosquito could be either due to their educational background or lack of effective IEC programs regarding MBDs such as malaria, dengue, and filariasis.

In the present study, more than half of the migrants and non-migrants replied that mosquitoes lay eggs and among them more than half of the participants in each group mentioned water as the breeding place for mosquitoes.

Among them, a higher proportion of migrants had knowledge about the breeding habit of *Anopheles*, and a higher proportion of non-migrants had knowledge about the breeding place of *Aedes* and *Culex*.

The findings of the present study can be compared with another study conducted in Rajkot *et al.* where more than half (54.2%) of the participants mentioned drains or polluted water as the breeding places of mosquitoes.^[9] As per the findings of a study conducted in Ethiopia, stagnant water was identified by majority (91.6%).^[10] Study conducted by Ghosh *et al.* in West Bengal reported that two-third (66.67%) of the people identified polluted water of drains as a major source of mosquito breeding.^[13] Not all the participants knew about the egg-laying habits of mosquitoes and even among those who were aware, not all knew the breeding habits of mosquitoes. Knowledge about the breeding habits is important to prevent breeding places in and around the vicinity of the house and hence prevent MBDs. The present study findings highlight the fact that people are not fully aware of factors favorable for transmission of MBDs. This could lead to an increase in potential and active breeding sites in and around their surroundings.

Findings of the present study report that breeding place/s of the mosquitoes in and around the house were observed in the significantly higher proportion of migrant as compared to non-migrant families. Adult mosquitoes were seen in the houses of 11.5% migrants and 6% non-migrants. The present study findings can be compared with a study conducted in Delhi by Anand *et al.* which reports that on house visit, majority of the houses (56%) had potential mosquito breeding sites in and around the house, and adult mosquitoes were seen in nearly two-third (67%) of the houses of the participants.^[6] Breeding sites (active and/or potential) in and around the houses indicate a high risk of transmission of MBDs such as malaria, dengue, and filariasis.

CONCLUSION

This study reported that overall, non-migrant respondents had higher knowledge about MBDs and mosquitoes as compared to the migrant respondents. Only a few participants had correct knowledge about the type of water in which vector for malaria and dengue breed. Hence, the presence of breeding sites could be due to lack of knowledge of the breeding sites of mosquitoes or lack of transformation of knowledge into action.

Recommendations

The data generated by this study can serve as useful baseline information for future studies. Awareness programs should be targeted specifically toward migrants in their local language, especially in areas dominated by the migrant population as overall knowledge regarding MBDs and mosquitoes was found to be less in the migrant population. There is a need to intensify the awareness programs to educate the community about symptoms of MBDs so that they can identify the disease at an early stage and seek medical care.

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Surgery for Carcinoma of Esophagus Pyloroplasty - Is it a Boon or Bane to the Patient?

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Abstract

Background: Pyloroplasty is a pyloric drainage procedure routinely done during transhiatal esophagectomy (THE) or video-assisted thoracoscopic surgery (VATS) to prevent delayed gastric emptying resulting from truncal vagotomy.

Aim: The ultimate aim of our study is to find out whether the pyloroplasty following THE or VATS is detrimental or beneficial to the patient by comparing the patient's symptoms and endoscopy finding after 1 month, with or without pyloroplasty.

Methods: It is a retrospective study comparing 40 patients with esophageal cancer who underwent THE or VATS from January 2015 to December 2017. 22 patients underwent THE or VATS without pyloroplasty, while the other 18 patients underwent THE or VATS with pyloroplasty.

Results: Respiratory complications are more in pyloroplasty group (6/18) compared to without pyloroplasty group. However, other symptoms are more in the pyloroplasty group compared to without pyloroplasty group, and it is statistically significant, i.e., $P < 0.05$. Endoscopy at 1 month follows up confirm duodenogastric reflux, i.e., 6/18 in pyloroplasty group and 0/22 in without pyloroplasty group.

Conclusion: We recommend in patients with normal pyloroduodenal opening and using tubularized stomach after THE or VATS, it is better to avoid pyloroplasty.

Key words: Esophagectomy, Gastric emptying time, Gastric pull up, Pyloroplasty

INTRODUCTION

The gold standard of surgery for carcinoma is the removal of the esophagus using transhiatal esophagectomy (THE) or McKeown's three-stage procedure or minimally invasive esophagectomy video-assisted thoracoscopic surgery (VATS). While replacing the excised part of the esophagus with the gastric conduit, truncal vagotomy is performed, and routinely a pyloric drainage procedure might follow. The impetus to perform a drainage procedure after esophagectomy is historically derived from experience with truncal vagotomy for peptic ulcer

disease.^[1] Controversy still surrounds the need for pyloric drainage following esophageal substitution with gastric conduit after esophagectomy. Although the randomized controlled trial has addressed the need for pyloric drainage after esophageal substitution, the variability of the surgical method, choice of conduit (whole stomach or gastric tube), conduit position, and anastomotic location confound the analysis. It became apparent that pyloroplasty or pyloromyotomy could potentially alleviate the emptying delay associated with the vagotomized stomach. In contrast, after esophageal substitution with the gastric conduit, delayed gastric emptying was not influenced by either pyloroplasty or pyloromyotomy.^[2] Establishing pyloric drainage after esophagectomy with complete vagotomy has not been widely accepted as the standard of therapy in high-volume esophageal centers. Previous studies documented the uselessness of pyloric drainage procedures by either pyloroplasty or pyloromyotomy following esophageal substitution with the gastric conduit. Only a few patients develop delayed gastric emptying after esophagectomy,

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and pyloroplasty patient may be predisposed to dumping and duodenal bile reflux and thus impairing post-operative functional outcome.^[3] Moreover, it has been reported that gastric drainage following esophagectomy has no influence on the delayed gastric emptying, and the foregut function improves with time, regardless of a pyloric drainage procedure. Interestingly, there are data to suggest that the need for a pyloric drainage procedure may be more related to the size of the gastric conduit, in that large conduits (whole stomach) are more susceptible to gastric stasis.^[4]

Aim

The ultimate aim of our study is to find out whether the pyloroplasty following esophagectomy (THE/VATS) is detrimental or beneficial to the patient by comparing the patient's symptoms, and endoscopy findings after 1 month, with or without pyloroplasty.

MATERIALS AND METHODS

The study population included patients who underwent THE or VATS for malignant disease in the Department of Surgical Gastroenterology, Government Mohan Kumaramangalam Medical College and Hospital, Salem, Tamil Nadu, South India, from January 2015 to December 2017. It is a retrospective study comparing the symptoms and signs related to the delayed gastric emptying of patients who underwent THE/VATS, with or without pyloroplasty. 18 patients underwent esophagectomy (THE/VATS) with pyloroplasty, and 22 patients underwent esophagectomy (THE/VATS) without pyloroplasty. Inclusion criteria: All patients who underwent esophagectomy regardless of the type of a tumor, site of a tumor (mid/lower 1/3rd) and all the patients who underwent esophagectomy regardless of the neoadjuvant status. Exclusion criteria: Repeat esophagectomy or emergency esophagectomy is excluded from the study. Patients with the history of gastric outlet obstruction (GOO), previous gastric procedure, and other intestinal obstructions are excluded from the study. Perioperative complicated patients and post-operative death patients. The patient underwent thoracotomy was excluded from the study patients who were in ventilatory support for more than 24 h or patients who needed reintubation, are excluded from the study. Signs and symptoms pertaining to delayed gastric emptying are analyzed postoperatively in all patients, namely vomiting, retching, heartburn, and regurgitation. All patients underwent upper gastrointestinal endoscopy after 1 month to find out whether the patient is having stasis or biliary gastritis. Operative techniques were standardized among surgeons. All conduits are placed in the posterior mediastinum. Esophagogastric anastomosis was done in end-to-side or end-to-end fashion with interrupted hand sewn technique. All patients underwent gastric tube

Table 1: Distribution of complication in both study groups

Complications	With pyloroplasty	Without pyloroplasty	P value
Respiratory complication	4	3	0.247
Vomiting	6	0	0.003
Retching	6	1	0.017
Heartburn	6	0	0.003
Regurgitation	6	0	0.003

Table 2: Endoscopy at 1 month

Gastroduodenoscopy	With pyloroplasty	Without pyloroplasty	P value
Biliary gastritis	6	0	0.000

pull up with the diameter ranging from 4 cm to 6 cm. The use of pyloric drainage procedure was surgeon dependent. A jejunal feeding tube was placed in all patients, and enteral nutrition was instituted usually in the second post-operative day and advanced as tolerated.

RESULTS

Review of the Department of Surgical Gastroenterology database at Government Mohan Kumaramangalam Medical College and Hospital revealed 40 patients underwent esophageal resection either by THE or VATS over a period of 36 months. Patients were divided into two groups based on the use of a pyloric drainage procedure. Pyloric drainage in the form of pyloroplasty was performed in 18 patients and 22 patients had no pyloric drainage. Patients' signs and symptoms pertaining to delayed gastric emptying and duodenal gastric reflux are analyzed and the results are given below, and upper gastrointestinal endoscopy was done at 1-month post-operative period for all patients and results are given below.

As per the above values even through respiratory complications are more "with pyloroplasty" group, it is not statistically significant ($P = -0.247$). However, other symptoms, namely vomiting, retching, heartburn, and regurgitation, are predominant in with pyloroplasty group. The above symptoms are further confirmed by endoscopy at 1-month follow-up, and also the endoscopy reveals biliary gastritis further confirmed that the patient "with pyloroplasty" group is having duodenogastric Tables 1 and 2.

DISCUSSION

A gastric conduit is usually used as the esophageal replacement after vagotomized THE for esophageal cancer. The gastric emptying may be impaired after this

operation, so some esophageal surgeons routinely add pyloric drainage procedures. The value of adding pyloric drainage to esophagectomy and whether the intervention is of benefit continues to be debated. Previous literature^[5,6] recommended the use of pyloroplasty on every patient to prevent the potentially lethal effects of gastric stasis in the early post-operative period following retrosternal reconstruction of the esophagus, especially if the whole stomach is used for esophageal substitution. In a frequently cited prospective randomized controlled study, Wang *et al.*^[5,7] reported a higher incidence (13%) of GOO and pulmonary complications in patients who did not undergo a pyloroplasty after Ivor-Lewis esophagectomy. Urshel *et al.* meta-analyzed clarified that pyloric drainage during esophagectomy and gastric reconstruction might reduce the occurrence of early post-operative GOO. This meta-analysis also revealed that the presence or absence of pyloric drainage has little impact on most relevant outcomes among patients. However, the validity of this meta-analysis was restricted due to the small number of patients, different conduit sizes, routes of reconstruction, and study endpoints of the compared controlled randomized trial.^[8] Lantoni *et al.* showed that pyloromyotomy did not reduce the incidence of delayed gastric emptying.^[3] In another study, pyloroplasty and pyloromyotomy could be effective and stage drainage procedures, but they might increase biliary reflux esophagus.^[9] Palmer *et al.* study indicated that not only pyloric drainage does not improve gastric emptying but it may also favor to bile reflux and esophagitis. Mucosal damage from acid and bile exposure in the esophageal remnant affects nearly 50% of these patients.^[10,11] In Yajima's study, pyloroplasty was the only important risk factor according to univariate and multivariate analysis (R.R 2.52, 95% confidence interval 1.29–4.96, $P = 0.007$). Pyloroplasty can lead to bile reflux to the cervical remnant through the gastric tube in the long term and thereby lead to reflux esophagitis in the cervical remnant.^[12] Zieren *et al.* showed no need for pyloric drainage in a randomized study comparing pyloroplasty to intact pylorus with a cervical anastomosis.^[13] Bemelman *et al.* reveals, delayed post-operative emptying after esophageal resection is dependent on the gastric substitute. Their study has theoretically been attributed to the more vertical position and superior gravity drainage of tubular size gastric remnant. Tabularized conduits are less distensible and achieve greater intestinal conduit pressure over a shorter period of time compared to the whole stomach which is larger and more distensible.^[4,13] Since intraconduit pressure rises in proportion to intraconduit volume, filling of the tabularized conduit overcomes pyloric sphincter-intraduodenal pressure more readily.^[4,15] Most of the studies^[3,4,9-15] above are in favor of against pyloroplasty, as it did not prevent delayed gastric emptying and also lead to biliary gastritis and esophagitis due to duodenal gastric

reflux. Our study is a retrospective comparative study, and it also goes in coherence with above studies. From our study, it clearly shows that the patient undergoing esophagectomy by means of THE or VATS with narrow gastric tube should better avoid pyloroplasty as it is detrimental to the patient.

CONCLUSION

In this retrospective study, we recommend in patients with the normal pyloroduodenal opening and using tabularized stomach after THE or VATS, it is better to avoid pyloroplasty as it is detrimental to the patient in the form of bile reflux gastritis.

Limitations of the Present Study

1. This is a retrospective comparative study,
2. The study needs to be performed in large number of patients, "n" number is low here.
3. Tubularized stomach conduit was compared in our study. Thus, we could not compare the ultimate results with whole stomach conduit.

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Comparison of Sucralfate, Silver Sulfadiazine, and Chlorhexidine Gluconate in Open Versus Close Partial Thickness Burn Dressing: A Comparative Study

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Abstract

Purpose: The purpose of this study was to compare open versus close partial thickness burn dressing with sucralfate, silver sulfadiazine (SSD), and chlorhexidine gluconate.

Materials and Methods: A prospective cross-sectional analytical study was carried out in Paediatric Surgical Ward of a tertiary center of West Bengal in a patient with 1 and 2° burns with close dressing with sucralfate, SSD, and chlorhexidine gluconate for a period of 3 weeks. The outcome was compared with the previous record of hospital in a patient with 1 and 2° burn under the age group of 15 years.

Results: Of 30 patients, 12 (40%) and 18 (60%) were male and female, respectively. 28 (93.33%) patients were <10 years of age who sustained the burn injury. The total number of death was observed only in 2 cases (6.66%). While comparing with the previous records of the past 5 years, it was noted that total death occurred in open dressing technique death was recorded in 11 (36.66%) patients.

Conclusion: Close dressing of partial thickness injury is better technique in comparison to open dressing to minimize the mortality.

Key words: Chlorhexidine gluconate, Close dressing, Partial thickness burn injury, Silver sulfadiazine, Sucralfate

INTRODUCTION

The main purpose of burn wound healing is to promote early healing and closure. The delayed healing has considerable influence on the long-term quality and cosmesis of a hypertrophic scar. A small scars have been considered negative psychosocial outcomes for children, hence, the importance of effective wound healing techniques.^[1] There is

a strong relationship between scar formation and time taken to re-epithelialize in children as explained by burn clinicians. Cubison *et al.*^[2] have explained that the partial thickness burns that re-epithelialize within the optimal time period of 10–14 days generally do so without scarring, and those taking >3 weeks will invariably scar. Burns re-epithelializing at between 2 and 3 weeks will have variable amounts of scar tissue laid down depending on many factors including skin type, anatomical location of the burn, and age of the child.^[2] If the healing takes more than 3 weeks, the risk of scarring is increased.^[2] However, in case of wound infection, there is delayed healing and followed by scarring and contracture formation thereafter.^[2] Scars, if situated around a joint, can lead to joint contracture and loss of function, resulting in ongoing scar reconstruction to keep up with the child's growing body.^[3]

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In the past 3–4 decades, the most commonly practiced method of burn treatment was daily baths, dressing changes, and antiseptic or topical silver sulfadiazine (SSD)-based creams; however, these procedures were very distressing and painful for children even after administration of analgesic.^[4] It is an established fact that burn wound care procedures are traumatic for children and the resultant stress has been shown to interrupt and delay the cascade of wound healing.^[4]

Hence, our aim is to minimize the wound infection, contracture formation to nil, and earliest possible rehabilitation. This necessitated that especially in the pediatric population, choosing a dressing that can be applied and removed with minimal pain stress and incidence of infection to the child to restore the rehabilitation at optimal level. Since it was observed that there is higher incidence of wound infection, septicemic shock, and death in open dressing, we tried close dressing and studied the ultimate outcome in terms of morbidity and mortality. A dressing that requires less frequent reapplication has obvious benefits by decreasing the number of dressing change procedures the child has to undergo.

MATERIALS AND METHODS

This prospective cross-sectional analytical study was conducted in a Paediatric Surgical Ward tertiary health care center of Kolkata, West Bengal, from September 2016 to August 2018 with a sample size of 30. Approval and prior permission for this study were taken from Institutional Ethical Committee. The participant for this study was recruited from Paediatric surgical emergency of tertiary health care center. The outcome was compared with the records of previous 5 years in same age group of child under the age of 15 years.

Inclusion Criteria

Children who were aged 0–15 years with 1° and 2° burn injury and a burn total body surface is of $\leq 60\%$ presenting within first 48 h post-injury were included in this study.

Exclusion Criteria

Children will be excluded from this study if they present >48 h post-burn, have received silver dressings before presentation, present with cold, flu, or viral symptoms, for example, upper respiratory tract infection, have received inappropriate first aid, have known reaction to silver products, and have a cognitive impairment.

Intervention

The patient was primarily washed with normal saline then dapped with normal saline soaked gauge followed by application of thin film of sucralfate-SSD (with SSD),

sucralfate-chlorhexidine gluconate ointment followed by application of jelonet and light roller bandage. The dressings in all cases will be carried out by staff experienced in burn dressing application. The pain, behavioral scores, hemodynamic status, and respiratory rate will be recorded by the primary investigator before and after the dressing has been applied. The dressing was repeated at an interval of 72 h and was looked for any discharge, smell color change, any slough granulation tissue, and pain sensation. At each dressing change, pain, behavior, and physiological measures (pulse rate and respiratory rate) will be taken before and after dressing removal and before and after the reapplication of a new dressing. The time is taken for the dressing removal, cleaning and reapplication procedure, and quantity of dressings. The time taken for the dressing removal, cleaning and reapplication procedure, the number of nurses required completing the entire procedure, quantity of dressings used, and analgesia given to the participant will be recorded.

The healing process started from 7 days onward. The epithelialization was observed around 21 days. After epithelialization, the wound was kept open for rest of period. The patient was discharged after 4 weeks with an advice of application only moisturizer. Follow-up of the patient was done for 6 months.

This study was compared with previous record of treatment 1°–2°C burn with the age matched same sample size treated in our ward in the past 5 years with the same pharmacological compound by open dressing.

Observation

Of 30 patients, 12 and 18 were male and female, respectively [Figure 1, Table 1]. Majority of the patients were <10 years of age who sustained the burn injury. So far, mode of injury was maximally with contact with boiling water. The total number of death was observed only in 2 cases (6.66%). While comparing with the previous records of

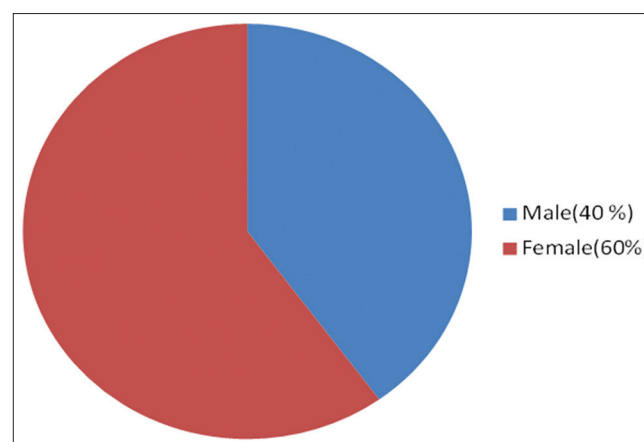


Figure 1: Sex distribution of the patient

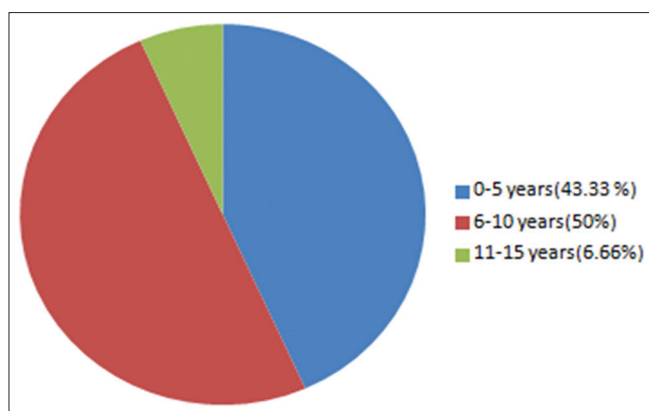


Figure 2: Distribution of patient in different age group

Table 1: Sex distribution

Male (%)	Female (%)
12 (40)	18 (60)

Table 2: Age distribution of the patient

Age group (year)	Number of the patient (%)
0-5	13 (43.33)
6-10	15 (50.0)
11-15	2 (6.66)

the past 5 years, it was noted that total death occurred in open dressing technique death was recorded in 11 (36.66%) patients [Figure 2, Table 2].

DISCUSSION

Majority of the patient were <10 years of the patient (93.33%). This can be explained by the fact that maximum number of patients were from low-income group residing in one room and crowded population in slum area of city. It was noted that <10 years of age group of child kept confined in one room. A portion of room was used for kitchen purpose. In our study, pain and distress during dressing procedures remain a major challenge while treating acute burn injuries.^[5] The silver dressing is the gold standard technique in burn dressing. The previous

study clearly depicts these dressings only show benefits using these silver dressings in comparison with SSD creams for burn injuries and is not specific to pediatric or adult patients.^[6] Therefore, in pediatric silver dressings are associated with lower levels of pain and rapid wound re-epithelialization and are considered imperative and for clinical care and evidence-based practice in this field as well. A strong correlation has been established between the rate of re-epithelialization of a burn wound and the risk of hypertrophic scarring. Partial thickness burn injuries that take healing time 10–14 days are at a very low risk of developing hypertrophic scarring, in comparison to those wounds taking >3 weeks to re-epithelialize are likely to result in hypertrophic scarring.^[2] Dressings that are comfortable and easy to move in and that require infrequent changes or open type are also beneficial for the pediatric population. Open types of dressing are more prone to get infection, septicemia, and death thereafter. Decrease in pain and distress experienced during a dressing procedure can have positive implications psychosocially for the child as well as encouraging re-epithelialization of the wound within the optimal healing timeframe.^[5]

Conclusively, it has been found that closed dressing in partial thickness burn injury is better option than that of open type because of faster rehabilitation and lesser mortality.

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Effect of High Altitude on Cardiovascular Parameters among Permanent Natives of Ladakh

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Abstract

Background: The study undertaken involved finding the effect of high altitude on cardiovascular parameters in a sample of 100 subjects of Ladakh divided into four groups, of age range 1–60 years with normal health, who migrate to lowland area (Jammu) during winter for 1–2 months and the results so obtained were compared with equal number of healthy residents of Jammu (control group).

Materials and Methods: Standard procedures were used. Blood pressure (BP) was recorded using a sphygmomanometer, pulse rate by the palpatory method and respiratory rate by counting the number of breaths for 1 min (observing how many times the chest and abdomen rises).

Results: It was found that the resting mean pulse rate in all the groups of high altitude subjects was higher on day 1 than at 2 months (almost equal to the control group) which was statistically highly significant. The difference in mean pulse rate between high altitude males and females was statistically non-significant. Furthermore, the elderly subjects showed a decreased mean pulse rate compared to the young subjects (mean pulse rate of Groups I, II, III, and IV males was 77 ± 2.6 , 73.5 ± 2.6 , 69.5 ± 1.8 , and 64.1 ± 1.1 and of females was 76.9 ± 2.1 , 73 ± 2.0 , 69.3 ± 1.8 , and 64 ± 1.1 , respectively). The high altitude subjects of all groups showed hypoventilation on day 1 of arrival to low altitude which after 2 months became almost equal to that of control group due to adaptation to sea level. There was a steeper increase in the mean BP with age in high altitude people than the lowland people. The increase in mean diastolic BP (DBP) of high altitude people was more which was statistically highly significant. Furthermore, the males had a higher mean DBP than the females. However, the difference in the mean systolic BP was statistically non-significant.

Conclusion: High altitude natives have distinctive biological characteristics that appear to offset the stress of hypoxia. Evolutionary theory reasons that they reflect genetic adaptations resulting from natural selection favoring more effective adaptive responses.

Key words: Acclimatization, Cardiovascular parameters, High altitude

INTRODUCTION

High altitude places are among the most inhospitable on earth. Two main challenges to life at high altitude come from hypobaric hypoxia and the low ambient temperatures. However, many people live and work at high altitude with no apparent adverse effects.^[1]

In the context of human responses to altitude, it is useful to consider three processes that are related but different. The first is high altitude acclimatization which refers to the physiological changes that occur in lowlanders (people who normally live near sea level) when they go to altitudes of up to about 5000 m to work or play. The second process is a true evolutionary adaptation which has occurred in humans who have resided for many generations at high altitude, especially in the South American Andes and the Tibetan plateau. The third process is the physiological changes that take place at extreme altitudes, and these should be distinguished from the first two processes.^[2]

Man and some other animals show a remarkable ability to adapt to living at high altitudes, a process known as acclimatization. Various factors participate in this

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acclimatization process including hyperventilation, increase in the red blood cell concentration of the blood, increase in the number of capillaries in peripheral tissues, and changes in the oxidative enzymes within the cells.^[3] These integrated responses improve oxygen delivery to the cells through adjustments in the respiratory, cardiovascular and hematological systems and augment the cellular oxygen uptake and utilization mechanisms.^[4]

Therefore, the major aim of this study is to assess the effects of high altitude on cardiovascular parameters (blood pressure [BP], pulse rate, and respiratory rate) among permanent natives of Ladakh and how it differs with respect to age and sex in comparison to the lowlanders.

MATERIALS AND METHODS

The present study was undertaken in the Department of Physiology, Government Medical College, Jammu, India. The subjects selected were permanent residents of Ladakh who migrate to Jammu during winter for 1–2 months. A written informed consent was taken from all eligible subjects.

Inclusion Criteria

Healthy permanent residents of high altitude (Ladakh) were included in the study.

Exclusion Criteria

1. History of hypertension
2. Diabetes mellitus
3. Heart diseases
4. Tuberculosis
5. Asthma
6. Occupational lung diseases; and
7. Chronic obstructive pulmonary disease were excluded from the study.

100 subjects who fulfilled the eligibility criteria were selected for the study. They were divided into two groups' males and females. Each group was further subdivided into four different age groups. Group I included subjects of age ≤ 20 , Group II included subjects from age 21 to 40, Group III included subjects from age 41 to 60, and Group IV included subjects of age > 60 . Their mean height and weight were calculated [Table 1]. They had to undergo two phases of examination, i.e. the first examination on the day of their arrival and the second examination 2 months later. The results so obtained were compared with an equal number of healthy residents of Jammu (control group).

All the eligible subjects were requested to present themselves in the Postgraduate Department of Physiology,

Government Medical College, Jammu, at their own convenient time. They were interviewed by the investigator herself, and details of information regarding age, occupation, and any significant recent or past illness were recorded.

BP was recorded using a sphygmomanometer by auscultatory method in sitting position. This method was devised by Korotkoff, in 1905. After a gap of 5 min for mental and physical relaxation, the cuff of the B.P apparatus was placed around the upper arm with center of the bag lying over the brachial artery, keeping its lower edge about 3 cm above the elbow. Chest piece of the stethoscope was placed at the level of the bifurcation of the brachial artery. Cuff was inflated and pressure was raised to about 40–50 mm Hg above the systolic BP ([SBP], found by palpatory method). The pressure was lowered gradually until a clear sharp, tapping sound was heard which was taken as SBP. Continued to lower the pressure and the level at which it became muffled was taken as diastolic BP (DBP). Mean of the three readings of both SBP and DBP was taken as the actual SBP and DBP.^[5]

Pulse rate was recorded for 1 min by palpating the radial artery in the wrist with the tips of three fingers, i.e., index, middle, and ring fingers, compressing the vessel against the head of the radius bone after making the subject's forearm slightly pronated and wrist slightly flexed.^[5]

Respiratory Rate

The subjects were made to lie comfortably on a bed exposing the chest and abdomen and then counting the number of breaths for 1 min by observing how many times the chest and abdomen rises.^[6]

The data were analyzed using computer software Microsoft Excel, SPSS statistics (version 20) for Windows. All parameters were reported as mean and standard deviation. The statistical difference in mean values was tested using Student's *t*-test to evaluate statistical significance. $P < 0.05$ was considered statistically significant and that > 0.05 was considered statistically non-significant.

RESULTS

The resting mean pulse rate of high altitude subjects was higher on day 1 which at 2 months was almost equal to the control group, i.e., on day 1 the mean pulse rate of high altitude subjects of Groups I, II, III, and IV males was 77 ± 2.6 , 73.5 ± 2.6 , 69.5 ± 2.5 , and 64.1 ± 2.3 and of females was 76.9 ± 2.1 , 73 ± 2.0 , 69.3 ± 1.8 , and 64 ± 1.1 , respectively [Table 2a]. At 2 months, these values decreased, i.e., mean pulse rate of Groups I, II, III, and IV males

was 74.7 ± 2.1 , 70.4 ± 2.5 , 66.7 ± 2.6 , and 62.1 ± 2.2 and of females was 74.5 ± 2 , 69.8 ± 2.1 , 66.7 ± 2.6 , and 61.6 ± 1.6 , respectively [Table 2b]. In the control group, the mean pulse rate of Groups I, II, III, and IV males was 74 ± 1.8 , 70.2 ± 1.7 , 66.2 ± 2.6 , and 61.6 ± 2.4 and of females was 74.7 ± 1.2 , 70.6 ± 2.8 , 65.7 ± 2.2 , and 62 ± 2.1 , respectively [Table 2b]. The difference in values between males and females was statistically non-significant [Table 2c]. However, the elderly people showed a decreased mean pulse rate compared to the young.

The high altitude subjects showed hypoventilation on day 1 of arrival to low altitude and were statistically highly significant. On day 1, the mean respiratory rate of Groups I, II, III, and IV males was: 11 ± 1 , 12.1 ± 1.1 , 13 ± 1.2 , and 13.5 ± 0.7 and of females: 11 ± 1 , 12 ± 1 , 12.7 ± 0.7 , and 14 ± 0.5 , respectively [Table 3a]. This after 2 months became almost equal to that of the control group due to adaptation to sea level, i.e., mean respiratory rate of Groups I, II, III, and IV males was: 14.6 ± 1.5 , 15.3 ± 2.0 , 15.5 ± 1.5 , and 15.3 ± 2 and of females: 15.9 ± 2.2 , 16 ± 2.2 , 16.6 ± 1.6 , and 16.1 ± 1.7 , respectively [Table 3b]. In the control group, the mean pulse rate of Groups I, II, III, and IV males was 14.5 ± 1.0 , 15.8 ± 2.0 , 15.7 ± 1.7 , and 15.3 ± 1.4 and of females was 15.2 ± 1.7 , 15.3 ± 1.3 , 14.8 ± 1.7 , and 14.8 ± 1.3 , respectively [Table 3b]. However, the difference in males and females mean respiratory rate on day 1 was statistically non-significant [Table 3c].

There was a steeper increase in the mean BP with age in high altitude people than the lowland people. The increase in the mean DBP in high altitude people was more and statistically highly significant. On day 1, the mean DBP of Groups I, II, III, and IV males was: 82.7 ± 2.3 , 84.1 ± 2.7 , 88.1 ± 3.2 , and 91.5 ± 2.8 and of females: 79.8 ± 2.4 , 82.1 ± 3.5 , 86.6 ± 3.6 , and 88.2 ± 2.2 , respectively [Table 4c] whereas in the control group, the mean DBP of Groups I, II, III, and IV males was: 78.3 ± 2.3 , 80.1 ± 2.1 , 83.1 ± 2.9 , and 85 ± 2.1 and of females: 76.6 ± 2.1 , 76.9 ± 3.0 , 81.3 ± 3.7 , and 81.6 ± 1.7 , respectively [Table 4d]. Furthermore, the high altitude males had a higher mean DBP than the females [Table 4e]. However, there was almost no difference in the SBP between the high and the low altitude people and also between males and females which was statistically non-significant [Table 4a, b, e].

DISCUSSION

Pulse Rate

Arterial pulse is the action of the left ventricle felt in a peripheral artery. The normal pulse rate at rest averages

about 72 beats/min. The rate is higher in children and slower in old age.^[5]

On initial exposure to high altitude hypoxia, the resting pulse rate of lowland natives increases rapidly from an average of 70 beats/min to as much as 105 beats/min. This increase is associated both with generalized increase in sympathetic activity and with abrupt augmentation of resting cardiac output.^[7] With acclimatization, the cardiac output declines so that in about a week it equals or is below that attained at sea level. This decline in the cardiac output appears to be associated with a decrease in the heart rate which usually remains above sea level values.^[8]

In the present study, the mean values of pulse rate in different age groups of both males and females study groups were higher on day 1 than the mean values of the pulse rate at 2 months of descent to low altitude, and the difference was statistically highly significant. The pulse rate also showed a decrease in elderly people.

Our findings are in agreement with those reported by Hansen and Sander^[9] who reported that acclimatization to high altitude hypoxia is accompanied by a striking and long-lasting sympathetic over activity which persisted for 3 days even after return to sea level.

Furthermore, the mean values of the pulse rate of high altitude males on day 1 were higher than the lowland controls. This finding is similar to the study done by Amitabh *et al.*^[10]

Respiratory Rate

The normal rate of respiration is 14–20 cycles/min. One inspiration and one expiration making up one cycle. It is faster in children and old age.^[5]

Hyperventilation is one of the most important features of acclimatization to high altitude.^[3]

Hypoxia directly affects the vascular tone of the pulmonary and systemic resistance vessels and increases ventilation and sympathetic activity through stimulation of the peripheral chemoreceptors.^[11]

In the present study, on day 1 the mean values of respiratory rate of both males and females were less than compared with the mean values at 2 months after coming to low altitude. This decrease was statistically highly significant. Furthermore, there was an increase in the respiratory rate in old age with almost no difference between males and females. However, at 2 months, the mean values of respiratory rate were similar to that of the control group.

Table 1: Mean height and weight of study and control groups

Groups	Age	Sex	Study group			Control group		
			Number (n)	Mean height (cm)	Mean weight (Kg)	Number (n)	Mean height (cm)	Mean weight (Kg)
I	≤20	Male	3	161	43.3	6	160.2	50.2
		Female	13	156.1	43.8	8	150.2	42.5
II	21–40	Male	23	166.7	67.6	18	163	65.3
		Female	22	160.1	53.2	28	161.7	56.8
III	41–60	Male	15	167.3	74.2	20	166	70.4
		Female	7	163.3	61.6	9	161.9	60.6
IV	>60	Male	9	164.7	64.7	6	162.6	53.3
		Female	8	161	58	11	162.4	60.2

Table 2(a): Group-wise comparison between males and females (study) on day 1 and at 2 months according to mean pulse rate (/min)

Groups	Age	Sex	Number (n)	Day 1 Mean ±SD	At 2 months Mean ±SD	t-test	P-value	Statistical inference
I	≤20	Male	3	77±2.6	74.7±2.1	3.50	0.003	HS
		Female	13	76.9±2.1	74.5±2	11.83	0.000	HS
II	21–40	Male	23	73.5±2.6	70.4±2.5	16.44	0.000	HS
		Female	22	73±2.0	69.8±2.1	9.59	0.000	HS
III	41–60	Male	15	69.5±2.5	66.7±2.6	5.25	0.000	HS
		Female	7	69.3±1.8	66.4±2.3	7.07	0.000	HS
IV	>60	Male	9	64.1±2.3	62.1±2.2	3.33	0.000	HS
		Female	8	64±1.1	61.6±1.6	3.66	0.008	HS

SD: Standard deviation

Table 2(b): Group-wise comparison between males and females (study) at 2 months and males and females (control) according to mean pulse rate(/min)

Groups	Age	Sex	Number (n)	At 2 months Mean ±SD	Control Mean ±SD	t-test	P-value	Statistical inference
I	≤20	Male	3	74.7±2.1	74±1.8	1.00	0.423	NS
		Female	13	74.5±2	74.7±1.2	0.00	1.000	NS
II	21–40	Male	23	70.4±2.5	70.2±1.7	-1.22	0.240	NS
		Female	22	69.8±2.1	70.6±2.8	2.15	0.044	NS
III	41–60	Male	15	66.7±2.6	66.2±2.6	0.00	1.000	NS
		Female	7	66.4±2.3	65.7±2.2	0.16	0.881	NS
IV	>60	Male	9	62.1±2.2	61.6±2.4	-4.39	0.070	NS
		Female	8	61.6±1.6	62±2.1	-1.37	0.242	NS

SD: Standard deviation

Table 2(c): Group-wise comparison between males (study) and females (study) on day 1 according to mean pulse rate (/min)

Groups	Age	Males Mean ±SD	Females Mean ±SD	t-test	P-value	Statistical inference
I	≤20	77±2.6	76.9±2.1	0.76	0.525	NS
II	21–40	73.5±2.6	73±2.0	0.90	0.376	NS
III	41–60	69.5±2.5	69.3±1.8	0.29	0.778	NS
IV	≥60	64.1±2.3	64±1.1	1.14	0.291	NS

SD: Standard deviation

Our findings are in agreement with Zubeta-Calleja^[12] who also reported that the resting ventilation decreased on the descent to sea level on the day of arrival.

If high altitude residents go to sea level, there organism is facing relative hyperoxia. The decrease in ventilation is probably defense mechanism for a hyperoxic environment that the body assumes is toxic at the cellular level. The

adaptation mechanism acquired over long-term high altitude residence is essentially the high hematocrit which would in the presence of excess oxygen increase the oxygen content of the blood and produce hyperoxemia.^[12]

The reasons for re-establishment of respiratory rate to almost sea level values after 2 months of descent could be the following:

Table 3(a): Group-wise comparison between males and females (study) on day 1 and at 2 months according to mean respiratory rate (/min)

Groups	Age	Sex	Number (n)	Day 1 Mean±SD	At 2 months Mean±SD	t-test	P-value	Statistical inference
I	≤20	Male	3	11±1	14.6±1.5	-11.00	0.008	HS
		Female	13	11±1	15.9±2.2	-8.29	0.000	HS
II	21–40	Male	23	12.1±1.1	15.3±2.0	-6.40	0.000	HS
		Female	22	12±1	16±2.2	-8.25	0.000	HS
III	41–60	Male	15	13±1.2	15.5±1.5	-6.51	0.000	HS
		Female	7	12.7±0.7	16.6±1.6	-4.65	0.003	HS
IV	>60	Male	9	13.5±0.7	15.3±2	-2.34	0.047	S
		Female	8	14±0.5	16.1±1.7	-3.60	0.008	HS

SD: Standard deviation

Table 3(b): Group-wise comparison between males and females (study) at 2 months and males and females (control) according to mean respiratory rate (/min)

Groups	Age	Sex	Number (n)	At 2 months Mean±SD	Control Mean±SD	t-test	P-value	Statistical inference
I	≤20	Male	3	14.6±1.5	14.5±1.0	-1.00	0.423	NS
		Female	13	15.9±2.2	15.2±1.7	-0.60	0.567	NS
II	21–40	Male	23	15.3±2.0	15.8±2.0	0.72	0.477	NS
		Female	22	16±2.2	15.3±1.3	-1.58	0.128	NS
III	41–60	Male	15	15.5±1.5	15.7±1.7	0.77	0.450	NS
		Female	7	16.6±1.6	14.8±1.7	-3.74	0.334	NS
IV	>60	Male	9	15.3±2	15.3±1.4	-0.56	0.595	NS
		Female	8	16.1±1.7	14.8±1.3	-1.08	0.338	NS

SD: Standard deviation

Table 3(c): Group-wise comparison between males (study) and females (study) on day 1 according to mean respiratory rate (/min)

Groups	Age	Males Mean±SD	Females Mean±SD	t-test	P-value	Statistical inference
I	≤20	11±1	11±1	-1.00	0.423	NS
II	21–40	12.1±1.1	12±1	0.00	1.000	NS
III	41–60	13±1.2	12.7±0.7	0.00	1.000	NS
IV	≥60	13.5±0.7	14±0.5	-1.87	0.104	NS

SD: Standard deviation

Table 4(a): Group-wise comparison between males and females (study) on day 1 and at 2 months according to mean systolic blood pressure (mm Hg)

Groups	Age	Sex	Number (n)	Day 1 Mean±SD	At 2 months Mean±SD	t-test	P-value	Statistical inference
I	≤20	Male	3	119.3±1.1	119.3±1.1	0.00	1.000	NS
		Female	13	119.1±1.5	119.2±1.3	-15.50	0.060	NS
II	21–40	Male	23	124.1±5.2	123.2±4.4	2.47	0.074	NS
		Female	22	124±4.0	122.9±3.6	2.04	0.053	NS
III	41–60	Male	15	134±7.1	133.6±7.3	0.67	0.510	NS
		Female	7	134±7.3	132.6±7.4	3.40	0.054	NS
IV	>60	Male	9	137.5±6.2	136.6±5.4	1.83	0.104	NS
		Female	8	137±6.3	135.7±5.4	3.46	0.070	NS

SD: Standard deviation

First, when the subjects from a high altitude are brought to sea level, the disappearance of the polycythemia occurs due to temporary diminution or inhibition of erythropoiesis and greater blood destruction.^[13]

Second, there is cessation of the sympathetic overactivity of high altitude people at sea level.

BP

BP is the force exerted by the blood against any unit area of the vessel wall. It is almost always measured in millimeters of mercury (mm Hg) because the mercury manometer has been used as the standard reference measuring pressure since its invention in 1846 by Poiseuille.^[14]

Table 4(b): Group-wise comparison between males and females (study) at 2 months and males and females (control) according to mean systolic blood pressure (mm Hg)

Groups	Age	Sex	Number (n)	At 2 months Mean±SD	Control Mean±SD	t-test	P-value	Statistical inference
I	≤20	Male	3	119.3±1.1	120±1.8	1.73	0.225	NS
		Female	13	119.2±1.3	118.7±1.5	-0.28	0.785	NS
II	21–40	Male	23	123.2±4.4	123±2.8	0.94	0.359	NS
		Female	22	122.9±3.6	122±2.9	-1.26	0.220	NS
III	41–60	Male	15	133.6±7.3	133±6.3	0.88	0.389	NS
		Female	7	132.6±7.4	133.3±7.3	2.10	0.069	NS
IV	>60	Male	9	136.6±5.4	137.3±2.4	0.23	0.822	NS
		Female	8	135.7±5.4	135.6±5.2	-0.40	0.704	NS

SD: Standard deviation

Table 4(c): Group-wise comparison between males and females (study) on day 1 and at 2 months according to mean diastolic blood pressure (mmHg)

Groups	Age	Sex	Number (n)	Day 1 Mean±SD	At 2 months Mean±SD	t-test	P-value	Statistical inference
I	≤20	Male	3	82.7±2.3	78.6±1.1	3.46	0.022	S
		Female	13	79.8±2.4	76±2	-7.03	0.000	HS
II	21–40	Male	23	84.1±2.7	80.1±1.3	5.69	0.000	HS
		Female	22	82.1±3.5	77±2.7	7.50	0.000	HS
III	41–60	Male	15	88.1±3.2	83.3±2.9	8.07	0.000	HS
		Female	7	86.6±3.6	81.4±2.2	7.29	0.000	HS
IV	>60	Male	9	91.5±2.8	85.1±2.6	15.01	0.000	HS
		Female	8	88.2±2.2	82.5±2.8	10.48	0.000	HS

SD: Standard deviation

Table 4(d): Group-wise comparison between males and females (study) at 2 months and males and females (control) according to mean diastolic blood pressure (mmHg)

Groups	Age	Sex	Number (n)	At 2 months Mean±SD	Control Mean±SD	t-test	P-value	Statistical inference
I	≤20	Male	3	78.6±1.1	78.3±2.3	1.00	0.423	NS
		Female	13	76±2	76.6±2.1	0.00	1.000	NS
II	21–40	Male	23	80.1±1.3	80.1±2.1	0.00	1.000	NS
		Female	22	77±2.7	76.9±3.0	-0.29	0.773	NS
III	41–60	Male	15	83.3±2.9	83.1±2.9	-0.12	0.906	NS
		Female	7	81.4±2.2	81.3±3.7	0.66	0.524	NS
IV	>60	Male	9	85.1±2.6	85±2.1	2.08	0.071	NS
		Female	8	82.5±2.8	81.6±1.7	-0.78	0.477	NS

SD: Standard deviation

Table 4(e): Group-wise comparison between males (study) and females (study) on day 1 according to mean systolic and diastolic blood pressure (mmHg)

Groups	Age	Blood pressure	Males Mean±SD	Females Mean±SD	t-test	P-value	Statistical inference
I	≤20	Systolic	119.3±1.1	119.1±1.5	-1.00	0.423	NS
		Diastolic	82.7±2.3	79.8±2.4	-6.87	0.030	S
II	21–40	Systolic	124.1±5.2	124±4	0.00	1.000	NS
		Diastolic	84.1±2.7	82.1±3.5	2.39	0.026	S
III	41–60	Systolic	134±7.1	134±7.3	0.00	1.000	NS
		Diastolic	88.1±3.2	86.6±3.6	0.52	0.017	S
IV	≥60	Systolic	137.5±6.2	137±6.3	-0.22	0.827	NS
		Diastolic	91.5±2.8	88.2±2.2	1.73	0.027	S

SD: Standard deviation

In the present study, the results were that the high altitude people, both males and females, showed a steeper increase in BP with age than the lowland people. The increase in the DBP in high altitude people was more than the lowland people, and the difference was statistically highly

significant. Furthermore, males showed a greater increase than the females and the difference was statistically only significant. However, there was almost no difference in the SBP between the high and low altitude people and also between males and females.

These findings are similar to the studies conducted by Wood *et al.*^[15] and Otsuka *et al.*^[16] Several reasons may account for the increase in BP in high altitude people. First, at higher altitude, atmospheric oxygen is lower; hypoxemia stimulates sympathetic nerve activity, which is associated with an increase in BP.^[17]

Second, it has been reported that carotid bodies from the Karakorams (including Ladakh) are heavier and larger, presumably related to the hypobaric hypoxia. Such histological characteristics of the carotid bodies may alter the cardiovascular coordination in Ladakhi people.^[18]

Third, Ladakh is a cold desert and its environmental temperature drops as low as -45°C in winter, whereas in summer, the temperature reaches up to 27°C , a factor that will also stimulate sympathetic activity and increase BP.^[16]

CONCLUSION

High altitude natives have distinctive biological characteristics that appear to offset the stress of hypoxia, such as the increased resting pulse rate and ventilation rate, elevated hemoglobin concentration, or the elevated total erythrocyte count. Evolutionary theory reasons that they reflect genetic adaptations resulting from natural selection favoring more effective adaptive responses.

The study of natural selection at high altitude is entering an era of linking genomics, genetics, molecular biology, and physiology to understand what makes an organism better able to function, survive, and reproduce - fit in the Darwinian sense - under the chronic lifelong stress of high-altitude hypoxia.

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A Study of Duodenal Ulcer Perforation Post-operative Outcome in A Tertiary Center

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Abstract

Introduction: Time trends in the epidemiology of perforated peptic ulcer disease reflect complex, multifactorial etiologies. Based on today's fast and instant lifestyle, it is evident that the epidemiology of peptic ulcer disease largely reflects environmental factors, primarily *Helicobacter pylori* infection, nonsteroidal anti-inflammatory drug (NSAID) use, and smoking.

Aim: The aim is to study the relationship between post-operative morbidity and comorbid illness and pre-operative risk factors in cases of duodenal ulcer perforation.

Methods: All non-malignant and non-traumatic duodenal ulcer perforation cases above the age of 12 years were taken. A total of 50 cases of duodenal perforation were studied over 18 months. The patients were treated with perforation closure with live omental patch repair after initial resuscitation and correction of electrolyte imbalances under the cover of broad-spectrum antibiotics.

Results: 24 patients had smoking history and 19 patients had history of alcohol consumption. 29 patients had the previous history of peptic ulcer disease. 17 patients had the history of NSAID intake. The size of the perforation >0.5 mm was noted in 23 patients. The amount of peritoneal contamination >1 L was noted in 29 patients. 8 patients had wound infection, 3 patients had septicemia, electrolyte abnormalities were encountered in 21% of patients, and morbidity rate was 17.02%.

Conclusion: Age, associated comorbid conditions, duration of symptoms, and clinical condition at the time of presentation all contribute in determining the post-operative morbidity and mortality.

Key words: Duodenal ulcer, Morbidity, Perforation

INTRODUCTION

Duodenal ulcers occur due to an imbalance between gastroduodenal mucosal defense mechanisms and the damaging forces, particularly gastric acid and pepsin. Hyperacidity is not a prerequisite for duodenal ulcers. Failure of mucosal defenses against gastric acid and pepsin results in ulceration. The sudden release of gastric or duodenal contents into the peritoneal cavity through the

perforation can lead to a sequence of events, which if not managed properly can result in mortality.^[1,2] In spite of the development in diagnostic and treatment modalities in peptic ulcer disease, the incidence of duodenal perforation seems to be unchanged and even increased incidence has been reported in older age groups. Mortality is influenced by a number of factors which include patients age, sex, site of the ulcer, treatment delay, concurrent disease, pre-operative shock, and type of anesthesia used.^[3] A majority of the factors are interrelated, and for instance, the treatment delay is likely to increase the mortality rate. Despite a lot of evidence in the literature, the knowledge regarding factors influencing the mortality that occurs after peptic ulcer perforation is limited.^[4,5] The purpose of this study is to find the factors that influence the mortality and morbidity among operated cases of duodenal

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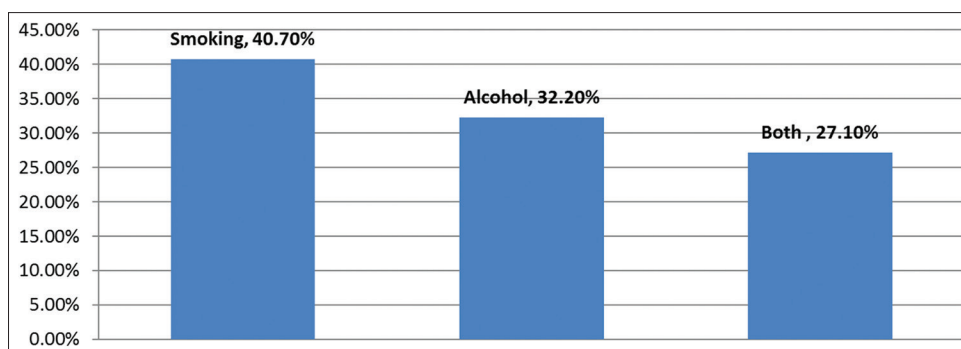


Figure 1: Distribution of personal habits

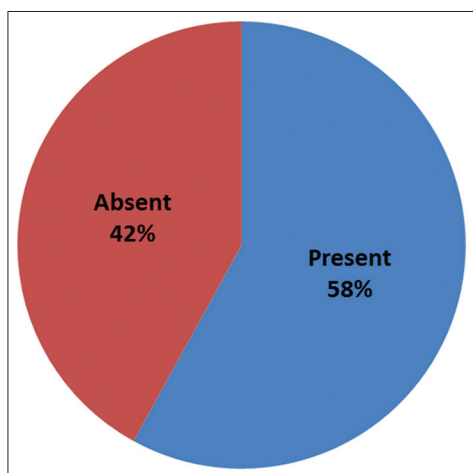


Figure 2: Distribution of peptic ulcer disease

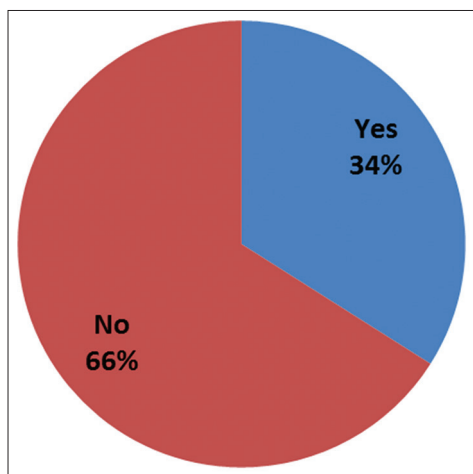


Figure 3: Distribution of nonsteroidal anti-inflammatory drug intake

ulcer perforation. There are multiple numbers of factors affecting the mortality and morbidity which would be dealt with in this study.

Aim

The aim is to study the relationship between post-operative morbidity and comorbid illness and pre-operative risk factors in cases of duodenal ulcer perforation.

MATERIALS AND METHODS

This study comprises of prospective analysis of the patients diagnosed with duodenal ulcer perforation in Tirunelveli Government Medical College, Tirunelveli.

Inclusion Criteria

All non-malignant and non-traumatic duodenal ulcer perforation cases above the age of 12 years were included in the study.

Exclusion Criteria

Traumatic perforation and perforated malignant ulcers were excluded from the study. The following data were collected from the hospital records such as age, sex, previous history of ulcer, nonsteroidal anti-inflammatory drugs (NSAID) intake, duration of symptoms, size of perforation, and the amount of peritoneal contamination. The outcome of treatment was elaborated by post-operative complications, hospital stay, and death.

A total of 50 cases of duodenal perforation were studied over 18 months. Of these 50 cases, 47 undergone laparotomy, and the perforation in all these cases was present in the anterior aspect of the first part of the duodenum. The patients were treated with perforation closure with live omental patch repair after initial resuscitation and correction of electrolyte imbalances under the cover of broad-spectrum antibiotics.

All the patients were continued treatment with anti-*Helicobacter pylori* regimen postoperatively.

RESULTS

In this study, 7 female and 43 male patients were enrolled. Most of the cases were in the more than 40 years age group. 24 patients had smoking history and 19 patients had a history of alcohol consumption [Figure 1]. 29 patients had the previous history of peptic ulcer disease [Figure 2]. 17 patients had the history of NSAID intake

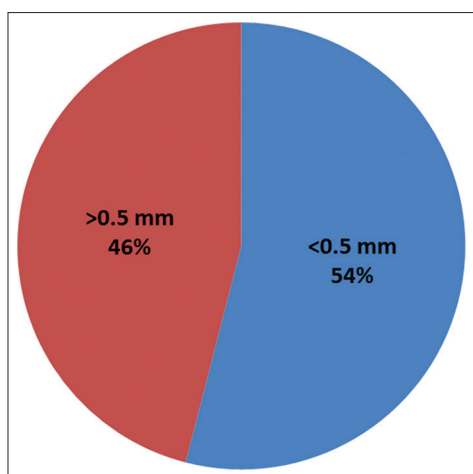


Figure 4: Distribution of size of perforation

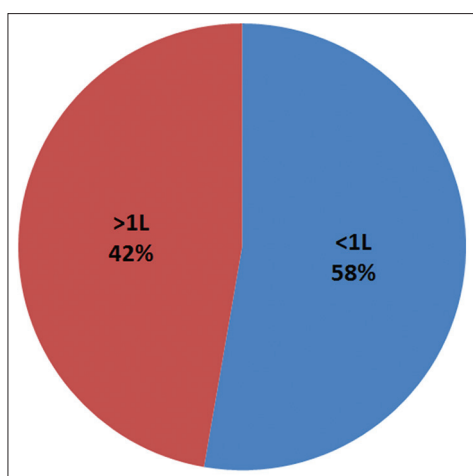


Figure 5: Distribution of amount of peritoneal contamination

[Figure 3]. The size of the perforation >0.5 mm was noted in 23 patients [Figure 4]. The amount of peritoneal contamination >1 L was noted in 29 patients and <1 L was noted in 21 patients [Figure 5]. Of 50 patients, 47 cases were treated with simple closure with omental patch. 3 cases were treated with B/L flank drain under local anesthesia because of poor general condition of the patient [Figure 6]. The average duration of symptoms was found to be 1.24 days (1–4 days). Average delay from the time of admission to surgery is 3.48 h (2–6 h). Average duration of hospital stay found to be 8.52 (8–15 days). Of total, 47 cases had underwent surgery, 8 patients had wound infection, 3 patients had septicemia, electrolyte abnormalities were encountered in 21% of patients, and morbidity rate was 17.02%. Of total cases 50, 6 patients expired due to septicemia, and mortality rate was 12%.

DISCUSSION

No single factor can readily identify patients at high risk for a poor outcome, but older age, presence of comorbidity,

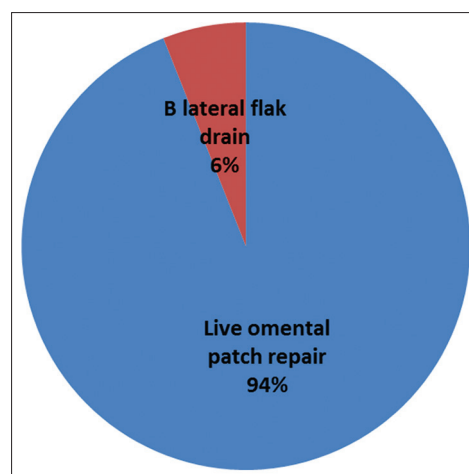


Figure 6: Management

Table 1: Peak incidence

Author	Years
Taylor ^[9]	>50
Hannan <i>et al.</i> ^[10]	31–40
Our study	40–49

Table 2: Gender incidence

Authors	Male-to-female ratio
Paul and Jack ^[11]	26:1
Rodney Maingot ^[12]	5:1
Our study	16:1

and delay to surgery have consistently been associated with higher risk of death. Clearly, identification of modifiable risk factors with the potential to improve outcome is of greatest interest. In a systematic review covering over 50 studies with 37 pre-operative prognostic factors comprising a total of 29,782 patients, risk factors consistently associated with mortality were found. Only two-thirds of the studies provided confounder-adjusted estimates [Tables 1 and 2].^[6]

Sepsis is frequently present and a leading cause of death in patients with perforated peptic ulcer (PPU). An estimated 30–35% of patients with PPU have sepsis on arrival at the operating theater, and sepsis is believed to account for 40–50% of fatalities. Within 30 days of surgery, >25% of the patients develop septic shock,^[7] which carries a mortality rate of 50–60%. Accordingly, investigation and interventions aimed at preventing, detecting, and treating sepsis in PPU patients may reduce mortality and morbidity. This can be accomplished by systematically assessing for the signs of sepsis and treating according to the principles of the surviving sepsis campaign, including fluid resuscitation, cultures, empirical broad-spectrum antibiotics, and source control.^[8] A multidisciplinary perioperative approach based on such principles has been

evaluated in a non-randomized clinical trial for PPU, with a statistically significant reduction in mortality shown (number-needed-to-treat of 10).

The age of patients in this study is ranging from 18 to >60 years. The peak age incidence was between 40 and 49 years, but age is no bar for the perforation.

In the current study of 50 cases, only 7 cases of females with perforated duodenal ulcers were observed. Our study found male predominance for perforated duodenal ulcers which correlates to the reported observation.

Patients aged above 50 years with a history of NSAID intake are at increased risk for duodenal ulcer perforation, and 34% of the patients had a history of NSAID intake.

Chronic use of NSAIDs including low-dose aspirin is associated with gastrointestinal mucosal injury. However, major adverse events are relatively infrequent. Patients with multiple risk factors such as a previous history of peptic ulcer disease, increasing age, coprescription of corticosteroids and anticoagulants, and high-dose and long-term use of NSAIDs are at the highest risk of major gastrointestinal toxicity. In patients with multiple risk factors, physicians need to assess these risks before prescribing NSAIDs and adopt risk-minimizing strategies.^[13]

Patients aged >60 years and associated comorbid illness had the highest rate of wound infection. 17 patients had associated comorbid illness. Of the 8 patients who had wound infection, 6 patients had associated comorbid illness and 50% of them were above 50 years of age. Electrolyte imbalance included hyponatremia in 21% of patients, hypokalemia in 19% of patients, and elevated serum creatinine in 18% of patients. Mortality rate was 12%, of which 3 patients were treated with B/L flank drain because of the very poor general condition of the patient at the time of admission, and all these patients were above the 60 years age group; of the operated patients, 6% mortality is present, and in these patients, there were associated comorbid illness and delay in presentation and amount of peritoneal contamination were all significantly present.

CONCLUSION

Duodenal ulcer perforation is more common in the age group of >40 years. Majority of the patients are male. Associated risk factors include smoking, alcohol intake, NSAID intake, and history of automated peritoneal dialysis. Morbidity rate is 17%, and wound infection and dyselectrolytemia are the most common. Mortality and morbidity are significantly higher in patients with comorbid illness. Age, associated comorbid conditions, duration of symptoms, and clinical condition at the time of presentation all contribute in determining the post-operative morbidity and mortality. Prognostic indicators can assist in risk stratification for PPU. The use of this system can help to delineate high-risk patients and to identify the need of early intervention and prompt treatment for a better outcome of the patient.

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Mandibular Ramus: An Indicator for Gender Determination - A Digital Radiographic Study

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Abstract

Aims and Objectives: The objectives of this study were as follows: (1) To measure, compare, and evaluate the various measurements of mandibular ramus as observed on orthopantomographs and (2) to assess the usefulness of mandibular ramus as an aid in gender determination.

Materials and Methods: A retrospective study was conducted on 50 males and 50 females using standard digital panoramic radiographs with age ranging from 18 to 58 years. The following five mandibular linear measurements were performed in cm such as maximum ramus breadth, minimum ramus breadth, condylar ramus height, projective ramus height, and coronoid ramus height. The obtained data were analyzed with the software SPSS (version 20.0) and Microsoft Excelled (version 5.00) for statistical analysis using discriminant methods.

Results: Mean measurements descriptive statistic shows that mean values were significantly higher in males compared to females ($P < 0.05$). Fisher-statistic values indicated that highest sexual dimorphism was seen with condylar ramus height and least with minimum ramus breadth, maximum ramus breadth, condylar height, condylar ramus height, coronoid height, and minimum ramus breadth. Sex was accurately determined in 44 cases of 50 male mandibular measurements with prediction accuracy rate of 88% and sex was accurately determined in 46 cases of 50 female mandibular measurements with an accuracy rate of 92%.

Conclusion: The result of the present study proved that the mandibular ramus plays a major role in gender determination due to its unique high sexual dimorphism and also possesses resistance to damage and disintegration processes. Hence, we conclude that the use of mandibular ramus is recommended as an aid for sex determination in forensic science.

Key words: Discriminant function analysis, Mandibular ramus, Orthopantomograph, Sexual dimorphism

INTRODUCTION

- Dentofacial radiography has become a routine procedure in the dental, medical, and hospital clinics, wherein radiographs are taken at different periods during the lifetime of large segments of the population.^[1] The determination of gender is important aspect of forensic anthropology and vital in medicolegal investigations.
- Among various measures, mandibular ramus can be used to differentiate between male and female

strongly expresses univariate sexual dimorphism. Determination of sex becomes more accurate after attainment of puberty. The differences are well marked in bony pelvis and skull.

- After both of these bony areas, mandible remains next in the human which will also help us in the identification of age, gender, and race.^[2] Humphrey *et al.*^[3] emphasized that almost any site of mandibular bone deposition, or resorption, or remodeling for that matter, seems to have a potential for becoming sexually dimorphic.
- Mandibular condyle and ramus, in particular, are generally the most sexually dimorphic as they are the sites associated with the greatest morphological changes in size and remodeling during growth.
- Among various radiographic technique, the orthopantomography (OPG) is still used as one of

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the measures in the determination of sex, wherein the morphology of mandibular ramus is studied.^[4] Hence, this study was taken to understand the sexual dimorphism, using digital OPG.

Aims and Objectives

This study aims to determine the usefulness of mandibular ramus as an aid in gender determination.

MATERIALS AND METHODS

- A retrospective study was conducted
- Using digital panoramic radiographs
- 100 subjects (50 males and 50 females)
- Age ranging from 18 to 58 years.
- After obtaining ethical clearance, standardized digital panoramic radiographs of patients taken as part of pretreatment planning for implants, extractions of third molars and for periodontal diseases were selected from the archives of the radiology department.
- Good quality standard digital panoramic radiographs (Sirona, ORTHOPHOS XG 5) of completely dentate and partially edentulous patients were selected for the study.
- Poor quality with any pathological lesions, fracture, or developmental disturbances of the mandible and edentulous mandibles were excluded from the study. The standardized exposure parameters 66 kVp, 8 mA, and 14 s were employed for every panoramic radiograph and assessed by taking measurements unilaterally (on the left side).
- The digital panoramic images were saved in a JPEG file format and exported to the SIDEX 2.5 software (Sirona Dental Systems, USA) where mandibular ramus linear measurements were performed.
- This study was conducted in the department of oral medicine and radiology. The following mandibular ramus linear parameters were measured after image calibration using mouse-driven method in cm [Figures 1 and 2]:

1. *Maximum ramus breadth*: The distance between the most anterior point on the mandibular ramus and a line connecting the most posterior point on the condyle and the angle of jaw.^[5,6]
2. *Minimum ramus breadth*: Smallest anterior–posterior diameter of the ramus.^[6]
3. *Condylar height/maximum ramus height*: Height of the ramus of the mandible from the most superior point on the mandibular condyle to the tubercle, or most protruding portion of the inferior border of the ramus.^[6]
4. *Projective height of ramus*: Projective height of ramus

between the highest point of the mandibular condyle and lower margin of the bone.^[6]

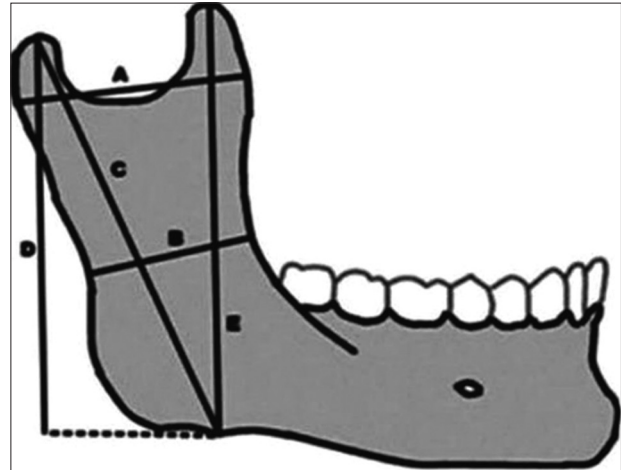


Figure 1: Diagram showing mandibular ramus measurements adapted from Saini *et al.*

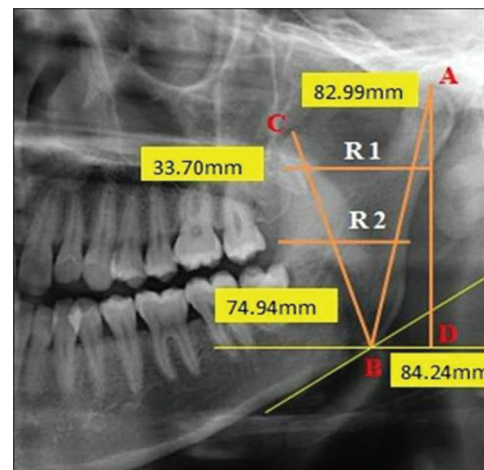


Figure 2: The five linear ramus measurements on digital panoramic radiograph. R1: Upper ramus breadth. R2: Lower ramus breadth. AB: Condylar ramus height. BC: Coronoid ramus height. AD: Projective ramus height

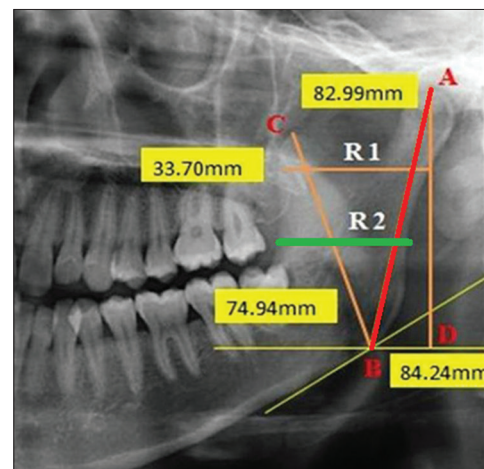
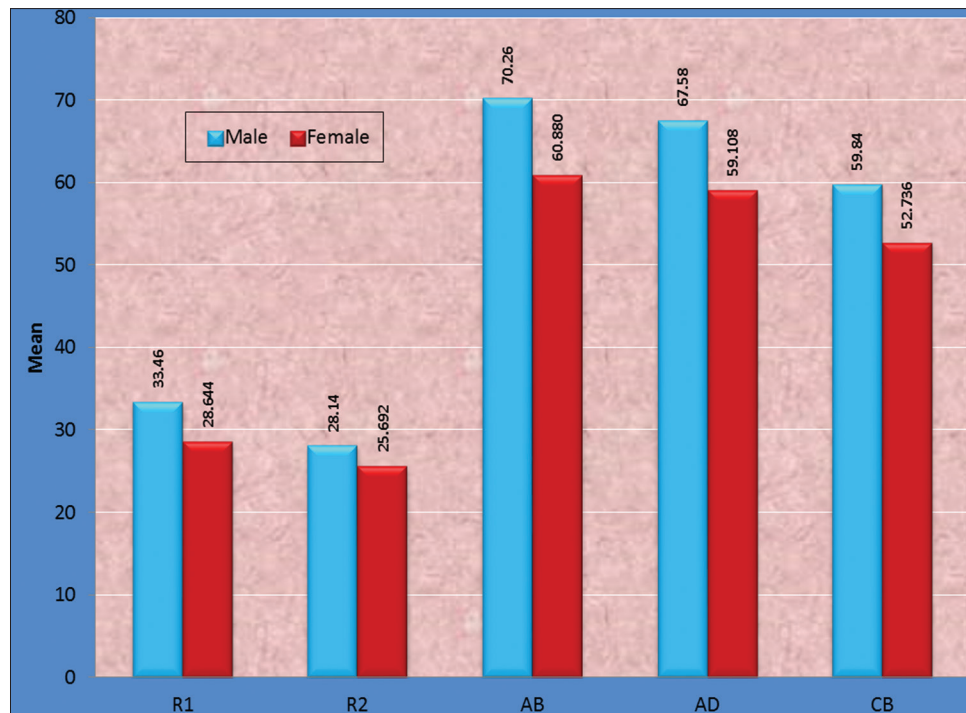


Figure 3: Highest sexual dimorphism was seen with condylar ramus height and least with minimum ramus breadth



Graph 1: Mean measurements in males and females

Table 1: Descriptive statistics of mandibular ramus linear measurements

Variable	Male Mean±SD	Female Mean±SD	Wilk's Lambda	F-value	P-value
R1	33.46±3.942	28.644±7.0187	0.843	8.93	0.004*
R2	28.14±2.955	25.692±3.6940	0.877	6.72	0.013*
AB	70.26±3.908	60.880±3.4713	0.373	80.58	<0.001*
AD	67.58±4.834	59.108±3.4054	0.483	51.32	<0.001*
CB	59.84±5.010	52.736±3.3197	0.579	34.97	<0.001*

*Statistically significant difference ($P < 0.05$)

5. *Coronoid height*: Projective distance between coronion and lower wall of the bone.^[6]

RESULTS

- Mean measurements descriptive statistic shows mean values were significantly higher in males compared to females ($P < 0.05$) [Table 1 and Graph1].
- Fisher-statistic values indicated that highest sexual dimorphism was seen with condylar ramus height and least with minimum ramus breadth [Table 2 and Figure 3].
- Gender was accurately determined in 44 cases of 50 male mandibular measurements with prediction accuracy rate of 88% [Table 3].
- Gender was accurately determined in 46 cases of 50 female mandibular measurements with an accuracy rate of 92% [Table 3].

The linear discriminate (D) function equation is as follows:

Table 2: Linear discriminate function variables

Variable	Male	Female
Constant	-204.6	-154.2
R1	-0.76	-0.72
R2	0.33	0.49
AB	7.78	6.38
AD	-3.06	-2.41
CB	1.42	1.31

Table 3: Prediction accuracy

True Group	Predicted Group		Total	Accuracy
	Male	Female		
Male	44	6	50	88%
Female	4	46	50	92%
Overall Accuracy=90%				

$$D_{\text{Female}} = -154.2 - 0.72 (R1) + 0.49 (R2) + 6.38 (AB) - 2.41 (AD) + 1.31 (CB)$$

$$D_{\text{Male}} = -204.6 - 0.76 (R1) + 0.33 (R2) + 7.78 (AB) - 3.06 (AD) + 1.42 (CB)$$

DISCUSSION

- Determination of gender by morphological assessment has remained as one of the oldest approaches in forensic anthropology and medicolegal examinations.
- When entire adult skeleton is available for analysis,

gender can be determined up to 100% accuracy (pelvis).

- However, in cases of mass disasters where usually fragmented bones are found, sex determination with 100% accuracy is not possible, and it depends largely on the available parts of skeleton.^[7] Skull is the most dimorphic and easily remarked portion of skeleton after pelvis.
- However, in cases where intact skull is not found, mandible may play a key role in gender determination as it is the most dimorphic bone of skull.^[8]
- The disadvantages OPG technique is unequal magnification and geometric distortion, which causes many problems. The vertical dimension as compared to the horizontal dimension is little altered. These distortions are the result of the horizontal movement of the film and X-ray source.^[9,10]
- Panoramic radiographic technique remains as quite sensitive to positioning errors because of relatively narrow image layer.^[11]
- A study conducted by Kambylafkas *et al.*^[12] concluded that the evaluation of total ramal height is reliable, and an asymmetry of more than 6% is an indication of a true asymmetry using panoramic radiograph.
- Dayal *et al.*^[13] found mandibular ramus height to be the best parameter in their study, with 75.8% accuracy.
- Another study conducted by Indira *et al.*^[14] on mandibular ramus measurements were subjected to discriminant function analysis. Each of the five variables measured on mandibular ramus using orthopantomograph . showed statistically significant sex differences between sexes, indicating that ramus expresses strong sexual dimorphism. The mandibular ramus demonstrated greatest univariate sexual dimorphism in terms of minimum ramus breadth, condylar height, followed by projective height of ramus. Overall prediction rate using all five variables was 76%.
- Shivaprakash and Vijaykumar^[15] conducted a study in diagnosing the sex by observing the mandibular ramus posterior flexure. Sex was accurately determined in 44 cases out of 55 male mandibles with an accuracy rate of 80%, and sex was accurately determined in 35 cases out of 49 female mandibles with accuracy rate of 71%.
- In our study, highest sexual dimorphism was seen with Condylar ramus height and least with minimum ramus breadth.
- Condylar ramus height and least with minimum ramus breadth.

- Maximum ramus breadth, condylar height, projective height of ramus, coronoid height, and minimum ramus breadth were statistically significant with $P < 0.05$.

CONCLUSION

- The result of the present study proved that the mandibular ramus plays a major role in gender determination due to its unique high sexual dimorphism and also possesses resistance to damage and disintegration processes.
- Hence, we conclude that the use of mandibular ramus is recommended as an aid for determination in forensic science.

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Evaluation of Sexual Dysfunction in Lower Urinary Tract Symptoms/Benign Prostatic Hyperplasia Patients

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Abstract

Introduction: Lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia (BPH) and sexual dysfunction are widely prevalent in aging population. There is a strong correlation between the severity of LUTS and sexual dysfunction either due to the direct effect of LUTS/BPH or due to treatment strategies adopted for LUTS/BPH. However, the symptoms of sexual dysfunction are not concentrated on both by the patient and the physician at least in our country.

Aim: The aim of this study is to evaluate the prevalence of sexual dysfunction in LUTS/BPH patients.

Methods: Patients admitted into ward with symptoms suggestive of LUTS/BPH were given the linguistic version of international prostate symptom score and male sexual health questionnaire and asked to respond. All details regarding the patients' demographics, scoring, and results were entered into a pro forma.

Results: A total of 120 patients were enrolled for the study. Majority of the patients who had bothersome LUTS also had bothersome sexual dysfunction. The correlation coefficient is 0.33 signifying a positive correlation.

Conclusion: The prevalence of sexual dysfunction in patients with LUTS is 70%. The severity of sexual dysfunction correlates with severity of LUTS. Ejaculatory function deteriorates after the treatment of LUTS/BPH.

Key words: Benign prostatic hyperplasia, Lower urinary tract symptoms, Sexual dysfunction

INTRODUCTION

Sexual dysfunction affects a couple's relationship and the quality of life (QoL) of the patient and the partner irrespective of age. Lower urinary tract symptoms (LUTS) suggestive of benign prostatic hyperplasia (BPH) is highly prevalent among the elderly.^[1] However, the symptoms of sexual dysfunction are not concentrated on both by the patient and the physician at least in our country. Sexual dysfunction manifests mainly as erectile dysfunction (ED), ejaculatory disorders (EjD), or decreased libido/hypoactive

sexual desire (HSD). Men with moderate-to-severe LUTS are at increased risk for sexual dysfunction. Although reduced rigidity and reduced ejaculate volume are the highly prevalent symptoms in aging men, reduced rigidity and pain on ejaculation are considered to be the most bothersome, affecting the QoL. Sexual dysfunction is much more prevalent in patients with LUTS/BPH than in men without them, even after controlling for confounding variables such as age and comorbid illnesses. Hence, LUTS/BPH is considered to be an independent risk factor for sexual dysfunction.^[2] The reason for the association is a common underlying pathology or the psychological effect of LUTS/BPH on sexual function needs to be confirmed. Despite a decline in the frequency of sexual intercourse, as well as in overall sexual functioning, most elderly men report regular sexual activity and consider their sex life as an important dimension of their QoL. However, most patients with LUTS/BPH experience a negative effect of LUTS on their sex life. Hence, treatment of LUTS/BPH should

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also aim to at least maintain or, if possible, improve sexual function.^[3] The successful management of patients with LUTS associated with BPH should include assessments of sexual function and monitoring of medication-related sexual side effects. For men with LUTS and sexual dysfunction, an appropriate integrated management approach, based on each patient's symptoms and outcome objectives, is warranted.^[4] We intended to evaluate the prevalence of sexual dysfunction in the LUTS/BPH patient population in our country, in our setup to analyze the amount of importance attached to the sexual QoL and also to see the correlation between LUTS and sexual dysfunction.

Aim

The aim of this study is to evaluate the prevalence of sexual dysfunction in LUTS/BPH patients.

MATERIALS AND METHODS

Between June 2017 and November 2017, all patients admitted into inpatient department with LUTS/BPH were included for evaluation. These patients were admitted for either evaluation or intervention for LUST/BPH.

- Informed consent obtained from all eligible patients
- All patients after admission were given the linguistic version of international prostate symptom score (IPSS) and male sexual health questionnaire
- Patients who are literate were asked to fill up the questionnaire (self-administered questionnaire)
- Patients who were not able to fill up (for various reasons such as illiterate and poor eyesight not able to understand the contents) were interviewed personally
- To avoid interviewer bias, the same interviewer interviewed all patients
- All details regarding the patients' demographics, scoring, and results were entered into a pro forma
- Post-treatment effect evaluation was done at the end of 3 months following treatment.

Initial Evaluation

The patients with complaints suggestive of LUTS/BPH were thoroughly evaluated with history and physical examination, Digital Rectal Examination and focused neurological examination, baseline blood parameters, USG kidneys–ureter–bladder, uroflow, and post void residual urine.

Inclusion Criteria

1. All patients with a history suggestive of LUTS/BPH with >50 years were included.
2. Patients who gave informed consent for the study were included in the study.

Exclusion Criteria

After the initial evaluation, the patients were excluded using the following exclusion criteria.

1. Patients who have been already treated for LUTS/BPH earlier.
2. Patients with comorbid illness such as diabetes mellitus and hypertension.
3. Patients with history or clinical examination suggestive of associated neurological disorder.
4. Patients who were not willing to self-administer the questionnaire are to be interviewed.

Symptom Severity and Sexual Function Assessment

All the patients were given with the linguistic version of the IPSS. Sexual function assessment was done using the linguistic version of the male sexual function scale. The male sexual function scale consists of a total of 8 questions, of which two questions are on erectile function domain and its bother, and three are on ejaculatory function domain and its bother, one question each on sexual desire and satisfaction. The final question assessed the overall bother or distraction of life due to the sexual dysfunction. The linguistic conversion was done by the investigator with the help of a psychologist who had experience in interviewing such type of patients. At most care was taken in phrasing the words so that it should not be embarrassing to the patient. Before put into use in this clinical study, the questionnaire was circulated among outpatients who were waiting for an ultrasound examination. They were asked to comment on the content whether it is understandable or not, and their suggestions were taken. The investigator interviewed patients (78 patients - 65%) who are illiterate and who could not read the questionnaire because of poor eyesight and who could not understand the content. To avoid bias, the same investigator interviewed all such patients. In all other patients (42 patients -35 %), it was used as a self-administered questionnaire.

Management

Management of these patients was done according to the institute's protocol. Management consisted of medical therapy in the form of α -blockers and 5 α -reductase inhibitors (5-ARIs). Surgical therapy was mainly transurethral resection of the prostate (TURP).

Post-treatment Evaluation

Evaluation following treatment was done at the end of the 3rd month. All patients were asked to come for a follow-up at the end of the 3rd month and were given the IPSS and male sexual function scale questionnaires. Uroflow with postvoid residue was also done to ascertain the effect of therapy.

Correlation between LUTS and Sexual Dysfunction

Correlation between LUTS severity and sexual function severity was assessed using the Microsoft Excel correlation coefficient.

RESULTS

A total of 120 patients were included in the study; the mean age of the patients is 64.5 years, in the range between 53 and 82. The majority (73) were in the age group of 60–69. [Figure 1] Most of the patients (64, 53.33%) had severe bothersome symptoms. Most of the patients in the 50–59 age group (78%) had mild or moderately severe symptoms. In the 60–69 age group, 94.5% of patients had bothersome moderate-to-severe symptoms. Severe degree of symptoms was present in most of the patients in the 70–79 age group. The correlation coefficient for age and LUTS score is 0.33, signifying a positive correlation. As age increases, the incidence of LUTS also increases [Figure 2].

Prevalence of Sexual Dysfunction

Most of the patients (50%) had moderate bother due to their ED. The rest had either no or severe bother in equal number. 64 of 73 patients in the age group of 60 moderate-to-severe ED, whereas only 9 of 14 patients had significant dysfunction in the age group of 50–59. The majority (66.6%) of the 120 patients had either no or mild bother due to their ejaculatory function. Only 1 was severely bothered. Just one patient in the age group of 50–59 had significant ejaculatory dysfunction, whereas 28 of 96 patients above 60 years had significant ejaculatory dysfunction. Majority of patients (60%) were not at all bothered by their sexual desire disorder. 7 patients (6%) were severely bothered by their sexual desire disorder. Among the 120 patients, 50 (41 %) were fully satisfied with their sexual activities. Around 30% of patients were either moderately dissatisfied or dissatisfied. 58 of 73 patients in the age group 60–69 had bothersome sexual dysfunction. 25 of 47 patients felt no bother due to sexual dysfunction in the other age groups [Figures 3 and 4].

Correlation between LUTS Severity and Sexual Dysfunction

All patients with mild LUTS symptoms had none or mild ED, and almost all of the patients in the severe LUTS group had moderate or severe ED. The correlation coefficient is 0.71, showing the significant positive correlation between LUTS and ED. Only the patients with severe LUTS had ejaculatory dysfunction, 34 of 40 patients. The correlation coefficient is 0.5. None of the patients with mild LUTS symptoms were bothered by sexual dysfunction. Around 30% of patients with moderate LUTS had mild bother. 45% of patients with severe LUTS had severe distress due to sexual dysfunction. The correlation coefficient is 0.65, significant positive correlation.

After baseline evaluation among the 120 patients, only 16 patients (13.3%) were eligible or willing to undergo medical therapy. Patients (8) who had the prostate volume of < 30cc were started on α -blockers. 8 patients

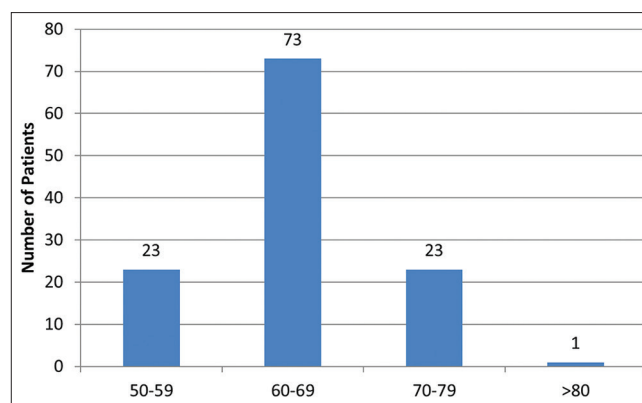


Figure 1: Distribution of age group

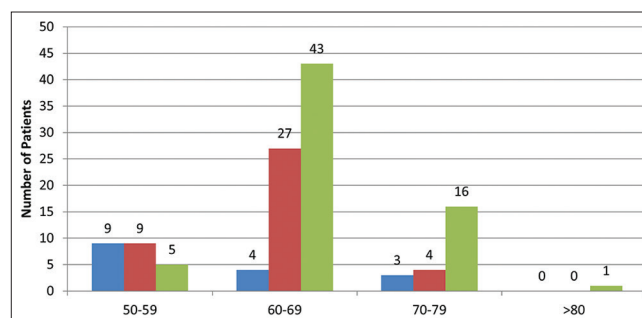


Figure 2: Age group-wise lower urinary tract symptoms severity

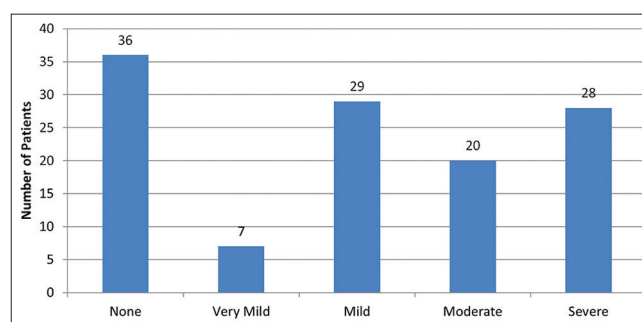


Figure 3: Overall bother/distraction due to sexual dysfunction

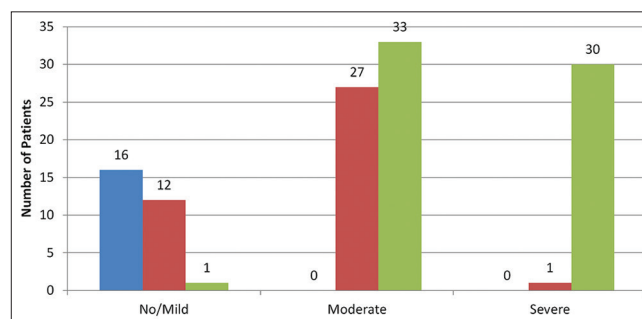


Figure 4: Correlation between lower urinary tract symptoms severity and sexual dysfunction bother

had the prostate volume of >30 cc, and they were advised to take combination therapy (α -blockers and 5-ARIs). All patients had significantly improved flow

rate and consequent reduction in IPSS score. The erectile function was not altered after medical therapy. 6 patients (38%) developed bothersome ejaculatory dysfunction after medical treatment. 50% of patients on combined therapy and 25% on α -blockers alone had ejaculatory dysfunction. Surgical treatment was mainly in the form of TURP. 104 patients underwent TURP under suitable anesthesia. All patients were asked to come for follow-up at the end of 3 months. Only 34 patients turned up for repeat evaluation. Postoperatively, among the 16 patients who had moderate bother, 7 patients (20%) had worsening of their erectile problems. Rest of the patients perceived no change. Among the 28 patients who had no issues with ejaculatory function preoperatively, 20 (71%) developed moderately bothersome ejaculatory dysfunction postoperatively. All the 6 patients who had moderate bother progressed to severe bother postoperatively.

DISCUSSION

LUTS suggestive of (LUTS/BPH) and sexual dysfunction are common, highly bothersome conditions in older men, and the prevalence of both disorders increases with age. Sexual dysfunction manifests mainly as ED, EjD, or decreased libido/HSD. Men with moderate-to-severe LUTS are at increased risk for sexual dysfunction. The successful management of patients with LUTS associated with BPH should include assessments of sexual function and monitoring of medication-related sexual side effects. For men with LUTS and sexual dysfunction, an appropriate integrated management approach, based on each patient's symptoms and outcome objectives, is warranted. Multinational survey of the aging male (MSAM-7) study showed that there is the progressive increase in LUTS and sexual dysfunction with age and independent increase in sexual dysfunction in patients with LUTS. Of a total of 232 patients who were enrolled in the study, 120 were finally included in the study after applying the inclusion and exclusion criteria. Although the sample size appears low, the patient group is the hospitalized patients only that form those who are very much distressed with the symptoms. Moreover, the sample size is comparable with that of Namasivayam *et al.*^[5] Patients with comorbidities were excluded from the study. They formed around one-third of the patients. It is important to note that 10% of patients refused to respond to the sexual health questionnaire, which carries significance. The mean age of the patients was 65.8. The predominant age group is 60–69 years. This age characteristic is comparable to the studies in the literature. The elderly age may be significant because age as such can have a bearing on sexual dysfunction as revealed in the

Cologne Male Survey.^[6] More than half of the patients had severe LUTS. This may be due to the patient sample selected, i.e., the inpatient group. The LUTS symptoms also had age-wise variation, with 78% of those in the 50–59 age group with mild symptoms, and most of them in the 70–79 group with severe symptoms. This signifies the increase in prevalence with age.^[7] The sexual function too showed variation among different age groups. Both the factors, the ED and ejaculatory dysfunction were more common in the age group of 60–69, compared to other age groups. Only the patients in the age group of 60–69 were significantly bothered by sexual dysfunction. This may be due to the association of sexual dysfunction with increasing age. Moreover, patients after the age of 70 years may not consider their sexual dysfunction bothersome, though they have a high prevalence. None of the patients in the mild LUTS group had ED, whereas 98% in the severe group and 70% in the moderate LUTS group had significant ED. The increasing age is associated with both increases in LUTS and ED. This correlates well with the reports of the MSAM-7. The correlation coefficient for LUTS with ED is 0.71, which is highly significant. It is similar to the world literature.^[8] The ejaculatory function was not that frequently affected by LUTS compared with ED. 67% of patients did not affect their ejaculatory function regardless of their LUTS status, whereas, in those affected, more than 90 % belonged to the severe LUTS group. This shows that, although severe LUTS may not always associate with ejaculatory dysfunction, the presence of ejaculatory dysfunction signifies a higher LUTS status. These results correlate well with the study by Rosen *et al.* who proposed a prevalence of 70–80% sexual dysfunction with LUTS.^[9] The correlation coefficient is 0.5, signifying an effective positive correlation. The degree to which the patients are bothered by their sexual dysfunction also varies well with LUTS. Almost all the patients (27/28) who had severe bother due to sexual dysfunction had associated severe LUTS. None of them had mild LUTS. 30% of the patients with LUTS had no bothersome sexual dysfunction. This includes patients in the higher age group strata who may have significant dysfunction but may not be bothered by it. Around 89% of patients with severe LUTS had bothersome sexual dysfunction. This bears evidence to the fact that sexual dysfunction increases with increasing LUTS. The MSAM-7 showed that the incidence of bothersome sexual dysfunction associated with LUTS. The correlation coefficient is 0.65, which shows that as LUTS increases, so too sexual dysfunction hand in hand requiring simultaneous effective management. In the government institutional setup, with predominantly poor patients, the standard medical management could not be given to the majority of the patients as they cannot afford it. Hence, around 90% of the patients were taken up for TURP. Another problem with our patients is the

poor compliance and lack of follow-up. This is proved by the fact that only 34 of 104 patients came for follow-up after TURP. In the post-treatment evaluation after medical therapy, the ejaculatory function decreased in around 36% of the patients. This can be expected because retrograde ejaculation is one of the most common adverse effects as associated with alpha-blockers.^[10] There was no change in the erectile function after medical therapy. Of the 34 patients who came for follow-up after TURP, 20% of patients in the moderate ED progressed to severe ED. This may be due to the thermal injury to cavernosal nerves caused by TURP. 70% of the patients developed ejaculatory dysfunction postoperatively. This is also well explained in the literature.

CONCLUSION

Sexual dysfunction is highly prevalent in the patients with LUTS in the range of 70%. The severity of LUTS also correlates with the severity of sexual dysfunction. Although the sample size is small and the follow-up is limited, we can suggest that treatment of LUTS should be combined with management of sexual dysfunction for better patient satisfaction and QoL.

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Idiopathic Granulomatous Mastitis - Diagnostic and Therapeutic Dilemma

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Abstract

Idiopathic Granulomatous Mastitis is a rare benign breast disease that has to be differentiated from tuberculosis and other benign diseases of the breast. The diagnosis is mainly through histopathology. Due to its rarity, treatment modalities have not yet been established. We present here a retrospective review of 25 patients of Idiopathic Granulomatous Mastitis. The cases were reviewed for their mode of presentation, diagnosis and treatment. Idiopathic Granulomatous Mastitis was diagnosed in 25 out of 1586 patients with benign breast disease. The age group was in the range of 17 – 60 years (mean age of 33 years). The most common mode of presentation was a lump in the breast – 23 patients (92%). FNAC was done in 21 patients and a diagnosis of Idiopathic Granulomatous Mastitis was made in 17 of them (81%). Expectant line of management was followed in 11 patients (44%). 14 patients (56%) were treated surgically or medically. The recurrence rate in medically treated patients was 50% and for the surgically treated patients was between 25 – 50%. We conclude that FNAC could be used to diagnose Idiopathic Granulomatous Mastitis and expectant line of management should be the treatment of choice for uncomplicated disease and in those who are compliant to follow up.

Key words: Idiopathic granulomatous mastitis, Tubercular mastitis, Histopathology, Treatment

from carcinoma of the breast^[1-4] and tuberculosis of the breast^[5-7] and other benign breast diseases. The diagnosis is arrived through histological means.^[5-8] Due to its rarity, treatment modalities have not yet been established and would rely on surgical, medical (corticosteroids and methotrexate), and expectant line of management.

In this report, we present here a series of 25 cases of IGM in a tertiary care hospital over a period of 3½ years and review the mode of presentation, histopathological reports, and the treatment modalities employed.

MATERIALS AND METHODS

In a retrospective study, the medical records and the histopathology files of patients diagnosed with IGM were retrieved at the St. John's Medical College Hospital, Bengaluru. The period of study was from January

were checked for the diagnosis of IGM. These slides should have shown negative staining for Ziehl–Neelsen stain for the presence of acid-fast bacilli. The mode of investigations was reviewed as well as the modality of the treatment. Patients were followed up for recurrence and complications.

RESULTS

The histopathology files gave a diagnosis of benign breast diseases in 1586 patients. Of the 1586, the diagnosis of idiopathic granulomatous mastitis was made in 25 (1.57%) slides. The age group was in the range of 17–60 years (mean of 33 years) [Figure 1]. 23 patients (92%) presented with a lump in the breast which was the most common presentation. Of the 23 patients with the lump, 20 (87%) presented with a single lump and 21 (91.3%) presented with a lump/s in a single breast with no predilection for sides. 14 patients (56%) presented with complains of pain along with other symptoms and 2 patients (8%) with pain as the only symptom. 2 patients (8%) presented with recurrent abscesses [Figure 2]. Axillary nodes were palpable in 7 patients (28%). Other modes of presentation included nipple retraction in 3 patients (12%) and skin changes in 6 (24%). The skin change included erythema - 3 (50%),

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ulcer - 2 (33%), and peau d' orange in one patient. 11 of the 25 patients (44%) had breastfed their children. 2 patients (8%) had elevated serum prolactin levels. In the patients with elevated serum prolactin levels, one was known to have hyperprolactinemia for 10 years and she presented with recurrent abscess. In the other patients, hyperprolactinemia was detected after a diagnosis of IGM was made. She presented with a lump and nipple discharge.

Tracing the histopathology records, fine-needle aspiration cytology (FNAC) was done in 21 of 25 patients (84%). In two patients, FNAC was not done. IGM was diagnosed in 17 patients through FNAC (68%) [Figure 3]. Of the rest four FNACs, one each was diagnosed as giant cell response, non-proliferative disease, fibrocystic disease, and suppurative inflammation. In these four patients in whom FNAC were not done, the diagnosis of IGM mastitis through biopsy. Taking the two abscesses and the two ulcers, in which FNAC could not be done before biopsy; FNAC gave a diagnosis of IGM in 17 of 21 patients (81%).

In our study, 14 patients (56%) were treated either surgically or medically. Expectant line of management was followed in 11 patients (44%) [Figure 4]. Of the 14 patients treated, 10 (71.4%) were treated surgically and 4 (28.6%) were treated medically. Eight patients had undergone wide local excision of the lump with two patients had undergone incision and drainage. The four patients treated medically were treated with corticosteroids [Figure 5].

On follow-up, one of the two patients who had undergone incision and drainage had a recurrence of the abscess and had subsequently undergone debridement and curettage of the abscess wall. Of the 8 patients who had undergone wide local excision of the lumps, two had recurrence, who underwent subsequent excision. Two of the four patients who were treated with corticosteroids had recurrence.

DISCUSSION

There has been an increased reporting of IGM in recent times. The disease is more common in Asian and African women.^[9-11] In one series from the USA, the prevalence was found to be 2.4/100,000 women in 20–40 years age group, and it was found to be 12 times higher in Hispanic women than the native white population.^[9] Baslaim *et al.* reported the prevalence to be around 1.8% of histopathologically confirmed cases of benign breast diseases.^[11] In our series, we found 25 cases (1.57%) of IGM from 1588 histopathologically confirmed cases of benign breast diseases. The disease most commonly occurs in the childbearing age group.^[10,12] The etiology of the disease remains unknown. Various etiological causes have been postulated from allergic reaction to medications,^[9] trauma,^[13]

autoimmune process,^[14] subclinical tuberculosis, previous exposure to tubercular protein,^[5,7] hyperprolactinemia,^[15,16] alpha-1 antitrypsin deficiency,^[8] oral contraceptive pills,^[12] breastfeeding practices, and delayed access to health-care services.^[9] The reported case series do not show any predilection to any one breast as in our series. Earlier it was thought that IGM does not affect the subareolar region, but of late cases have been reported where the disease affects the subareolar region.^[2]

The disease has to be differentiated from tubercular mastitis.^[5,7] Other less common conditions from which

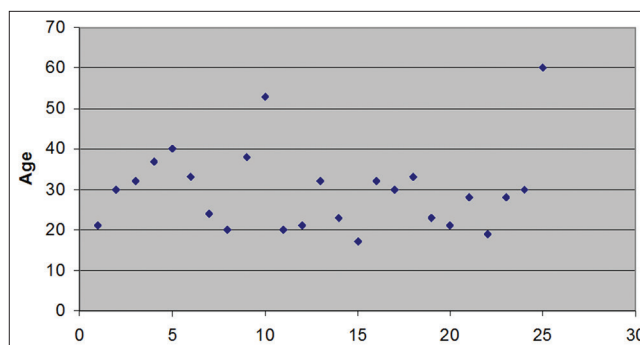


Figure 1: Age distribution of the patients diagnosed with idiopathic granulomatous mastitis

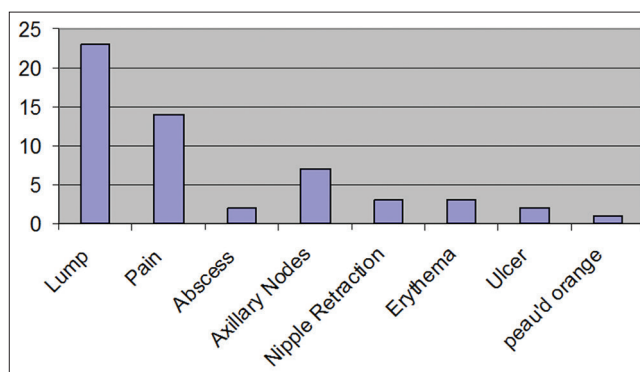


Figure 2: Chart showing the modes of presentation

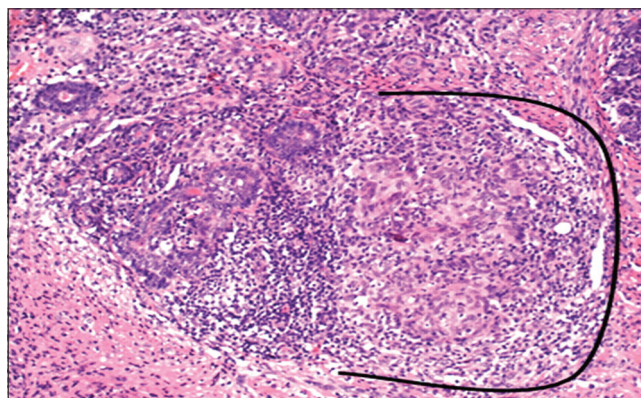


Figure 3: FNAC showing non-caseating granuloma with multinucleate giant cells and plasma cells

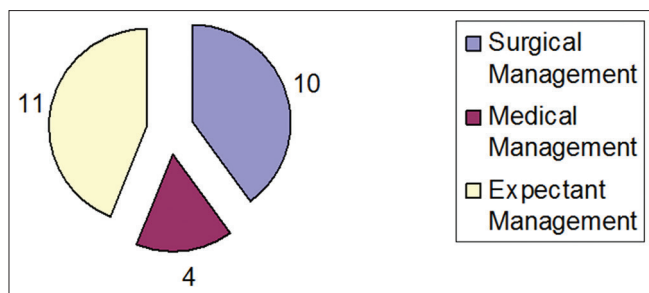


Figure 4: Treatment modalities adopted for the idiopathic granulomatous mastitis patients

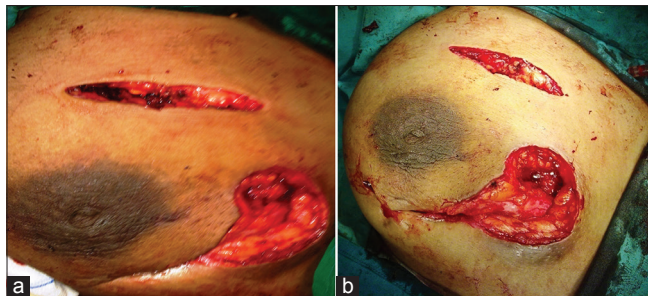


Figure 5: (a and b) Intraoperative images - drainage and excision for unilateral, multiple abscesses, and idiopathic granulomatous mastitis

it has to be differentiated are sarcoidosis,^[8,17,18] Wegener's granulomatous mastitis,^[19] blastomycosis, cryptococcosis, histoplasmosis, actinomycosis,^[5,7] *Corynebacterium* infection,^[20] giant cell arteritis, and foreign body reaction - which all shows granulomatous reaction.

The diagnosis is mainly arrived through histological means and a process of elimination. The slides have to be stained with hematoxylin and eosin, Ziehl–Neelsen stain, and other special stains for specific fungi and bacteria.^[7,8]

The typical histological feature is the presence of a granuloma containing epithelioid histiocytes, plasma cells, lymphocytes, eosinophils, neutrophils, multinucleated giant cells, and very rarely necrosis.^[5,21] In a study comparing IGM and tubercular mastitis, Lacambra *et al.* reported^[5] that in IGM, the lesion occurred in older population; the lesions were smaller, showed more plasma cells and had less eosinophils, necrosis, and fibrosis. Further studies are warranted to validate the histological differences between IGM and tubercular mastitis based on histopathological features. Polymerase chain reaction (PCR) has a higher sensitivity than Ziehl–Neelsen staining and Bactec culture in diagnosing tuberculosis.^[22-24] The diagnosis of IGM was arrived through FNAC in 17 of the 21 patients. FNAC seems to be a reasonable method to make a diagnosis of granulomatous mastitis.^[25] However, there were four cases that were not picked up by FNAC but later confirmed through biopsy. Because PCR is more readily available now

and reasonably priced, we recommend that PCR alone or in combination with other tests should be carried out in every patient that has a histological diagnosis of granulomatous mastitis until further studies validate the histopathological picture.

There has been a report of an association between IGM and prolactinoma.^[15,16] In our study, we found two patients associated with hyperprolactinemia. Further studies would be required to investigate the presence of this association.

On examining histology slides, emphasis has to be laid on the presence or absence of vasculitis in differentiating from sarcoidosis and Wegener's granulomatosis. The presence of vasculitis should lead to serological tests for serum angiotensin-converting enzyme levels, antinuclear antibody levels, or any evidence of involvement such as lung and kidney.^[18]

Radiology plays a less significant role in the diagnosis of IGM. Ultrasound, computed tomography (CT) scanning, mammography, or magnetic resonance imaging (MRI) do not seem to offer distinct diagnostic features for diagnosis of IGM.^[2,3,26] In a series reported by Lee *et al.*,^[2] asymmetric density with no distinct margin or mass effect or mass effect formed the most common finding in mammogram. Ultrasound most commonly showed irregular tubular hypoechoic lesions. CT scan showed heterogeneously echoing mass lesion while MRI showed masses with low intensity in T1W1-weighted images. Ultrasound offers a good method to follow-up lesions that have been diagnosed as IGM.^[27]

No specific protocol has been established for the treatment of IGM. The disease takes an indolent course more often than not and would take 1–1½ years to settle.^[10] The options available are expectant line of treatment, medical treatment with corticosteroids, to which methotrexate may be added; surgical management - which would include incision and drainage, wide excision, and mastectomy.

In our series, expectant line of management was followed in 11 patients (44%). These patients had smaller masses without any complications and all of them either remained static or their sizes decreased during the follow-up period of 1 year–18 months. 25% of those treated with excision had recurrence while 50% of those treated with corticosteroids had recurrence.

The surgical options available are wide local excision^[4] and mastectomy.^[28,29] If the disease is extensive, mastectomy could be offered and reconstruction gives good result if no residual disease is left behind.^[29] Corticosteroids were first advocated as a treatment modality by DeHertogh *et al.*, in 1980.^[30] Corticosteroids

have shown varying success rate whether used alone or in conjunction with other modalities.^[22,27,31] While deciding to use corticosteroids, tubercular mastitis has to be ruled out^[7] and the patient has to be monitored for complications of corticosteroids.^[32] Methotrexate could also be used if response to corticosteroids is not satisfactory.^[33,34] More often than not in uncomplicated cases, expectant line of management forms the best line of management.^[10,17] The pragmatic approach would be to use different modalities of treatment depending on the severity of the disease.^[35-37]

In our view, if the mass is small and the disease is not progressing, we can follow an expectant line of management. Abscess formation would require an incision and drainage. Since we found lower recurrence rates in the surgical arm, we would prefer wide excision as the next option. Due to the rarity of the disease, randomized controlled trials may not be possible to establish treatment protocols in the near future.

In our series, two cases presented with recurrent abscesses. The diagnosis of IGM was made after we sent the abscess wall for histopathological examination. Breast abscess is one of the most common manifestations of benign breast diseases in Asian countries. Hence, it would be prudent to send the wall of the abscesses for histological examination at least in recurrent cases, so as not to miss the diagnosis of granulomatous mastitis.

CONCLUSION

IGM is a rare disease of the breast. It has to be differentiated from tubercular mastitis and other granulomatous mastitis. The disease can be treated in an expectant manner if there are no complications. Further studies would be required to establish treatment modalities. In cases of recurrent abscesses of the breast, we recommend biopsy of the abscess wall to diagnose this condition.

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Ocular Changes in Pregnancy: An Observational Study

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Abstract

Introduction: Ocular changes which occur during pregnancy are broad and common. They can be divided into physiological or pathological, and some changes may be associated with pre-existing conditions. Physiological changes are lid telangiectasia, ptosis, increased pigmentation around the eyes and cheeks, corneal edema, decreased corneal sensation, increased corneal thickness, and curvature. Contact lens intolerance, dry eye syndrome, and decreased intraocular pressure are also some of the physiological changes seen during pregnancy. Although ocular complications are common in pregnancy, most of them are mild which requires no treatment. However, it is important to identify serious conditions that occur during pregnancy requiring immediate medical attention.

Purpose: The aim of the present study is to report significant ocular changes that occur during pregnancy.

Materials and Methods: A prospective cross-sectional clinical study was done in 120 women with pregnancy (gestational period from 24 weeks to 38 weeks). A detailed medical, ocular, and gestational history was obtained. All pregnant women underwent detailed eye examination including assessment of visual acuity, refraction, ocular motility, keratometric reading, anterior segment examination with slit lamp biomicroscope, intraocular pressure recording with noncontact tonometer, corneal sensitivity, and dilated fundus examination.

Results: A total of 120 women with pregnancy (gestational period 24–38 weeks) underwent detailed eye examinations. 38% showed clinically significant retinal changes with high blood pressure, and in these cases, only 31% showed physiological changes along. Other significant pathological conditions were also noticed. Most ocular disease can be treated with drugs.

Conclusions: All pregnant women during antenatal and postpartum period should undergo complete ophthalmic examination and treatment. Early detection of retinal abnormalities can prevent serious complications.

Key words: Corneal curvature, Hypothyroidism, Ocular changes, Pregnancy, Refractive error, Retinal abnormalities

INTRODUCTION

Ocular changes that occur in pregnancy are usually temporary in nature, but occasionally, there may be permanent disorders. These ocular changes can be either physiological or pathological or both. If we talk about pathological changes in a pregnant woman, it can be new developed ocular changes due to the pregnancy or a pre-existing ocular changes (which worsen due to the pregnancy) or a systemic disease

(which can be pre-existing or developed due to pregnancy); physiological changes in pregnancy are low IOP, chloasma, hyposphagma, tear film composition alterations, decreased sensations, krukensberg's spindles increased thickness alteration in refractive power, increased thickness of lens leading to refractive changes, and pituitary gland enlargement.^[1] Pathological changes are the growth of hemangiomas, carotid-cavernous fistula, ptosis, Horner's syndrome, facial nerve palsy, vasospasm in preeclampsia, worsening of diabetic retinopathy, vascular changes in preeclampsia, serous retinal detachment, central serous chorioretinopathy, growth of melanomas, ischemic optic neuropathy, papilledema, and cortical blindness in eclampsia.^[2] Physiological changes usually resolve in postpartum period. Pre-existing diseases such as Graves' disease, retinitis pigmentosa, optic neuritis, diabetic retinopathy, hypertensive retinopathy, glaucoma, intracerebral tumors, uveitis, multiple sclerosis, and other

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inflammatory conditions or pregnancy-induced conditions such as gestational diabetes, pre-eclampsia, and eclampsia should be monitored during and post pregnancy. There are certain rare conditions which are also noted during the phase, i.e., neuro-ophthalmological condition such as pseudotumor cerebri (benign intracranial hypertension), prolactinoma (adenoma of pituitary gland), and venous sinus thrombosis. They present as headache, visual field defect, and optic disc edema. Systemic diseases with ocular complications are Sheehan syndrome, Grave's disease, idiopathic intracranial hypertension, antiphospholipid antibody syndrome, and disseminated intravascular coagulation. Although ocular complications are common in pregnancy, most of them are mild which requires no treatment. However, it is important to identify serious conditions that occur during pregnancy requiring immediate medical attention.

Aims

The aim of the study is to report significant ocular changes during pregnancy.

MATERIALS AND METHODS

It was a cross-sectional observational study carried out jointly in the Department of Ophthalmology and Department of Obstetrics and Gynaecology of Rajarajeswari Medical College and Hospital, Bengaluru (Karnataka), from October 2016 to March 2017 (6 months). Study subjects include 120 pregnant women (gestational period from 24 weeks to 38 weeks). An oral informed consent was obtained from all women participating in the study.

Exclusion Criteria

Pregnant women with any preexisting comorbidity such as diabetes and hypertension and pregnant women with any pre-existing ocular morbidity such as cataract, uveitis, glaucoma, retinal, and optic nerve disorders were excluded from the study.

Evaluation of the Patient Included the Following in Each Case

Complete ophthalmic history and medical history were taken. The measurement of the uncorrected visual acuity and best-corrected visual acuity was done. Intraocular pressures were recorded using noncontact tonometer. Anterior segment of both the eyes was examined under the slit lamp biomicroscope. Corneal sensitivity was noted with the help of cotton wisk. Dry eye evaluation were done with the help of schmeirs test and manually binocular eye movement were observed. Fundus evaluation of both the eyes was done through dilated pupils using direct ophthalmoscope, and keratometry was done using Bausch

and Lomb Keratometer. The data were expressed in the form of percentages.

RESULTS

These 120 women based on their analysis showed a varied result. 38% showed clinically significant retinal changes with high blood pressure leading to the categoric division of the pathological condition along with its physiological [Figure 1]. Physiological changes were seen in 79% of the patients [Figure 2]. 10 among these 120 showed papilledema [Figure 3].

DISCUSSION

In pregnant women, various physiological changes take place due to hormonal effect in the placenta that is increased estrogen, increased progesterone, and increased melanocyte stimulating hormone. In pathological ocular condition, discussing about the ptosis which is seen is because of fluid and hormonal effect on the levator aponeurosis. Increased immune reaction in lacrimal duct cell and dehydration due to nausea and vomiting is the cause of tear film alteration. Corneal changes that can increase thickness and reduce sensation are due to corneal

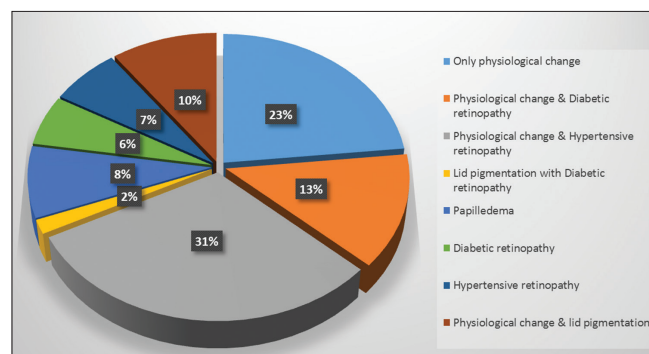


Figure 1: Percentage of ocular changes in pregnancy

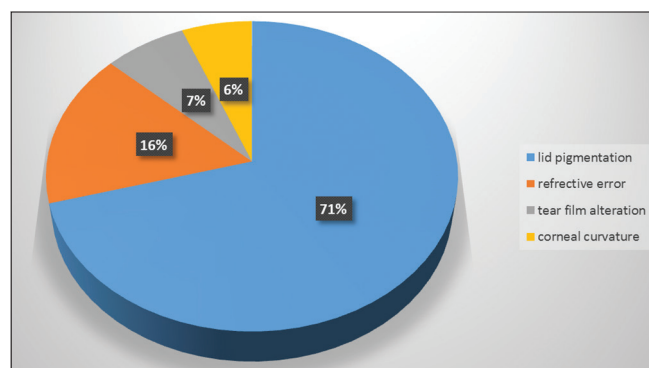


Figure 2: Percentage of physiological ocular changes in pregnancy

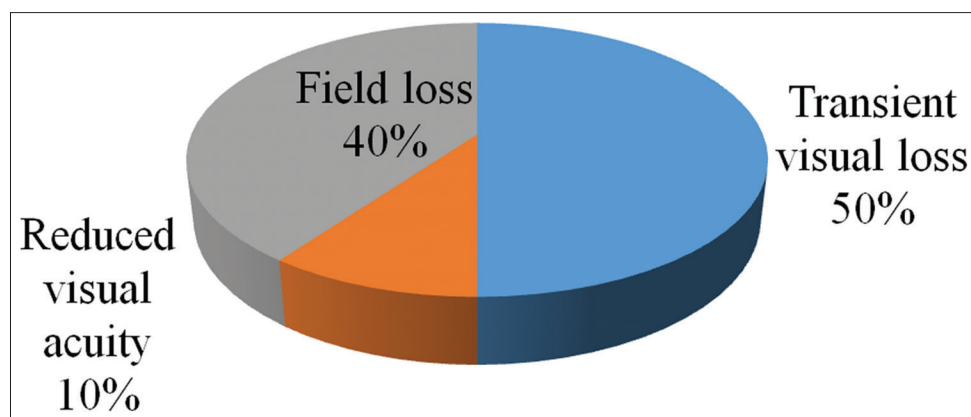


Figure 3: Patients with papilledema

edema.^[3] This leads to refractive error and contact lens intolerance. Hence, it is important to avoid new spectacles prescription and avoid any refractive surgery. Intraocular pressure was found to be less among pregnant women. Retinal changes which are significant are either diabetic retinopathy or hypertensive retinopathy. Case of diabetic retinopathy is of low-risk which disappears on blood sugar control, while on the other side, pre-eclampsia the most common finding being retinal arterial narrowing, followed by retinal hemorrhages and exudates which also give rise to exudative RD.^[4] 80 patients complained of headache, among which ten patients had papilledema. Most common symptom of papilledema is transient visual obscuration which is described as the dimming of vision of one or both the eyes for up to 30 s. These visual changes often occur due to orthostatic changes in the patient. The patient may also complain of loss of peripheral vision in one or both the eyes starting in the nasal inferior quadrant which progresses to the central visual field. The field loss tends to mimic glaucoma field loss. Visual acuity may also be affected.^[5] Increase in headaches is caused by a surge of hormones in pregnancy along with an increased volume of blood circulating throughout the body.^[6]

CONCLUSION

Hypertensive retinopathy is a common ocular manifestation in pregnant women. Ocular changes in pregnancy can help to differentiate the physiological changes from ocular manifestations of systemic disease pertaining to the eye in a pregnant woman. All pregnant women during antenatal period should undergo complete ophthalmic examination. Early detection of retinal changes in pregnancy can prevent serious complications.

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Trabeculectomy: A Follow-up Study of 120 Cases in Terms of Intraocular Pressure

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Abstract

The aim of the study was to access the efficacy of conventional trabeculectomy in lowering the intraocular pressure (IOP) in various types of glaucoma.

A clinical evaluation of trabeculectomy was done in 120 cases of different types of glaucoma. 60 were primary open-angle glaucoma, 13 were primary angle closure glaucoma, 42 were exfoliation glaucoma, and five were steroid-induced glaucoma.

Patients were operated by conventional trabeculectomy and followed up for 6 months.

Statistically there was highly significant reduction from mean pre operative level (36.12 ± 10.84) to last postoperative IOP (14.7 ± 3.17). Average postoperative IOP fall at 06 months from initial value was 21.42 mm Hg (59.3%).

The complications were seen in 29.16% cases. Main complications were shallow AC 16.6% followed by hypahema 10 % and progression of lenticular changes 10 % cases. The study concludes the conventional trabeculectomy is equally effective in controlling IOP in all four types of Glaucoma with few complications and is still gold standard for management of glaucoma.

Trabeculectomy was successful in controlling IOP to <21 mmHg in 92% of cases and visual activity improved or was maintained in 80% of cases.

Key words: Glaucoma, Intraocular pressure, Trabeculectomy

INTRODUCTION

The term glaucoma refers to a group of disorders that have in common characteristic optic neuropathy with associated failure loss for which the elevated intraocular pressure is one of the primary risk factor.

Glaucoma is a leading cause of irreversible blindness throughout the world. Although the condition more commonly affects the elderly, it occurs in all segments of society with significant health and economic consequences

Glaucoma can be classified into developmental, primary and secondary. Primary open angle glaucoma is clearly the most common single form of glaucoma.

Once the blindness of glaucoma has occurred, there is no known treatment that will restore the lost vision. However in nearly all the cases, blindness from glaucoma is preventable. This prevention requires early detection and proper treatment.

In spite of introduction of so many new drugs medical treatment many a times fails either due to patient non compliance with the regimen or the prescribed regimen may be incapable of effectively controlling the disease.

When non surgical means of reducing pressure fail, surgical method are justified.

The basic aim of most of the surgical procedures is to establish a fistula between anterior chamber and subconjunctival space

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so that aqueous should drain from the eye with the least resistance. They differ primarily according to the method of creating the fistula with the two main variations:

1. Full thickness fistula
2. Guarded fistula beneath a partial thickness scleral flap.

Full thickness fistula is associated with high complication rate. One attempt to minimize complications has been to place partial thickness scleral flap over the fistula. This concept was suggested by Sugar (1961) but was popularized by 1986 report of Cairnes. Both authors referred the technique as trabeculectomy. The intention is to excise a short length of Schlemm's canal, with its trabecular adnexia, thus leaving two cut ends, opening directly into aqueous humour with no trabecular tissue remaining as a barrier at that point and restoring the integrity of corneoscleral coat over the area of excision.

PATIENTS AND METHODS

The study was conducted in the Department of Ophthalmology, District Hospital Baramulla. In the study, 120 diagnosed cases of different types of glaucoma were operated between January 1, 2015, and December 31,

Table 1: Types of glaucoma and their mean pre-operative IOP^[1]

Types of glaucoma	Mean pre-operative IOP
POAG	35.87±9.1
PACG	40.77±12.4
Exfoliation glaucoma	32.73±5.5
Steroid-induced glaucoma	42±11.40

IOP: Intraocular pressure, POAG: Open-angle glaucoma, PACG: Primary angle closure glaucoma

Table 2: Distribution of cases according to post-operative IOP (mmHg) ^[2,3]

Types of glaucoma	1 st week	1 st month	3 rd month	6 th month
POAG	13.6±3.61	14.54±4.55	14.54±4.3	15.32±3.95
PACG	12.92±3.7	14.46±4.33	13.85±2.23	14.0±2.31
Exfoliation glaucoma	12.86±3.1	13.73±4.2	14.0±4.19	13.9±3.57
Steroid-induced glaucoma	12.0±2.83	12.4±2.19	12.8±2.7	13.2±2.28

IOP: Intraocular pressure, POAG: Open-angle glaucoma, PACG: Primary angle closure glaucoma

2017. Indication for trabeculectomy was uncontrolled intraocular pressure (IOP) despite maximum tolerated medical therapy and disease progression. All patients were admitted 1 day before surgery and given antiglaucoma treatment for lowering raised IOP. (Timolol 0.5 % e.d., oral acetazolamide, oral Glycerol or mannitol IV depending on level of IOP) Patients were operated under local (peribulbar) anesthesia. A fornix-based conjunctival flap^[18] was made at 12 O'clock position. Trabeculectomy was performed with borders of superficial sclera flap triangular (4 mm × 4 mm) outlined to two-thirds of sclera thickness. Deep sclerotomy involved corneoscleral block of 1.5 mm × 3 mm. Peripheral iridectomy was performed. The superficial triangular flap was sutured with 10-0 nylon, with one suture at apex. Conjunctiva was closed with two sutures by 10-0 nylon at two corners of the flap. Anterior chamber was formed by injecting fluid through paracentesis made at 9 O'clock position and bleb was formed on table. Bandage was removed after 24 h and particular attention was paid to condition of filtering bleb, cornea, anterior chamber for depth and contents, pupil, and lens postoperatively. After 24 h, patients were put on antibiotic steroid e.d., 2 h and cyclopentolate 1% e.d., QID for 1 week. Steroids QID were continued for 1 month IOP that was measured by Goldmann applanation tonometry using 2% fluorescein strips in immediate post-operative period. Post-operative follow-up was done on 1st, 2nd, and 4th weeks, and 3rd and 6th months.

Observation

The patient ranged in age from 16 to 80 years with mean age of patients being 58.41 ± 13.6 years. The primary open-angle glaucoma (POAG) constituted 60 cases, primary angle closure glaucoma (PACG) 13 cases, exfoliation glaucoma 42 cases, and steroid-induced glaucoma five cases. Preoperatively, majority of cases were in >21–30 mmHg IOP range with mean IOP being 36.12 ± 9.31 mmHg (Table 1).

Pre-operative visual acuity was 6/12 or better in 15% of cases, 6/18–16/36 in 39% of cases, and 6/60 or less in 46% of cases.

Statistically, there was highly significant reduction from mean pre-operative level (36.12 ± 10.84) to the last post-operative IOP (14.7 ± 3.17). Average post-operative IOP fall at 6 months from initial value was 21.42 mmHg (59.3%) (Table 2).

Table 3: Pre-operative and post-operative IOP according to glaucoma type seen was ^[4,5,6]

Types of glaucoma	Pre-operative IOP	Last post-operative IOP (6 months)	Change in IOP in mmHg (%)	Significance level <i>P</i> value based on student's <i>t</i> -test
POAG	35.87	15.32	20.55 (57.29)	<0.001
PACG	40.77	14.0	26.77 (65.66)	<0.001
Exfoliation glaucoma	32.73	13.9	18.83 (57.53)	<0.001
Steroid-induced glaucoma	42	13.2	28.8 (68.57)	<0.001

IOP: Intraocular pressure, POAG: Open-angle glaucoma, PACG: Primary angle closure glaucoma

Table 4: The various complications encountered with percentage of occurrence was [7,8,9]

Complication	Number of cases	Age (%)
Hyphema	12	10
Shallow AC	20	16.6
Flat AC	2	1.66
Conjunctival leak	6	5
Iritis	1	0.83
Striate keratitis	3	2.5
Iris prolapsed	1	0.83
Hypotony (transitory)	2	1.66
Choroidal effusion	2	1.66
Blebitis	1	0.83
Encapsulated bleb	2	1.66
Cataract progression	12	10
Total cases	35	29.16

Trabeculectomy was considered to be successful if post-operative IOP was <21 mmHg at 6 months without medication or with single addition medication. Trabeculectomy was successful in 92% of cases at 6 months. 90% of cases were controlled without treatment. Failure was seen in 7%. When post-operative status of vision at 6 months was compared with pre-operative vision, it was found that vision deteriorated >1 line in 20% of cases. Vision improved in 7% and remained same in 73% of cases.

The total number of complication exceeds as more than one complication occurred in some cases.

Conjunctival resuturing was done in 6 cases (5%), cataract extraction was done in 12 cases (10%).

DISCUSSION

Our success rate of 90% without medication is close to success rate published by Watson and Greirson (86%)^[10] and Anand *et al.* (85%)^[11] but higher than as reported by Schwartz and Anderson (56%)^[12] and Freesom *et al.* (57%)^[13].

Our success rate of 92% with or without additional treatment is similar to as reported by Fridgway *et al.* (92%)^[14] and Jerndal and Lundstorm. (92%)^[12] but higher than as reported by Schwartz and Anderson^[13] and Freesom *et al.* (84%)^[16] and is lower than as reported by Watson and Barnet (95%)^[7] and Al Smarai (95.5%)^[17].

Our success regarding improvement or no change in visual acuity (80%) is similar to as reported by Fridgway *et al.* (80%) and Mills (84.8%)^[18].

Our incidence of post-operative shallow anterior chamber (16.6%) is higher than as reported by Watson and Barnet (22.2%)^[16].

Our incident of hyphema (10%) is close to as reported by Anand *et al.* (12.7%)^[11] but lower than as reported by Fridgway *et al.* (15%)^[14].

Our incident of cataract progression (10%) is lower than as reported by Watson and Barnet (15.5%)^[16] and Mills (35.4%)^[18] but higher than as reported by Ananad *et al.* (2.8%)^[11].

Our incidents of choroidal effusion are in accordance with as reported by Watson and Greirson (2%)^[10] and Mills (5.3%)^[18] 2% of patients developed encapsulated bleb.

CONCLUSION

A clinical evaluation of trabeculectomy was done in 120 cases of different types of glaucoma. 60 were POAG, 13 were PACG, 42 were exfoliation glaucoma, and five were steroid-induced glaucoma. Patients were operated by conventional trabeculectomy and followed up for 6 months. Preoperatively, mean IOP was 36.12 mmHg. Post-operative IOP remained comparatively low up to 1 week (mean 13.23 mmHg). It showed that a rising tendency is subsequent follow-ups with mean IOP at 6 months being 14.6 mmHg. Average post-operative fall of IOP from initial level was 21.42 mmHg at 6 months (Table 3). The fall in IOP was statistically significant ($P < 0.0001$) mmHg in 92% of cases and visual acuity improved or was maintained in 80% of cases. The complications were seen in 29.16% of cases. Main complications were shallow AC 16.6% followed by hyphema 10% and progression of lenticular changes 10% of cases (Table 4). The study concluded that the conventional trabeculectomy is equally effective in controlling IOP in all four types of glaucomas with few complications and is still the gold standard for the management of glaucoma.

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Effects of Perioperative Hyperoxygenation on Surgical Site Infection in Patients with Acute Appendicitis

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Abstract

Introduction: Surgical wound infection is nightmare for any surgeon following elective and emergency operations. In recent studies, the possibility of reducing surgical site infection (SSI) by perioperative hyperoxygenation has been raised. Hypoxia at the level of local wound site retards proper healing. Proper oxygenation of the tissue through microcirculation is vital for the healing process and resistance to infection. The data obtained from the related randomized, controlled trials for the benefits of perioperative hyperoxygenation to reduce SSI remain controversial. To overcome this problem, we have performed a randomized, controlled trial in a patient population with a single diagnosis (acute appendicitis), using standard surgical approach (open appendectomy).

Key words: Hyperoxygenation, Surgical site infection, Acute appendicitis

INTRODUCTION

Surgical wound infection is nightmare for any surgeon. The surgical team takes all the precautions before, during and after the surgery to avoid and control the surgical wound infections. In spite of our efforts surgical site infection (SSI) constitutes a noteworthy problem in emergency and planned surgeries. Among nosocomial infection surgical wound infection is the most common. The cause of surgical wound infection is multifactorial depending on the overall well-being of the patient, types of surgery, surgical skill, and use of other preventive measures like prophylactic antibiotics. Other factors which may influence SSI include operative time, core body temperature, post-operative pain, and tissue hypoxia.^[1]

Hypoxia at the level of local wound site retards proper healing. Proper oxygenation of the tissue through microcirculation is vital for the healing process and

resistance to infection.^[2] In recent studies, the likelihood of surgical wound infection by perioperative hyperoxygenation has been raised, but the data obtained from the related randomized, controlled trials remain controversial. In three studies, perioperative inhalation of an oxygen-enriched (80%) mixture led to a significant reduction of surgical wound infection following miscellaneous or only lower gastrointestinal tract surgery. However, in another three randomized, controlled studies concerning various gastrointestinal tract, colorectal, or gynecological operations, perioperative hyperoxygenation was not associated with an improved rate of wound infection. However, in meta-analyses gathering almost all of the participating subjects cumulative results favor the use of hyperoxygenation for surgical wound infection reduction.

MATERIALS AND METHODS

This was a prospective case-control study conducted at BLDEU's Shri B. M. Patil Medical College Hospital and Research Centre, Vijayapur, from October 2015 to August 2017 and included 180 patients with acute appendicitis and in each group, 90 patients were allotted. A total of 180 patients who underwent open surgery for acute appendicitis, pre-operative intravenous antibiotics were given to all patients. In the control group, 90 patients

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received oxygen from the room air, while in the study group, the fraction of inspired oxygen (FIO_2) reached 80% with the use of nonrebreathing mask in the rest 90 patients and continued for 2 h in the recovery room following completion of the operation in the study group with high-flow oxygen (10 L/min) through a nonrebreathing mask, while control group received oxygen from room air. We used the ASEPSIS system score to assess the degree of healing and infection of the surgical wound. The results of the two groups were compared and analyzed.

RESULTS

From October 2015 to June 2017, a total of 180 patients of having confirmed diagnosis of acute appendicitis are included in this study. To have uniformity in both the groups, we excluded all the patients having diabetes and immunocompromised status. We also excluded the patients having clinical evidence and imaging study confirming the diagnosis of perforated or gangrenous appendicitis. Superficial infective skin disease can influence the result, so excluded from the study. All the patients included in the study underwent open appendicectomy surgery by McBurney's approach. A total of 180 patients were alternately alienated between the study group (90 patients, FIO_2 of 0.80) and control group (90 patients, FIO_2 of 0.30). Our institute serves the relatively low and middle socioeconomic group of people. All the patients included in the study were having almost similar socioeconomic status.

Out of 180 patients included in this study, 80 (44.45%) patients were female and 100 (55.55%) patients were male. In the control group out of 90 patients, 47 (52.2%) patients were female and 43 (47.8%) patients were male. In the study group, 33 (36.7%) patients were female and 57 (63.3%) patients were male. There is no significant difference in sex-wise distribution of patients in both the group.

In total group range of the age was from 9 to 72 years with mean age of 28.9 ± 11.9 years. In the control group range of the age was from 9 to 62 years, with a mean age of 27.8 ± 11.2 years. In the study group range of the age was from 9 to 72 years, with a mean age of 30.0 ± 12.5 years statistically there were no significant differences in age.

There were no major differences between the groups in medical history and clinical presentation. Parameters such as smoking history, obesity, timing of perioperative antibiotic administration, and abdominal shaving (in the operating room) as well as laboratory results were similar in both groups. Intraoperative hemodynamic parameters and intraoperative findings were not statistically different either.

In our study, we noticed a marked difference in requirement of antibiotic in the control group (98.9%) as compared to the study group (1.1%) making it significant. In study group, 5 (5.6%) patients had SSI ranging from minimal to moderate degree as per the ASEPSIS score. In the control group, 17 (18.9%) patients had SSI ranging from minor to severe degree as per the ASEPSIS score.

All the open appendicectomy surgery was done by different surgeons. We noted operative time from making of an incision to the complete skin closure. Operative time in the study group was 37.6 ± 4.5 min and in control group 37.8 ± 6.2 min. There is no significant difference in operative time in both the groups.

Average stay in the hospital also differs in both the group. Control group has an average stay of 7.6 ± 2 days while the study group has 6.4 ± 2.4 days. Stay in hospital is statistically lower in the study group (P significance 0.001).

The total cost of the disposable nonrebreathing mask and antibiotics in the study group is Rs. 39,240, means Rs 436 per patient. Control group has a total cost of 86,580 means Rs 962 per head. Cost of treatment in the study group is significantly lower than the control group.

As per asepsis scoring method erythema was noted on the 2nd post-operative day in 13 out of 90 patients (14.4%) in control group while only 1 out of 90 patients (1.1%) in the study group had developed erythema. 9 patients had serous discharge on the 2nd post-operative day, 9 patient had on the 3rd post-operative day, and 3 patient had on the 4th post-operative day. 5 patients had purulent discharge on the 5th post-operative day. Pus culture was taken for sensitivity study and antibiotics were modified accordingly. In the control group, 17 patients (18.9%) required additional antibiotics while in study group only 1 patient (1.1%) required additional antibiotics. This is significantly lower in the study group as compared to control group.

Analysis

SSI is a major complication of abdominal surgery, associated with prolonged hospitalization, increased costs, and excess mortality. In recent years, randomized trials have identified a number of preventive measures that can substantially reduce the risk of SSI. These include appropriate perioperative antibiotic prophylaxis, maintenance of perioperative normothermia, and control of hyperglycemia.^[3,4] Achieving high oxygen tension at the site of surgery has been proposed as a means of reducing the risk of SSI, based on data that oxygen can enhance the oxidative processes in white cells, thus facilitating bacterial killing.^[3,5] A number of preclinical studies have shown

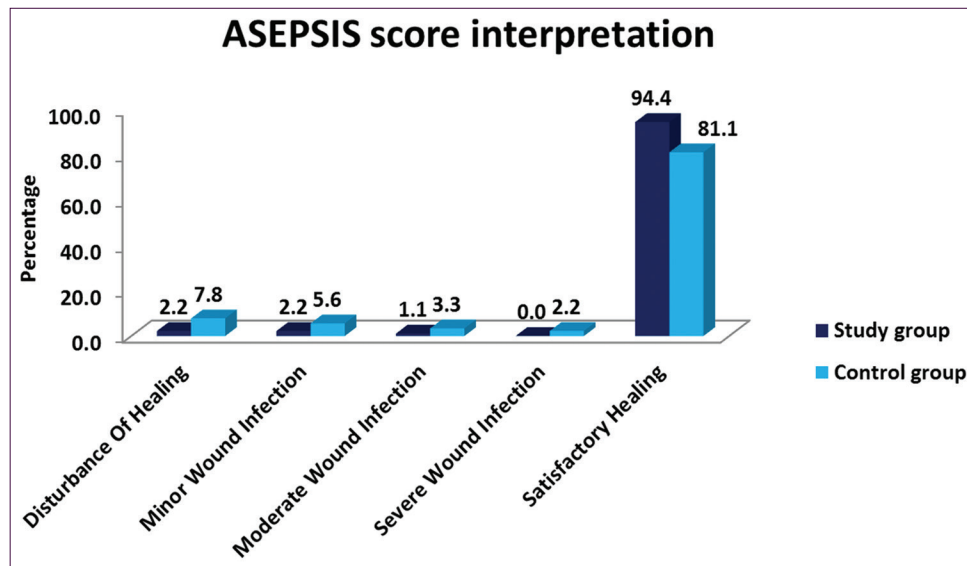


Chart 1: ASEPSIS score between study and control groups

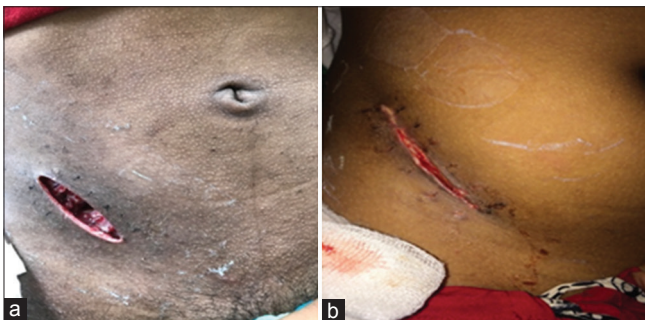


Figure 1: (a-b) Asepsis in control group

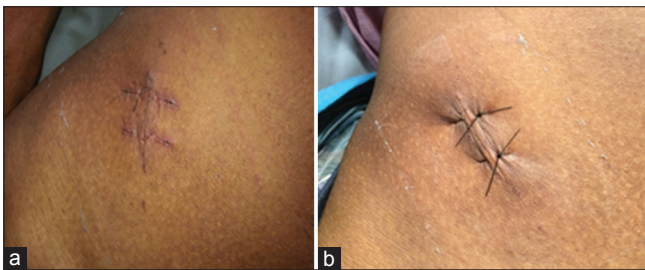


Figure 2: (a-b) Healing in study group

that the provision of high tissue oxygen concentrations promotes local wound healing in animal models. Recent studies in humans have found that administration of supplemental oxygen in the perioperative period to patients undergoing colorectal surgery may reduce the risk of SSI.^[6] However, not all studies have found this benefit, and one paradoxically found an increased risk of SSI with supplemental perioperative oxygenation administration.^[7] Recent evidence-based reviews and editorials have recommended the use of supplemental perioperative oxygenation for the prevention of SSI,^[1] but no meta-analysis has systematically quantified the magnitude of the effect.

Table 1: Asepsis score between study and control groups

ASEPSIS score interpretation	Study group	Control group	P value
	n (%)	n %	
Disturbance of healing	2 (2.2)	7 (7.8)	0.093
Minor wound infection	2 (2.2)	5 (5.6)	
Moderate wound infection	1 (1.1)	3 (3.3)	
Severe wound infection	0 (0.0)	2 (2.2)	
Satisfactory healing	85 (94.4)	73 (81.1)	
Total	90 (100.0)	90 (100.0)	

We studied the role of perioperative hyperoxygenation in patients undergoing open appendectomy by McBurney's incision at BLDE Hospital [Figures 1 and 2]. We attempted to minimize heterogeneity in the included studies by including only patients that were undergoing open appendectomy by McBurney's incision. Our hospital is located in remote district place, Bijapur. Peoples residing in 50 km radius are taking treatment. The population is mainly from low and middle socioeconomy class. It has served in our study of having homogenous mass in both the groups. Our hospital provides almost free medical service to the surrounding population.

Analysis of all the collected data statistically confirmed that there is no significant difference in age, sex, class, and clinical presentation. The homogenous population is the important factor in our study.

Analysis of our results demonstrated statistically decreased rate of surgical wound site infection following administration of perioperative hyperoxygenation in a patient undergoing open appendectomy. Our result correlates with many studies such as Bickel *et al.*, Qadan *et al.*, and Schietroma *et al.* favoring perioperative hyperoxygenation are

beneficial to prevent SSI. Significant point in our study is homogeneity inpatient population with the same type of surgery as compared to the other literature.^[1,3,4]

Prolonged operative time is one of the factors which predispose the surgical wound to the infection. As per guideline from NNIS operative time in both the group was <75 percentile. This eliminates the factor of prolonged surgery time in our study.

We used the ASEPIS scoring method, and it is one of the easy and reliable systems to judge the SSI [Table 1]. Moreover, we included the patients of acute appendicitis operated by McBurney's incision, so it's easy to judge and compare the same right lower abdomen incision in all the patients. In our studies, we used single dose of pre-operative antibiotics in the study group as compared to 3 days antibiotics in the control group. In spite of that just providing perioperative hyperoxygenation SSI could be reduced to a significant level, avoiding unnecessary usage of antibiotics. As such, we are all worried about the development of drug resistance due to unnecessary usage of antibiotics. Recent report by the WHO on antibacterial agents in clinical development shows serious lack of newer antibiotics to combat the growing threat of antimicrobial resistance. The WHO also remark that antimicrobial resistance is global health emergency and will seriously jeopardize the progress in modern medicine. Our study justifies the use of perioperative hyperoxygenation to avoid unnecessary use of antibiotics and at the same time reducing the cost to the patient [Chart 1].

Hospital atmosphere is one of the common places to spread cross infection and thereby developing drug resistance. Our study demonstrated that the study group has significantly lower hospital stay as compared to the control group. Just providing perioperative hyperoxygenation can reduce the post-operative stay; resultant decrease in the chances of cross infection and decrease in financial burden to our charitable hospital. Moreover, early discharge in the study group makes the beds free for other waiting patients.

As per our protocol, we used maximum FIO₂ of 80% to provide hyperoxygenation. There was no reported adverse event showing a significant difference in pulmonary complications or other adverse effects.^[8,9]

Limitation of this study is that open appendectomy surgeries were done by different surgeons. Although approach and incision are the same, there may be difference in intraoperative tissue handling skill. It could not be eliminated in this study. However, it remained the same for both the groups.

CONCLUSION

The use of perioperative hyperoxygenation is advantageous in operations for acute appendicitis. As this is the most common emergent operation in general surgery, decreasing the rate of SSI carries significant clinical and economical gains in the form of judicious use of antibiotics, shorter hospital stay, and cost-effectiveness. In addition, as our study was conducted in a relatively homogeneous study population, our results support the beneficial effects of supplemental oxygen in clean-contaminated surgery in general.

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A Retrospective Study of Clinical Profile of Acute Poisoning in a Tertiary Care Teaching Hospital in Kerala, India, during 2014–2016

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Abstract

Introduction: Most cases of poisonings reported in India were insecticides because in agricultural society they are the readily available source. Whether urbanization, literacy, and access to health care in Kerala have brought about any change in the pattern of poisoning such as mode of poisoning and type of poisoning, clinical profile of patients and outcome of treatment need to be analyzed.

Purpose: Cases admitted with poisoning pose an immense diagnostic and therapeutic challenge to treating physicians. An insight into the epidemiology of poisoning and detection of the current trends will not only help in preparedness in handling such cases but also for planning to deal with the changing trends and preventive strategies.

Materials and Methods: This was a retrospective study. Case records of all cases of poisoning from 2014 to 2016 were procured from the medical records section after obtaining clearance from Institutional Review Board and Ethics Committee. The data were entered into Microsoft Excel and analyzed.

Results: Pesticides continue to be the most common agent (52%), and cause of mortality in poisoning closely followed by drugs and other chemical agents (41.4%), and unknown substances (6.5%) drugs alone showed an increasing percentage of abusers, 28.5% for the year 2016. Males were more than females attempting deliberate self-harm. Alcohol consumption was reported in 61% of male cases. Most common age group was between 20 and 30 years. Psychiatric evaluation of survivors showed a large number of cases having psychiatric disorders such as affective disorders, personality disorders, and neurotic syndromes. Marital and social issues and financial problems were the stressors identified.

Conclusion: Although pesticide was the most common agent used, there is an increase in the number of cases abusing drugs and other chemicals. Most commonly used drugs such as paracetamol and other analgesics available over the counter were the drugs being commonly misused. Alcoholism and psychiatric illnesses, present in a large number of survivors needs to be identified early and treated for decreasing the attempts at deliberate self-harm by poisoning.

Key words: Acute poisoning, Clinical profile, Pesticides and drugs, Psychiatric evaluation, Tertiary care hospital

BACKGROUND

Most cases of poisonings used to be with insecticides because in agricultural society they are the most readily

available agents. Whether urbanization, increased literacy, and health facilities in Kerala have brought any change in the pattern of poisoning such as mode of poisoning and type of poisoning, clinical profile of patients and outcome of treatment need to be analyzed, for future preparedness and prevention strategies.

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INTRODUCTION

Acute poisoning is a cause for significant mortality and morbidity all over the world. Poisoning is the 4th most common cause of mortality in India.^[1] The number of

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suicides in India has increased by 22.7% in the decade 2002–2012 according to National Crime Records Bureau. Attempted suicide is of interest because it has been found to be a predictor of future suicides.^[2] Interventions aimed at suicide attempters will, therefore, be a logical strategy for the prevention of deaths due to deliberate self-harm.^[3] Profile of patients and their choice of agents depend on the availability of substances locally, and the socioeconomic and cultural backgrounds. It is seen to vary in different regions.^[4–6] Motives and modes are different in India from other countries.

Clinical course and outcome depend on the agent used, amount consumed, the time taken for hospitalization and treatment^[7] in India 5–6 persons/Lakh population die due to poisoning yearly.

Pesticides were found to be the most common agent used in the developing world poisoning with medicines such as benzodiazepines and antipsychotics being common in urban areas.^[4] Developing world countries such as Bahrain, Chile Kuwait Malaysia, and Singapore have reported paracetamol as a common agent.^[4]

Kollam in South Kerala has the highest suicide rate for a city in Kerala and also has the 6th highest suicide rate among all cities in India.^[8] This retrospective analysis of poisoning cases admitted to a government tertiary care center in a municipality in central Kerala, with 2nd highest literacy rate in the country, was, therefore, done to analyze the profile and outcome of poisoning cases admitted between 2014 and 2016.

MATERIALS AND METHODS

Records of the poisoning cases admitted in this institute from January 2014 to December 2016 were collected from the medical records section and details regarding age, sex, time after intake, circumstances, type of poison, mode of intake, clinical evaluation at admission, duration of hospitalization, and outcome were collected and analyzed.

RESULTS

There were 240 cases of poisoning admitted to hospital during the study period of 3 years, with 66, 84, and 90 cases in 2014, 2015, and 2016, respectively. Of 240 cases, 128 (53.3%) were males and 112 (46.6%) were females [Figure 1]. The maximum cases were in the age group 21–30 years (32.5%) followed by 31–40 years (21.6%) [Figure 2]. The most common poison was pesticides (52%) followed by drugs and chemicals (41.4%), and substance was not known in 6.5% cases [Figure 3]. History of

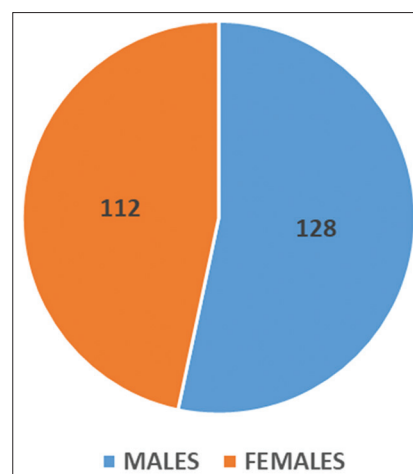


Figure 1: Gender distribution of total cases

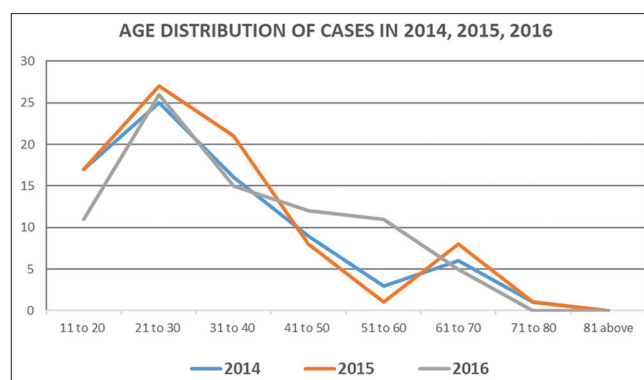


Figure 2: Age distribution

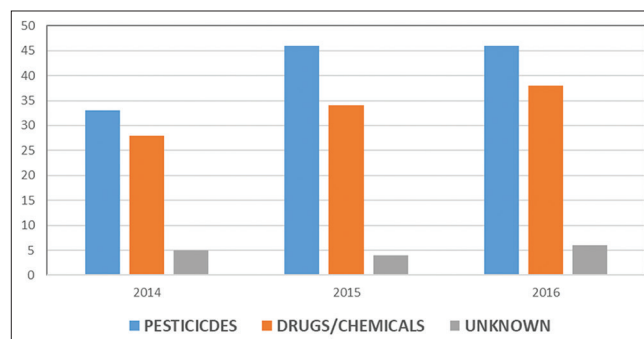


Figure 3: Substance consumed

psychiatric illness in the past was present in 54 (23%) cases while that of previous suicidal attempts was present in 24 (10%) cases [Figure 4].

Majority of cases (80%) had hospitalization for <1 week. 77% of cases recovered. 18% of cases left against medical advice. 2.9% cases were referred and 8.7% expired [Figure 5].

Psychiatric evaluation of survivors showed that 24% of cases had affective disorder, 15% had behavioral syndromes, 24% had personality disorders, and 7% had

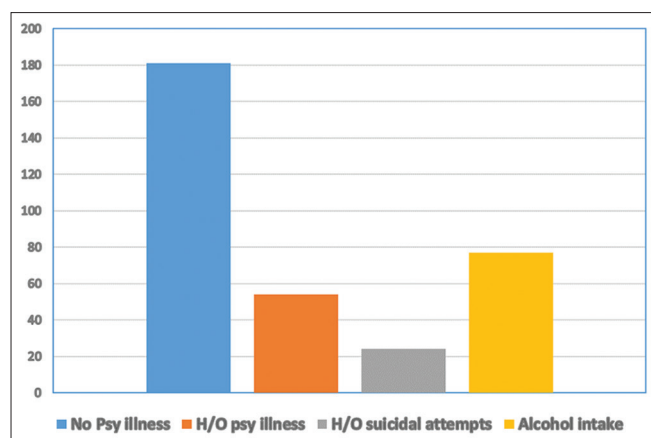


Figure 4: Past history

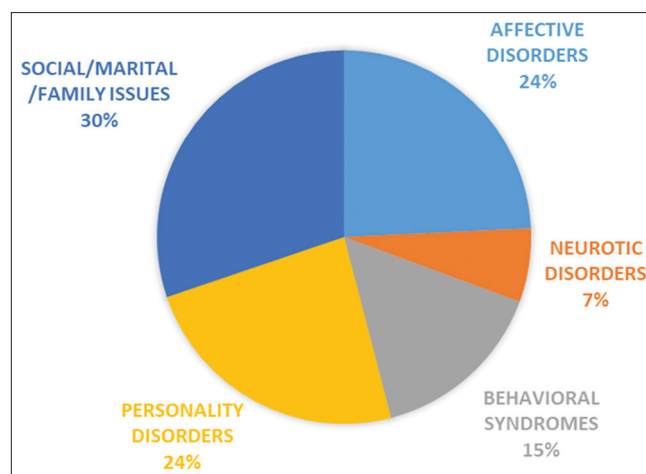


Figure 6: Psychiatric evaluation of survivors

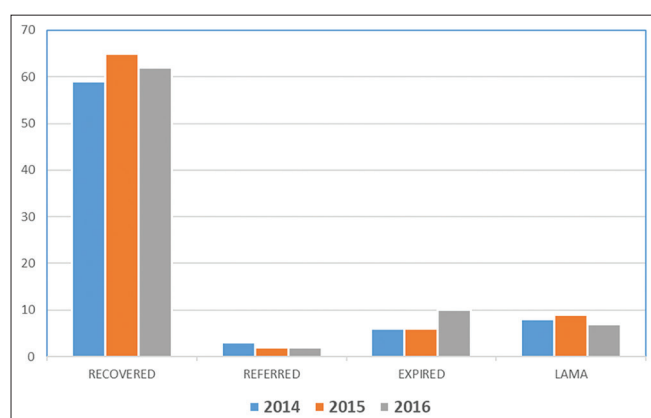


Figure 5: Outcome of cases

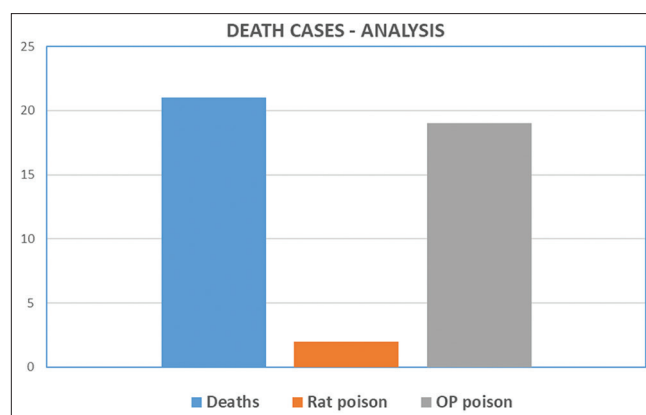


Figure 7: Outcome analysis

neurotic disorders and there were multiple social marital and other family issues in 30% of cases [Figure 6]. There were total 21 deaths (8.7% mortality rate) all in pesticide group [Figure 7].

DISCUSSION

Self-poisoning is the most common method to commit suicide (33%) followed by hanging (26%) and self-immolation (9%) in India, in 2012, according to statistics of government.^[9]

The most common agent used for self-poisoning in India was pesticides.^[4,10,21,11-19,27] In our study through the most common agent was pesticides (52%), there was a high percentage of poisoning with drugs and chemicals (41.4%). The substance consumed was unknown in 6.5% cases.

Drugs showed an increase from 17.1% in 2014, 18.5% in 2015, to 28.5% in 2016. The substance used was unknown in 6.5% of cases over the 3-year period. This is similar to other studies from urban India reported by National Poison Information Bureau at AIIMS New Delhi.^[20] They

found that drugs constituted 18.8% and chemicals 8.9% samples received.

Most common pesticide in our study was organophosphorus compounds, rodenticide being next common. Similar findings have been reported from Tamil Nadu with organophosphorus constituting 58.6% followed by rat poison the second most common agent^[17] we had no case of aluminum phosphide poisoning which is similar to the findings from a study in Kerala.^[11]

Drug overdose constituted a significant number in more recent studies (2017) even when pesticides were most common cause.^[19,27] In a study from the UK, in 2001, there was a substantial increase in self-poisoning with paracetamol and that with non-opiate analgesics, which rose from 48%, in 1985, to 60.6%, in 1997.^[5] In our study, the most common drugs abused were paracetamol and analgesics constituting 26.4% of total cases of drug overdose. Other drugs abused were sedatives, antipsychotics, antiepileptic, antihistamines bronchodilators, and thyroxine. Eddleston in a 2000 study had reported that self-poisoning with drugs was being increasingly reported from urban areas.^[4] A study

from a corporate hospital in New Delhi had reported benzodiazepines as a most common agent.^[7]

Most of the cases in our study belonged to the age group of 21–30 years in all 3 years of study 2014–2016. This is similar to other studies.^[7,10,12-15,1,17,18,21,27]

The youngest patient was 14 years and oldest 80 years. In our study, there were 53.4% males and 45.8% females, which has been reported in other studies.^[1,10,12-14,20,21] A study from Kerala, in 2009, also reported more males.^[16] This is interesting as Kerala has a sex ratio favoring women (WWW, Census 2011. co.in) unlike other states in India.

The route of poisoning was oral in all cases during the study period similar to other studies.^[7,17,21,22]

In our study, 22.5% of cases had a history of past psychiatric illness, while 10% had a suicidal attempt in the past. In a 2016 study from a tertiary care center, psychiatric illness was as high as 81%.^[23] Physical and mental illness, societal structure, and specific stressors such as financial problems and interpersonal relationships have been shown to play a major role.^[24]

Attempted suicide is a significant predictor of suicide and, therefore, is a focus area for further research.^[5] >5% people admitted in hospital following an incident of deliberate self-harm have committed suicide within a year,^[6] therefore, the need for psychiatric evaluation and treatment in attempted cases.

Alcohol abuse was present in 61% of male cases, while only 4 female cases reported alcohol abuse. This was higher than that reported in a study from Karnataka.^[13]

Psychiatric evaluation was done in 164 patients (68.3%). Among this Affective disorder was present in 34.7% of cases, personality disorder was seen 34.1% of cases, behavioral syndrome reported in 21.9% of cases, and neurotic syndromes in 9.1% of cases. Marital discord, social and family issues were the immediate stressors found in 43.29% cases. In a study, where psychiatric evaluation was done in 60% of cases, reactive depression was found in 35%. Another study done over a 10 year period reported, in 2016, there was increase in depression cases to 67%.^[23] Other studies have also reported depression, personality disorders, alcohol abuse, low income, and marital discord as stressors.^[18,25]

Mortality was 8.7% in our study with a total of 21 deaths of whom 19 were due to organophosphorus and 2 due to rodenticide. The death reported in another study, in 2000, was 3.3%.^[26] A study from Kerala, in 2011, reported

mortality of 1.5%.^[25] Another study from Karnataka, in 2005, reported deaths in 15.7% cases.^[1] Most of the cases admitted to our hospital were referred from smaller peripheral hospitals. The time taken for hospitalization plays a key role in mortality, as also whether patient vomited soon after taking the poisonous substance. In our study, 90% of those who expired had either not vomited or vomited after >½ after ingestion. Of the 21 deaths, 19 were due to organophosphorus compounds and 3 were due to rodenticide. Significantly, there were no deaths in the drugs and chemicals group.

Of the total cases, 83.3% had a hospital stay of <1 week while 18.75% stayed >1 week. This might be reflective lesser severity and lethality of substance consumed, and therefore suggest low intentionality. In another study from Kerala^[25] almost 82% were discharged in <6 days. It was noted that aggressive treatment, early hospitalization can influence outcome positively.

Attempted suicide has been found to be a predictor of suicide. Interventions targeting suicide attempters will, therefore, be helpful in reducing suicide rates. Kerala has one of the highest suicide rates. Studies have shown that regulating the supply of pesticides has not been of help in reducing suicide rates^[3] Study of the profile of suicide attempters will be helpful in devising local strategies. High suicide rates have been identified in persons with psychiatric illness and alcoholism. Identifying and treating psychiatric diseases and spreading awareness on the ill effects of alcoholism and drug abuse in early teens can prove helpful.

The lower mortality rates from studies from Kerala show that timely hospitalization, aggressive management, and preparedness in hospitals can result in better outcomes.

Drawbacks

Being a retrospective study, there was no information available regarding other comorbidities or risk factors in the study population. There being no follow-up records, the long-term outcome was not assessed.

CONCLUSION

Pesticide continues to be the most common agent in the study period, but there is an increase in the abuse of drugs and other chemicals, indicating a changing pattern. Mortality in acute poisoning is due to pesticides. A large number of survivors had psychiatric disorders. Early diagnosis and treatment of psychiatric disorders are a target area for potential intervention to reduce the cases of deliberate self-harm.

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Endometrial Biopsy: Need of Present Time in the Management of Abnormal Uterine Bleeding

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Abstract

Introduction: Abnormal uterine bleeding (AUB) refers to symptoms of excessive, scanty, prolonged, cyclic, acyclic bleeding regardless of diagnosis, or cause. In MCSG, SMS Jaipur, AUB accounts for approximately 20% of complaints of gynecology outpatient department (OPD) attendance. In this study, we have attempted to analyze endometrial patterns in cases of AUB and to correlate the histopathology with clinical parameters and age groups.

Materials and Methods: This study is a hospital-based prospective study done on 214 patients of AUB attending obstetrics and gynaecology OPD from a period of August 2017 to August 2018. Endometrial biopsy was taken with the help of Pipelle biopsy curette. Statistical analysis was done using Epi info 7. Mean frequency was used to elaborate the data.

Results: Maximum 125 patients belonged to reproductive age group followed by 65 in perimenopausal and 24 in postmenopausal age group. The most common pattern of bleeding was menorrhagia (52.3%), followed by menometrorrhagia (17.29%), metrorrhagia (13.08%), postmenopausal bleeding (11.21%), premenstrual spotting (3.27%), and last was oligomenorrhea (2.8%) Maximum 41.1% showed secretory phase followed proliferative phase in 20% and 4.21% showed atrophic endometrium. Among abnormal findings, maximum were disordered proliferative endometrium (10.28%) followed by pill endometrium (7.01%).

Conclusion: Endometrial biopsy is an simple and inexpensive procedure which should be used as a first line procedure, thereby minimizing need of other costly and complicated procedures.

Key words: Abnormal uterine bleeding, Age group, Endometrial biopsy, Histopathology

INTRODUCTION

Abnormal uterine bleeding (AUB) refers to a symptom of excessive, scanty, prolonged, cyclic, unexpected, or acyclic bleeding regardless of diagnosis or cause. It is one of the most common gynecological problems that health-care providers face, accounting for approximately 15–20% of office visits and 25% of gynecological operations.^[1,2] In India, women attending gynecological outpatient department (OPD), AUB constitutes 30–50%.^[3]

In Mahila chikitsalya, Sangneri gate, Jaipur (MCSG), SMS tertiary apex Centre of Rajasthan, AUB cases account for approximately 20% of gynecology OPD attendance.

Endometrial biopsy is a procedure in which a tissue sample is taken from the endometrium and is examined under the microscope for detecting the hormonal status or any pathology.

Endometrial tissue sampling should be performed in patients with AUB who are older than 45 years as a first-line test. Endometrial sampling should be performed in patients younger than 45 years with a history of unopposed estrogen exposure such as in prolonged or delayed cycle, oligomenorrhoea, failed medical management, and persistent AUB.^[4] Office endometrial biopsy replaces dilation and curettage and is currently the

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most commonly used technique for the initial assessment of the endometrium for these women.

Management of AUB is not complete without tissue diagnosis, especially in perimenopausal and postmenopausal state as they are at higher risk for endometrial carcinoma. It is of great importance to stratify patients into high-risk and low-risk groups before therapy is initiated so that medical treatment or conservative surgery can be offered and unnecessary radical surgery can be avoided.^[5,6]

In this study, we have attempted to analyze different patterns of endometrium in cases of AUB and to correlate the histopathology of endometrium with clinical parameters and age groups.

MATERIALS AND METHODS

This study is a hospital-based prospective study done on 214 patients of AUB attending Obstetrics and Gynaecology OPD of MCSG, SMS Medical College, Jaipur, from a period of August 2017 to August 2018. Detailed clinical history was taken; physical examination and pelvic examination were done. The patients were subdivided into five groups according to the pattern of AUB, i.e., menorrhagia, metrorrhagia, polymenorrhea, menometrorrhagia, and postmenopausal bleeding. Patients were also categorized into the following age groups: Reproductive (18–45 years), perimenopausal (>45-till menopause), and postmenopausal.

Endometrial biopsy was taken with the help of Pipelle biopsy curette of those satisfying inclusion criteria. Ethical clearance from IHEC, SMS Medical College, Jaipur, and detailed written informed consent was taken.

Inclusion Criteria

The following criteria were included in the study:

1. All women with AUB >45 years of age.
2. Women with <45 years with failed medical management or unexposed estrogen exposure.
3. Women with endometrial thickness >16 mm in reproductive and perimenopausal age group in phase of menstrual cycle.
4. Women with endometrial thickness >5 mm in postmenopausal age group.
5. Women with postmenopausal bleeding.

Exclusion Criteria

The following criteria were excluded from the study:

1. Pregnancy and other related conditions.
2. Blood disorders and coagulopathy.
3. Bleeding due to cervical pathology.

4. Pelvic inflammatory disease.
5. Intrauterine contraceptive device *in situ*.

Histopathological examination of the endometrial biopsies was done and followed by correlation of endometrial histology with age and bleeding pattern.

Statistical Analysis

Statistical analysis was done using Epi info 7. Mean, frequency was used to elaborate the data.

RESULTS

The present study is of 214 cases of AUB in which endometrial biopsy was done. All the biopsies were taken with Pipelle endometrial biopsy curette using standard technique.^[7] The cause of AUB could be determined in only 201 of 214 endometrial biopsy as 13 biopsy samples were inadequate for evaluation.

Patients were divided into three age groups: Reproductive (younger than 45 years), perimenopausal (45-till menopause), and postmenopausal.

Maximum 125 patients belonged to reproductive age group (58.41%) followed by 65 (30.37%) in perimenopausal age group and 24 (11.21%) in postmenopausal age group [Table 1]. The youngest patient was of 22 years in this series and the oldest was of 71 years of age.

The most common pattern of bleeding was menorrhagia (112 patients, 52.3%), followed by menometrorrhagia (37 cases, 17.29%), metrorrhagia (28 cases, 13.08%), postmenopausal bleeding (24 cases, 11.21%), premenstrual spotting (7 cases, 3.27%), and last was oligomenorrhea (6 cases, 2.8%) [Table 2].

Different patterns of endometrium were observed on histopathological examination. Maximum 88 samplings (41.1%) showed secretory phase [Figure 1] followed proliferative phase [Figure 2] in 43 biopsies (20%) and 9 cases showed atrophic endometrium (4.21%) [Table 3, Figure 4].

Among endometrial findings, maximum were disordered proliferative endometrium [Figure 3] (22 cases, 10.28%) followed by pill endometrium (15 biopsies, 7.01%). Endometrial hyperplasia was classified according to the WHO classification 1994. Simple hyperplasia without atypia [Figure 5] was seen in 12 biopsies (5.6%) and with atypia [Figure 6] in 3 cases (1.4%). Complex hyperplasia without atypia [Figure 7] was observed in 2 samples (0.9%) and with atypia [Figure 8] in 3 biopsies (1.4%). Endometrial adenocarcinoma [Figure 9] was seen in 2 cases, both belonged to postmenopausal age group [Table 3].

Endometritis was seen only in two cases, whereas 13 samples (6.07%) could be evaluated due to insufficient tissue sample. Menorrhagia was the most common complaint in most perimenopausal (55.93%) and reproductive age group (62.8%) [Table 4].

On correlating complaints with biopsy findings, maximum patients with menometrorrhagia showed secretory phase endometrium (38.8%) on histopathological examination. Similarly in menorrhagia also, secretory phase was the most common finding (50.4%). Proliferative phase and secretory phase were seen equally in metrorrhagia cases (36% each). Atrophic endometrium was the most common in postmenopausal bleeding (33%) [Table 5]. All the cases of premenstrual spotting had secretory endometrium.

DISCUSSION

Normal menstrual bleeding is defined as cyclic menstruation every 21–35 days that last fewer than 8 days with 20–80 ml of blood loss.^[8] AUB can involve heavy or prolonged periods, frequent periods, intermenstrual bleeding, light periods, infrequent periods, or complete absence of periods.^[9] In women of child-bearing age, AUB includes any change in menstrual frequency or duration, or amount of flow, as well as bleeding between cycles.^[10]

Perimenopause is defined by the World Health Organization as the 2–8 years preceding menopause and the 1 year after the final menses. In postmenopausal women, AUB includes appearance of vaginal bleeding, 12 months or more after the cessation of menses, or unpredictable bleeding in postmenopausal women who have been receiving hormone therapy for 12 months or more.^[11]

For practical purposes, any patient who complaints of a change in her previously established menstrual pattern may be considered to have AUB.

AUB can occur due to organic causes in the uterus or due to functional disturbances related to ovulation. Various terminologies used universally for subtypes of AUB as per Speroff are:

A new classification system for AUB (polyp, adenomyosis, leiomyoma, malignancy and hyperplasia, coagulopathy, ovulatory dysfunction, endometrial, iatrogenic, and not yet classified), known by the acronym PALM-COEIN, was introduced in 2011 by the International Federation of Gynaecology and Obstetrics.^[12]

Endometrial curettage is a routine diagnostic procedure in the evaluation of menstrual disorders.

The present study comprises 214 cases of AUB, for which endometrial biopsy was done as a diagnostic procedure attending AIIMS, Bhopal, Gynecology OPD.

Age of Presentation

All patients were subdivided into three age groups in an attempt to establish incidence of AUB with age. In the present study of 214 cases, maximum 58.42% of cases were in reproductive age group which is concordance with the study of Shilpa and Subramanya.^[13] Many studies have revealed that occurrence of menstrual disorders increases with advancing age.^[14,15] They had found maximum incidence of AUB in perimenopausal age group. Considering these discrepant observations, one may conclude that, any age after menarche is not exempt from AUB.

Pattern of Bleeding in AUB

Various patterns of bleeding were studied in an attempt to establish its incidence with age. The most common complaint observed was menorrhagia (52.3%) followed by menometrorrhagia (17.29%) and metrorrhagia (13.08%) which are almost equal. The finding is consistent with the studies of Anvikar *et al.*^[16] and Jairajpuri *et al.*^[17] These studies concluded that the most common pattern of bleeding in

Table 1: Distribution of age group

Age group	Frequency (%)	Cum (%)	95% CI lower	95% CI upper
Postmenopausal	24 (11.21)	11.21	7.32	16.23
Premenopausal	65 (30.37)	41.59	24.29	37.01
Reproductive	125 (58.41)	100.00	51.50	65.09
Total	214 (100.00)	100.00		

CI: Confidence interval

Menorrhagia	Bleeding occurs at normal intervals (21–35 days) but with heavy flow (80 mL) or duration (7 days)
Oligomenorrhea	Bleeding occurs at intervals of >35 days and usually is caused by a prolonged follicular phase
Polymenorrhea	Bleeding occurs at intervals of <21 days
Menometrorrhagia	Bleeding occurs at irregular, non-cyclical intervals, and with heavy flow (80 mL) or duration (7 days)
Metrorrhagia or intermenstrual bleeding	Irregular bleeding occurs between ovulatory cycles
Postmenopausal bleeding	Bleeding recurs in a menopausal woman at least 1 year after cessation of cycles
Dysfunctional uterine bleeding	This ovulatory or anovulatory bleeding is diagnosed after the exclusion of pregnancy or pregnancy-related disorders, medications, iatrogenic causes, obvious genital tract pathology, and systemic conditions

Table 2: Distribution of complaints

Complaints	Frequency (%)	Cum (%)	95% CI lower	95% CI upper
Menometrorrhagia	37 (17.29)	17.29	12.48	23.04
Menorrhagia	112 (52.34)	69.63	45.42	59.19
Metrohaggia	28 (13.08)	82.71	8.87	18.35
Oligomenorrhea	6 (2.80)	85.51	1.04	6.00
Postmenopausal bleeding	24 (11.21)	96.73	7.32	16.23
Premenstrual spotting	7 (3.27)	100.00	1.33	6.62
Total	214 (100.00)	100.00		

CI: Confidence interval

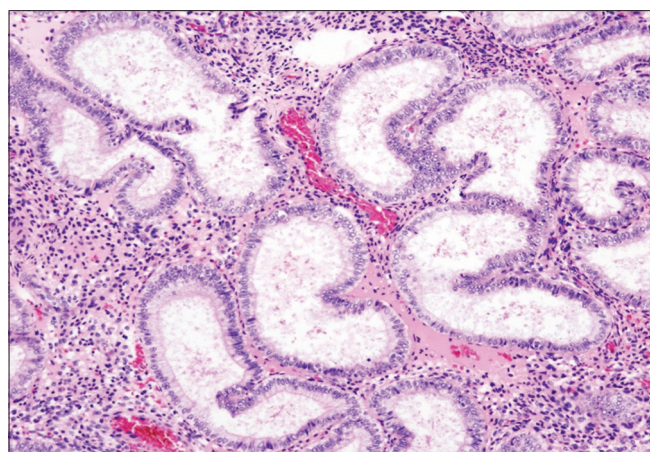
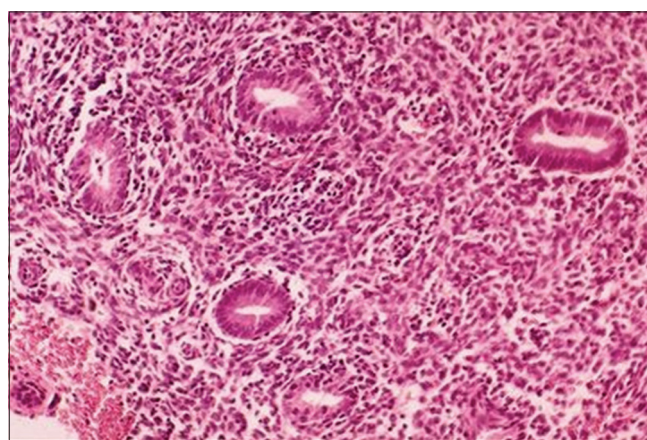
Table 3: Distribution of biopsy findings

Biopsy findings	Frequency (%)	Cum (%)	95% CI lower	95% CI upper
Atrophic endometrium	9 (4.21)	4.21	1.94	7.83
Complex hyperplasia with atypia	3 (1.40)	5.61	0.29	4.04
Complex hyperplasia without atypia	2 (0.93)	6.54	0.11	3.34
Disordered proliferative endometrium	22 (10.28)	16.82	6.56	15.15
Endometrial carcinoma	2 (0.93)	17.76	0.11	3.34
Endometritis	2 (0.93)	18.69	0.11	3.34
Inadequate tissue	13 (6.07)	24.77	3.27	10.16
Pill endometrium	15 (7.01)	31.78	3.98	11.30
Proliferative phase	43 (20.09)	51.87	14.94	26.10
Secretory phase	88 (41.12)	92.99	34.46	48.03
Simple hyperplasia with atypia	3 (1.40)	94.39	0.29	4.04
Simple hyperplasia without atypia	12 (5.61)	100.00	2.93	9.59
Total	214 (100.00)	100.00		

CI: Confidence interval

Table 4: Age group wise distribution of complaints

Age group	Meno metrorrhagia	Menorrhagia	Metrorr hagia	Oligomenorrhea	Post menopausal bleeding	Premenstrual spotting	Total
Postmenopausal	0	0	0	0	21	0	21
Premenopausal	17	33	8	0	0	1	59
Reproductive	19	76	17	4	0	5	121
Total	36	109	25	4	21	6	201

**Figure 1: Secretory endometrium****Figure 2: Proliferative endometrium**

AUB is menorrhagia. In the present study, menorrhagia was the most common complaint in reproductive age group, i.e., 69.7% which is far more than any other bleeding pattern observed. Similarly in perimenopausal age group,

menorrhagia was the most common complaint (55.8%) followed by metrorrhagia in 28.8%. These findings had been observed in many studies conducted previously such as those of Damle *et al.*^[18] and Muzaffar *et al.*^[15]

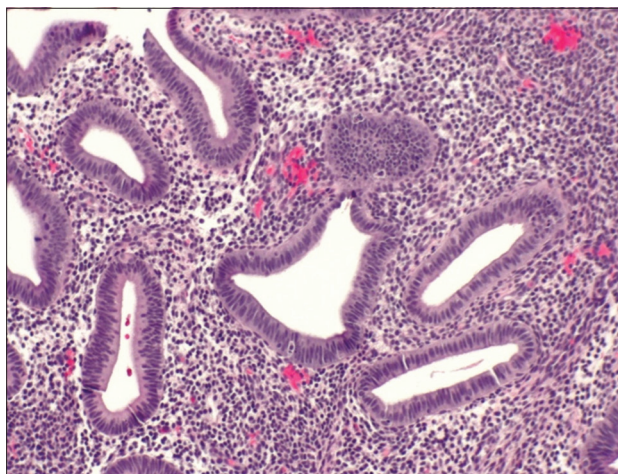


Figure 3: Disordered proliferative endometrium

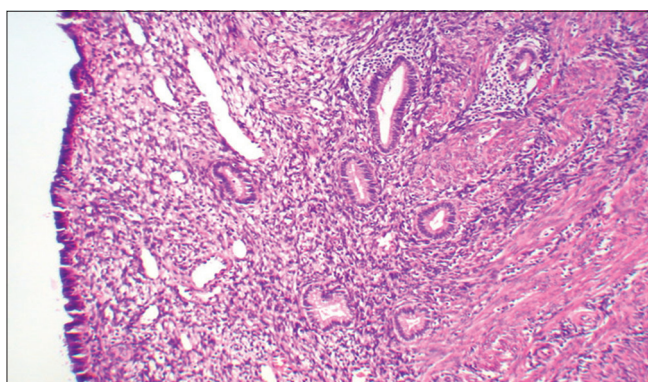


Figure 4: Atrophic endometrium

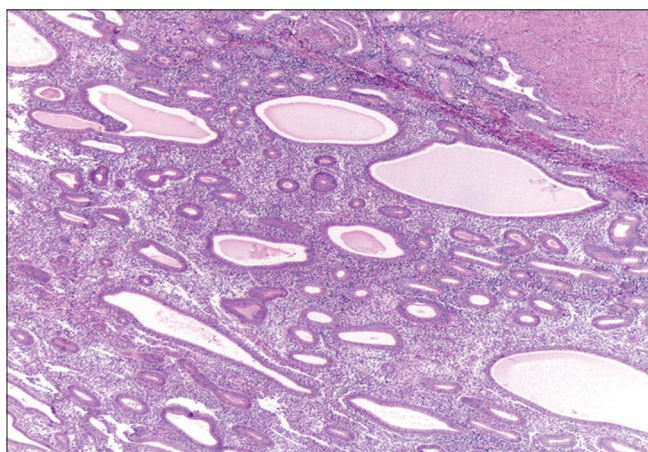


Figure 5: Simple hyperplasia without atypia

Endometrial Pattern in AUB

For establishing the incidence of different endometrial patterns in AUB, this criterion had been taken up.

In the present study, the most common patterns were normal cyclic physiological changes, i.e., secretory (41.12%) followed by proliferative (20.03%). This endometrial finding is consistent with the studies of Moghal^[19] and

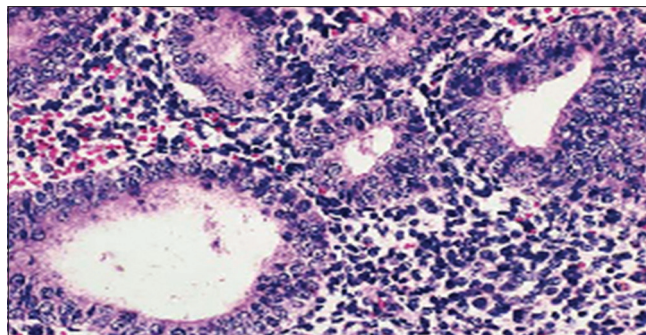


Figure 6: Simple with atypia

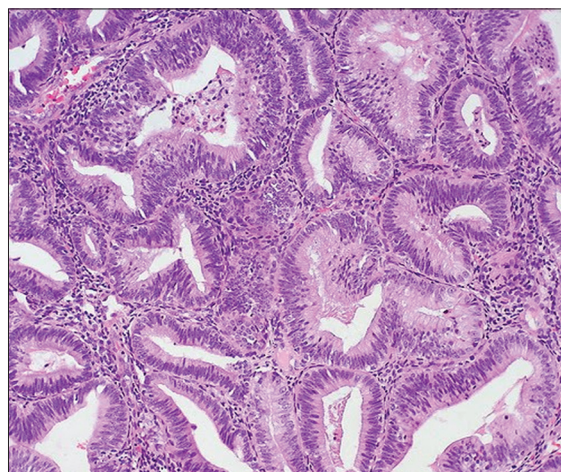


Figure 7: Complex hyperplasia without atypia

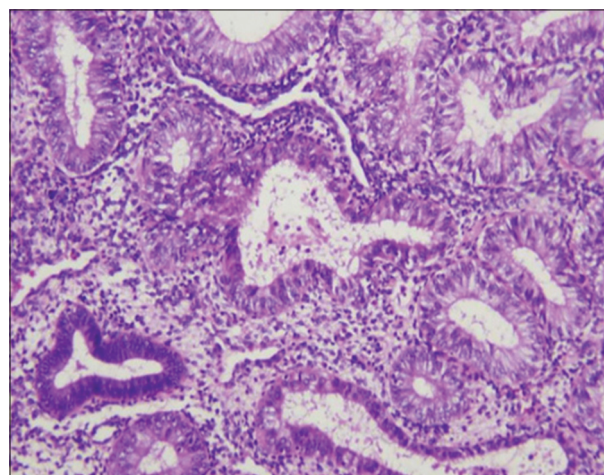


Figure 8: Complex hyperplasia with atypia

Gazozai *et al.*^[20] The bleeding in the proliferative phase may be due to anovulatory cycles and bleeding in the secretory phase is due to ovulatory dysfunctional uterine bleeding.

However, the studies of Khan *et al.*^[21] and Deshmukh *et al.*^[22] concluded that proliferative endometrium was the most common pattern followed by secretory endometrium and hyperplastic endometrium. According to the study of Singhal *et al.*^[23] hyperplastic endometrium was the most

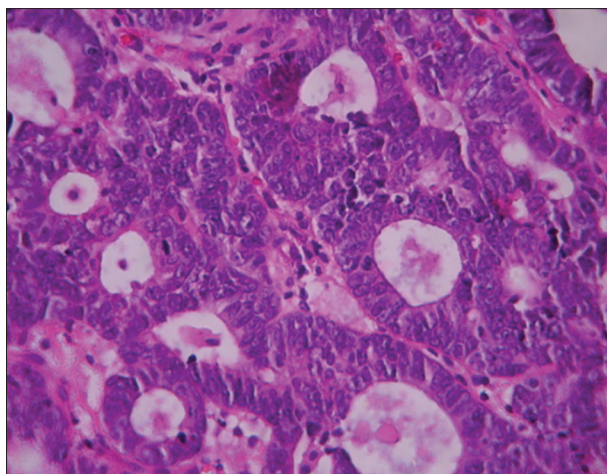


Figure 9: Endometrial cancer (adenocarcinoma)

common pattern followed by proliferative endometrium and proliferative secretory endometrium.

In the present series, disordered proliferative endometrium was seen in 10.2% of cases which is quite significant number which is comparable with the study of Doraiswami *et al.*^[14] Disordered proliferative endometrium is part of a continuum with endometrial hyperplasia. It resembles normal exuberant proliferative endometrium, but without uniform glandular development (some glands cystically dilated, others have shallow budding). There is increase of cystically dilated glands, but relatively normal ratio of glands to stroma. It also refers to a proliferative phase endometrium that does not seem appropriate for any one time in the menstrual cycle but is not abnormal enough to be considered hyperplastic. Atrophic endometrium is the most common cause of bleeding in postmenopausal stage.^[24] In atrophic endometrium, thin-walled veins, superficial to the expanding cystic glands make the vessel vulnerable to injury. In the present study, atrophic endometrium was seen in 4.2% which is similar to study of Corneticus *et al.*^[24] and Sajitha *et al.*^[25]

Pill endometrium

In the present study, effect of exogenous hormone was found in 7% of cases. Histological pattern of women receiving hormonal pills shows combination of inactive glands, abortive secretion, decidual reaction, and thin blood vessels is characteristic. Similar incidence, i.e., 1.7%–4.81% was seen in other studies.^[17,26,27]

Endometritis

Endometritis is seldom the direct cause of AUB but is often a contributing factor. Subepithelial capillary plexus and surface epithelium are rendered fragile by inflammatory mediators, leading to breaks and microerosions. In our study, endometritis contributed to only 0.93% of AUB.

Table 5: Biopsy finding in different complaints

Complaints	Atrophic endometrium	Complex hyperplasia with atypia	Complex hyperplasia with out atypia	Disordered proliferative	Endometrial carcinoma	Endometritis	Pill endometrium	Proliferative phase	Secretory phase	Simple hyperplasia with atypia	Simple hyperplasia without atypia	Total
Menometrorrhagia	2	0	1	5	0	1	3	6	14	1	3	36
Menorrhagia	0	2	0	12	0	1	9	24	55	0	6	109
Metrorrhagia	0	0	0	2	0	0	3	9	9	0	2	25
Oligomenorrhea	0	0	0	0	0	0	0	1	3	0	0	4
Postmenopausal bleeding	7	1	1	3	2	0	0	3	1	2	1	21
Premenstrual spotting	0	0	0	0	0	0	0	0	6	0	0	6
Total	9	3	2	22	2	2	15	43	88	3	12	201

Hyperplasia

Endometrial hyperplasia is precursor for endometrial carcinoma. The classification system used by the WHO and the international society of gynecological pathologists designates four different types with varying malignant potential. Based on the presence or absence of architectural abnormalities such as glandular complexity and crowding, hyperplasias are classified as simple or complex. Most important hyperplasia are further designated as atypical if they demonstrate cytologic (i.e., nuclear) atypia. Only atypical endometrial hyperplasia is clearly associated with the subsequent development of adenocarcinoma. If left untreated, approximately 8% of patients with simple atypical hyperplasia will progress to carcinoma, whereas the progression rate in women with complex atypical hyperplasia is almost 30% in one study and as high as 52% in another.^[28]

In the present study, simple hyperplasia without atypia was seen in 12 cases (5.6%), whereas with atypia was seen only in 3 cases (1.40%). Complex hyperplasia with and without atypia both was found in 3 cases (1.40%) and 2 cases (0.93%), respectively. All the cases presented with complaint of menometrorrhagia and postmenopausal bleeding.

Endometrial Carcinoma

In the present study, only two cases of endometrial carcinoma were seen. Both cases were >65 years of age presenting with postmenopausal bleeding. On histopathological examination, both were diagnosed as having adenocarcinoma. Out of these, one patient had vaginal metastasis as well as lung metastasis.

Unsatisfactory for evaluation

There have been very little publications about the criteria for considering an endometrial specimen as adequate or inadequate. In our study, we had 13 (6%) cases of unsatisfactory samples. Most of these showed only large areas of hemorrhage and scanty glands or stroma. These were labeled unsatisfactory to report and repeat biopsy was taken.

CONCLUSION

Thus, it can be concluded that endometrial biopsy forms one of the strongest pillars for the management of AUB in all sexually active females. It gives clinician an accurate diagnosis and thus helps in deciding proper management plan. Thus, it is a simple and inexpensive procedure which should be used as a first-line procedure, thereby minimizing need of other costly and complicated procedures.

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A Study of Modified Alvarado Score and Rovsing's Sign in Diagnosis of Acute Appendicitis

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Abstract

Background: Acute appendicitis remains a common abdominal emergency throughout the world. The diagnosis of acute appendicitis continues to be difficult due to the variable presentation of the disease and the lack of reliable diagnostic test. None of the investigations such as ultrasonography and computed tomography can conclusively diagnose appendicitis. Hence, even to date, a thorough clinical examination with basic investigations like white blood cells count remains cornerstone in the diagnosis of acute appendicitis. This study aims to evaluate the usefulness of modified Alvarado score and Rovsing's sign in diagnosing acute appendicitis.

Materials and Methods: Patients presenting with pain in the right iliac fossa and suspected to have appendicitis into unit 4 of general surgery, Osmania General Hospital, during the period of December 2017–June 2018 are included in the study.

Results: Migratory pain, nausea, and anorexia are presented in only up to half of the patients having inflamed appendix and Rovsing's sign was positive in 93.7% of patients. 31% of patients with scores <7 have inflamed appendix.

Conclusion: The study shows the need for downgrading the value given to anorexia, nausea, migratory pain, and inclusion of Rovsing's sign in diagnosing acute appendicitis.

Key words: Acute appendicitis, Migratory pain, Modified Alvarado score, Rovsing's sign

INTRODUCTION

Appendicitis is the most common surgical emergency attended by surgeon across the world. Appendicitis is the most common surgical emergency attended by surgeon across the world. Appendicitis has been a topic of discussion since the inception of diagnosis and various methods have been used to diagnose the disease. It has always posed a challenge in the diagnosis, however with the advent of radiology the accuracy has improved. Yet the clinical methods of detecting appendicitis should not be underestimated^(1,2) as the radiology reports are often operator dependent and appendix might also be not visualized at times due to various factors. Patients also

often afford and cannot be always exposed to ionizing radiation. Hence, this study tries to identify the accuracy of modified Alvarado score when added with a Rovsing's sign in diagnosing acute appendicitis.

Aim of Study

The aim of the study was to study the modified Alvarado score and the Rovsing's sign in aiding the diagnosis of acute appendicitis.

METHODS

Patients presenting with pain in the right iliac fossa and suspected to have appendicitis into unit 4 of general surgery, Osmania General Hospital, during the period of December 2017–June 2018 are included in the study, and decision regarding surgery for appendicitis has been taken on clinical and radiological grounds. Those with low suspicion have been excluded from the study and put under observation and none of them needed surgical care [Table 1].

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Table 1: Modified Alvarado score

Migratory pain	1
Anorexia	1
Nausea	1
Right iliac fossa tenderness	2
Rebound tenderness	1
Fever	1
Leukocytosis	2
Additional criteria added in this study	
Rovsing's sign	1

Table 2: Percentage of patients presenting with the parameters in modified Alvarado score

Criteria	Percentage of patients
Migratory pain	28.1
Anorexia	42
Nausea	51.5
Right iliac fossa tenderness	100
Rebound tenderness	95.3
Fever	65.6
Leukocytosis	65.6
Rovsing's sign	93.7

Modified Alvarado score, as shown above, is taken into consideration and an extra criteria, i.e. Rovsing's sign has been added to it. Rovsing's sign when present is given a value of 1.

RESULTS

Percentage of patients with positive parameter has been shown in Table 2.

Percentage of patients with different scores shown in Table 3, percentage of patients having normal appendix at surgery with scores <7 and scores ≥7 are shown in Table 4.

Percentage of patients with inflamed Appendix at surgery with scores <7 is 31%.

DISCUSSION

Acute appendicitis remains a common abdominal emergency throughout the world. The diagnosis of acute appendicitis continues to be difficult due to the variable presentation of the disease and the lack of reliable diagnostic test. None of the investigations such as ultrasonography and computed tomography can conclusively diagnose appendicitis. Hence, even to date, a thorough clinical examination with basic investigations like white blood cells count^[3,4] remains cornerstone in the diagnosis of acute appendicitis.

The percentage of normal appendices reported in various series varies from 8% to 33%.^[5]

Table 3: Percentage of patients based on the modified Alvarado score of the study

Score	Percentage
4	1.5
5	10.9
6	23.4
7	26.5
8	23.4
9	7.8
10	6.25

Table 4: Negative appendectomy

Score	Percentage
<7	4.6
≥7	3.1

A score of 7 or more is generally considered as a predictive score for the diagnosis of acute appendicitis, and in the present study, it a score of ≥7 included only 65.55% of patients, thus again it is proving the need for better evaluation techniques.

Six of seven patients with score of 5 have inflamed appendix in spite of a low score, and similarly, 14 patients with a score of 6 had appendicitis, right iliac fossa tenderness, and rebound tenderness and Rovsing's sign is presented in most cases, whereas fever and migratory pain are presented in less than half of the patients, thus need for considering these criteria if to be retained or score to these parameters be decreased has to evaluated; however, fever and leukocytosis were presented in all cases of perforated appendix.

Patients of score 5 and 6 with appendicitis were evaluated and none reported migratory pain or fever, but they have tenderness, rebound tenderness, and anorexia or nausea and of the patients operated on this combination, only one patient was found to have normal appendix.

Patient with score of 6 has tenderness and rebound tenderness Rovsing's sign with a combination of two of the four parameters (fever, nausea, and anorexia/migratory pain), but only one had elevated leukocytosis. Patients operated on this combination, only one patient was found to have normal appendix.

Thus, a combination of tenderness rebound tenderness and Rovsing's sign is most important for the diagnosis with a high negative predictive value and positive predictive value.

Rovsing's sign even has more negative predictive value than the other where only one of 60 patients with positive Rovsing's sign has a normal appendix. Percentage of

patients with inflamed appendix at surgery with scores <7 is 31%. Percentage of patients with normal appendix at surgery with scores ≥ 7 is 3.1%.

CONCLUSION

Rovsing's sign being presents in 93.7 patients and only one patient of 60 patients has a normal appendix, and this study recommends its inclusion into the scoring systems after further evaluation.

Migratory pain, fever, anorexia, and nausea are presented in less number of patients and are skewing the results toward low scores in spite of an inflamed appendix and there in need for further multicentric larger study to downgrade

the value given to them. However, when migratory pain is presented, it is a definite pointer toward the diagnosis except in some cases; thus, it cannot be omitted. Moreover, all patients with perforation have fever and leukocytosis.

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Assessment of Nutritional Status of Primary School Children through Anthropometric in Rural Practice Area of IGIMS, Patna: A Cross-Sectional Study

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Abstract

Background: Nutritional status is the condition of health of an individual, influenced by nutrient intake and its utilization in the body. Nutrition of primary school children is of paramount importance because the foundation for their lifetime health, strength, and intellectual vitality is laid during this period. Hence, it is a dynamic period of their physical growth as well as of their mental development. Undernutrition is a major public health problem worldwide, particularly in developing countries.

Methods: A cross-sectional study was conducted during July 2018–September 2018 to assess the nutritional status of children between age group 5 and 12 years among primary school students taken a random sample of 5 government school located in rural practice area of IGIMS, Maner, (Patna). Out of 560 children examined, 304 were male and 256 were female. Data were collected through personal in-depth interviews such as sociodemographic profile, clinical examination, and anthropometric measurement using pre-tested semi-structured questionnaire. All data were compiled, tabulated in Microsoft Excel 2013 software and data were analyzed using SPSS 18 version. The proportion is proposed to be estimated with a precision that it is not likely to differ by more than standard deviation (SD) from the actual with a confidence interval of 95%.

Results: There was a total of 560 children out of which 304 were male (54.29%) and 256 (45.71%) were female. Age range of the children was between 5 and 12 years, and maximum number of children was in the age group of 5–6 years (26.78%). The total increase in mean height from 5 to 10 years in boys was $135.54 - 100.41 = 35.13$ cm and in girls $136.83 - 99.80 = 37.03$. The mean weight was more in boys than girls in the age group 5–10 years and it was more in girls in the age group 11–12 years. Among children, boys are more malnourished (54.285%) than 45.714% and severe underweight more in girls (10.476%) than boys (3.809%) and severe stunting more among girls (7.69%) than boys (3.84%).

Conclusion: Nutrition education was one of the appropriate, effective, and sustainable approaches to improving the knowledge level of mothers regarding malnutrition and its preventive measures. There is also a need for school health programs to monitor regular children's eating habit and personal hygiene.

Key words: Nutritional profile, School children, Stunting, Underweight, Wasting

INTRODUCTION

Nutritional status is the condition of health of an individual, influenced by nutrient intake and its

utilization in the body. Nutrition of primary school children is of paramount importance because the foundation for their lifetime health, strength, and intellectual vitality is laid during this period. Hence, it is a dynamic period of their physical growth as well as of their mental development.^[1]

According to the WHO (Anon., 2012), globally, 162 million under-fives were stunted among them 56% lived in Asia and 36% in Africa; 99 million under-fives were underweight among them 67% lived in Asia and 29% in Africa. 50 million children under-five were wasted, and

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17 million were severely wasted. Approximately 71% of them lived in Asia and 28% in Africa, with similar figures for wasted children (69% and 28%, respectively). Children who suffer from wasting face a markedly increased chance of death.^[2]

According to the United Nations Children's Emergency Fund (UNICEF), 13% of children under 5 years old in the developing world were wasted, and 5% were extremely wasted, an estimated 26 million children (Anon., 2011). In the developing world, UNICEF estimates 129 million children under five to be underweight, nearly one in four and 10% of them being severely underweight. The prevalence of underweight is higher in Asia than in Africa, with rates of 27% and 21%, respectively.^[3]

According to National Family Health Survey (2010–2012) of Karnataka, among 30 crore preschool children 63.61% were mildly malnourished with 34.23% and 2.17% moderate and severe malnourishment. About 3323 children were suffering from malnutrition in Dharwad district alone. According to a survey conducted up to August 2012, the number of malnourished children in Hubli-Dharwad was 836, Dharwad rural was 808, Navalgund - 516, Kalghatagi - 442, Kundgol - 374, and Hubli rural were 347.^[4]

Undernutrition is a major public health problem worldwide, particularly in developing countries.^[5] One-third of the children under 5 years old worldwide is moderately or severely undernourished. Undernutrition impairs physical, mental, and behavioral development of children and is a major cause of child death.^[6,7] Growth monitoring provides a diagnostic tool for health and nutrition surveillance of individual children and to instigate effective action in response to growth faltering (Ashworth *et al.*, 2008). Growth monitoring can serve as an entry point for community mobilization and social action, especially when growth monitoring data are aggregated and used for community-level assessment and analysis of child malnutrition, targeting supplementary feeding and reporting the prevalence of underweight.^[8]

Anthropometry is one of the most useful tools for assessment of the nutritional status of primary school children. There are many anthropometric indicators that describe the nutritional status of children. These are height-for-age (stunting), weight-for-height (wasting), and weight-for-age (underweight). The height-for-age index is an indicator chronic illness, and weight-for-height index is an indicator of acute illness. Weight-for-age is a composite index, and it takes into account both acute and chronic malnutrition.^[9]

Aims and Objective

Aims

The aim of the study was to assess the nutritional status of primary school children and to suggest ways to improve it.

Objective

The objectives are as follows:

1. To record anthropometric measurements
2. Early identification of malnutrition
3. To assess knowledge about balanced diet
4. To identify food practices and existing sociocultural taboos
5. To create nutritional awareness among mothers of children belonging to the intervention group.

Inclusion Criteria

All primary school children from 5th standard to 12th standard of five government schools were included in the study.

Exclusion Criteria

Children and parents who were not willing to participate in the study and those children who were suffering from major illness or undergone recent major surgery were excluded from the study.

MATERIAL AND METHODS

A cross-sectional study was conducted during July 2018–September 2018 to assess the nutritional status of children between age group 5 and 12 years among primary school students located in the rural practice area of IGIMS, Maner, (Patna), Maner and taken random sample of 5 government school. All children of selected school were enrolled into the study after obtaining the permission of respective principal of the school was taken after explaining the aims, objective, and procedure of the study.

Out of 560 children examined, 304 were male and 256 were female. A maximum number of children were in the age group 6 years, and the minimum number was in the 12 years age group. Data were collected through personal in-depth interviews such as sociodemographic profile, clinical examination, and anthropometric measurement using pre-tested semi-structured questionnaire. The body weight was measured in kg using a standardized weighing machine. Weight of all students was taken using an electronic weighing scale, and the students were asked to stand upright, without shoes on the weighing machine looking straight while the measurement was read. Height was to measure in cm using a portable stadiometer. Height was taken using a standard three-piece anthropometric rod at their classroom corrected up to 1 mm. Students were asked to stand upright against a wall with the heels

touching the wall and chin held horizontally so that the tragus of the ear and eye is in straightway, then the stick was adjusted and the height in cm was read. All data were compiled, tabulated in Microsoft Excel 2013 software and data were analyzed using SPSS 18 version. The proportion is proposed to be estimated with a precision that it is not likely to differ by more than standard deviation (SD) from the actual with a confidence interval of 95%.

RESULTS

Table 1 shows the age distribution of children. Maximum number of children was in the age group of 5–6 years and then progressively the number decline in higher age groups both in males and females. The progressive decline in age structure may be due to the school dropouts as the age increases. The other reason may be the identical age structure of the community as such.

Out of 560 students, 304 were males and 256 were females. Males are more than females.

Table 2 shows the sex distribution of students in the sample schools. 54.29% were males and 45.71 were females. Higher percentage of males' students is in accordance with the national sex ratio in favor of males. The other reason may be the social factors in which the education of female children was given less importance.

Table 3 shows the range and mean weight of the children of Government Primary School. Mean weight increased with age in both sexes. The mean weight was more in boys than girls in the age group 5–10 year, and it was more in girls in the age group 11–12 years.

Table 4 shows the age wise range and mean height of children. Up to 10 years of age boys were taller than girls but thereafter female took over height slightly. Total

increase in mean height from 5 to 10 years in boys was $135.54 - 100.41 = 35.13$ cm and in girls $136.83 - 99.80 = 37.03$.

Table 5 shows the range and mean of left upper mid-arm circumference. There was a total increase in mean M.A.C was 2.20 cm in boys and 2.84 cm in girls in 5–12 years of age. There was a gradual increase in M.A.C in both boys and girls.

Maximum number of healthy children was observed in 5 years age groups.

Boys are more malnourished than girls

Underweight more among girls than boys

Stunting more among girls than boys.

Most of the children had dental carries 17.857%. Missing tooth was found in 5.357% of children. Sign of anemia such as pale conjunctiva was found in 13.214% of children.

- Chi-square = 14.654
- $P = 0.012$
- In comparison with school children whose fathers were graduate, children whose father was lower education and illiterate was more malnourished.
- Chi-square = 6.831
- $P = 0.234$.
- In comparison with school children whose mothers are graduate, children whose mothers were lower education and illiterate was more malnourished [Tables 6-12].

DISCUSSION

The nutritional status of a population determines the overall health status which affects the growth and development of society. Hence, undernutrition and over nutrition are one of the important health problems encountered commonly in school going children.

In the present study, we observed comparatively majority of government school children (50.30%) were malnourished out of which suffered from Grade III malnutrition. Percentage of healthy children was found more in male than females. A similar study was reported by Mendhi *et al.* at for Assam in 6–8-year-old children as undernourished 51.7%, respectively.^[10] Similarly, Bandopadhyay from Navinagar Mumbai reported prevalence for undernutrition 42.3%.^[11] This finding is similar to a study conducted by Joshi *et al.*^[12] in schools of Western Nepal, where 26% of the students were found to be undernourished. This finding is in contrast with the study conducted by Hasan *et al.*,^[13] in 2010, in Bengaluru in which the prevalence of

Age group	Male	Female	Total (%)
5–6	82	68	150 (26.78)
7–8	78	66	144 (25.71)
9–10	76	64	140 (25.00)
11–12	68	58	126 (22.50)

Sex of the child	n (%)
Male	304 (54.29)
Female	256 (45.71)
Total	560 (100)

Table 3: Weight of the children under study

Male			Age group	Female			Difference in mean weight (kg) (m-f)
No. of boys	Range of weight (kg)	Mean weight (kg)		No of girls	Range of weight (kg)	Mean weight (kg)	
42	10.9–20.7	15.21	5	36	9.9–18.2	14.62	0.59
40	11.8–20.9	16.56	6	32	12.0–23.3	16.04	0.52
40	13.7–22.0	18.03	7	34	12.3–23.0	17.45	0.58
38	15.5–26.9	20.08	8	32	14.2–26.4	20.20	0.12
36	17.3–29.7	22.05	9	34	15.8–27.6	21.14	0.91
40	18.2–33.0	24.16	10	30	17.2–32.0	24.07	0.09
30	19.0–32.9	26.15	11	30	19.6–33.3	26.78	-0.63
38	21.0–37.6	28.05	12	28	20.6–39.7	30.20	-1.95

Table 4: Height of the children under study

Male			Age group	Female			Difference in mean height (cm) (Male+Female)
No. of boys	Range of height (cm)	Mean height (cm)		No. of girls	Range of height (cm)	Mean height (cm)	
42	84.5–112.0	100.41	5	36	80–109	99.8	0.60
40	85–118	106.51	6	32	87–116	104.63	1.88
40	84–123	110.25	7	34	84–118.5	108.75	1.5
38	89.5–128.5	115.33	8	32	88.5–128.0	114.33	1.00
34	99–134.5	112.16	9	34	89–131.5	119.57	2.65
30	105–140	126.56	10	30	94.5–138.0	124.56	2.00
30	107–145	131.59	11	30	105.5–155.5	131.16	0.43
28	114–148.5	135.54	12	28	136.16	136.16	-1.29

Table 5: Left upper mid-arm circumference of the children under study

Male			Age group	Female			Difference in mean MUAC (cm) (Male+Female)
No. of boys	Range of MUAC (cm)	Mean MUAC (cm)		No. of girls	Range of MUAC (cm)	Mean MUAC (cm)	
42	12.0–16.9	14.73	5	36	10.8–17.2	14.54	0.19
40	12.6–17.0	14.94	6	32	11.4–17.0	14.82	0.12
40	12.5–18.1	15.30	7	34	11.4–18.3	15.32	0.2
38	12.6–18.5	15.56	8	32	16.6–18.2	15.62	0.6
34	12.9–18.9	15.85	9	34	12.2–19.4	15.95	0.10
30	13.1–19.8	16.06	10	30	11.7–19.5	16.15	0.9
30	12.2–20.9	16.42	11	30	12.2–20.2	16.60	-0.18
28	14.4–21.7	16.93	12	28	13.9–21.7	17.38	-0.45

Table 6: Relation of age with nutritional status

Age in year	Nutritional status			
	Malnutrition			
	Normal 81% and above	Grade - I 71–80%	Grade - II 61–70%	Grade - III 51–60%
	n (%)	n (%)	n (%)	n (%)
5	40 (7.14)	18 (3.214)	14 (2.5)	6 (1.07)
6	37 (6.60)	19 (3.392)	11 (1.96)	5 (0.89)
7	36 (6.428)	21 (3.75)	10 (1.78)	6 (1.07)
8	36 (6.428)	18 (3.214)	9 (1.60)	7 (1.25)
9	35 (6.25)	15 (4.462)	12 (2.14)	6 (1.07)
10	32 (5.71)	13 (2.321)	10 (1.78)	5 (0.89)
11	31 (5.33)	14 (2.5)	10 (1.78)	5 (0.89)
12	30 (5.35)	14 (2.5)	8 (1.42)	4 (0.71)

malnutrition was 52%. This is also in contrast to a study conducted by Neelu *et al.*^[14]

In the present study, the proportion of malnourished in boys was more (54.285%) than girls (45.714%) and underweight and stunting more among girls (10.476%), (7.69%) than boys (14.285%), (3.84). However, another study Fazili *et al.* reported a prevalence of 11.1%, 9.25%, 12.3%, and 29% for underweight, stunting, wasting, and thinness, respectively.^[15] In a study by Amruth *et al.*, found that the prevalence of malnutrition among the surveyed primary school children is 26.5 % and the prevalence of underweight is 26.5%. Our finding also coincides with study by Singh *et al.* found that 90 (30%) children were found underweight for their age, 55 (18.33%) were found overweight, and 4 (1.33%) were found obese, respectively.^[16] The overall prevalence of malnutrition (including underweight, overweight, and obesity) was found to be 49.67%. In a study by Masthi *et al.*, found that

Table 7: Relations of sex with nutritional status

Nutritional status	Government primary school	
	No. of boys (%)	No. of girls (%)
81% and above (normal)	154 (27.5)	124 (22.142)
71–80% (Grade - I Malnutrition)	103 (18.39)	52 (9.285)
61–70% (Grade - II malnutrition)	38 (6.785)	46 (8.214)
51–60% (Grade - III malnutrition)	9 (1.607)	34 (1.607)
Total	304 (54.285)	256 (45.714)

Table 8: Comparison of nutritional status in school children (weight for age)

Variable	All children	Boys	Girl
	n (%)	n (%)	n (%)
Normal	278 (49.642)	154 (55.395)	124 (44.604)
Mild underweight	50 (47.619)	18 (17.142)	32 (30.476)
Moderate underweight	40 (38.095)	13 (12.380)	27 (25.714)
Severe underweight	15 (14.285)	4 (3.809)	11 (10.476)

Table 9: Comparison of nutritional status in school children (height for age)

Variable	All children	Boys	Girl
	n (%)	n (%)	n (%)
Normal	278 (49.64)	154 (27.5)	124 (22.14)
Mild stunting	26 (50)	11 (21.15)	15 (28.84)
Moderate stunting	20 (38.46)	8 (15.38)	12 (23.07)
Severe stunting	6 (11.53)	2 (3.84)	4 (7.69)

Table 10: Morbidity profile for school children

Morbidity condition	n (%) out of 560
De-pigmented hair	9 (1.607)
Pigmentation on face	20 (3.571)
Dental caries	100 (17.857)
Pale conjunctiva	74 (13.214)
Missing tooth	30 (5.357)
White spot on nail	20 (3.571)
Bowleg	1 (0.178)
Swollen leg	8 (1.428)
Bitot's spot	4 (0.71)
Brown spot on the conjunctiva	3 (0.53)

overall 64.2% were found to be normal, 9.1% were found to have severe thinness, 20.9% thinness, 4.4% overweight, and 1.4% obesity. Severe thinness was found to be highest among 12 years, i.e., 12.1%, thinness among 10 years, i.e., 24.9%, overweight among 14 years, i.e., 8.4% and obesity among 11, 14, and 15 years, i.e., 1.8%. Thinness and severe thinness were higher among males (24.2% and 12.5%) compared to females (17.6% and 5.6%).^[17] In another study, the prevalence of undernutrition in Chenchu population was comparable with other tribal and rural counterparts in Andhra Pradesh; however, the crude death rate was higher among the Chenchus as studied by

Table 11: Comparison of father educational status between malnourished boys and malnourished girls

Father's education	Malnourished	Boys	Girls
	n (%)	n (%)	n (%)
Illiterate	23 (21.904)	11 (10.476)	12 (11.428)
Primary school	18 (17.142)	8 (7.619)	10 (9.523)
Middle school	16 (15.238)	7 (6.666)	9 (8.571)
High school	29 (27.619)	6 (5.714)	23 (21.904)
Intermediate	16 (15.238)	2 (1.904)	14 (13.333)
Graduate	3 (2.857)	1 (0.952)	2 (1.904)

Table 12: Comparison of father educational status between malnourished boys and malnourished girls

Mother's education	Malnourished	Boys	Girls	P value
	n (%)	n (%)	n (%)	
Illiterate	21 (3.75)	10 (1.78)	11 (1.96)	0.521
Primary school	44 (7.85)	15 (2.67)	29 (5.18)	0.114
Middle school	20 (3.57)	9 (1.60)	11 (1.96)	0.389
High school	18 (3.21)	7 (1.25)	11 (0.17)	0.142
Intermediate	2 (0.35)	1 (0.17)	1 (0.18)	0.164
Graduate	0 (0)	0 (0)	0 (0)	

Rao *et al.*^[18] However, in another study the prevalence was higher than Srinivas *et al.* (27.16%, 20%, and 10.6%) and Patil *et al.* (22% and 20%) as these studies were done in urban areas.^[19,20] Our findings were comparable with the findings of Patil *et al.* (37%, 33%) and NFHS-4 Chhattisgarh state data. However, Rao *et al.* in their studies which included tribal preschool children found higher prevalence (61.6%, 51.6%, and 32%).^[20,21] The findings were similar to the findings revealed by Somanwar *et al.*, Purohit *et al.*, and Yadav *et al.* who also found more nutritional deprivation among girl child.^[22-24]

In the present study, comparison with school children whose mothers and fathers are graduate, children whose mothers and fathers were lower education and illiterate was more malnourished. However, another study revealed Boyle *et al.* obtained similar result using household-level data about mother's education to be positively associated with a number of measures of infant and child health and nutritional status.^[24] Furthermore, in another study by Miller *et al.* in bivariate tabulations, mother's education was strongly inversely associated with risks of both small birth size and stunting, but not with wasting, respectively.^[25]

In the present study regarding morbidity profile among study population, most of the children had dental carries 17.857%. Missing tooth was found in 5.357% of children. Sign of anemia such as pale conjunctiva was found in 13.214% of children. Hence, these findings coincide similar to study by Panda *et al.* in Ludhiana

city was anemia the most common finding being 26%, and second, most common findings were 23.1% dental caries and 5.6% with a refractive error.^[26] In another study by Shivprakash *et al.*, found that pallor was noted in 123 (25.4%). Teeth changes were noted in the form of dental caries in 137 (28.3 %) and enamel mottling in 19 (3.9 %).^[27] In a similar study by Amruth *et al.* found that most of the children had dental caries (47.2%) respectively.^[16] In another study by Pandey *et al.* in Bhaktapur from Nepal shows that most common health problems were Ear problem such as wax, otitis media, and otitis externa 22.3% and next most common problem again was dental caries (13.56%).^[28]

CONCLUSION

Nutrition education was one of the appropriate, effective, and sustainable approach in improving the knowledge level of mothers regarding malnutrition and its preventive measures. Improved knowledge of mothers helps to choose and feed good nutritious foods to children thus enhances nutritional status. There is also a need for school health programs to monitor regular children's eating habit and personal hygiene. Supplementary foods will help to overcome both protein and calorie deficiencies among preschoolers, thus enhancing the national economy if employed in other centers. Along with the improvement in physical growth and development, it lays the foundation for lifetime health, strength, and intellectual vitality which also acts as a determinant of nutritional status in later life. Further, the improvement in the knowledge of the mothers is the key to health and nutrition security of the entire family.

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Patterns of Restricted Diffusion within Corpus Callosum in Neonatal Hypoxic-Ischemic Encephalopathy and its Significance in Predicting the Clinical Outcome

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Abstract

Background: Hypoxic-ischemic encephalopathy (HIE) continues to be a dreadful cause of morbidity and mortality in neonates and is a leading cause of cerebral palsy and other neurodevelopmental deficits. It manifests in different patterns of brain involvement on magnetic resonance imaging (MRI), of which restricted diffusion within the splenium, genu, or body of the corpus callosum has received less attention in the literature. In this review, we will describe a series of cases showing this pattern of injury.

Materials and Methods: MRI including diffusion-weighted imaging was performed in 28 neonates with known or clinically suspected HIE, including both premature and term neonates.

Results: 11 out of 28 patients demonstrated restricted diffusion in the corpus callosum. Out of these 11 patients, 6 showed restricted diffusion in the entire corpus callosum, 3 showed isolated splenium involvement, 1 had body and splenium signal abnormality, and 1 showed diffusion restriction in the genu and splenium.

Aims: The aim is (1) to study the patterns of restricted diffusion in corpus callosum in neonatal HIE and (2) to demonstrate that corpus callosum involvement is associated with extensive brain insult.

Conclusions: Cytotoxic lesions of the corpus callosum in neonate with HIE are associated with extensive brain injury and emerges to be an early neuroradiologic marker of adverse outcome. Splenium of corpus callosum is the most vulnerable location for ischemic injury. Corpus callosal injury is more common among term than preterm neonates.

Key words: Corpus callosum, Hypoxic-ischemic encephalopathy, Magnetic resonance imaging, Restricted diffusion, Splenium

INTRODUCTION

Hypoxic-ischemic encephalopathy (HIE) is a major cause of mortality and morbidity in newborns. The pattern of brain injury depends on factors such as brain maturity, duration, and severity of the insult. The pattern of injury is of four types, i.e., involvement of the watershed areas, basal ganglia-thalamus, total injury (maximal basal

ganglia-thalamus and watershed), and focal-multifocal injury (presence of strokes and/or white matter injury alone).^[1] Restricted diffusion within the corpus callosum is not frequently studied in HIE. Restricted diffusion of the corpus callosum on magnetic resonance imaging (MRI) is due to acute cytotoxic edema within the affected area. Cytotoxic lesions of the corpus callosum (CLOCCs) are secondary lesions associated with various entities including epilepsy,^[2] the usage as well as sudden withdrawal of antiepileptic drugs,^[3] ischemia,^[4] multiple sclerosis; Marchiafava-Bignami syndrome, cerebral trauma, neoplasm, AIDS dementia complex, and infections such as influenza, herpes, salmonella, varicella zoster, rotavirus,^[5] HIV, tubercular meningitis, and hemolytic-uremic syndrome with encephalopathy, neonatal hypoglycemia,

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demyelination disorders, and many other conditions. This study is to show the pattern of restricted diffusion within the corpus callosum on MRI in neonatal HIE.

MATERIALS AND METHODS

This study was conducted at the Department of Radiodiagnosis, MGM Hospital, Warangal, Telangana State, between January 2018 and July 2018. We studied 28 neonates, 5 preterms, and 23 term infants, with known or clinically suspected HIE. Patient's history and clinical staging by Sarnath were documented before MRI. This was a prospective, observational study conducted among patients of both sexes. The study was carried out using GE BRIVO 1.5T MRI system with the 8-channel pediatric head coil. Following sequences (time of relaxation/time of echo/flip angle/field of view) were acquired as a part of the study: Axial T1-weighted spin echo images (500/14/90/256/4 mm), axial spin-echo T2-weighted images (4000/98/180/256), and isotropic diffusion-weighted images (DWI) (b 0, 1000), with apparent diffusion coefficient (ADC) maps. Before the MRI study, the procedure was explained to the parents/guardians of the patient, and a written informed consent was obtained. Sedation was given, either orally (syrup pedicloryl- $\frac{1}{2}$ h before the study) or intravenously (ketamine/propofol), before the start of the study, as deemed appropriate by the attending anesthetist.

RESULTS

Restricted diffusion on DWI within corpus callosum was noted in 11 out of 28 patients (40%) [Table 1]. Signal abnormality in the rest of the brain parenchyma was also recorded.

Table 1: Patterns of corpus callosal involvement in neonatal hypoxic ischemic encephalopathy

Patterns of corpus callosal involvement	Number of cases (%)
Entire corpus callosum	6 (55)
Splenium	3 (27)
Body and splenium	1 (9)
Genu and splenium	1 (9)
Total	11 (100)

Out of these 11 patients, restricted diffusion in the entire corpus callosum was noted in 6 cases which was the most common finding. Out of the 6 cases, 4 cases showed total brain injury pattern of involvement [Figure 1], 1 case showed watershed pattern, and 1 case showed basal ganglia-thalamus pattern of involvement. The splenium of the corpus callosum was the second most common area involved and was seen in 3 patients. Out of 3 patients, 1 showed total pattern of involvement, 1 patient showed watershed pattern [Figure 2], and 1 was isolated splenium involvement [Figure 3]. 1 patient showed combined involvement of the body and splenium with watershed pattern [Figure 4]. Involvement of the genu and splenium was noted in 1 case who had basal ganglia-thalamus pattern of involvement [Figure 5].

Out of 28 patients, 5 neonates were premature neonates. One of these neonates showed corpus callosum injury which showed involvement body and splenium. In our study, corpus callosum injury was found to be more common among term neonates.

In our study, we documented patients with the restricted diffusion of the entire corpus callosum, isolated involvement of the splenium and the genu, isolated involvement of the splenium and the body and isolated splenium involvement. Corpus callosum injury was associated with more severe clinical presentation. Corpus callosal injury was more common among term neonates, and most of the injuries were associated with total (maximal basal ganglia-thalamus and watershed) pattern of brain injury (45%) [Table 2].

DISCUSSION

The pathophysiologic effects of HIE on corpus callosum are complex. The main underlying pathology in HIE is insufficient cerebral blood flow and decreased oxygen delivery to the brain.

Restricted diffusion of the corpus callosum on MRI represents acute cytotoxic edema within the affected area and could be a generalized response to the underlying hypoxic ischemia. On DWI the affected area of corpus callosum shows restricted diffusion with a corresponding dark signal intensity on ADC.

Table 2: Incidence of different patterns of brain injury associated with restricted diffusion in corpus callosum

Corpus callosal injury	Total brain injury pattern	Watershed pattern	Basal ganglia-thalamus pattern	Isolated splenial restricted diffusion	Total
Entire corpus callosum	4 (66)	1 (17)	1 (17)	0	6 (100)
Splenium	1 (33)	1 (33)	0 (0)	1 (33)	3 (100)
Body and splenium	0 (0)	1 (100)	0 (0)	0 (0)	1 (100)
Genu and splenium	0 (0)	0 (0)	1 (100)	0 (0)	1 (100)
Total	5 (45)	3 (28)	2 (18)	1 (9)	11 (100)

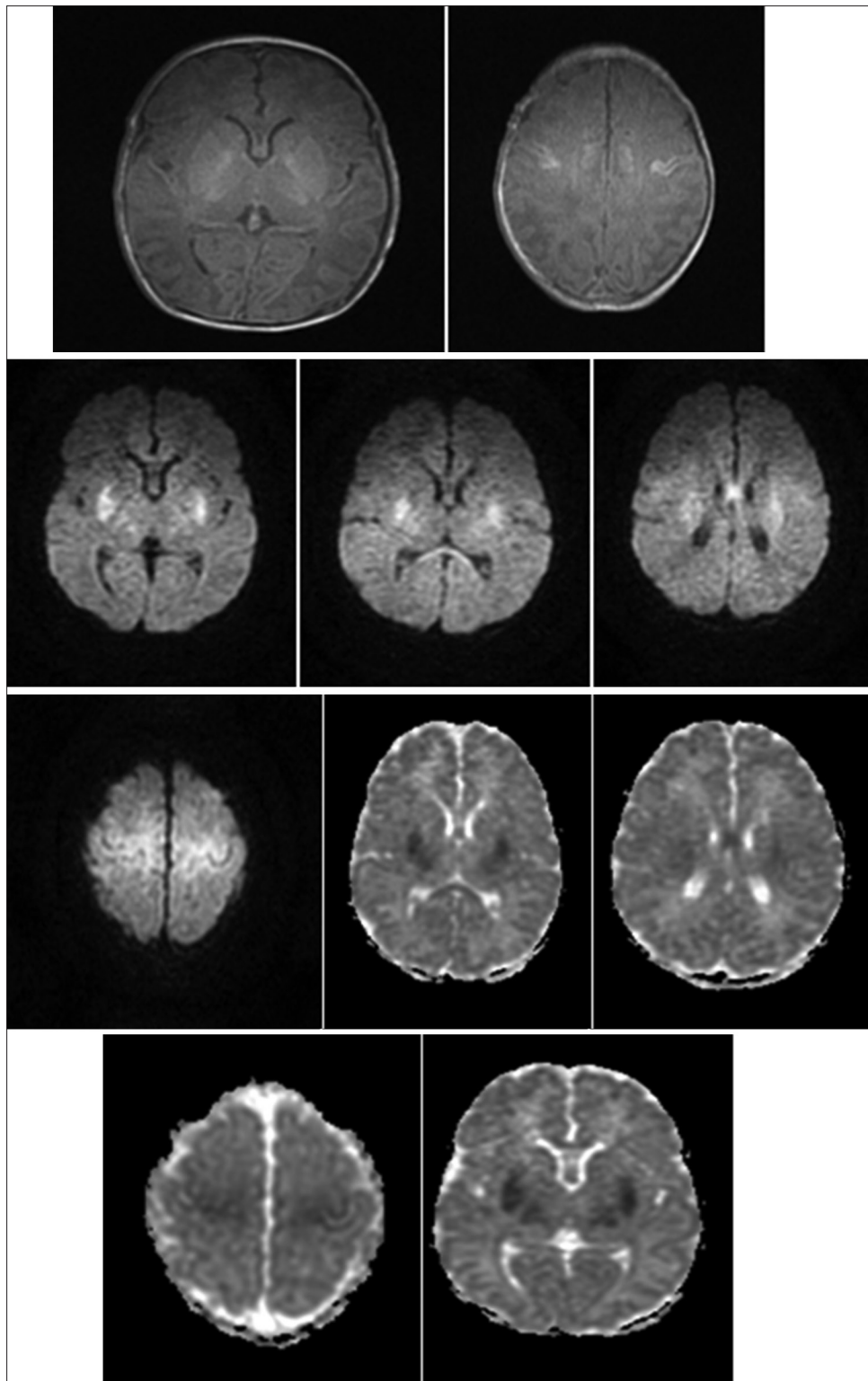


Figure 1: Magnetic resonance imaging in 8-day full-term female with a neonatal hypoxic injury. Axial T1-weighted image shows abnormally increased signal intensity in bilateral basal ganglia, thalamus, and perirolandic cortex. In addition, there is the absence of normal bright signal in the posterior limb of internal capsule, referred to as “absent posterior limb sign.” Axial diffusion-weighted images show hyperintense signal in bilateral basal ganglia, thalamus, perirolandic cortex, bilateral parietal lobes, genu, body and splenium of corpus callosum. Apparent diffusion coefficient maps show hypointense signal in same structures confirming that abnormal signal intensity is due to restricted diffusion

Glutamate excitotoxicity is one of the important mechanisms that lead to cytotoxic edema. The corpus callosum and the basal ganglia are rich in glutamate receptors and are, therefore, more vulnerable to glutamate neurotoxicity by hypoxic-ischemic injury.^[6,7] Seizures^[8] and anticonvulsant therapy^[9] may also be contributing factors of diffusion restriction within the corpus callosum. Oster

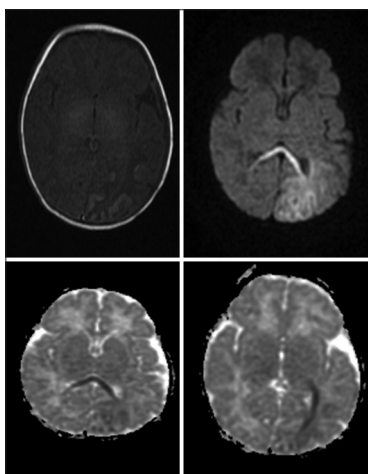


Figure 2: Magnetic resonance imaging in 5-day-old male with neonatal hypoxic injury. Axial T1-weighted image shows hyperintensity of the left occipital lobe. Axial diffusion-weighted images show restricted diffusion in the splenium of the corpus callosum and left occipital lobe (infarct).

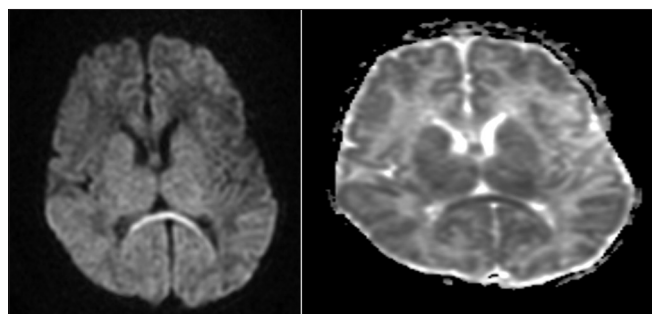


Figure 3: Magnetic resonance imaging in 3-day-old female with neonatal hypoxic injury. Axial diffusion-weighted image shows hyperintensity of the isolated splenium of corpus callosum, and apparent diffusion coefficient map shows hypointense signal ("Boomerang sign").

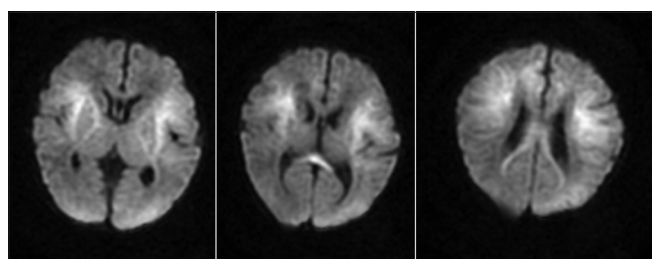


Figure 4: Magnetic resonance imaging in 4-day-old female with neonatal hypoxic injury. Axial diffusion-weighted image shows restricted diffusion in bilateral parietal lobes, external, and internal capsule, body and splenium of corpus callosum.

et al.^[10] proposed that repeated and excessive electrical discharges along the commissural fibers during seizures caused transient changes in energy metabolism and ionic transport, resulting in rapidly resolving intramyelinic edema.

Complex interdependent mechanisms increase cytokine levels and, ultimately, glutamate levels in the brain.^[11,12] With an insult to brain, macrophages are recruited which release the inflammatory cytokines interleukin-1 (IL-1) and IL-6, beginning the cascade that leads to cytokinopathy. This cytokinopathy causes massively increased levels of glutamate in the extracellular space. Compared with those in other brain areas, the neurons, astrocytes, and oligodendrocytes of the corpus callosum have a higher density of receptors, including cytokine receptors, glutamate, and other excitatory amino acid receptors, toxin receptors, and drug receptors.^[7] The excitotoxic action of glutamate on receptors on corpus callosum, sodium-potassium pumps, and aquaporins results in an influx of water into both astrocytes and neurons. This water is trapped within the cells, which results in cytotoxic edema and hence restricted diffusion on MRI. The splenium of corpus callosum is particularly more vulnerable to cytokinopathy^[13] [Table 3].

As the corpus callosal lesions with reduced diffusion (low ADC value) are caused by cytotoxic edema,^[14,15] the term CLOCCs are used.

Involvement of the splenium, based on signal changes, can be divided into two types according to its shape and extent: Oval, circumscribed, with well-defined borders usually located in the midline, or wider, more extensive less regular lesions involving the entire splenium ("Boomerang sign").^[4]

A study by Takenouchi *et al.*^[16] on restricted diffusion within the corpus callosum in HIE, reviewed images of 34 infants. 10 of the 34 (29%) infants demonstrated restricted diffusion within the splenium of the corpus callosum, with a significantly higher incidence of severe neurodevelopmental delay or death, compared to infants without restricted diffusion in the splenium of the corpus callosum. Our study showed similar results with 10 out of 28 infants (35%) manifesting adverse outcome. 1 of 28 patients showed isolated splenium involvement and was associated with good neurodevelopmental outcome.^[16]

Table 3: Incidence of restricted diffusion within genu, body, splenium in corpus callosal injury

Restricted diffusion	Number of cases (%)
Genu	7 (63)
Body	7 (63)
Splenium	11 (100)

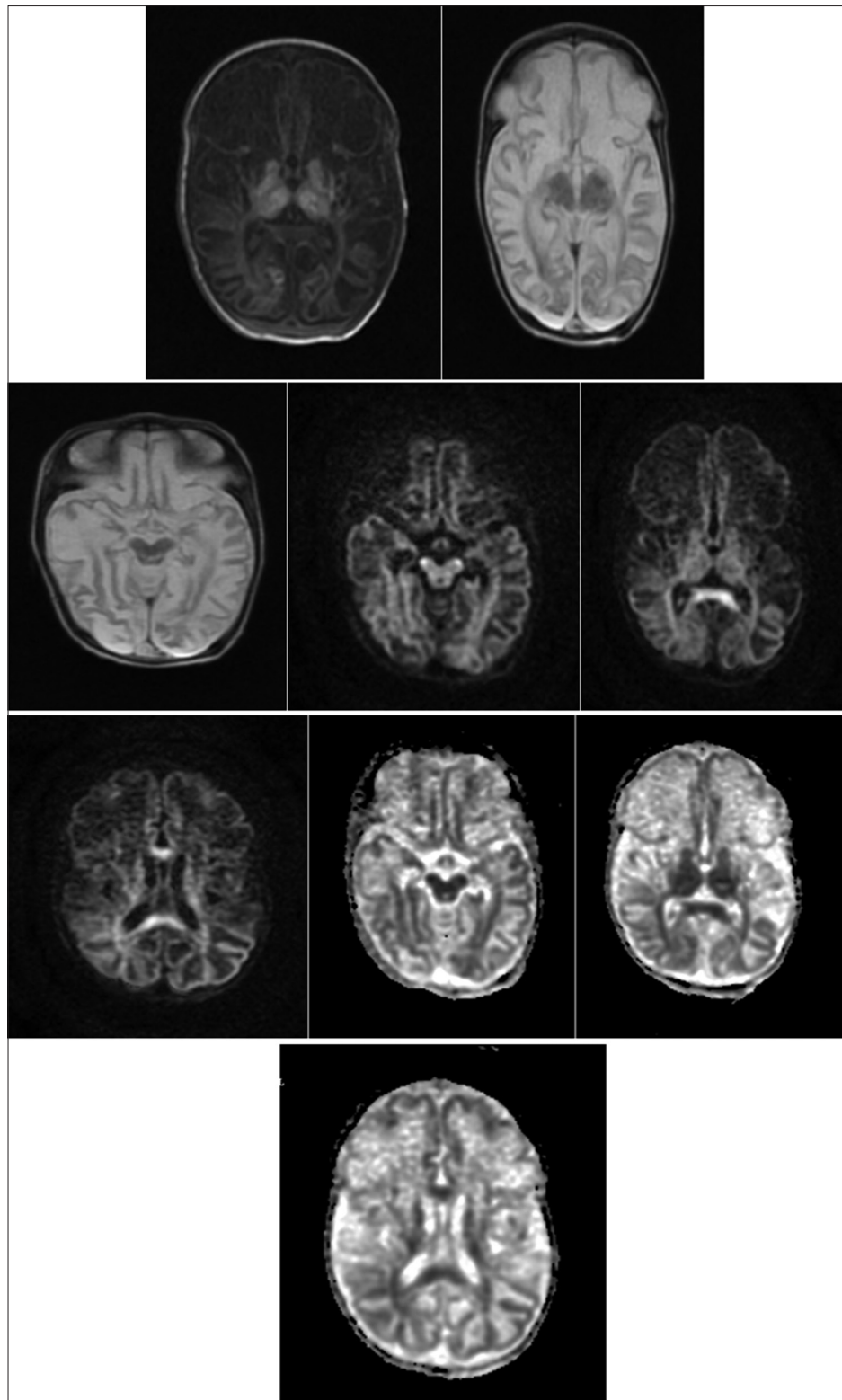


Figure 5: Magnetic resonance imaging in 13-day-old male with neonatal hypoxic injury. Axial T1-weighted image shows abnormally hyperintense and atrophied basal ganglia, thalamus. The white matter shows abnormal signal intensity and cystic encephalomalacia with thinned out cortex. Axial T2-weighted image shows the corresponding hypointensity of basal ganglia and thalamus and hyperintense white matter suggestive of severe cystic encephalomalacia. Axial diffusion-weighted images show hyperintense signal in basal ganglia, thalamus anteromedial midbrain, splenium, and genu of corpus callosum. Apparent diffusion coefficient maps show hypointense signal in same structures confirming that abnormal signal intensity is due to restricted diffusion

A study by Nagy *et al.*^[17] showed that corpus callosal injury in teenagers with a history of moderate neonatal hypoxic ischemia injury was associated with worse neuropsychological performance. Thus, perinatal corpus callosal injury is an important marker of poor neurological outcome.

CONCLUSION

We present a series of neonates, term, and preterm of both sexes, with HIE who underwent MRI. Restricted diffusion within the corpus callosum is a part of the spectrum of injury patterns in HIE, which is often associated with extensive brain injury and splenium of the corpus callosum is the most vulnerable location for ischemic injury. It serves as an early neuroradiologic marker of adverse neurologic prognosis.

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Radio-pathological Factors that Predict the Surgical Outcome of Ossification of *Ligamentum flavum* of Spine – Series of 31 Cases

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Abstract

Introduction: Ossification of the *Ligamentum flavum* (OLF) is a pathological condition that affects the ligament and causes slowly progressive myeloradiculopathy in adults.

Aim: To study the radiological and pathological factors that are predictive of the surgical outcome of patients with OLF.

Materials and Methods: A prospective study of 31 consecutive patients, including 24 men and 7 women with a mean age of 50.45 years, was conducted from 2013 to 2016. Radio-pathological factors included are: Number of segments affected by OLF, Sato's computed tomography-based classification, and the presence of intramedullary hyper-intensity on T₂w magnetic resonance imaging and calcium pyrophosphate dihydrate (CPPD) crystal deposition (pseudogout). All cases underwent decompressive laminectomies. Specimen sent for polarized-light microscopic studies and analyzed for characteristic rod-shaped, birefringent CPPD crystals. Follow up done with a mean duration of 5 months. Recovery rate was calculated with pre-operative and post-operative "Modified Japanese Orthopedic Association" scoring system.

Results: Recovery was excellent in 10 cases, good in 6 cases, fair in 12 cases, poor in 3 cases. The author conducted a review of literature in English, Japanese and Korean literature and compared their studies.

Conclusion: Early and correct diagnosis is required to avoid poorer results. Long-term follow up needed to determine the factors that predict the surgical outcome. This study also shows how this disease is highly under-reported in India.

Key words: Calcium pyrophosphate dihydrate crystals, Modified Japanese Orthopedic Association score, Ossification of *Ligamentum flavum*, Prognostic factors, Pseudo gout, Sato's classification

INTRODUCTION

Ossification of the *Ligamentum flavum* (OLF) is a pathological condition that causes myelopathy, radiculopathy or both in a patient. It is relatively common in the Japanese population compared to that in American or European populations.^[1] However, nowadays it has been reported from other areas also, especially from Asian countries. It has been highly

underreported in India. The etiology of hypertrophy and OLF is still not fully understood, but an association with ossification of the posterior longitudinal ligament (OPLL) or diffuse idiopathic skeletal hyperostosis (DISH) has been found.^[2] Microscopic findings in OLF specimens showed an overgrowth of Type II collagen preceding the development of ossification. There was also a reduction in the amount of elastin [Picture 1]. OLF was confirmed to be mainly enchondral ossification. Additional intramembranous ossification was, however, seen at the tip of the nodule-shaped ossification.^[3] Ossification extended along the superficial layer of the hypertrophied ligament, as in OPLL. It was suggested that the mechanism of OLF development depends intimately not only on dynamic and static mechanical stresses but also on the role of some growth

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factors as well. OLF can be diagnosed by lateral radiographs, manifesting as ossification of the spinal foramen [Picture 2]. When comparing the narrowing of the spinal canal as seen by computed tomography (CT) or magnetic resonance imaging (MRI), the CT scan may provide information superior to that of MRI because it shows precisely the areas where there is protruding ossification from the posterior to the anterior aspect of the spinal canal.^[4]

Historically, OLF was first observed on lateral radiographs [Picture 2] and reported by Polgarin 1920. In 1938, Anza described the first case with neurological symptoms and identified OLF in a specimen removed during the operation. Oppenheimer also observed OLF on plain radiographs in DISH and ankylosing spondylitis. He speculated that such Ossification might be responsible for a radicular neuropathy. In 1960 Yamaguchi *et al.* reported an operative case with severe myelopathy; Koizumi, Yanagi, *et al.* and Nagashima subsequently reported similar cases.^[5-8]

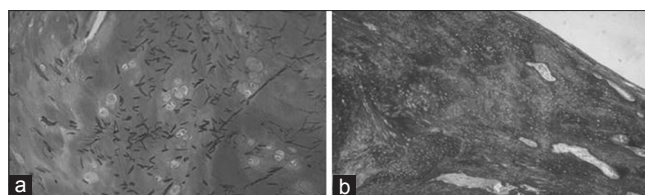
Most cases of OLF occur in the thoracic spine, especially the lower third of thoracic or the thoracolumbar spine; OLF rarely occurs in the cervical spine. Because thoracic spinal canal stenosis resulting in thoracic myelopathy or radiculopathy has been noted recently, OLF is now recognized as a clinical entity causing thoracic myelopathy manifesting as OPLL and spondylosis. When OLF was considered a contributing factor in patients with herniated thoracic discs, the surgical results were poorer than those in patients without OLF. However, outside Japan, unlike OPLL in the cervical spine, thoracic myelopathy secondary to OLF is sometimes overlooked or misdiagnosed as degenerative overgrowth by the posterior spinal element consisting of the superior articular processes.^[9] This error results from a lack of knowledge about this pathological condition. OLF has been recognized as a composite lesion because of the combination of ossification of the spinal ligaments with hyperostotic changes. Small degrees of OLF may be considered a degenerative change, as its incidence in radiographic studies of the spinal columns of aged persons has ranged from 4.5% to 25.0%. It has been suggested that the mechanism of hypertrophy, overgrowth, and progression of ossification of the ligaments plays an important role in the pathological process of myelopathy.

Aim

To study the Radiological and pathological factors that are predictive of the surgical outcome of patients with OLF.

MATERIALS AND METHODS

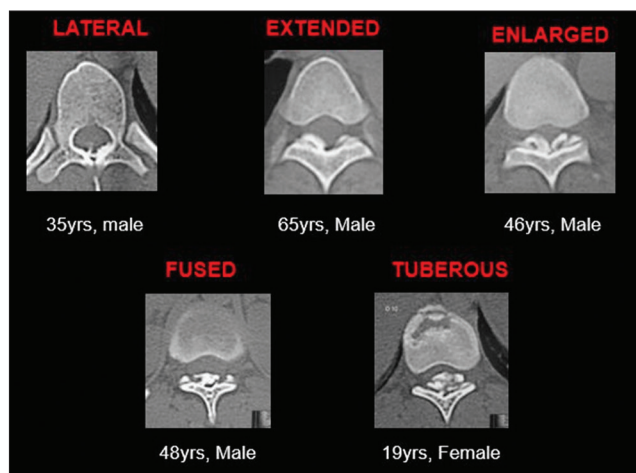
This was a prospective study, which was done on patients suffering from OLF of Spine. This study was conducted



Picture 1: Photomicrograph of ossification of *Ligamentum flavum* (OLF). (a) Enchondral type of ossification in OLF, (b) Cartilage cells among increased and swollen collagen fibres; the elastic were scanty and ruptured



Picture 2: Ossification of the *Ligamentum flavum* (OLF) in a 74-year-old woman. (a) Lateral radiograph shows oval nodular masses in the posterior spinal canal at the C3-C4 and C5-C6 levels (arrows), (b) sagittal T1-weighted magnetic resonance imaging shows a round area of very low signal intensity at the corresponding location that indents the posterior aspect of the spinal cord at the C5-C6 level (arrow). Intervertebral disc herniation is also seen at the C4-C5 level



Picture 3: Computed tomography classification

over the period from February 2013 to February 2016.

Due clearance were obtained from the ethical committee of Government Rajaji Hospital and Madurai Medical College, Maduraiprior to this study.

Thirty one patients consecutively diagnosed of OLF of Spine with myelopathy. They were diagnosed on the basis of clinical examination, radiological imaging and histopathological confirmation. All the surgeries were done at the same operation theatre in Government Rajaji Hospital, Madurai.

Decompressive laminectomy, with removal of the OLF, was performed for all patients. Polarized-light microscopic examinations done on the excised *L. flavum* for characteristic rod-shaped, birefringent crystals. No. of segments of the spine involved, Sato's CT classification^[15] of OLF [Picture 3], presence of intramedullary signals on MRI, presence of calcium pyrophosphate dihydrate (CPPD) crystals in Light microscopy, modified Japanese Orthopedic Association (JOA) cervical spine myelopathy functional assessment scale data were collected.

RESULTS

Mean age of these patients were 50.1 years with range of 19–70 years. From radiological studies, patients were grouped into 5 groups according to the number of levels of spine involved. One level involved in 8 cases (26%), two levels involved in 9 cases (29%), three levels involved in 7 cases (22%), four levels involved in 4 cases (13%) and more than 4 levels involved in 3 cases (10%) [Figure 1].

Based on Sato's^[15] CT based classification, the types of OLF was classified as: Lateral (52%), extended (16%), enlarged (10%), fused (3%) and tuberos (19%) [Figure 2].

Intramedullary signal changes in T2w MRI images were positive in 45% and absent in 55% of cases [Figure 3].

Surgically excised *L. flavum* of each level were sent for histopathological examination and analysis under polarized light microscopy for the presence of “CPPD” crystals which will be seen as rhombic shaped birefringent crystals [Picture 4]. 8 cases were positive for CPPD crystals [Figure 4].

Recovery rate from symptoms was calculated using the following formula;

$$\text{Recovery rate (\%)} = \frac{(\text{Post operative mJOA score} - \text{Pre operative mJOA score})}{(11 - \text{Pre operative mJOA score})} \times 100$$

Based on the results the patients were grouped into 4 Types of recovery.

They are excellent (>75%), good (50–75%), fair (25–50%) and poor (<25%) as Figure 5.

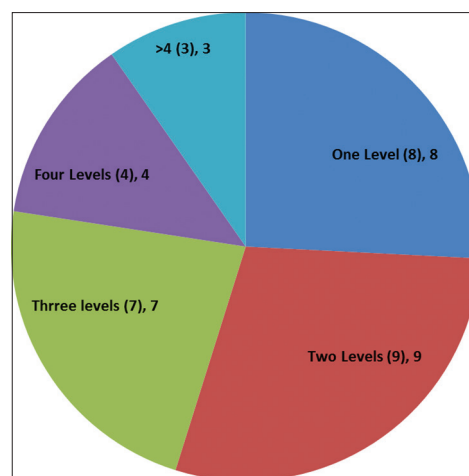


Figure 1: Distribution of number of segments

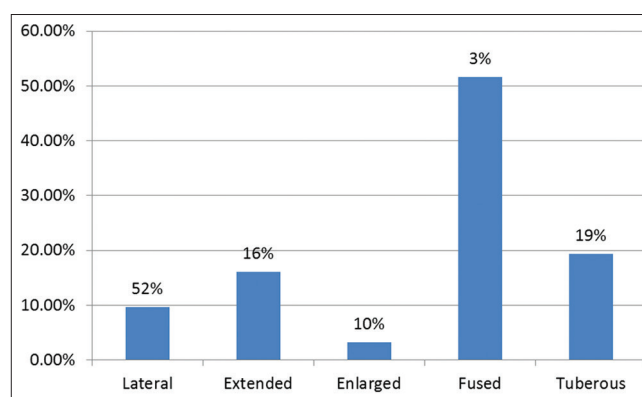


Figure 2: Distribution of computed tomography classification

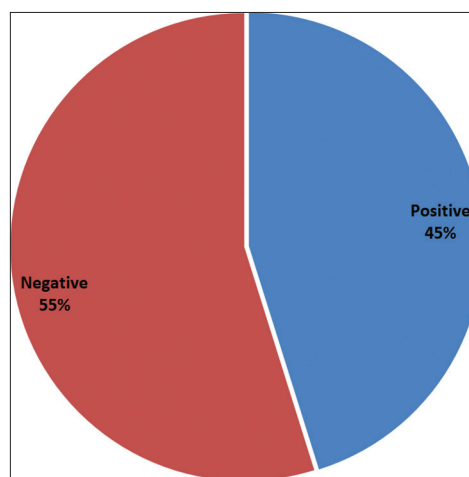


Figure 3: Distribution of magnetic resonance imaging intramedullary signals

All the patients were followed up post operatively at OPD. Out of 31 patients, 14 cases (14%) for <3 months, 15 cases (48%) for 4–6 months, 1 case (3%) for 7–12 months and 1 case (3%) for more than a year done. Only short term follow up were possible for most cases. We need to continue the follow up for longer term for

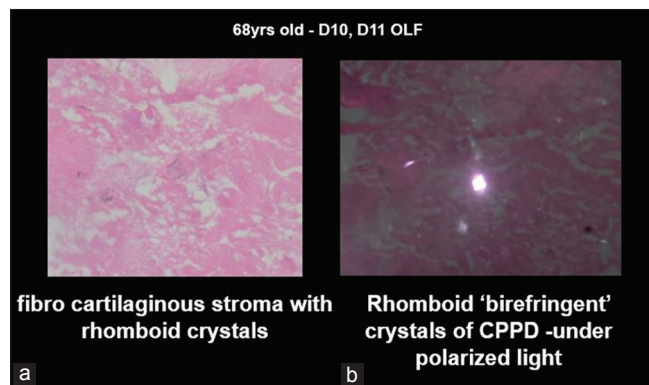
more accurate prediction of surgical outcome for OLF of Spine.

Relationship between Recovery and Radio-pathological Factors

All the four radio-pathological factors analyzed were statistically evaluated and determined whether it has significant influence in predicting the surgical outcome of OLF of Spine. The results were tabulated as follows;

Recovery and no of segments of the spine involved: $P = 0.2607$; not significant

1. Recovery and Sato's CT classification of OLF: $P = 0.0933$; not significant



Picture 4: Calcium pyrophosphate dihydrate crystals. (a) Fibro cartilaginous stroma with rhomboid crystals, (b) rhomboid "birefringent" crystals of calcium pyrophosphate dihydrate – under polarized light

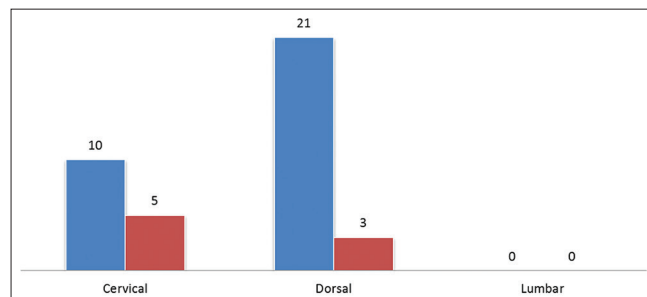


Figure 4: Distribution of calcium pyrophosphate dihydrate positivity

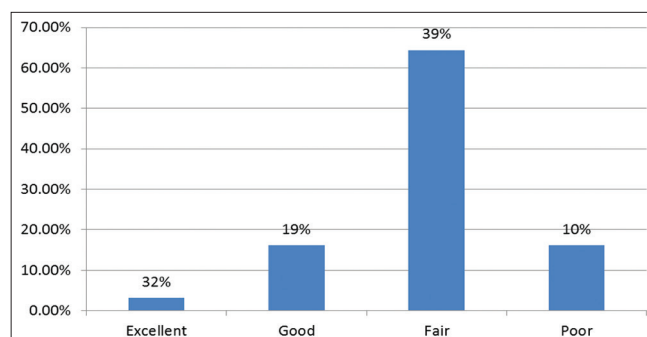


Figure 5: Recovery from symptoms – types

2. Recovery and presence of intramedullary signals on MRI: $P = -0.6001$; significant [Figure 6]

Recovery and presence of CPPD crystals in Light microscopy: $P = -0.3032$; significant [Figure 7].

Above statistical analysis results shows that the radio-pathological factors that likely to predict the outcome for surgery for OLF spine are:

1. MRI signal changes
2. CPPD positivity.

DISCUSSION

Development of OLF

In most OLF cases, the initial changes in the *L. flavum* occur at the site of attachment of the caudal portions [Picture 5], and ossification extends from the lateral aspect to the center along the superficial layer of the hypertrophied *L. flavum* and then above to the anterior parts of cephalic portions. Ossification of the cephalic portions progresses to the caudal portions, and hyperostosis of the pedicle occurs, resulting in nodular formations. However, the cephalic and caudal parts of OLF never unite completely in the intervening space, even in specimens with thickened nodular OLF in the fibro cartilaginous matrix.

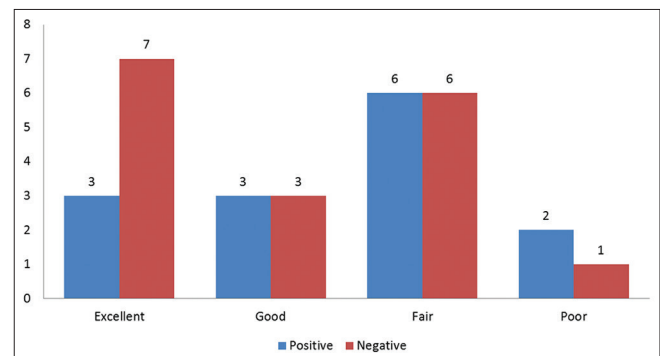


Figure 6: Recovery and magnetic resonance imaging signal changes

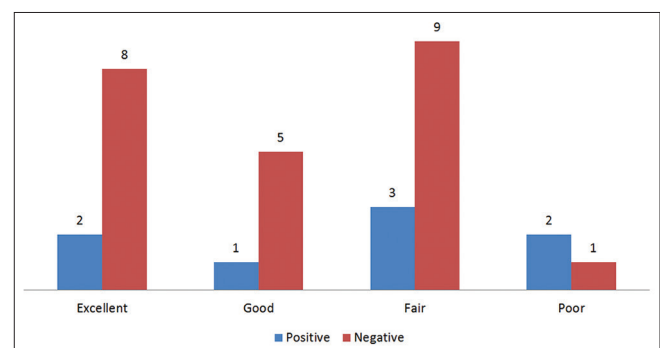
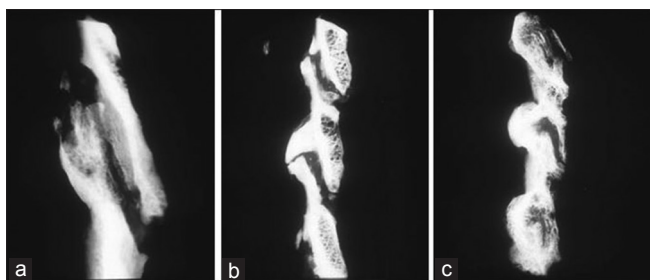


Figure 7: Recovery and calcium pyrophosphate dihydrate positivity



Picture 5: Development of ossification of *Ligamentum flavum* (OLF). (a) Initial ossification at the attachment of the caudal portion, (b) nodular type OLF, (c) final stage of OLF. Both the cephalic and caudal portions of OLF were fused but never united in the intervening space

Histopathology of the *L. flavum*

Anatomically 20, the *L. flavum* exists in the interlaminar space and supporting tissue, forming part of the posterior wall of the spinal canal. The *L. flavum* has two portions at each intervertebral disc level: The central (inter-laminar) and lateral (capsular) portions. The average composition of the fibers is 80% elastin and 20% collagen, as described by Yong-Hing *et al.*^[10] This composition changes with age, however, and it has been reported that collagen increases in relation to decreasing elastin [Figure 2]. The bony attachment of the *L. flavum* is a four-layered structure, the enthesis, as described by Niepel and Sitaj.^[11] The four layers are the ossification layer, calcified cartilage, non-mineralized cartilage, and ligament. The enthesis also occupies a key position in the pathological process of the diseases or so-called enthesopathy. It is well known that the enthesis has a rich vascular supply, highly active metabolism, an ample and specialized nerve supply, and a few scattered fibrocartilage cells with reserved activity, among other structures. With aging, small osteophytes develop in the *L. flavum* at the ligamento-osseous junction (enthesis), which shows marked intraligamentous calcification, swelling, and hyalinization of the collagen fibers, the appearance of fibrocartilagenous cells, and a reduction in the elastic fibers [Picture 1]. It is thought that this small OLF is a degenerative enthesophytes that developed from the enthesis.

Differentiation between Degenerative Osteophytes and OLF

To understand the cause of the overgrowth of cartilaginous tissue that precedes the development of OLF, we investigated the changes in the enthesis of the *L. flavum* immunohistochemically using type-specific human monoclonal anti-collagen antibodies I–VI. Collagen Types I, III, and VI were found in the unossified ligaments. Type II collagen was demonstrated only in the ossified cartilage and non-mineralized cartilage layers of the enthesis [Picture 1]. There was no significant difference in the width of the ossified cartilage layer, but the difference in the width of the non-mineralized layer between the OLF group and the controls was substantial.

Active production of Type II collagen by the chondrocytes was revealed in the hyperplastic extracellular matrix. Therefore, it was thought that proliferation of Type II collagen at the enthesis resulted in the formation of a hypertrophied ligament before it developed into OLF.^[12]

Pathology of OLF

The OLF extended along the superficial layer of the hypertrophied ligament, as in OPLL. However, numerous fibro-cartilaginous cells with abundant matrices including Type II collagen were seen more abundantly in OLF than in OPLL. At the transitional areas adjacent to the ossified areas, there were various morphological phenomena: Irregular arrangement of the fibrous structures; abundant collagen fibers; irregular, ruptured, and fewer elastic fibers; numerous cartilage cells; calcified tissues; premature ostens; and proliferating vessels. These characteristic histological findings suggest that numerous Fibro cartilaginous cells existed in the abundant collagen fibers and produced a large amount of Type II collagen. Thus, the developmental mode of OLF was confirmed to be mainly endochondral ossification. The accompanying hypertrophic cartilaginous proliferation, however, showed additional intramembranous ossification at the margin of the thickened OLF.^[13]

Factors Related to the Development of Ossification

Role of mechanical stress

When considering the mechanism of ossification development, the theory states that both dynamic and static mechanical stresses act as local factors in the development of OLF under a general ossifying diathesis. Yamazaki *et al.* described disc degeneration and vertebral wedging acting as local factors that increase the tension of the *L. flavum*. They, therefore, indicated that localized mechanical stress that affected the *L. flavum* was a contributing factor to ossification development.^[14] Anatomically, the *L. flavum* in the thoracic region is subjected to static stress continuously, and it is greater in flexion than in extension. Therefore, it is thought that the development of OLF depends on mechanical stress. However, the formation of the ossified tissue at the enthesis (enthesopathy) is self-limited, and massive ossification is uncommon. OLF is therefore due to something more than enthesopathy.

Role of growth factors

Growth factors are believed to be important in the pathogenesis of the OPLL and the *L. flavum*. Bone morphogenetic proteins (BMPs) and transforming growth factor- β (TGF- β) may have important roles in the pathogenesis of OPLL and OLF. BMPs initiate cartilage and bone differentiation and induce new cartilage and bone formation *in vivo*, whereas TGF- β stimulates cartilage and bone formation via determined chondroprogenitor and osteoprogenitor cells *in vivo*. A recent study also

showed differentiation of spinal ligament fibroblasts into chondrocytes as a result of induction by BMP-2. On the other hand, Ono *et al.* examined the appearance and localization of TGF β 1, fibronectin, and bone alkaline phosphatase in OLF lesions from four patients. Based on these results, it is believed that TGF β 1 and fibronectin may contribute to the hypertrophy and ossification of the *L. flavum*. Recently, a key molecule called cartilage-derived morphogenetic protein (CDMP-1) and has been identified as a member of the TGF β super family. Nakase *et al.* reported that CDMP-1 was immunolocalized in spindle-shaped cells distant from the ossification front.^[15]

CONCLUSION

Radio-pathological factors that are likely to negatively affect the short term outcome includes MRI intramedullary signal changes and CPPD crystals positivity. Thus detailed radiological and histopathological studies are also required to predict the outcome. Long term follow up needed to determine the factors that predict the surgical outcome.

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A Study to Show Postprandial Hypertriglyceridemia as a Risk Factor for Macrovascular Complications in Type 2 Diabetes Mellitus

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Abstract

Introduction: Diabetes mellitus (DM) comprises a group of metabolic disorders that share the phenotype of hyperglycemia with a predisposition to macro- and micro-vascular complications.

Aims: Estimation of fasting triglycerides (TG) levels in patients with Type 2 DM with and without macrovascular complications. Compare postprandial triglyceridemia with already established independent markers such as fasting TG and high-density lipoprotein cholesterol.

Materials and Methods: This case-control study was done at SVS Medical College and Hospital, Mahabubnagar, between 2012 and 2014. In the present study, 75 patients between the age group of 30–65 years were selected, 50 patients with known diabetes were grouped as cases, and 25 healthy subjects without any coincidental illness were selected as control.

Results: The present study was undertaken in the Department of General Medicine, S.V.S Medical College and Hospital, Mahabubnagar.

Conclusion: Macrovascular complications are more commonly observed in type 2 diabetes Mellitus. Chief observation in the present study was that elevated fasting triglyceride level was significantly associated in patients with diabetes.

Key words: Hypertriglyceridemia, Macrovascular complications, Type 2 diabetes mellitus

INTRODUCTION

Diabetes mellitus (DM) comprises a group of metabolic disorders that share the phenotype of hyperglycemia with a predisposition to macro- and micro-vascular complications. India is referred to as the world diabetic capital; incidence of DM is rising in alarming proportions. The worldwide prevalence of diabetes has risen dramatically over the past two decades, from an estimated 30 million cases, in 1985, to 177 million, in 2000. Based on current trends, >360 million individuals worldwide will have diabetes by the year 2030. Although the prevalence of both Type 1 and Type 2 diabetes

is increasing worldwide, the prevalence of Type 2 diabetes is rising much more rapidly due to increasing obesity and reduced physical activity levels as countries become more industrialized.

Diabetes leads to impaired carbohydrate metabolism in association with derangement in lipid metabolism, virtually every lipid, and lipoprotein is affected in Type 2 DM. Elevated triglycerides (TG) associated with low high-density lipoprotein cholesterol (HDL-C) levels, the preponderance of small dense lipoproteins and increased apolipoprotein B in diabetics is the most prevalent pattern of dyslipidemia.

While fasting hypertriglyceridemia may be an independent risk factor for atherosclerosis, particularly in the presence of DM, this the association has not been consistent and fasting HDL-C appears to be a far more significant risk factor for atherosclerosis.

Diabetic patients are frequently hyperlipidemic (approximately 70% of diabetic patients are dyslipidemic)

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and are at a higher risk for coronary heart disease due to atherosclerosis that accounts for approximately 80% of all mortality caused by diabetes and for most of the hospitalizations necessitated by complications of diabetes. The major risk factors contributing to an excess of cardiovascular disease caused by diabetes include hyperglycemia, insulin resistance, dyslipidemia, hypertension, smoking, albuminuria, and pro-coagulant state. Type 2 diabetes is associated with the development of premature atherosclerosis. Diabetic dyslipidemia is believed to play an important role in the pathogenesis of accelerated atherosclerosis. The most important components of this dyslipidemia are elevated very low-density lipoproteins (VLDL), total TG, and a decreased HDL concentration in the serum. Several studies have proved that in type 2 diabetes, elevated TG levels may be a better predictor of ischemic heart disease (IHD) than elevated LDL cholesterol levels. Fasting hypertriglyceridemia has been consistently shown to be associated with a greater risk for coronary artery disease and atherosclerosis in those with Type 2 diabetes. It is now increasingly being recognized that atherosclerosis is a postprandial phenomenon. Serum TGs are generally increased maximally 3–6 h after a meal, particularly in diabetics. Once post-prandial hypertriglyceridemia occurs, it is exacerbated by the next meal and persists for the entire day. The vascular tree is exposed to this postprandial metabolic milieu most of the time.

As type 2 diabetic patients have significant postprandial lipid abnormalities, increased risk of atherosclerosis among them might be related to higher postprandial lipemia; hence, in the present study the aim is to investigate post-prandial lipid abnormalities in type 2 diabetic patients with and without macro-vascular disease and establish their role as a risk factor for atherosclerosis.

Aims and Objectives of the Study

Estimation of fasting TG levels in patients with type 2 DM with and without macrovascular complications. Estimation of post-prandial TG levels after an oral fat challenge in patients with type 2 DM with and without macrovascular complications. Compare post-prandial triglyceridemia with already established independent markers such as fasting TGs and HDL-C to establish post-prandial TG levels as an independent risk factor for atherosclerosis.

MATERIALS AND METHODS

This case–control study was done at SVS Medical College and Hospital, Mahbubnagar, between 2012 and 2014. In the present study, 75 patients between the age group of 30 and 65 years were selected, 50 patients with known diabetes were grouped as cases and 25 healthy patients without any coincidental illness were selected as controls.

The cases were sub divided into two groups based on the history of macrovascular complications. Group I comprises patients with type 2 DM with history of macrovascular complications such as IHD and cerebrovascular disease (CVD), Group II comprises patients with Type 2 DM, of >1 year duration without evidence of IHD, CVD and peripheral vascular disease, and Group III comprises normal healthy age- and sex-matched patients without any history of diabetes, or any evidence of risk factors.

The diagnosis of DM was based on the recommendations of International Expert Committee that included representatives of the American Diabetes Association, the International Diabetes Federation, and the European Association for the Study of diabetes. The patients of type 2 DM >1 year duration were included in the study.

Inclusion Criteria: Cases

The following criteria were included in the study:

1. Patients with type 2 DM who visited the OPD or admitted in the hospital were selected.
2. Aged around 30–65 years.
3. Duration of diabetes >1 year.
4. Type 2 DM admitted with myocardial infarction or cerebrovascular events.
5. Type 2 DM with a history of myocardial infarction or cerebrovascular events on treatment.
6. Type 2 DM on treatment but without any history of treatment or admission for any IHD or cerebrovascular events were included in Group II.

Inclusion Criteria: Controls

The following criteria were included in the study:

1. 25 normal healthy patients were selected as controls.
2. Aged around 30–65 years.
3. There was no previous history of hypertension.
4. There was no previous history of Type 2 DM.
5. There was no evidence of any micro or macrovascular complications in the past.

Exclusion Criteria

The following criteria were excluded from the study:

1. Those patients who are <30 years and patients >65 years.
2. Those patients with evidence of nephropathy, retinopathy, and peripheral vascular disease
3. Those patients who are known diabetic for <1 year.
4. Those patients with history of smoking or alcoholism.

RESULTS [TABLES 1-5]

The present study was undertaken in the Department of General Medicine, S.V.S Medical College and Hospital, Mahabubnagar.

Table 1: Distribution of subjects by age group

Age group in years	Group 1: Diabetes with complication	Group 2: Diabetes without complication	Group 3: Controls
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
30–40	9 (36)	9 (36)	8 (32)
41–50	8 (32)	7 (28)	10 (40)
51–60	7 (28)	8 (32)	6 (24)
61–70	1 (4)	1 (4)	1 (4)
Total	25 (100)	25 (100)	25 (100)
Mean±SD	45.16±9.4	45±10.8	45.6±9.34
Range	30–61	30–62	30–63

F=0.25, P=0.97. SD: Standard deviation

Table 2: Sex-wise distribution of subjects among three groups

Sex	Group 1: Diabetes with complication	Group 2: Diabetes without complication	Group 3: Controls
	<i>n</i> (%)	<i>n</i> (%)	<i>n</i> (%)
Male	17 (68)	16 (64)	17 (68)
Female	8 (32)	9 (36)	8 (32)
Total	25 (100)	25 (100)	25 (100)

$\chi^2=0.12$, P=0.947

Table 3: Distribution of subjects based on duration of diabetes

Duration of DM years	Group 1: Diabetes with complication	Group 2: Diabetes without complication
	<i>n</i> (%)	<i>n</i> (%)
1–5	3 (12)	17 (68)
6–10	18 (72)	8 (32)
11–15	4 (16)	0 (0)
Total	25 (100)	25 (100)
Mean±SD	8.28±2.37	3.5±1.7

DM: Diabetes mellitus

Table 4: Distribution of subjects based on treatment

Rx	Group 1: Diabetes with complication	Group 2: Diabetes without complication
	<i>n</i> (%)	<i>n</i> (%)
OHA	11 (44)	18 (72)
Insulin	7 (28)	5 (20)
Both	7 (28)	2 (8)
Total	25 (100)	25 (100)

$\chi^2=4.81$, P=0.09

A total of 75 age-, sex-, and body mass index (BMI)-matched subjects were recruited from S.V.S Medical College and Hospital for the present study, of which 25 subjects constituted the control group called as Group 3 and remaining 50 subjects constituted the case group which was subdivided into two groups: Group 1 comprised 25 subjects with a history of diabetes and macro vascular complication and Group 2 comprised 25 subjects with a history of diabetes without macrovascular complication.

The following parameters were analyzed.

- Fasting blood glucose
- Post-prandial blood glucose

- Blood urea
- Serum creatinine
- Total cholesterol
- Fasting TGs
- LDL cholesterol
- HDL-C
- VLDL
- Serum TG (after an oral fat challenge).

The results were expressed in mg/dl for glucose, urea, creatinine, total cholesterol, HDL, LDL, VLDL, and TG.

The data were analyzed using SPSS software version 17.0. Descriptive results are expressed as mean and SD of various parameters in different groups, multiple comparisons ANOVA was used to assess the significance of the difference of mean values of different parameters in between control, groups, diabetes without complication, and diabetes with complication. F value was used to calculate the significance in between groups.

The age of the patients varied from a minimum age of 30 years to a maximum of 63 years. The mean age of the patients in the three groups was not significantly different from each other F = 0.25, P > 0.05.

Among the total 50 patients, 33 were males (66%) and 17 were females (34%).

In Group 1 of the 25 patients, 17 were males (68%) and 8 were females (32%).

In Group 2 of the 25 patients, 16 were males (64%) and 9 were females (36%).

Table 5: Distribution of subjects according to the BMI in different groups

BMI	Group 1: Diabetes with complication	Group 2: Diabetes without complication	Group 3: Controls
	n (%)	n (%)	n (%)
21–25	10 (40)	12 (48)	18 (72)
26–30	1 (56)	12 (48)	7 (28)
31–35	1 (4)	1 (4)	0 (0)
Total	25 (100)	25 (100)	25 (100)
Mean±SD	26.2±2.42	25.92±2.76	24.4±2.25
Range	21–31	21–31	21–39

F=3.82g, P=0.026. BMI: Body mass index

In Group 3 of the 25 patients, 17 were males (68%) and 8 were females (32%).

There was no significant difference observed in the sex distribution of subjects among the three groups; Chi-square value was 0.12 and significance $P > 0.05$.

In Group 1, 11 patients were in OHA (44%), and 7 patients were on insulin (28%), whereas 7 patients (28%) received both insulin and OHA together. In Group 2, 18 patients were in OHA (72%), and 5 patients were on insulin (20%), whereas 2 patients (8%) received both insulin and OHA together. There was no significant difference observed in the mode of treatment Chi-square value 4.81, and significance $P > 0.05$.

The mean BMI was significantly more in Group 1 compared to Group 3 ($P = 0.039$) there was no significant difference in the mean BMI between Group 3 and Group 2 ($P = 0.118$) and Group 2 and Group 1 ($P = 0.878$).

The mean values for FBS, PPBS, total cholesterol, creatinine, and post-meal TGs are significantly higher in diabetes with complication group compared to diabetes without complication and controls.

The mean values of fasting TGs, LDL, and VLDL were not significantly higher in diabetes with complication group compared to diabetes without complication.

The mean value of HDL was not significantly lower in diabetes with complication group compared to diabetes without complication.

The mean values for FBS, PPBS, total cholesterol, creatinine, VLDL, and post-meal TGs are significantly higher in diabetes without complication group compared to controls, whereas HDL values were significantly lower in diabetes without complication group compared to controls as shown in Table 6-8.

In Group 1, 7 patients (28%) had suffered from MI as the complication, 8 patients (32%) had suffered from

cerebrovascular accident (CVA) as the complication, and 10 patients (40%) had suffered from both MI and CVA as the complication.

To assess the maximum sensitivity, specificity, and diagnostic efficiency of TGs in identifying abnormality, the best cutoff values are calculated using ROC analysis. Best cutoff values are established by selecting a point closer to top left-hand curve that provides greatest sum of sensitivity and specificity as shown in Table 9. Diagnostic efficiency is defined as the portion of all currently classified as having or not having complications.

$$\text{Diagnostic efficiency} = \frac{\text{True Positive} + \text{True Negative}}{\text{Total No. Of Patients Evaluated}}$$

Best cutoff values for different parameters along with sensitivity, specificity, and diagnostic efficiency values for Group 1 and Group 2 are presented in Table 10.

At 167.5 mg/dl fasting TGs levels were able to differentiate the presence of complications in diabetes with 88% sensitivity and 40% specificity compared to post-prandial TGs which had 80% sensitivity and 60% specificity and an overall diagnostic efficiency of 70% at 325 mg/dl.

DISCUSSION

DM is the most common metabolic disorder, a social and economic burden to the society due to the increased morbidity and mortality associated with its complications.^[1]

Macrovascular disease is a major cause of death in diabetic individuals.

Since many diabetic individuals have multiple risk factors for atherosclerosis, the relative risks of IHD and CVD are 2–4-fold and 2–3-fold higher, respectively, than the risk in nondiabetic subjects.^[2]

Table 6: Mean±SD values of studied parameters in diabetes with complication, diabetes without complication and controls

Parameter	Group 1: Diabetes with complication	Group 2: Diabetes without complication	Group 3: Controls
	Mean±SD	Mean±SD	Mean±SD
FBS	205.2±71.4	150.6±26.6	85.1±9.07
PPBS	294.68±103.48	204.16±45.62	114.44±13.8
Urea	29.64±5.2	27.92±3.55	26.8±2.91
Creatinine	1.07±0.19	0.89±0.14	0.84±0.16
Total cholesterol	196.6±32.9	176.2±30.17	156.8±19.08
Triglyceride fasting	223.43±61.8	199.6±56.9	126.08±24.86
HDL	31.8±7.5	31.6±6.69	44.92±5.23
LDL	120±30.2	103.29±28.3	86.6±21.7
VLDL	44.6±12.3	39.9±11.3	25.2±4.97
Triglyceride post fat meal	407.2±109.8	337.6±80.7	211.3±40.8

SD: Standard deviation, HDL: High-density lipoprotein, LDL: Low-density lipoprotein, VLDL: Very low-density lipoproteins

Table 7: F, P value of various parameters between cases and controls

Parameter	F value	P value
FBS	45.9	<0.001
PPBS	46.9	<0.001
Urea	3.18	0.047
Creatinine	12.6	<0.001
Total cholesterol	12.58	<0.001
Triglyceride fasting	25.13	<0.001
HDL	33.77	<0.001
LDL	9.53	<0.001
VLDL	25.06	<0.001
Triglyceride post fat meal	36.519	<0.001

HDL: High-density lipoprotein, LDL: Low-density lipoprotein, VLDL: Very low-density lipoproteins

Table 8: ANOVA multiple comparison of significance

Parameter	Group 1	Group 2
	Group 2	Group 3
FBS	<0.001	<0.001
PPBS	<0.001	<0.001
Urea	0.322	0.616
Creatinine	0.002	0.605
Total cholesterol	0.042	0.057
Triglyceride fasting	0.257	<0.001
HDL	0.994	<0.001
LDL	0.097	0.102
VLDL	0.259	<0.001
Triglyceride post fat meal	0.014	<0.001

HDL: High-density lipoprotein, LDL: Low-density lipoprotein, VLDL: Very low-density lipoproteins

In the present study, the mean age group in the controls was 45.6 years, in diabetic patients without complication 45 years and diabetic patients with complication 45.16 years.

In a study done by Kumar *et al.*: On evaluation of Post-Prandial hyper triglyceridemia in Patients with Type 2 DM with and without macrovascular disease, have shown that the mean age group in the controls was 51.1 years, in diabetic patients without complication 54.6 years and in diabetic patients with complication 54.5 years respectively.

Table 9: Distribution of subjects based on complication in Group 1

Complication	Group 1: Diabetes with complication
	n (%)
MI	7 (28)
CVA	8 (32)
Both	10 (40)
Total	25 (100)

CVA: Cerebrovascular accident

Summary

A prospective study of 75, sex, BMI matched patients, in this 50 patients are cases in this two groups are there group 1 is TYPE 2 DM with macrovascular complications and group 2 is TYPE 2 DM without any macrovascular complications and remaining 25 were controls this is group 3 without DM was done in Kakatiya Medical College, Mahatma Gandhi Memorial Hospital, Warangal Dist., Telangana State. The inclusion and exclusion criteria were followed according to the criteria's mentioned in the materials and methods.

1. The age range of the patient was 30–63 years, with male and female ratio in Group 1 is 2.125:1, in Group 2 is 1.77:1, and in Group 3 is 2.125:1.
2. Duration of diabetes in Group 1 is around 8.28 years, in Group 2 is 3.5 years.
3. Among the cases 44% of Group 1 and 72% of Group 2 on OHA'S, 28% of Group 1 and 20% of Group 2 on insulin, 28% of Group 1 and 8% of Group 2 taking both medications.
4. Fasting blood sugars in Group 1; 205.2 mg/dl, Group 2; 150.6 mg/dl, and Group 3 85.1 mg/dl, fasting TGs in Group 1; 223.43 mg/dl, Group 2; 199.6 mg/dl, and Group 3; 126.08 mg/dl.
5. Post-prandial blood sugars in Group 1; 294.68 mg/dl, Group 2; 204 mg/dl, and Group 3 114.6 mg/dl, post-prandial TGs after fat meal in Group 1; 407.2 mg/dl, Group 2 337.6 mg/dl, and Group 3; 211.3 mg/dl.

Table 10: Best cutoff values, diagnostic efficiency, sensitivity, specificity, in discriminating diabetes with complication and diabetes without complication

Parameter	Best cut off values	Sensitivity (%)	Specificity (%)	Diagnostic efficiency (%)
Duration of diabetes	6.5 years	80	84	82
Triglycerides fasting	167.5 mg/dl	88	40	64
Triglycerides post fat meal	328.5 mg/dl	80	60	70

6. In Group 1; 28% of patients having MI, 32% of patients having CVA, and 40% having both.

CONCLUSION

1. Macrovascular complications are more commonly observed in Type 2 DM.
2. Chief observation in the present study was that elevated fasting TG level was significantly associated in patients with diabetes. However, the more higher association was observed in this study between elevated post-prandial TG level and patients with diabetes and macrovascular complication.
3. Post-prandial hypertriglyceridemia, in addition to

fasting hypertriglyceride levels, may be an independent risk factor for early atherosclerosis in type 2 diabetes.

4. Evaluating not only FTG level but also PPTG level during clinical assessment of patients with type2 diabetes is important as PPTG was observed to have higher diagnostic efficiency compared to FTG levels.

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Study of Lipid Profile in Patients with Chronic Kidney Disease on Conservative Management and Hemodialysis

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Abstract

Background: Chronic renal failure results in profound lipid disorders which stem largely from the deregulation of high-density lipoproteins (HDL) and triglyceride-rich lipoprotein metabolism which increases the risk of arteriosclerotic cardiovascular disease which is the leading cause of mortality among chronic kidney disease (CKD) patients.

Materials and Methods: This is a cross-sectional observational study conducted after ethical committee approval about lipid profile on CKD patients on conservative management and hemodialysis compared with normal healthy controls at our hospital and movement for global mental health between June 2015 and June 2016, after considering inclusion and exclusion criteria. Lipid profile was collected from eligible patients and controls.

Results: There were a statistically significant decrease in HDL and increase in thyroglobulin, low-density lipoprotein (LDL), and total cholesterol levels when compared with normal healthy controls. There was a negative correlation between serum creatinine and HDL levels. Among CKD patients, there was a significant decrease in HDL and increase in LDL level in both conservative and hemodialysis groups.

Conclusion: Treatment of dyslipidemia helps to decrease mortality in CKD patients.

Key words: Chronic kidney disease, Hypertriglyceridemia, Lipid profile

INTRODUCTION

Chronic kidney disease (CKD) has become a public health problem with a global prevalence of around 8–16%^[1,2] and with an estimate of >10% (i.e., >20 million) prevalence in the adult United States population.^[3] Data from National Health and Nutrition Examination Survey showed that CKD prevalence among ages 60 and above increased from 18.8% in 1988-1994 to 24.5% in 2003-2006.^[4]

Cardiovascular diseases (CVD) remain the number one cause of death among patients with kidney diseases.^[5,6] The United States Renal Data System 2013 annual data report

indicates that CKD patients not only have higher rates of congestive heart failure, acute myocardial infarction, and cerebral vascular accident compared to non-CKD patients but they also have lower survival rates compared to non-CKD patients. This survival further decreases with severity of CKD.^[7]

Dyslipidemia is a well-established risk factor for CVD in the general population but this relationship is not straightforward in CKD population. While dyslipidemia is associated with CVD in pre-dialysis CKD and hemodialysis population, data regarding its association in peritoneal dialysis patients is lacking. With an ever increasing CKD burden worldwide, providing treatments for modifiable risk factors, like dyslipidemia, becomes an essential component for improving outcomes.

Since hyperlipidemia can be modulated by therapeutic intervention, it is worthwhile to study and compare lipid profile abnormalities in CKD patients. Indian studies on lipid abnormalities in CKD have not been

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consistent. Sharma *et al.*^[10] and Kunde *et al.*^[11] found no hyperlipidemia, whereas Gupta *et al.*^[12] and Das *et al.*^[13] observed hypertriglyceridemia and reduced high-density lipoprotein (HDL) levels in CKD patients as in western countries. In view of inconsistency and limited evidence in the southern part of this country, it was decided to study the lipid profile in our patients with CKD patients.

Aims of the Study

The aims of this study are as follows:

1. To estimate various lipid profile abnormalities in CKD patients and normal healthy controls.
2. To study the correlation between the serum creatinine levels and lipid profile abnormalities in CKD.
3. To compare lipid profile in patients with CKD on conservative management and hemodialysis.

MATERIALS AND METHODS

This study was conducted in 50 patients with CKD and 50 normal healthy persons.

All the patients in this study group were selected from the Department of Medicine, MGM Hospital, Warangal, during June 2015–June 2016. The controls were selected from those who were accompanying the patients.

Study Design

This was a cross-sectional observational study.

Inclusion Criteria for Patients

The following criteria were included as patients in the study:

1. Patients between the age group of 15 and 85 years with established CKD.
2. Patients who were on conservative or dialysis treatment for CKD.
3. Established renal failure was ensured by radiological evidence or biochemical evidence for >3 months.

Inclusion Criteria for Controls

Normal healthy patients who were age and sex related to patients were included as controls.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients with acute renal failure and nephrotic syndrome.
2. Patients having diabetes, liver disease, Cushing's, or other metabolic disorder.
3. Those who are on drugs affecting lipid metabolism such as β -blockers, statins, and oral contraceptive pills.
4. Female patients who were pregnant.

Patients with CKD and controls included in the study

Table 1: Age distribution in patients

Age in years	Number of patients (%)
15–25	2 (4)
26–35	14 (28)
36–45	11 (22)
46–55	11 (22)
56–65	10 (20)
66–75	1 (2)
>75	1 (2)
Total	50 (100)

Table 2: Sex distribution

Gender	Total (%)
Male	34 (68)
Female	16 (32)

Table 3: Comparison of lipid profile between other studies and our study

Studies	TGL	LDL	HDL	TC
Shah <i>et al.</i>				
Study group	222.78	109.63	52.69	211.33
Control group	121.78	140.33	44.22	184.11
Diana <i>et al.</i>				
Study group	194.051	170.148	38.6	239.75
Control group	06.28	131.47	2.53	189.14
Our study				
Study group	186.86	131.57	42.82	209.29
Control group	102.18	112.26	54.14	184.89

TGL: Triglyceride, LDL: Low-density lipoprotein, HDL: High density lipoprotein, TC: Total cholesterol

were matched according to age and the results were analyzed.

Written consent was obtained from both patients and controls. A detailed history regarding symptoms and duration of the kidney disease, hypertension, diabetes, smoking, alcoholism, drug intake, and treatment was elicited.

A detailed clinical examination was performed in all patients. Blood pressure, renal function tests, and abdominal ultrasonogram were done for all patients. Blood sample was taken for lipid profile from patients and controls.

ATP-III NCEP guidelines were applied to the lipid profile.

Glomerular filtration rate (GFR) was calculated using modification of diet in renal disease (MDRD) formula:

$$\text{GFR (mL/min/1.73 m}^2\text{)} = 175 \times (S_{cr})^{-r^5} \text{ mL} \times (\text{Age})^{-1} \times (\text{Ag} \times (0.742 \text{ if female}) \times (1.212 \text{ if African American})).$$

Table 4: Various studies on progression of kidney disease and associated plasma lipid abnormalities

Study	Patients	Number of patients	Follow up	Lipid
MDRD	CKD	840	2.2 years	↓HDL
Samuelsson <i>et al.</i>	CKD	73	3.2 years	↑TCh, ↑LDL, ↑ApoB
Locatelli <i>et al.</i>	CKD	456	2 years	No relationship
Massy <i>et al.</i>	CKD	138	12 years	↑TG, ↓HDL
Our study	CKD	50	-	↓HDL, ↑TG, ↑TC, ↑LDL

TGL: Triglyceride, LDL: Low-density lipoprotein, HDL: High-density lipoprotein, TC: Total cholesterol, CKD: Chronic kidney disease

All individuals with eGFR <60 ml/min/1.73 m² are taken into the study.

Ultrasonogram showing reduced kidney size (<9 cm) was taken as radiological evidence of CKD.

RESULTS AND OBSERVATIONS

Age Distribution

Age of the patients varied from 17 years to 82 years. Majority of patients fall in the age group between 26 and 55 years. The mean age in this study was 45.28 years.

Sex Distribution

Males constitute 34 (68%) and females constitute 16 (32%) in this study.

Occupation

Patients in this study belonged to low socioeconomical status which is being reflected by their occupations. A quarter of the patients were doing agriculture or agriculture-related profession. Most women were homemakers.

Blood Pressure Readings

Patients with blood pressure of >140/90 mmHg were considered hypertensives. Most patients (39 patients) were hypertensives at the time of presentation. Only 11 patients had blood pressure <140/90 mmHg.

Personal Habits

In this study, 38% (19 patients) were smokers and 50% (25 patients) were alcoholics.

Renal Parameters

Lowest urea value found in these patients was 17 mg/dl and the highest was 230 mg/dl. Mean value of blood urea was 121.22. Creatinine values ranged between 0.5 mg/dl and 22.6 mg/dl. Mean values of creatinine was 6.74 mg/dl.

Radiological Examination

Radiological examination was done by abdominal ultrasonogram. In 37 patients (74%), the right kidney was <9 cm; in 34 patients (68%), the left kidney was <9 cm; and both kidneys were <9 cm in 30 patients (60%). Both kidneys were normal in 9 patients.

Treatment Scenario

Among the 50 patients, 33 patients (66%) were on conservative treatment only and 17 patients (34%) received hemodialysis. 66% of patients were treated with drugs only. During our study, no patients were admitted with a history of previous transplantation [Table 1].

Lipid Pattern in Our Study

HDL PATTERN Serum HDL values ranged between 30mg/dl to 80mg/dl. Patients showed abnormal HDL levels (<40 mg/dl) were 25 (50%). Its mean value was 42.82 and standard deviation was 12.37 [Table 2]. Its mean value was 42.82 and standard deviation was 12.37. Among the control groups, the lowest value of HDL was 46 mg/dl and the highest was 65 mg/dl. Their mean was 54.14 and standard deviation was 4.06.

Mean deviation and standard error of the difference between two means were calculated. The standard error of the difference between two means was 1.841. This was statistically significant since the actual difference was 2 times higher than the standard error of difference between two means. $P < 0.05$ was statistically significant. It showed that there was a significant reduction in HDL-C levels in patients with CKD than that of controls.

LDL PATTERN Lowest value of LDL 65 mg/dl and the highest value was 173mg/dl. Abnormally high LDL levels (>130mg/dl) were found in 23 patients and they constitute 46%. Their mean value was 131.57 mg/dl and standard deviation was 26.44.

In controls, the mean and SD were 112.26 and 13.69 (range 85–150 mg) respectively. Standard error of difference between two means was 4.21. Actual difference between two means was 2 times greater than the standard error of difference between two means. Student t value was calculated and $P < 0.05$ was considered as statistically significant.

Triglyceride (TGL) pattern TGL value in our study group ranged between 95 mg/dl and 350 mg/dl. Range of TGL value in control group was 90–122 mg/dl. TGL levels were abnormal in 24 patients which constitute 48%. Mean and standard deviation of the study group were 186.86 and 49.94, respectively. In controls, the mean and standard

deviation were 102.18 and 7.84. Standard error of the difference between two means was 7.140. $P < 0.05$ was considered as statistically significant.

Total cholesterol (TC) The range of TC levels in the study group was 120–258 mg/dl. The lowest value in the control group was 119 and the highest value was 222 mg/dl. TC was >240 mg/dl in 8 patients (16%).

The mean values of the study group and control group were 209.29 and 184.89 mg/dl, respectively. Their standard deviations were 36.9 and 15.31, respectively. Standard error of the difference between two means was obtained. It was 5.706, but the actual difference was >2 times higher than that of standard error of difference between the two means. $P < 0.05$ was considered to be statistically significant.

DISCUSSION

This study was conducted to determine the lipid profile changes in CKD patients on conservative management and regular hemodialysis and to compare them with normal healthy controls [Table 3].

The study population was 100, of which 50 were patients and 50 were controls. They were selected as per the inclusion criteria. Serum TC, HDL cholesterol (HDL-C), LDL-C, and TGLs were measured using autoanalyzer. The results were statistically analyzed.

In our study, most common lipid abnormalities found were low HDL levels (50%) and hypertriglyceridemia (48%) along with a modest increase in LDL and TC.

Decreased HDL Levels

The low HDL levels in patients with CKD in our study were consistent with Lee *et al.* who studied the lipid profile in CRF patients. This low HDLC levels were also an independent risk factor for the development of CKD in the Framingham offspring study.

Several mechanisms may underlie these reductions in HDLC levels, which is usually an indication of impaired reverse cholesterol transport. Thus, uremic patients usually exhibit decreased levels of apolipoprotein AI and AII (the main protein constituent of HDL). Diminished activity of LCAT (the enzyme responsible for the esterification of free cholesterol in HDL particles) as well as increased activity of cholesterol ester transfers protein that facilitates the transfer of cholesterol esters from

HDL to TGL-rich lipoproteins that reduce serum concentrations of HDL cholesterol. In MDRD study, low

HDL levels in CKD patients were one of the independent risk factors for the progression of kidney disease. Although, in our study, the mean value was 42.82, it is significantly less than the age-matched healthy controls.

Elevated TGLs

Hypertriglyceridemia was observed in 48% of patients. TGLs were significantly elevated in our study than control group. Abnormal TGL values were found in 48% of patients in our study. Shah *et al.* most western studies demonstrated that hypertriglyceridemia was the abnormality found in CKD patients. Gupta *et al.*, Das *et al.*, Bagdade, and Chan *et al.* also found that hypertriglyceridemia was the major abnormality in their studies.

Hypertriglyceridemia represents an early feature of renal failure. Indeed, previous studies have shown that patients with impaired renal function exhibit increased concentrations of TGLs even though serum creatinine levels were within normal limits.

In addition, individuals with renal insufficiency usually display abnormal increase in serum TGLs after a fat meal (postprandial lipemia). Experimental studies revealed that accumulation of TGL-rich lipoprotein (very LDL [VLDL], chylomicrons, and their remnants) in individuals with predialysis CKD is mainly due to their decreased catabolism. The downregulation of the expression of several genes along with the changes in the composition of lipoprotein particles and the direct inhibitory effect of various uremic toxins on the enzymes involved in lipid metabolism represents the most important pathophysiological mechanism underlying the development of hypertriglyceridemia in renal failure. Interestingly, it has been proposed that secondary hyperparathyroidism may also contribute to the impaired catabolism of TGL-rich lipoproteins and that parathyroidectomy or the administration of calcium channel blocker Verapamil may partially ameliorate the hypertriglyceridemia of CKD. It is well known that impaired insulin sensitivity represents an early feature of CKD. Thus, it could be due to insulin resistance driven over production of VLDL may significantly contribute to the development of hypertriglyceridemia in CKD patients.

Elevated LDL

LDL was significantly elevated than that of controls in our study. We found that 44% of patients showed elevated LDL levels. This observation is similar to the studies of Lee *et al.* In an article published in archives of internal medicine, 32 patients were studied and compared the lipid profile on CKD and non-CKD patients. It was found that 60.5% of patients have elevated LDL-C than non-CKD patients ($P = 0.06$). However, most studies

find that uremic patients usually have normal or slightly reduced concentrations of LDL-C levels, and they exhibit important disturbance in the density distribution of LDL subfraction that is characterized by a predominance of small-dense LDL particles.

In our study, this elevated LDL-C may be due to the inaccuracy of Friedewald formula in estimating LDL-C.

Elevated TC

TC levels were significantly elevated in our study group. We observed the same findings in the study by Lee *et al.* However, most of the studies did not observe hypercholesterolemia. The possible reason for the hypercholesterolemia in our study is significant elevation of cholesterol-containing lipid fractions (IDL and LDL).

Correlation Studies

It was found that serum TGLs, TC, and LDL were not correlated significantly, whereas serum HDL levels had a significant negative correlation with serum creatinine. It means that when serum creatinine level rises, serum HDL level falls. This was the observation found in MDRD study.

Lipid Profile in CKD Patients on Conservative Management: Reported Studies

1. The characteristic plasma lipid abnormality is moderate hypertriglyceridemia - this is due to impaired carbohydrate tolerance leading to the increased hepatic synthesis of VLDL and decreased activity of lipoprotein lipase and hepatic TGL lipase leading to decreased fractional catabolic rate of TGLs.
2. Decrease in HDLC - this is due to the deficiency of LCAT which is essential for the esterification of cholesterol. LCAT plays an important role in HDL-mediated cholesterol uptake from the extrahepatic tissues and serves as a main determinant of HDL maturation and plasma HDLC level. Decrease in HDL level is also contributed by elevation of CETP.
3. Normal or slightly increased LDLC level.
4. Normal or slightly increased TC level.

Observation on Lipid Profile Changes on Conservative Management Showed the Following Results

The final results in our study revealed are as follows:

1. Significant decrease in HDLC.
2. Significant increase in TGL.
3. Non-significant changes in serum LDL and TC. According to Bagdade *et al.* there was moderate hypertriglyceridemia and decrease in HDL levels in CKD patients. Indian studies on lipid profile abnormalities in chronic renal failure have varied from no abnormalities at all to significant abnormality Hypertriglyceridemia and reduced HDL as described

in Western literature. Sharma *et al.* and Kunde *et al.* observed no hyperlipidemia in patients of CKD. On the other hand, Gupta *et al.* and Das *et al.* observed lipid abnormalities similar to those reported in Western studies.

Lipid Profile in CKD Patients on Hemodialysis: Reported Studies

1. Moderate increase in TGL levels.
2. Decrease in HDL levels.
3. Normal/slightly elevated TC and LDLC.
4. Increased Lp(a), increased apoB and apoA IV, and decreased apoA I.

In addition to factors responsible for renal dyslipoproteinemia, the other contributing factors in a CKD-HD patient are as follows:

1. Reduced lipolytic activity following repeated heparinization. The exact reason is not understood but may be due to functional insulin deficiency or insulin resistance and also due to the presence of non-dialyzable factor of lipolytic enzyme (lipoprotein lipase), in the plasma of CKD-HD patients. The changes are more pronounced with the use of conventional heparin than low molecular weight heparin.
2. The presence of acetate in the dialysate which gets converted to long chain fatty acids and later to cholesterol in the liver.
3. Carnitine deficiency where carnitine is necessary for fatty acid oxidation.

Observation on lipid profile changes on hemodialysis showed the following results:

The final results revealed are:

1. Significant decrease in HDLC.
2. Significant increase in triglyceride levels.
3. Non-significant changes in serum TC and LDL-C.

Variation in lipid profile in hemodialysis patients in previous studies has not been consistent. Shah *et al.* noticed hypertriglyceridemia in 11% of patients on hemodialysis. Zolezzi *et al.* noticed raised TC in 20%, decreased HDL in 50% and raised TGLs in 45% of their patients on hemodialysis. Ibels *et al.* noticed a decrease in TGL levels after dialysis.

Limitations of the Study

1. Most studies showed low or normal LDL-C levels, whereas this study observed significantly elevated LDL-C levels for reasons little known.
2. Smoking, alcoholism and may alter the lipid pattern in the body which were not excluded due to lack of cumulative dose criteria Their influences in the study group also have to be considered.

CONCLUSION

1. L-C levels were lower and TGLs, TC, and LDL-C levels were higher in the study group compared to controls. All were statistically significant.
2. There was a negative correlation exists between serum HDL-C level and serum creatinine levels which were statistically significant.
3. There was a significant decrease in HDL-C and increase in TGLs in both conservative and hemodialysis groups. Decrease in HDL is more in conservative management and increase in TGLs is more in hemodialysis group.

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Hyperuricemia as a Prognostic Marker in Acute Ischemic Stroke

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Abstract

Serum uric acid has also been linked to prognosis of patient with acute ischaemic stroke. Evidence suggests that increased level of uric acid is protective in patients with acute ischaemic stroke although this issue has been debated, the neuroprotective role of uric acid in patient with acute ischaemic stroke is now established. So it could be marker of value in prognosis of patient with acute ischaemic stroke.

Key words: Risk factor, Stroke, Uric acid

INTRODUCTION

Stroke entails a high socioeconomic burden due to increased mortality and morbidity. Early identification of individual at risk could be of help in stroke entails a high socioeconomic burden due to increased mortality and morbidity. Early identification of individual at risk could be of help in designing primary prevention strategies.^[1]

The role of serum uric acid (SUA) level as an independent risk factor for stroke has been questioned for many years. Evidence from epidemiological studies suggest that elevated SUA levels may predict an increased risk for stroke and cardiovascular events.^[2,3] Moreover, therapeutic modalities with an SUA-lowering potential have been shown to reduce cardiovascular disease morbidity and mortality. In this respect, SUA levels could be as an “easy to measure” serum marker in selecting and appropriately treating subjects at risk.

SUA has also been linked to prognosis of patient with acute ischemic stroke. Evidence suggests that increased

level of uric acid is protective in patients with acute ischemic stroke.^[4] Although this issue has been debated, the neuro-protective role of uric acid in patient with acute ischaemic stroke is now established.^[5] Hence, it could be marker of value in prognosis of patient with acute ischemic stroke.

Despite the widely held view that elevated SUA concentrations confer increased risk of atherosclerotic disease, there is no compelling biological evidence of a causal link. Free radical activity is characteristically increased in patients with any one of several major cardiovascular risk factors and is thought to play a key role in the early development of atherosclerosis. As an antioxidant, uric acid could be expected to confer protection against free radicals. In the context of acute ischemic stroke, there is growing evidence to support a protective role for uric acid. This shows the importance of oxidative stress in the pathogenesis of acute stroke and strengthens the rationale for further investigation of antioxidant treatments in this condition. The feasibility of uric acid administration to temporarily increase circulating concentrations has recently been established and might allow its potential therapeutic impact to be examined in a clinical setting. Ongoing basic research is likely to shed new light on the cardiovascular effects of uric acid and will hopefully allow the significance of serum concentrations to be interpreted more clearly.

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The present study is designed to study the association between SUA and stroke. This study also intends to study the association between major and minor risk factors for stroke and SUA level in patients of acute ischemic stroke.

Aims and Objectives

The objectives of this study were as follows:

To study the clinical profile of acute ischemic stroke patients with normal and elevated uric acid.

To study the incidence of ischemic stroke with uric acid levels and its correlation with major and minor risk factors (i.e., hypertension, diabetes, smoking, alcohol, and hyperlipidemia).

MATERIALS AND METHODS

Population

The present study was carried out on 100 patients of acute ischemic stroke admitted at Mahatma Gandhi Memorial Hospital, Warangal.

Study

This was a prospective observational study.

Period of Study

The study duration was from January 2016 to August 2017.

Inclusion Criteria

Patients with stroke as defined by the World Health Organization (WHO) criteria

Stroke or cerebrovascular accident was defined as rapidly developing clinical symptoms and signs of focal or global loss of cerebral function with symptoms lasting more than 24 h or leading to death with no apparent cause other than that of vascular origin (WHO, 1980).^[6] In each case, the diagnosis of recent ischemic stroke was confirmed by computed tomography (CT) scan of brain.

Exclusion Criteria

Patients having disease known to increase SUA or taking drugs which can cause hyperuricemia were excluded from the study.

Hemorrhagic stroke, old cases of stroke, was excluded from the study.

Patient admitted within 3 h and had thrombolysis.

Secondary causes of hyperuricemia as mentioned.

Methods

The prospective observational study conducted in MGM Hospital, Warangal. On admission in hospital, detailed

history was taken and thorough physical examination was performed as per pro forma made. The severity of neurological deficit was recorded according to the Scandinavian stroke scale (SSS).

Individual found suitable for the study was subjected to the following investigation:

- Hemoglobin, total leukocyte count, differential leukocyte count, platelet count, and erythrocyte sedimentation rate.
- Blood sugar (fasting and postprandial). Patient was diagnosed as having diabetes based on the Americans with disabilities act 2004 criteria.
- Blood urea, serum creatinine, and serum electrolytes.
- Lipid profile was obtained after 12 h of fasting.
- Electrocardiography was done in every case to detect atrial fibrillation, ischemic heart disease, and left ventricular hypertrophy.
- Echocardiography was done as and when indicated.
- Echocardiography was done as and when indicated

Table 1.

CT scan of the brain was done in every patient to confirm the diagnosis of acute ischemic stroke.

SUA - hyperuricemia was defined as SUA level >7 mg/dl Table 2.

Table 1: Distribution of cases according to age and sex in patients with acute ischaemic stroke

S. No.	Age groups (in years)	Sex		Total (100)
		Male (%)	Female (%)	
1	<40	05 (09)	01 (2)	06
2	41–50	08 (15)	08 (17)	16
3	51–60	12 (22)	11 (24)	23
4	61–70	17 (31)	17 (37)	34
5	71–80	10 (19)	09 (20)	19
6	>81	02 (04)	00 (00)	02
7	Total	54	46	100

Table 2: Distribution of cases according to age and its relation with uric acid in acute ischaemic stroke

S. No.	Age groups (in years)	Level of SUA		Total (100)
		SUA ≤7 mg% n=71 (%)	SUA >7 mg% n=29	
1	<40	05 (07)	01 (3.5)	06
2	41–50	15 (21)	01 (3.5)	16
3	51–60	16 (23)	07 (24)	23
4	61–70	22 (28)	12 (41)	34
5	71–80	11 (18)	8 (28)	19
6	>81	02 (03)	00 (00)	02
7	Total	71	29	100

≤60 years versus >60 years; Chi-square; $P < 0.05$; significant. SUA: Serum uric acid

OBSERVATION AND RESULTS

About 54% of patients were male and 46% of patients were female, majority of patients (34%) were in the age group of 61–70 years.

Of 29 hyperuricemic patients, 20 (69%) were above the age of 60 years as compared to patient with normal SUA in whom out of 71 only 35 (49%) patients were above 60 years.

This study includes 54 males and 46 females, males were having higher incidence (31%) of hyperuricemia as compared to females (26%) Table 3.

Association of uric acid with smoking in acute ischemic stroke patients was not significant Table 4.

The prevalence of alcoholism in the present study was 33% Table 5. Of which, 13 (39%) patients are hyperuricemic. All alcoholics were male. Although overall there was no significant correlation in between SUA and alcoholism. Statistically significant positive correlation $P < 0.05$ was present among male alcoholics.

None of the hyperuricemic patient was normotensive Table 6. In 29 patients with hyperuricemia, 11 (38%) were having prehypertension and 18 (62%) were hypertensive as compared to patient with normal SUA where 54% were hypertensive.

About 34% of patients with hyperuricemia were diabetic as compared to patient with normal SUA in which only 20% of patients were diabetic Table 7.

The incidence of dyslipidemia was almost equal among patient with hyperuricemia and without hyperuricemia Table 8.

Majority (83%) of patients were having infarct in MCA artery territory Table 9. In 7% of patients, MCA and ACA both were involved. In 10% of patients, PCA artery was involved.

Mean SSS score in patient with elevated SUA was 38.90 versus 30.27 in patient with normal SUA $P = 0.0076$ which is statically significant. Majority of patients 20 (69%) with elevated SUA were having SSS score >30 as compared to patients with normal SUA in whom only 35 (50%) were having SSS score >30 Table 10.

Mean mRS score in patients with elevated serum uric acid 3.82 mg/dl Vs 3.41mg/dl in patient with normal uric acid; student t test $P > 0.05$ statistically insignificant Table 11.

Table 3: Distribution of cases according to sex and its relation with uric acid in acute ischaemic stroke

S. No.	Sex	Level of SUA		
		SUA ≤ 7 mg% $n=71$ (%)	SUA > 7 mg% $n=29$	
1	Male	37 (52)	17 (59)	54
2	Female	34 (48)	12 (41)	46
3	Total	71	29	100

Male versus female, Chi-square, $P > 0.05$, insignificant. SUA: Serum uric acid

Table 4: Correlation of SUA and smoking in acute ischaemic stroke

S. No.	Status	Level of SUA		Total (100)
		SUA ≤ 7 mg (%)	SUA > 7 mg (%)	
1	Smoker	28 (39)	10 (34)	38
2	Nonsmoker	43 (61)	19 (66)	62
3	Total	71	29	100

Smoker versus nonsmokers, Chi-square test, $P > 0.05$, insignificant. SUA: Serum uric acid

Table 5: Correlation of SUA and alcoholism in acute ischaemic stroke

S.No.	Status	Level of SUA		Total
		SUA < 7 mg $n=71$ (%)	SUA > 7 mg $n=29$ (%)	
1	Alcoholic	20 (28)	13 (45)	33
2	Nonalcoholic	51 (72)	16 (55)	67
3	Total	71	29	100

Alcoholic versus nonalcoholic, $P > 0.05$, insignificant. SUA: Serum uric acid

Table 6: Correlation of hypertension and SUA in acute ischaemic stroke

S. No.	BP	Level of SUA		Total
		SUA ≤ 7 mg% $n=71$	SUA > 7 mg% $n=29$	
1	Normal BP	16 (23)	Nil	16
2	Pre hypertension SBP-120–139 DBP-80–89	17 (24)	11 (38)	28
3	Stage 1 hypertension SBP-140–159 DBP-90–99	16 (23)	6 (21)	22
4	Stage 2 hypertension SBP > 160 , DBP > 100	22 (31)	12 (41)	34
5	Total	71	29	100

Hypertensive versus nonhypertensive; Chi-square; $P < 0.05$; Significant. SUA: Serum uric acid, BP: Blood pressure, SBP: Systolic blood pressure, DBP: Diastolic blood pressure

Table 7: Correlation of diabetes and SUA in acute ischaemic stroke

S. No.	Status	Level of SUA		Total
		SUA ≤ 7 mg% $n=71$	SUA > 7 mg% $n=29$	
1	Diabetic	14 (20)	10 (34)	24
2	Non diabetic	57 (80)	19 (66)	76
3	Total	71	29	100

Diabetics versus nondiabetics; Chi-square test; $P > 0.05$; Insignificant. SUA: Serum uric acid

Table 8: Correlation of lipid profile and SUA in acute ischaemic stroke

S. No.	Lipid profile (mg %)	Level of SUA		Total
		SUA ≤7 mg% n=71	SUA >7 mg% n=29	
1	No dyslipidemia (S. cholesterol<200 mg%) S. triglyceride<160 mg%	32 (45)	07 (24)	39
2	Hypercholesterolemia (S. cholesterol>200)	10 (14)	05 (17)	15
3	Hypertriglyceridaemia S. triglyceride>160 mg%	19 (27)	10 (35)	29
4	Combined dyslipidemia	10 (14)	07 (24)	17
5	Total	71	29	100

No dyslipidemia versus dyslipidemia; Chi-square $P>0.05$, insignificant. SUA: Serum uric acid

Table 9: CT scan arterial territory involved

S. No.	Arterial territory involved	Level of SUA		Total
		SUA ≤7 mg% n=71	SUA >7 mg% n=29	
1	MCA	60 (85)	23 (79)	83
2	MCA, ACA	06 (8)	01 (3)	07
3	PCA	05 (7)	05 (18)	10
4	Total	71	29	100

CT: Computed tomography, SUA: Serum uric acid

Table 10: Correlation of SUA and SSS in acute ischaemic stroke

S. No.	SSS	Level of SUA		Total
		SUA ≤7 mg%	SUA >7 mg%	
1	<20	18 (25)	03 (10)	21
2	21–30	18 (25)	06 (21)	24
3	31–40	19 (27)	07 (24)	26
4	41–50	14 (20)	09 (31)	23
5	>51	02 (3)	04 (14)	06
6	Total	71	29	100

SSS ≤30 versus >30; Chi-square test; $P<0.05$; significant. SSS: Scandinavian stroke scale. SUA: Serum uric acid

Table 11: Correlation of SUA and outcome by mRS in acute ischaemic stroke

S. No.	mRS	Level of SUA		Total
		SUA <7 mg (%) n=71	SUA >7 mg (%) n=29	
1	1	04 (06)	00 (00)	04
2	2	08 (11)	09 (31)	17
3	3	16 (23)	08 (28)	24
4	4	20 (28)	06 (21)	26
5	5	15 (21)	03 (10)	18
6	6	08 (11)	03 (10)	11
7	Total	71	29	100

mRS <3 versus mRS ≥3, Chi-square test, $P>0.05$, insignificant. SUA: Serum uric acid. mRS: Modified Rankin's scale

DISCUSSION

The study was conducted in 100 patients of acute ischemic stroke admitted to MGM Hospital, Warangal. A detailed history and systemic examination were carried out in every patient. In each case, the diagnosis was confirmed by CT scan brain. On admission, patients' neurological status was assessed by the SSS and outcome was graded using mR's.

SUA was measured within 24 h of onset of stroke and value >7 mg/dl was considered hyperuricemia.

The present study included a total of 100 patients with new onset of acute ischemic stroke. Of 100 patients, 54% of patients were male and 46% of patients were female. Majority of patients (57%) were in the age group of 50–70 years. Six patients were below the age of 40 years and two patients were above the age of 80 years.

In the present study, old age appears to be a big risk factor for both stroke and hyperuricemia Table 12. In the present study, the prevalence of hyperuricemia in stroke patient was 29%. Mean SUA was 6.25 ± 2.72 mg/dl. Of 29 hyperuricemic patients, 20 (69%) were above the age of 60 years as compared to patients with normal SUA in whom 35 (49%) patients were above 60 years ($P < 0.05$, significant). Overall, 55% of patients were above the age of 60 years. Mean age of stroke in our study was 61.18 ± 13.43 years. Average SUA in patient above 60 years was 6.58 ± 2.75 mg/dl as compared to patient under the age of 60 years in whom mean SUA level was 5.84 ± 2.72 mg/dl.

Bansal *et al.* reported the prevalence of hyperuricemia of 30% in patient with acute ischemic stroke, with mean SUA of 6.5 ± 1.19 mg/dl. They reported the mean age of 59.40 ± 12.15 years.

The present study finding is consistent with the finding of Bansal *et al.*

The prevalence of hyperuricaemia was higher in male (59%) out of 29 were male Table 13. In the present study, mean SUA among male was 6.39 ± 2.74 mg/dl, and in female, mean SUA level was 6.07 ± 2.68 mg/dl. However, the difference in SUA level and the gender is not statistically significant (Student's *t*-test $t > 0.05$). Males usually have higher prevalence of hyperuricemia as compared to female. This difference is maintained till menopause, after that this difference normalized. The difference is due to uricosuric effect of estrogen in premenopausal woman.

Table 12: Distribution of cases according to age and its relation with uric acid in acute ischaemic stroke and comparison with other studies

Study	Prevalence of hyperuricaemia (%)	Mean SUA	Mean age
Present series (n=100)	29	6.25±2.72 mg/dl	59.40±12.15 years
Bansal <i>et al.</i> 2000 (n=50)	30	6.5±1.19 mg/dl	59.40±12.15 years

Table 13: Distribution of cases according to sex and its relation with uric acid in acute ischaemic stroke and comparison with other studies

Study	Present study	Chamorro <i>et al.</i> 2002 (n=881)	Milionis <i>et al.</i> 2005 (n=100)
Prevalence of hyperuricaemia in males	59%	52%	53.5%
Significance of male gender	<0.05	0.0001	0.01

Chamorro *et al.*, 2002, showed a significant relationship between SUA and male gender of patient with acute ischemic stroke ($P = 0.0001$).

Milionis *et al.*, 2005, also showed significant relation between SUA level and male gender in patient with acute ischemic stroke ($P = 0.01$).

In the present study, possible reason for getting insignificant relationship in between sex and SUA level may be due to the fact that majority of woman in the present study were postmenopausal, as after menopause uric acid difference tends to equalize in between male and female.

Summary

The study was conducted in 100 patients of acute ischemic stroke admitted to MGM Hospital, Warangal. A detailed history and systemic examination were carried out in every patient. In each case, the diagnosis was confirmed by CT scan brain. On admission, patients neurological status was assessed by the SSS and outcome was graded using mRS. SUA was measured within 24 h of onset of the stroke and value >7 mg/dl was considered hyperuricemia. Patients with conditions which can cause hyperuricemia were excluded from the study.

About 54% of patients were male and 46% of patients were female. Majority of patients (57%) were in the age group of 50–70 years. The prevalence of hyperuricemia in stroke patients was 29%. Mean SUA was 6.25 ± 2.72 mg/dl.

Of 29 hyperuricemic patients, 20 (69%) were above the age of 60 years as compared to patient with normal serum uric acid in whom 35 (49%) of 71 patients were above 60 years, and there was significant relationship in between age and uric acid in acute ischemic stroke patient ($P < 0.05$, significant).

In the present study, mean serum uric acid among male was 6.39 ± 2.74 mg/dl, and in female, mean serum uric acid level

was 6.07 ± 2.68 mg/dl. However, this difference in serum uric acid and gender is not statistically significant ($P > 0.05$).

Total 56% of patients were hypertensive and there was a significant correlation in between hyperuricemia and hypertension in patient with acute ischemic stroke ($P < 0.05$).

Total 24% of patients were diabetic and there was no significant correlation in between diabetes and SUA level in patient with acute ischemic stroke ($P > 0.05$).

Of total 29 hyperuricemic, 22 (76%) of patients were dyslipidemic as compared to patient with normal serum acid in which only 39 (55%) of 71 patients were dyslipidemic. There was also no statistically significant relationship was found in between hyperuricemia and dyslipidemia ($P > 0.05$).

The prevalence of smoking was less 10 (34%) in patient with hyperuricemia as compared to patient with normal SUA level 28 (39%). There was no significant relationship in between smoking and SUA level ($P > 0.05$).

Mean SUA among alcoholic was 6.75 ± 2.76 mg/dl as compared to non-alcoholic in which it was 6.02 ± 2.72 mg/dl. Significant positive correlation was present among male alcoholics ($P > 0.05$).

Majority (83%) of patients were having in fraction MCA territory. In 7% of patients, MCA and ACA both were involved. In 10% of patients, PCA was involved.

There was a modest but significant positive association in between SSS and hyperuricemia (mean SSS score in hyperuricemic patients was 38.90 vs. 30.27 in patient with normal SUA) ($P < 0.05$).

At the time of outcome, mean mRS in hyperuricemic patient was 3.82 mg/dl versus 3.41 mg/dl in patient with

normal level of SUA. There was no significant difference between these two groups ($P > 0.05$).

CONCLUSION

The prevalence of hyperuricemia in acute ischemic stroke patients in the present study was 29%.

Of all the risk factors for stroke analyzed age, hypertension and alcoholism among male showed statistically significant positive correlation with hyperuricemia in patient with acute ischemic stroke.

Patients with hyperuricemia were having better neurological status as compared to patients without hyperuricemia when assessed at the time of admission.

After 1 week, there is no statistically significant relationship was found in between outcome of patient and hyperuricemia in patients with acute ischemic stroke.

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A Clinical Study of Plasma Fibrinogen Level in Ischemic Stroke

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Abstract

Introduction: In urban India, stroke accounts for 1% mortality of all hospital admissions, 4% in all medical cases, and about 20% in all disorders of central nervous system. Most cerebrovascular accidents are manifest by the abrupt onset of focal neurologic deficit as if the patient is “struck by the hand of the God.”

Aims and Objectives of the Study: This study aims to detect the plasma fibrinogen levels in patients with acute ischemic stroke.

Materials and Methods: Fasting plasma fibrinogen level of 50 consecutive patients presenting with acute ischemic stroke admitted in Mahatma Gandhi Memorial Hospital, Warangal, from August 2012 to August 2014 and compared with 50 controls not suffering from stroke with matched age, sex, and risk factors.

Observations and Results: The present study was undertaken in the Department of General Medicine. A total of 100 patients age, sex, and matched were recruited from Mahatma Gandhi Memorial Hospital, Warangal, for the present study, of which 50 subjects constituted the control group called as Group A and remaining 50 subjects constituted the study group called as Group B.

Conclusion: Fasting plasma fibrinogen levels of cases were compared to fasting plasma fibrinogen levels of age, sex, and risk factor-matched controls selected randomly at Mahatma Gandhi Memorial Hospital, Warangal.

Key words: Cardiovascular diseases, Ischemic stroke, Fibrinogen

INTRODUCTION

In urban India, stroke accounts for 1% mortality of all hospital admissions, 4% in all medical cases, and about 20% in all disorders of central nervous system.^[1] Most cerebrovascular accidents are manifest by the abrupt onset of focal neurologic deficit as if the patient is “struck by the hand of the God.”^[2] Stroke is defined as an abrupt neurologic deficit that is attributable to focal vascular cause. Risk factors for stroke are hypertension, atrial fibrillation, carotid stenosis, hyperlipidemia, diabetes, myocardial infarction, atrial myxomas, and smoking.^[2]

Epidemiological observations indicate that high plasma fibrinogen levels strongly correlate with the frequency of two major thrombotic complications of atherosclerosis, stroke, as well as myocardial infarction. Thrombosis is increasingly recognized as a central mechanism in stroke and myocardial infarction, and fibrinogen is believed to be involved in events thought to play a major role in thrombosis. Therefore, elucidation of the relationship between fibrinogen and thrombosis may strengthen the predictive value of this protein and suggest new treatment in the management of stroke.^[3]

In Warangal district, there are no studies published to show the correlation between the plasma fibrinogen levels and ischemic stroke. Hence, this study is designed to investigate the association between plasma fibrinogen levels and acute ischemic stroke.

Aims and Objectives of the Study

The objectives of this study were as follows:

1. To detect plasma fibrinogen levels in patients with

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- acute ischemic stroke
2. To compare and correlate the significance of plasma fibrinogen levels in patients with acute ischemic stroke with that of age-, sex-, and risk factor-matched controls.

MATERIALS AND METHODS

Source of Data

Fasting plasma fibrinogen level of 50 consecutive patients presenting with acute ischemic stroke admitted in Mahatma Gandhi Memorial Hospital, Warangal, from August 2012 to August 2014 and compared with 50 controls not suffering from stroke with matched age, sex, and risk factors.

Method of Collection of Data

The study will be carried out on 50 consecutive patients admitted to Mahatma Gandhi Memorial Hospital, Warangal, with acute ischemic stroke within 24 h of the onset of symptoms. Detailed history will be taken to find out the risk factors such as hypertension, diabetes, smoking, and alcohol consumption.

- Hypertension will be diagnosed by the Joint National Committee (JNC) VIII criteria.
- Diabetes will be diagnosed by the American Diabetes Association criteria.
- Smoking will be recorded in terms of number of cigarette pack-years smoked.
- Ischemic nature of stroke confirmed with computed tomography (CT) brain (plain).
- Through general and systemic examination will be carried out as per the pro forma.

In addition to routine investigations as per the standard protocol in the evaluation of stroke patient, fasting plasma fibrinogen level is estimated and compared to age-, sex-, and risk factor-matched controls.

Patient will be followed up until they are discharged from the hospital. Controls will be taken who are not suffering from stroke and are age, sex, and risk factor matched.

Inclusion Criteria

The following criteria were included in the study:

1. Patients presenting with acute stroke within 24 h of onset of symptoms
2. Patients of acute cerebrovascular accident in whom CT scan shows infarct
3. Age group between 20 and 60 years.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients with evidence of uremia.
2. Patients with evidence of infection.

3. Patients with evidence of active hepatic disease.
4. Patients who have suffered from myocardial infarction in past 3 months.
5. Patients who have undergone surgery in the past 3 months.
6. Patients with acute cerebrovascular accident whose plain CT scan brain showing hemorrhage.

OBSERVATIONS AND RESULTS

The present study was undertaken in the Department of General Medicine, Mahatma Gandhi Memorial Hospital, Warangal. A total of 100 patients age, sex, and matched were recruited from SVS Medical College and Hospital, for the present study, of which 50 subjects constituted the control group called as Group A and remaining 50 subjects constituted the study group called as Group B.

The above cases were recruited irrespective of the presence of any risk factors such as hypertension, diabetes, smoking, and alcohol. Hypertension was diagnosed by JNC VIII criteria and diabetes will be diagnosed by the American Diabetes Association criteria.

Group A comprised controls that were selected randomly from subjects attending the outpatient department of the hospital for minor ailments, subjects accompanying patients, or among office working staff from various departments. Controls were selected irrespective of the presence of any risk factors such as hypertension, diabetes, smoking, and alcohol but without having ischemic stroke in the present or past or any evidence of CVA.

All the Controls were Screened by Clinical Examination and Normal Electrocardiogram

Group B comprised cases of acute ischemic stroke presenting within 24 h of onset of symptoms CT scan brain was done to confirm the ischemic origin of stroke by the presence of infarct. The presence of any risk factors was also recorded in patients.

Through general and systemic examination will be carried out as per pro forma. In addition to routine investigations as per the standard protocol in the evaluation of stroke patient, fasting plasma fibrinogen level is estimated and compared to age, sex, and risk factor-matched controls.

Risk Factor Matching

The age of the patients varied from a minimum age of 20 years to a maximum of 60 years. The mean age of the patients in Group A was 49.22 and the mean age in Group B was 49.12, the mean age in two groups was not significantly different from each other $t = 0.66$, $P = 0.94$. 54% of patients in Group A and Group B were in the age

Table 1: Distribution of subjects by age group

Age group in years	Group A	Group B
	n (%)	n (%)
20–30	1 (2)	1 (2)
31–40	4 (8)	5 (10)
41–50	18 (36)	17 (34)
51–60	27 (54)	27 (54)
Total	50 (100)	50 (100)
Mean±SD	49.22±7.08	49.12±8.13

T: 0.66, P: 0.94

Table 2: Sex-wise distribution of subjects among two groups

Sex	Group A	Group B
	n (%)	n (%)
Male	26 (52)	26 (52)
Female	24 (48)	24 (48)
Total	50 (100)	50 (100)

 χ^2 : 0.0, P: 1.0**Table 3: Distribution of subjects according to BMI in different groups**

BMI	Group A	Group B
	n (%)	n (%)
15–20	12 (24)	4 (8)
21–25	29 (58)	34 (68)
26–30	9 (18)	12 (24)
Total	50 (100)	50 (100)
Mean±SD	22.82±2.4	23.4±2.3

T: 1.36, P: 0.175, BMI: Body mass index

Table 4: Mean±SD values of studied parameters in controls and patients with acute ischemic stroke

Parameter	Group A	Group B	t-value	P value
	Mean±SD	Mean±SD		
Plasma fibrinogen	292.22±73.7	523.1±175.9	8.55	<0.001

SD: Standard device

Table 5: Smoking

Smoking	Group A	Group B	Chi-square value	P value
	Number of patients (%)	Number of patients (%)		
Present	11 (22)	10 (20)	0.6	0.8
Absent	39 (78)	40 (80)		

group of 51–60 years, 36% of patients in Group A were in the age group of 41–50 years compared to Group B where 34% of patients were in the age group of 41–50 years.

Among the total 50 patients in Group A, 26 were male (52%) and 24 were female (48%) compared to Group B where 26 were male (52%) and 24 were female (48%).

Table 6: Alcoholism

Alcohol	Group A	Group B	Chi-square value	P value
	Number of patients (%)	Number of patients (%)		
Present	8 (16)	8 (16)	0	1.0
Absent	42 (84)	42 (84)		

Table 7: Hypertension

HTN	Group A	Group B	Chi-square value	P value
	Number of patients (%)	Number of patients (%)		
Present	16 (32)	20 (40)	0.69	0.4
Absent	34 (68)	30 (60)		

Table 8: Diabetes

Diabetes	Group A	Group B	Chi-square value	P value
	Number of patients (%)	Number of patients (%)		
Present	14 (28)	12 (24)	0.2	0.6
Absent	36 (72)	38 (76)		

There was no significant difference observed in the sex distribution of subjects among two groups, Chi-square value was 0.0 and statistical significance $P > 0.05$.

There was no statistical difference in mean body mass index (BMI) in Group B compared to Group A ($P < 0.001$). 58% of subjects in Group A had a BMI between 21 and 25, 24% had a BMI between 15 and 20, and 18% had BMI between 26 and 30 compared to Group B where 68% of subjects had a BMI between 21 and 25, 24% had BMI between 26 and 30, and 8% had a BMI between 15 and 20.

The mean values for plasma fibrinogen were significantly higher in Group B compared to Group A ($P < 0.001$).

Group A comprised 22% of cases who gave a positive history of smoking compared to 20% in Group B. There was no significant difference in number of smokers in between groups ($\chi^2 = 0.6$) ($P > 0.05$).

Group A comprised 16% of cases who gave a positive history of chronic alcoholism compared to same 16% in Group B [Table 1]. There was no statistical significance in the distribution of alcoholic patients in either group ($\chi^2 = 0$) ($P > 0.05$).

Group A comprised 32% of cases who had a positive history of hypertension compared to 40% in Group B. There was no statistical difference observed in the distribution of hypertensive patients in both groups ($\chi^2 = 0.69$) ($P > 0.05$) [Table 2].

Table 9: Mean±SD of plasma fibrinogen in diabetic and non-diabetic subjects within groups

Parameter	Group A		Group B		F value	P value
	Non-diabetic	diabetic	Non-diabetic	diabetic		
Plasma fibrinogen	291.11±73.3	295.07±77.38	568.87±170.3	378.17±100.8	36.64	< 0.001

SD: Standard deviation

Group A comprised 28% of cases who had a positive history of diabetes compared to 24% in Group B. There was no statistical difference observed in the distribution of hypertensive patients in both groups ($\chi^2 = 0.2$) ($P > 0.05$).

In the present study, it was observed that plasma fibrinogen was significantly more in the non-diabetic study group compared to others ($F = 36.64$, $P < 0.001$).

Hypertension and Fibrinogen

In the present study, it was observed that plasma fibrinogen was significantly more in the hypertensive study group compared to others ($F = 66.08$, $P < 0.001$).

It was observed that fibrinogen levels significantly more in hypertensive cases compared to non-hypertensive cases, hypertensive controls, and non-hypertensive controls, $P < 0.001$ [Table 3].

Plasma fibrinogen levels significantly more in hypertensive cases compared to non-hypertensive controls ($P < 0.001$). In the present study, there was no statistical significance in plasma fibrinogen levels between hypertensive controls and non-hypertensive controls.

Lee *et al.*^[4] have demonstrated that plasma fibrinogen was higher among hypertensive [Table 4].

Showed that fibrinogen levels are more in hypertensive patients when compared to controls which are statistically significant < 0.01 [Table 5].

Alcohol and Fibrinogen

In the present study, it was observed that plasma fibrinogen was significantly more in the non-alcoholic study group compared to others ($F = 31.27$, $P < 0.001$) [Table 6].

It was observed that fibrinogen levels significantly more in nonalcoholic cases compared to alcoholic cases, alcoholic controls, and non-alcoholic controls, $P < 0.001$ [Table 7].

There was no statistical significance in plasma fibrinogen levels between alcoholic controls and non-alcoholic controls, alcoholic cases and alcoholic controls, and alcoholic cases and non-alcoholic controls, $P > 0.05$.

Meade *et al.*^[5] study showed that plasma fibrinogen levels are low in alcoholics than non-alcoholics.

Fibrinogen is an intermediate factor in the association between alcohol consumption and cardiovascular disease.^[6]

Alcohol intake is associated with lower fibrinogen levels.^[7] Several cross-sectional studies showed an inverse association between fibrinogen and alcohol consumption.^[6]

Alcohol seems to be related to cardiovascular disease in a U-shaped fashion and fibrinogen may be one of the mediators for its effect on cardiovascular disease.^[6]

Smoking and Fibrinogen

In the present study, it was observed that there was no statistical significance in plasma fibrinogen levels between smoker controls and non-smoker control, $P > 0.05$.

In the present study, it was observed that plasma fibrinogen was significantly more in the non-smoker study group compared to others ($F = 24.38$, $P < 0.001$).

In the present study, it was observed that fibrinogen levels significantly more in non-smoker cases compared to smoker controls and non-smoker controls, $P < 0.001$.

However, there was no statistical significance in plasma fibrinogen levels between non-smoker cases and smoker cases, $P > 0.05$.

Plasma fibrinogen levels significantly more in smoker cases compared to non-smoker controls and smoker controls ($P < 0.001$). There was no statistical significance in plasma fibrinogen levels between smoker controls and non-smoker control.

Vannien *et al.* study showed higher plasma fibrinogen levels in smokers than non-smokers.^[8]

In the study of Eliasson *et al.*, male smokers had 3.58 g/L and non-smokers had 3.29 g/L fibrinogen value.^[9]

In the study of Mennen *et al.*, the male current smokers had 3.84 ± 0.02 g/L fibrinogen value compared to non-

smokers who had 2.87 ± 0.02 g/L fibrinogen value, respectively.

The other studies, which found higher fibrinogen levels in smokers than non-smokers, were Rankinen *et al.* study and Balleisen *et al.* study in this study, current male smokers had 263.0 mg/dL fibrinogen value and non-smokers had 232.0 mg/dL [Table 8].

In the study of Bruno *et al.* and Raynaud *et al.*, they found that fibrinogen level increases with smoking and Folsom in his study found a correlation between fibrinogen and smoking.

In the study of Kannel *et al.*, the current male smokers had 296mg/dL compared to non-smokers who had 275 mg/dL [Table 9].

Cross-sectional studies indicate that cigarette smokers have higher mean fibrinogen values than non-smokers, and it increases in proportion to the amount smoked. 25–50% of the relation of cigarette smoking to occurrence of atherosclerotic cardiovascular disease is attributable to the effect of smoking on fibrinogen levels which, in turn, enhances thrombotic tenderness, leading to occlusive clinical events.

DISCUSSION

Fibrinogen and Ischemic Stroke

The present study involved 50 ischemic stroke patients and 50 age-, sex-, gender-, and risk factor-matched controls. The mean fibrinogen level among cases is 523.1 mg% in ischemic group; in controls, the mean fibrinogen is 291.22 mg% which is statistically significant.

Mistry *et al.*^[1] in their study involving 56 patients admitted in the hospital within 24 h of onset of symptoms. The levels were found to be raised significantly (531.73 ± 74 mg%) compared to those of the age- and sex-matched control group (445.78 ± 92.28 mg%).

When the levels of plasma fibrinogen in stroke group with one risk factor were compared to those of individuals with comparable control group with same risk factor, a significant difference was observed in hypertensive, smokers, alcoholics, and atherosclerotic stroke groups.

Hazra *et al.*, 48 in their study involving 33 patients of cerebral thrombosis and 30 patients with cerebral hemorrhage admitted within 24 h of onset of stroke concluded that the mean plasma fibrinogen concentration in patients of cerebral thrombosis (378.67 mg/dL) is significantly higher when compared to patients with

cerebral hemorrhage (224.4 mg/dL) and in the control group (216.67).

CONCLUSION AND SUMMARY

1. This is a case–control study conducted on 50 acute ischemic stroke patients presented to SVS Medical College Hospital between 2012 and 2014 (who were selected according to inclusion and exclusion criteria mentioned earlier) in them through history, physical examination, and routine laboratory tests were sent along with fasting plasma fibrinogen levels.
2. Fasting plasma fibrinogen levels of cases were compared to fasting plasma fibrinogen levels of age-, sex-, and risk factor-matched controls selected randomly at SVS Medical College Hospital.
3. Mean plasma fibrinogen levels were significantly higher in cases compared to age-, sex-, and risk factor-matched controls.
4. In cases, the relationship between risk factors and mean plasma fibrinogen was studied.
5. Diabetic cases had significantly lower mean plasma fibrinogen than non-diabetic cases.
6. Hypertensive cases had significantly high mean plasma fibrinogen levels than non-hypertensive cases.
7. Non-alcoholic cases had significantly higher mean plasma fibrinogen levels than alcoholic cases.
8. No significant difference found in mean plasma fibrinogen levels between smoker and non-smoker cases.
9. No significant difference found in mean plasma fibrinogen levels between obese and non-obese cases.
10. As it is a small case–control study done on small number of cases, further large prospective studies are needed to further support this association.

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A Study on the Clinical and Laboratory Profile of Patients Having Thrombocytopenia in Pediatrics

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Abstract

Introduction: Fever is a symptom which is caused by a variety of illnesses and it usually occurs in response to an infection or inflammation. Patients presenting with fever in tropical country like India usually have an infectious etiology, and many have associated thrombocytopenia.

Aim: This study aims to assess the clinical and laboratory profile of patients having thrombocytopenia (<1 lakh) in pediatrics.

Materials and Methods: The patients of both sexes aged 2 months–12 years. Patients with platelet count <1 lakh at during the course of hospital stay, irrespective of the cause for admission were included. Data regarding the patient were entered into preset pro forma as regard to the history, general and systemic examination, Hess test, and vital signs. The bleeding manifestation's patients presented with or developed during their course in hospital were recorded.

Results: The most common age group of presentation of thrombocytopenia among the study group is 6–10 years, constituting 47.3% of the cases. Mortality is highest among infants. The most common etiology for newly diagnosed thrombocytopenia among children admitted is dengue. The most common presenting symptom among the study group is fever (95.5%) with vomiting being the second most common symptom (65.2%). 76.1% of children with vomiting had bleeding manifestations. In children with thrombocytopenia, the presence of altered sensorium, tachycardia, tachypnea, shock at presentation, and seizures was all significantly associated with low platelet counts, bleeding, and mortality.

Conclusion: Febrile thrombocytopenia is a commonly observed hematological entity commonly caused by infections such as viral illnesses, dengue, malaria, and enteric fever. Dengue shock syndrome is the leading cause of mortality in the present study.

Key words: Dengue, Platelet, Thrombocytopenia

INTRODUCTION

Normal hemostasis is not only a complex but also an ingenious system which maintains blood in the vascular system free from clots, the vital element of the process being the platelet. Decreased platelet count is not as common as anemia, the hematological cousin. Literature quotes the incidence of thrombocytopenia to vary from 13% to 58% in various studies. However, it is far more

dangerous and resource consuming to the emergency department and the intensive care unit (ICU) setting. It can be associated with bleeding ranging from minor bleeds to life-threatening intracranial hemorrhage.^[1-3]

There is very often a poor correlation between the extent of thrombocytopenia and the severity of the bleed. Guidelines on platelet transfusions are also varied and confounding. Hence, the treatment of thrombocytopenia has to be guided by an understanding of the cause and clinical course. It is often said that the main treatment goal in all patients with decreased platelet count is to maintain a safe platelet level so as to prevent significant bleeding. However, what constitutes a safe count in a specific patient varies, depending on the etiology of the thrombocytopenia as regard to whether it is transient or chronic, as well as the patients expected level of disease activity.^[4,5]

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There has been a plethora of studies on anemia and its impact on various disease processes. However, thrombocytopenia is still a grey waiting to be explored. Again, there are lot of studies in the adult population detailing the outcome of patients with thrombocytopenia in the intensive care setting. However, similar studies in the pediatric age group are lacking. No particular study has been addressed toward studying the relative frequency of different disease conditions presenting as newly diagnosed thrombocytopenia in pediatric patients presenting to an Indian tertiary care hospital. The need arises to look at thrombocytopenia as a whole and to gather knowledge regarding the common disease entities presenting as such and whether or not active treatment modalities such as platelet transfusions, steroids, and platelets are required in them. This knowledge will give the clinician an idea of approach to pediatric patients detected to have thrombocytopenia on admission to a tertiary care hospital in India.

Aim

This study aims to assess the clinical and laboratory profile of patients having thrombocytopenia (<1 lakh) in pediatrics.

MATERIALS AND METHODS

This descriptive, cross-sectional study was done on children who were admitted to the children medical ward of Tirunelveli Medical College Hospital during the period from December 2011 to April 2012. 112 consecutive patients who satisfied the following inclusion criteria were studied. Prior ethical committee approval was obtained for the study.

Inclusion Criteria

The patients of both sexes aged 2 months–12 years. Patients with platelet counts <1 lakh anytime during the course of hospital stay, irrespective of the cause for admission.

Exclusion Criteria

Patients with spurious thrombocytopenia-laboratory induced errors where immediate repeat platelet counts or the peripheral smear did not grossly correlate with the first count were excluded from the study. Patients who were earlier diagnosed to have conditions that are known to cause thrombocytopenia (e.g., known cases of hematological malignancies, aplastic anemia, myelodysplastic syndromes, and immune thrombocytopenia). Patients who have already received platelet transfusion before admission. Patients who were very sick at admission or expired within few hours of admission who could not be subjected to the full set of investigations.

Data regarding the patient were entered into preset pro forma as regard to the history, general and systemic examination, Hess test, and vital signs. The bleeding manifestation's patients presented with or developed during their course in hospital were recorded. An awareness questionnaire on dengue with three simple questions was also included for the parents. Informed consent was obtained.

Once the specific diagnosis was reached, patients were treated for specifically and symptomatically (mechanical ventilation, shock correction, and steroids). Blood products were transfused as per the treating physician's discretion. The proportion of study patients requiring interventions to improve platelet count such as platelet transfusion, steroids, and the reason for such interventions were recorded.

RESULTS

The total number of admissions during the study period in children medical ward is 702. The number of patients who had thrombocytopenia or developed it subsequently during the course of hospital stay is 112 (after application of the exclusion criteria), which means one among every 6.25 children admitted developed thrombocytopenia (15.95% incidence). In 107 patients, a cause for the thrombocytopenia could be identified with the panel of investigations applied. Five patients were left undiagnosed despite full battery investigations. The most common age group of presentation of thrombocytopenia among the study group is 6–10 years, constituting 47.3% of the cases. Mortality is highest among infants. Of 11 infants studied, 5 expired (45.5%). However, this is not statistically significant ($P > 0.05$).

The most common etiology for newly diagnosed thrombocytopenia among children admitted is dengue. Total dengue cases were 66, comprising 58.8% of the study population. Among the dengue cases, dengue fever (DF) with or without hemorrhage DF was most common (32.1%) [Table 1]. Leading cause of mortality in the study population is dengue shock syndrome (DSS), causing four of the eight total deaths. DSS comprised only 8% of cases with thrombocytopenia but had the highest mortality rate of 44.4%. The next leading cause of mortality was septicemia. Infections caused most of the thrombocytopenia. 44.6% of the children presented with fever of 5–7 days duration. Mean duration of hospital stay in the study group is 6.15 days. Mean duration for which fever lasted is 7.69 days (Standard deviation = 3.498). 47.35% of children became afebrile after 5–7 days. Children who had prolonged fever >15 days had the worst outcome (25% mortality). However, this is not statistically significant ($P = 0.383$).

The most common presenting symptom among the study group is fever (95.5%) with vomiting being the second most common symptom (65.2%). 76.1% of children with vomiting had bleeding manifestations. This is statistically significant ($P = 0.003$) [Table 2]

In children with thrombocytopenia, the presence of altered sensorium, tachycardia, tachypnea, shock at presentation, and seizures was all significantly associated with low platelet counts, bleeding, and mortality ($P < 0.05$). Children requiring inotrope support, mechanical ventilation also had poor outcome ($P < 0.05$). The mortality was also significantly high ($P < 0.05$) in malnourished children with thrombocytopenia. Occurrence of seizures in cases with septicemia and thrombocytopenia had strong correlation with death (100%) [Table 3].

Among the platelet counts, the initial values were not significantly related to the mortality while the second repeat platelet value had a significant bearing on the outcome ($P < 0.05$). Bleeding manifestations were seen in a total of 67 patients (59.8%). GI bleed was the most common bleeding manifestation associated with thrombocytopenia, seen in total of 46 patients. 39.3% of patients had malena and 20.5% of children had hematemesis. 3.6% had more than one bleeding manifestation. Children with hematemesis had a significantly poor outcome ($P = 0.000$) compared to children with malena ($P = 0.52$).

Children with anemia had a significantly poor outcome ($P = 0.008$). The mean Hb in the discharged patients was

11.32 g% compared to 8.69 g% in children who expired ($P = 0.007$). The other laboratory parameters did not significantly alter the outcome [Table 4].

Patients with enteric fever and thrombocytopenia had higher incidence of bleeding compared to even dengue cases. In fact, coinfection with both diseases had the highest incidence of bleed (75%). In children with dengue, counts $< 20,000$ had high association with bleeding, while in enteric fever, there was no such correlation with the counts for the predisposition to bleed.

DSS children had a higher incidence of bleeding manifestations (77.8%), and the bleeding risk in DSS was high when the counts were $< 10,000$. Comparatively, only 11.1% of DHF cases had bleeding. In dengue hemorrhagic fever (DHF) too, the incidence of bleeding manifestations was high (71.4%), but there was no correlation with lower counts to occurrence of bleeding manifestations [Table 5].

The mean hemoglobin value in the study group is 11.13 g%. The mean hematocrit value is 35.99%, and the outcome is significantly poor among children with hematocrit below the mean ($P < 0.05$) probably indicative of the mortality risk associated with bleeding. Anemia with thrombocytopenia was common in leukemia and septicemia (4.27 g% and 9.96 g%, respectively) [Table 6].

Abnormal X-ray findings had a significant association with mortality ($P < 0.05$). Ultrasound abdomen was a very useful radiological tool among the study population. It was able to pick up features of polyserositis with high sensitivity in both DHF and DSS. However, the findings were not specific for dengue alone [Table 7]. Anemic patients with thrombocytopenia had significantly increased need for transfusions ($P < 0.05$). The mean Hb of transfused patients was 9.65 g% compared to 11.46 g% in non-transfused patients ($P = 0.006$).

There was also statistically significant association between need for transfusion and mortality ($P < 0.05$). All the poor predictors of mortality also had a significant association with the need for transfusions. Hence, it can be implied that transfusions have not significantly altered the outcome.

Table 1: Etiology and disease-wise mortality of thrombocytopenia

Diagnosis	Frequency <i>n</i> =112 (%)	Death <i>n</i> =8 (%)
DF	36 (32.1)	0 (0)
DHF	21 (18.7)	0 (0)
DSS	9 (8)	4 (44.4)
Enteric	13 (11.6)	0 (0)
Dengue/enteric coinfection	4 (3.6)	0 (0)
Malaria	3 (2.7)	0 (0)
All	5 (4.5)	0 (0)
Septicemia	5 (4.5)	0 (0)
Undiagnosed	5 (4.5)	0 (0)
Miscellaneous	11 (9.8)	2 (18.2)

DHF: Dengue hemorrhagic fever, DSS: Dengue shock syndrome, DF: Dengue fever

Table 2: Symptom analysis of cases based on etiology

Features	Total <i>n</i> =112 (%)	Dengue <i>n</i> =66 (%)	Enteric <i>n</i> =13(%)	D/E <i>n</i> =4(%)	All <i>n</i> =5(%)	Sepsis <i>n</i> =5 (%)
Fever	107 (95.5)	66 (100)	13 (100)	4 (100)	5 (100)	5 (100)
Abdomen pain	59 (52.7)	35 (53)	9 (69.2)	3 (75)	1 (20)	0
Vomiting	73 (65.2)	42 (63.6)	11 (84.6)	3 (75)	2 (40)	4 (80)
Cough	42 (37.5)	23 (34.9)	3 (23)	3 (75)	1 (20)	5 (100)
Myalgia	60 (53.6)	35 (53)	6 (46.2)	2 (50)	3 (60)	0 (0)

Table 3: Predictors of mortality in various diseases

Features	Total n=112 (% of n)	Death n=8 (%)	P value outcome	Dengue deaths n=4 (%)	Septicemia deaths n=2(%)
Altered sensorium	49 (43.8)	8 (100)	0.001	4 (100)	2 (100)
Tachycardia	48 (42.9)	8 (100)	0.001	4 (100)	2 (100)
Tachypnea	20 (17.9)	8 (100)	0.000	4 (100)	2 (100)
Shock	18 (16.1)	8 (100)	0.000	4 (100)	2 (100)
Seizure	13 (11.6)	3 (37.5)	0.018	1 (25)	2 (100)
Mechanical ventilation	7 (6.3)	6 (75)	0.000	2 (50)	2 (100)
Inotrope	8 (7.1)	7 (87.5)	0.000	3 (75)	2 (100)
Narrow pulse pressure <20	19 (17)	2 (25)	0.484	1 (25)	1 (50)
Malnutrition	63 (56.3)	1 (12.5)	0.041	1 (25)	0

Table 4: Comparison of the laboratory parameters

Investigation	Total n=112 (% of n)	Dengue n=66 (% of n)	Enteric n=13(% of n)	Leukemia n=5	Septicemia n=5 (% of n)
Leucopenia	32 (28.6)	17 (25.8)	5 (38.5)	2 (40)	1 (20)
Leukocytosis	29 (25.9)	13 (19.7)	4 (30.7)	3 (60)	0
Pancytopenia	4 (3.6)	1 (1.5)	0	2 (40)	0
Anemia (p<0.05)	40 (35.7)	15 (22.7)	3 (23)	5 (100)	4 (80)
Incesr.	41 (36.6)	14 (21.2)	7 (53.9)	4 (80)	4 (80)
Inc. urea/creatinine	27 (24.1)	17 (25.8)	1 (7.7)	1 (20)	2 (40)
Inc. liver enz.	33 (29.5)	15 (22.7)	5 (38.5)	0	0
Inc. bilirubin	12 (10.7)	2 (3.03%)	1 (7.7%)	0	0

Table 5: Comparison of platelet counts based on etiology

Counts	Dengue n=66 (% of n)	Enteric n=13 (% of n)	D/E mixed n=4 (%)	Malaria n=3 (% of n)	All n=5 (% of n)	Sepsis n=5 (% of n)
<10,000	2 (3)	0	0	0	1 (20)	1 (20)
11,000–20,000	10 (15.2)	0	0	0	1 (20)	0
21,000–50,000	22 (33.3)	4 (30.8)	3 (75)	2 (66.7)	2 (40)	2 (40)
51,000–100,000	32 (48.5)	9 (69.2)	1 (25)	1 (33.3)	1 (20)	2 (40)

Table 6: Comparison of mean hematological values based on etiology

Diagnosis	Mean Hb (g %)	Mean PCV (%)	Mean platelet count
DF	11.93	3.74	60666
DHF	11.98	39.77	46714
DSS	11.21	38.04	18000
Enteric	12.15	35.58	62076
Ent/den coinf	11.38	35.55	41500
Malaria	11.03	34.47	46333
Leukemia	4.27	13.36	35600
Septicemia	9.96	30.56	50800
Total (n=112)	11.13	35.99 (P=0.016)	48250

DHF: Dengue hemorrhagic fever, DSS: Dengue shock syndrome, DF: Dengue fever, PCV: Packed cell volume

DISCUSSION

As discussed in the literature, thrombocytopenia being associated with bleeding manifestations is now considered an independent parameter predicting outcome in the pediatric ICU. Here, critical analysis of the observations of our study is performed, comparing it with other Indian and foreign studies. Analysis of our study shows the highest incidence of thrombocytopenia in the 6–10 years

age group, with a mean age of 6.56 years. The incidence of thrombocytopenia has been quoted to vary from 13% to 58% in various studies. The present study has shown 15.95% incidence, which is comparable to other studies, Agrawal *et al.* showing 23.2–22% in a neonatal ICU.^[6] The present study had significantly less number of children with counts <10,000 compared to Agrawal *et al.* (20%).^[6] Children with counts <10,000 had the worst outcome (57.1% mortality). Mortality in the present study was 7.1% with DSS contributing to 50% of the deaths. Krishnan *et al.* reported 17.1% mortality, while Agrawal *et al.* reported a mortality of 10.9%. Mortality was highest among infants (45.5%) and younger children (<3 years).^[6] Gomber *et al.* defined 36.3% as the cutoff hematocrit for DHF.^[7] In the present study, the mean hematocrit among dengue patients was well above this cutoff, indicating high predisposition for the development of severe dengue in the study group. Furthermore, the hematocrit values are significantly associated with mortality. Unlike previous studies, the incidence of coinfections in the present study was low (5.7%). However, the children with dengue/enteric coinfection had abdominal tenderness in a higher proportion. The mortality rate among dengue patients as

Table 7: Comparison of radiological abnormalities

Features	Total n=12 (%)	P value	DF n=36	DHF n=21	DSS n=9	Enteric n=13
X-ray eff/pneumonia	15 (13.4)	0.002	1 (6.6)	4 (26.6)	1 (6.6)	2 (13.3)
Gallbladder edema	31 (27.7)	0.001	0	11 (52.4)	4 (44.4)	8 (61.5)
Pleural effusion	29 (25.9)	0.008	0	15 (71.4)	5 (55.5)	4 (30.7)
Ascites	18 (16.1)	0.062	0	8 (38.1)	3 (33.3)	3 (23.1)
Hepatomegaly	45 (40.2)	0.338	10 (27.8)	9 (42.9)	3 (33.3)	10 (76.9)
Splenomegaly	27 (24.1)	0.397	6 (16.7)	5 (23.8)	0	4 (30.7)

DHF: Dengue hemorrhagic fever, DSS: Dengue shock syndrome, DF: Dengue fever

a whole was low (4/66 = 6.06%). Erythematous rash with flushing was very commonly observed in children with dengue in the present study (70.4%). This is in spite of the dark complexion in our children. Altered sensorium, tachycardia, tachypnea, shock (all having 100% association with death), requirement of inotrope support (87.5%), mechanical ventilation (70%), seizures, and malnutrition were all significantly associated with increased mortality. Requirement of mechanical ventilation in Agrawal *et al.* was 23.9%, whereas in the present study, it was 6.3%. The incidence of shock was 17.3% in Agrawal *et al.*, while in the present study, it was 16.1%.^[6] Bleeding manifestations were seen in a total of 67 patients (59.8%) in the present study compared to 19.5% in Agrawal *et al.* GI bleed was the most common bleeding manifestation associated with thrombocytopenia, seen in total of 46 patients.^[6] 17.9% of children in the present study required transfusions. They received 43.75 mL/kg/patient. In comparison, 21.9% of patients were transfused in the study by Agrawal *et al.*, and transfusions were reported to be significantly associated with mortality. Most of the patients transfused in our study were DSS patients (77.8%). The mean platelet count of transfused patients was 24,000. Yet, 80% mortality was seen in the transfused patients, which was also statistically significant. Patients with low platelet counts and bleeding manifestations also did not show statistically significant improvement in comparison to non-transfused patients. Hence, the role of prophylactic platelet transfusions is to be questioned until uniform guidelines are established. The WHO advises that platelet transfusion is to be avoided

in dengue. The only clinical situation where platelet transfusion is needed in dengue is when the counts are <10,000.

CONCLUSION

Febrile thrombocytopenia is a commonly observed hematological entity commonly caused by infections such as viral illnesses, dengue, malaria, and enteric fever. DSS is the leading cause of mortality in the present study. It commonly manifests with clinical features of underlying disease condition and sometimes with bleeding manifestation also. Mortality in febrile thrombocytopenia is not directly associated with the degree of thrombocytopenia.

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Behavioral and Emotional Changes among Adolescent Populace

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Abstract

Background: Adolescents are vulnerable population who would experience emotional changes. Lack of proper channeling their emotions would lead to drastic behavioral change. Psychological or emotional changes during puberty manifest in different ways but often through a change in behavior. The confusion and the indecisiveness that your teenager experiences during the transition period also translate into a conflict of interest at times.

Materials and Methods: This study was done among the adolescent populace as community-based cross-sectional study among 450 students from private schools and 342 students from government schools who were taken for the study.

Results: This study included 792 adolescents' school children from both private and government schools with the mean age of 15.3 years. Majority 420 (53%) of the study population were belonging to 12–15 years, whereas the remaining 372 (47%) were from 16 to 19 years. The study population showed conscious about losing weight (296, 37%), building muscles (366, 46%), spending more time in front of the mirror (320, 40%), and conscious about facial beauty (437, 55%). Feeling of uncertainty was expressed by 375 (47%) of the study population and conflict of thought was seen among 457 (57%) of the study population.

Conclusion: Our study has described that the majority of the adolescent populace are undergoing emotional distress which is actually a dangerous sign for the future community, to be initiated as soon as possible for the well-being of the future generation.

Key words: Adolescence, Behavioral changes, Emotional changes

INTRODUCTION

The World Health Organization (WHO) defines adolescents as those people between 10 and 19 years of age. The great majority of adolescents are, therefore, included in the age-based definition of “child,” adopted by the convention on the rights of the child, as a person under the age of 18 years. Other overlapping terms used in this report are youth (defined by the United Nations as 15–24 years) and young people (10–24 years), a term

used by the WHO and others to combine adolescents and youth. Adolescence is one of the most rapid phases of human development where biological maturity precedes psychosocial maturity. The characteristics of both the individual and the environment influence the changes taking place during adolescence. These changes in adolescence have health consequence not only in adolescence but also over the life course. Adolescent age groups are often thought of as a healthy group. Nevertheless, many adolescents do die prematurely due to accidents, suicide, violence, pregnancy-related complications, and other illnesses that are either preventable or treatable. In addition, many serious diseases in adulthood have their roots in adolescence. For example, tobacco use, sexually transmitted infections including human immunodeficiency virus, poor eating, and exercise habits lead to illness or premature death

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later in life. Our study was planned to assess the social, behavioral, and emotional changes occurring during adolescent period among the school-going population.

Aims and Objectives

The aims and objectives of this study were to assess the emotional and behavioral changes during adolescent age group among school-going population.

MATERIALS AND METHODS

The study was conducted from January 2018 to July 2018, as a school-based cross-sectional descriptive study. With a list of all the government and private coeducational schools, four government and three private schools were randomly selected by simple random sampling method. After getting the official permission from school authorities, the study population was approached in the classrooms with the help of concerned class teachers. Informed and written consent was obtained from parents on a printed pro forma distributed a day before filling the questionnaire. On the day of administering the questionnaires, the study participants were addressed by their teachers followed by the research team and were offered to participate or opt out of the study. Some items comprised factual information about family size, type, income, and educational background, and employment, chronic illness in adolescents and addiction in family. Other questions were designed to assess child's self-esteem, satisfaction with his academic performance, parents' satisfaction with child's academic performance, and child's perception of closeness and proximity to one of the parents. There were separate items for assessing child abuse. This questionnaire was also written in both the languages, pretested, and suitably modified before forming a part of the questionnaire set. Approval of the ethical committee of the institute was sought before conducting the study.

Data Collection

The data were collected by self-administering the questionnaire in the classroom after informing the study participants about the details of the questionnaire. The doubts raised by them were cleared immediately.

Statistical Analysis

The data were entered in Microsoft Excel sheet and expressed in frequencies and percentages.

RESULTS

This study included 792 adolescents' school children from both private and government schools with the mean age of

15.3 years. As illustrated in [Table 1] Majority 420 (53%) of the study population were belonging to 12–15 years, whereas the remaining 372 (47%) were from 16 to 19 years. Most of the study participants, 565 (71%), belonged to class I socioeconomic status and 588 (74%) were from nuclear family.

The emotional and behavioral attributes were classified as feeling overly sensitive, looking for identity, feeling uncertain, conflicts in thought, peer pressure, mood swings, and sleep difficulty [Table 2].

Feeling Overly Sensitive

The study population showed conscious about losing weight (296, 37%), building muscles (366, 46%), spending more time in front of mirror (320, 40%), and conscious about facial beauty (437, 55%).

Looking for an Identity

Among the study participants, 633 (80%) had shown more thought toward getting more marks than their friends, 565 (71%) had shown interest to join sports, and daydreaming about unrealistic goals 577 (73%) was expressed.

Feeling of uncertainty was expressed by 375 (47%) of the study population, and conflict of thought was seen among 457 (57%) of the study population.

The marks obtained by the friends is being the great peer pressure than dressing up, makeup, and worthwhile things.

Table 1: Sociodemographic factors

Variables	Frequency (%)
Age	
12–15	420 (53.1)
16–19	372 (46.9)
Sex	
Male	327 (41.3)
Female	465 (58.7)
Standard	
IX	197 (24.9)
X	201 (25.4)
XI	212 (26.8)
XII	182 (23)
Socioeconomic status	
Class I	565 (71.3)
Class II	166 (21)
Class III	43 (5.4)
Class IV	11 (1.4)
Class V	7 (0.9)
Siblings	
Present	427 (53.9)
Absent	365 (46.1)
Type of family	
Nuclear	588 (74.2)
Joint	204 (25.8)

Table 2: Emotional And Behavioral Attributes

Emotional and behavioral attributes	What do you feel?	Yes n (%)	No n (%)
Feeling overly sensitive	Are you conscious about losing your weight ?	296 (37.4)	496 (62.6)
	Have you thought of building your muscles?	366 (46.2)	426 (53.8)
	Will you often spend time in front of mirror?	320 (40.4)	472 (59.6)
Looking for an identity	Are you conscious about pimples and taking care of it?	437 (55.2)	355 (44.8)
	Did you think of getting good marks than your friends?	633 (79.9)	159 (20.1)
	Have you joined in sports to show up your talents?	565 (71.3)	227 (28.7)
	Are you daydreaming about unrealistic goals and wanted to be a supermodel one day?	577 (72.9)	215 (27.1)
Feeling uncertain	I never wanted to do certain things (eg. doctor) Because I thought it doesn't suit with my talent?	375 (47.3)	417 (52.7)
Conflicts in thought	Are you finding difficult to take any decision? Yes or no	457 (57.7)	335 (42.3)
	Are you struggling with your studies and lead to a state of emotional tension yes or no	458 (57.8)	334 (42.2)
Peer pressure	Will you feel depress often		
	When your friends getting good marks, but you Couldn't	461 (58.2)	331 (41.8)
	When your friend dress up nicely, but you couldn't	229 (28.9)	563 (71.1)
	When your friend having mobile or worthful things	195 (24.6)	597 (75.4)
Mood swings	Are you often change your mind from happy to sad or irritable suddenly	492 (62.1)	300 (37.9)
	Will you argue or fight for small things with your friends or parents?	337 (42.6)	455 (57.4)
	Are you feeling isolated	257 (32.4)	535 (67.6)
	Do you have lack of sleep or disturbed sleep	335 (42.3)	457 (57.7)

Mood Swings

The mood swings expressed were sudden change of happy to sad or irritable mood, argue or fight for small things, and feeling of isolation.

DISCUSSION

Adolescence is a period of life with specific health and developmental needs and rights.^[1] It is also a time to develop knowledge and skills, learn to manage emotions and relationships, and acquire attributes and abilities that will be important for enjoying the adolescent years and assuming adult roles.^[2,3] This study done among school-going adolescent population had explored the various emotional and behavioral attributes such as feeling overly sensitive, looking for an identity, conflicts in thoughts, and mood swings. In all the attributes, the study population showed that around 50% of them was having these social and emotional changes which are an iceberg. Factors like perceiving popularity with peers, body dissatisfaction, focus on sport, involvement in competitive sport, strategies to lose weight, strategies to increase muscle, disordered eating, use of food supplements and steroids, and exercise dependence was demonstrated in a study among 881 adolescent boys and girls by McCabe and Ricciardelli.^[4] The behavioural and papillary changes for emotional words identification studied among pubertal age group population suggested that the mid-/late pubertal children showed greater peak pupillary reactivity to words presented during the emotional word identification task than pre-/early pubertal children, regardless of word

valence.^[5] These cognitive and emotional changes were clearly demonstrated by various studies on MRI imaging and frontal lobe functioning during adolescent period.^[6,7] Adolescents' neurodevelopmental changes and evolving capacities affect how they perceive risk, how they act on communication about risky behaviors, how they think about the present and the future, and what influences their ideas and actions. The changes during puberty affect the incidence and clinical manifestations of a number of diseases. Many of the health-related behaviors that arise during adolescence have implications for both present and future health and development.

CONCLUSION

Our study had explored the social, behavioral dimensions of the most vulnerable stage of life. So as far as the adolescent period is concerned, age is not the whole story, but the physical, neuro-developmental, social, and psychological changes and its implications on health and disease has to be considered for leading normal life.

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Perception, Promotion, and Practice of Healthy Eating and Physical Activity among Primary School Teachers in Sokoto, Nigeria

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Abstract

Introduction: Studies have shown that teachers have considerable influence on the eating and physical activity behavior of school pupils and ultimately the prevalence of overweight and obesity among them.

Objectives: This study aimed to assess the perception, promotion, and practice of healthy eating and physical activity among primary school teachers in Sokoto, Nigeria.

Materials and Methods: A cross-sectional descriptive study was conducted among 277 teachers practicing in the primary schools in Sokoto, Nigeria. A structured self-administered questionnaire was used to collect data on the research variables. Data were analyzed using IBM SPSS version 20 statistical computer software package.

Results: The mean age of the respondents was 31.98 ± 8.07 years. Apart from students having access to adequate and safe drinking water within the school premises, less than half respondents strongly perceived the need for the other measures for facilitating healthy eating and any of the measures for facilitating physical activity among school pupils. Only about a third and less of respondents very often promote healthy eating and physical activity among their pupils. More than a third of respondents practice unhealthy eating, and about a fifth of them (19.1%) live sedentary lifestyle. The main barriers to healthy eating and physical activity were lack of information, poor motivation, unavailability of healthy foods, and lack of access to facilities for physical activity.

Conclusion: These findings underscore the need for the management of Sokoto State Primary Education Board to develop and implement healthy eating and physical activity policies and practices in the primary schools across the state.

Key words: Healthy eating, Perception, Physical activity, Practice, Promotion, Teachers

INTRODUCTION

The prevalence of obesity and overweight among school-age children and adolescents continues to rise at alarming rates across the globe with an estimated 340 million overweight or obese children and adolescents aged 5–19 years in 2016.^[1] The prevalence of obesity has tripled among persons aged 6–19 years globally in the

past 3 decades, with a dramatic rise in the prevalence of overweight and obesity from just 4% in 1975 to over 18% in 2016.^[1] This trend is believed to be related to the rising prevalence of childhood obesity globally (as childhood obesity is known to track into adulthood), with the number of overweight children under five estimated to have risen from 32 million in 2000 to 42 million in 2013 and projected to rise to 70 million in 2025 if the current global trends continue.^[2]

Whereas obesity was hitherto considered to be a disease of developed countries, the rise in its prevalence has been >30% higher in developing than developed countries in recent years, and its prevalence in developing countries is now almost on a par with that of developed countries.^[3,4] This is corroborated by the findings from

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studies conducted in sub-Saharan Africa that revealed a trend toward increasing prevalence of overweight and obesity among school-aged children in the region.^[5,6] In addition, high overweight/obesity prevalence rates were reported in studies conducted among school-aged children in studies conducted in many sub-Saharan African countries including Kenya (19.0%),^[7] Tanzania (22.6%),^[8] and Nigeria (17.4%).^[9]

The rising prevalence of overweight and obesity among both children and adults globally has been attributed to an increased intake of energy-dense foods that are high in fat, and an increase in physical activity due to the increasingly sedentary nature of many forms of work, changing modes of transportation, and increasing urbanization.^[1] Unhealthy eating and physical inactivity are among the leading preventable cause of deaths worldwide.^[10] A study among the United States youths reported that concurrent healthy eating and regular physical activity were favorably associated with cardiovascular disease (CVD) biomarkers when compared with unhealthy diet and sedentary lifestyle.^[11]

A cause for concern is the fact that overweight and obesity are major risk factors for non-communicable diseases (NCDs) including diabetes, certain cancers, and CVDs; and overweight and obese children are more likely to develop NCDs at younger age.^[1] Furthermore, childhood obesity has been associated with other problems including low school performance, social isolation, and other psychological problems which are detrimental to mental health, while healthy eating and physical activity have been shown to play a significant role in students' academic performance.^[12,13]

Even though regular physical activity and healthy eating are crucial to halting the rising prevalence of overweight and obesity among children and young adults globally, reports from studies conducted in many developing and developed countries showed that majority of them fail to meet the recommended healthy eating and physical activity standards due to several barriers including lack of information, poor motivation, access to unhealthy foods, unavailability of equipment/facilities for physical activity, and time constraints among others.^[14,15] Whereas motivation by parents has been associated with increased compliance with healthy eating and physical activity among school-aged children, there has been a progressive decrease in parental encouragement for healthy eating and physical activity as children grow older, and over time, and with the parents perceiving various intrapersonal, interpersonal, and environmental barriers to supporting healthy eating and physical activity among their children.^[16-19]

The school is an institution for socialization, children and adolescents are at a critical transition period in their

lives, it is believed that behavior patterns and trajectories established now will influence their health for a lifetime.^[20] School-aged children constitute substantial proportions of the populations across the globe. Nigeria is the most populous country in Africa, with an estimated population of over 140 million people based on the 2006 census, of which 28.3% were aged 5–14 years.^[21] By providing unmatched access to this large population of young people, schools, therefore, offer ideal settings for delivering health-promoting strategies that provide opportunity for students to learn about and practice healthy behavior. With the poor motivation for healthy eating and physical activity among school-aged children by parents, and the rising prevalence of overweight and obesity among them globally, promotion of healthy eating and physical activity in schools has been recommended by the Centers for Disease Control and Prevention (CDC) and is believed to be the most viable option for halting the current trend.^[3]

Teachers cannot promote healthy eating and physical activity among their pupils if they are unaware of the benefits of these behaviors to their health or practice them (as the pupils see them as role models). Studies have shown that teachers have considerable influence on the eating and physical activity behavior of the children in their care. Associations have also been established between teachers' perception of healthy eating and physical activity and their compliance with/promotion of these behaviors among pupils and their parents. In addition, teachers that complied with healthy eating and physical activity guidelines were found to have lower risk of overweight and obesity.^[22,23]

Understanding teachers' perception, promotion, and practice of healthy eating and physical activity is important in identifying the barriers to these healthy behaviors, particularly within the school environment and to develop strategies for addressing them. There is a dearth of research examining the perception and promotion of healthy eating and physical activity among teachers in Nigeria. This study was conducted to assess the perception, promotion, and practice of healthy eating and physical activity among primary school teachers in Sokoto, Nigeria.

MATERIALS AND METHODS

Study Design and Population

A cross-sectional descriptive study was conducted among teachers practicing in the primary schools in Sokoto metropolis, the capital of Sokoto State, Nigeria, between October and November 2014. Sokoto State with a population of about 4 million (based on the 2006 census) has a primary school-age population of about 1 million, 1963 public schools, 12,737 teachers, and an enrollment of

610,886 pupils^[24]; and in recent years, many private schools have been established in Sokoto metropolis. Teachers who have been in practice for at least 1 year and consented to participate in the study were considered eligible for this study.

Sample Size Estimation and Sampling Technique

The sample size was estimated at 272 using the statistical formula for calculating sample size in cross-sectional studies,^[25] a 78.7% prevalence of moderate physical activity among teachers in a previous study,^[26] a precision level of 5%, and an anticipated 95% participant response rate.

The eligible participants were selected by multistage sampling technique. At the first stage, two of four local government areas (LGAs) in Sokoto metropolis were selected by simple random sampling using the ballot option. At the second stage, six primary schools were selected in each of the selected LGAs by systematic sampling technique using the list of schools in the respective LGAs to constitute the sampling frame. At the third stage, selection of participants in each of the selected schools was done by systematic sampling technique using the staff list in the respective schools to constitute the sampling frame. Proportionate allocation of the study participants was done based on the staff strength in the selected schools. 277 participants were enrolled into the study.

Data Collection and Analysis

A structured self-administered questionnaire was developed after a thorough review of relevant literature and used to obtain information on the sociodemographic characteristics of the study participants, their perception of healthy eating and physical activity, promotion of healthy eating and physical activity among their pupils, and their practices regarding healthy eating and physical activity. It was reviewed by researchers in the Department of Community Health, Usmanu Danfodiyo University, Sokoto, Nigeria. Corrections were made based on their inputs on content validity. The questionnaire was pretested on 20 primary school teachers in one of the LGAs that were not selected for the study. Some questions were rephrased for clarity based on the observations made during the pretesting. Five resident doctors assisted in questionnaire administration after pre-training on conduct of survey research, the objectives of the study, selection of study participants, and questionnaire administration.

Data were analyzed using the IBM SPSS version 20 computer statistical software package. Quantitative variables were summarized using mean and standard deviation, while categorical variables were summarized using frequencies and percentages; and the results were presented as frequency distribution tables.

Ethical Consideration

Institutional Ethical Clearance was obtained from the Ethical Committees of Usmanu Danfodiyo University Teaching Hospital, Sokoto, Nigeria, and Sokoto State Ministry of Health, Sokoto, Nigeria. Permission to conduct the study was obtained from the management of Sokoto State Primary Education Board; informed written consent was also obtained from the participants before data collection.

RESULTS

Sociodemographic Characteristics of Respondents

All the 277 questionnaires administered were adequately completed and found suitable for analysis, giving a response rate of 100%. The respondents' ages ranged from 20 to 59 years (mean = 31.98 ± 8.07), and most of them (83.7%) were aged 20–39 years. Majority of respondents were males (54.2%), married (56.4%), and practiced Islam as religion (69.3%). Majority of respondents (52.3%) graduated from the university, followed by those that graduated from the college of education (42.2%). Majority of respondents were mainly classroom teachers (62.0%), have practiced for a decade and less (77.0%), and worked in public schools (64.1%) as shown in Table 1.

Table 1: Sociodemographic characteristics of respondents

Variables	Frequency n=277 (%)
Age group (years)	
20–29	140 (53.2)
30–39	92 (35.0)
40–49	21 (8.0)
50–59	24 (8.7)
Marital status	
Single	115 (41.8)
Married	155 (56.4)
Divorced	1 (0.4)
Widowed	4 (1.5)
Religion	
Islam	192 (69.3)
Christianity	85 (30.7)
Level of education	
Quranic school only	5 (1.8)
Secondary school	5 (1.8)
College of education	117 (42.2)
Polytechnic	5 (1.8)
University	145 (52.3)
Nature of duty	
Teaching only	171 (62.0)
Administrative only	13 (4.7)
Both teaching and admin	91 (33.0)
Length of practice (years)	
1–10	201 (77.0)
11–20	45 (17.0)
≥ 21	16 (6.0)
Ownership of school	
Government	177 (64.1)
Private	99 (35.9)

Respondents' Perception on Measures for Facilitating Healthy Eating among School Pupils

Whereas about two-thirds 183 (66.1%) of the 277 respondents strongly perceived the need for students to have access to adequate and safe drinking water within the school premises, less than half of them strongly perceived the need for the other measures for facilitating healthy eating among school pupils. However, close to half of respondents strongly perceived the need for the school nutrition services unit to provide adequate, safe, clean, and well-maintained spaces and facilities for eating (48.4%), and the need to ensure that foods and beverages sold in the schools meet nutritional standards (47.7%). The respondents' perception on the other measures for facilitating healthy eating among school pupils is shown in Table 2.

Respondents' Perception on Measures for Facilitating Physical Activity among School Pupils

Less than half of respondents strongly perceived the need for any of the measures for facilitating physical activity among school pupils. However, close to half of respondents (49.8%) strongly perceived the need to ensure that the space and facilities provided for physical activity meet safety standards (49.8%), provision of safe and age-appropriate playground and equipment (47.3%), and ensure that injuries sustained during physical activity are adequately treated (47.3%). The respondents' perception on the other

measures for facilitating physical activity among school pupils is shown in Table 3.

Promotion of Healthy Eating and Physical Activity by Respondents

Only about a third and less of respondents very often promote healthy eating and physical activity among their pupils. One hundred and four (37.5%) of the 277 respondents very often educate their pupils on healthy eating, while 96 (34.7%) very often educate them on the need to engage in regular physical activity. The other respondents' healthy eating and physical activity promotion practices are shown in Table 4.

Respondents' Dietary Habits and Physical Activity Status

While majority of respondents practice healthy eating such as consumption of fruits thrice or more in a week (71.4%) and eating vegetables thrice or more in a week (78.0%), more than a third of them practice unhealthy eating such as drinking fruit juice thrice or more in a week (48.7%) and eating snacks/fast foods thrice or more in a week (30.3%). Less than a third of respondents trek to work thrice or more in a week (23.8%) or engage in moderate-intensity activity at leisure time thrice or more in a week (27.0%) as shown in Table 5.

Fifty-three (19.1%) of the 277 respondents live sedentary lifestyle by virtue of riding a car or motorcycle to work every day, their work schedule not involving moderate

Table 2: Respondents' perception on measures for facilitating healthy eating among school pupils

Measures for facilitating healthy eating among school pupils	Responses (n=277)			
	Strongly disagree frequency (%)	Disagree frequency (%)	Agree frequency (%)	Strongly agree frequency (%)
School authorities should periodically train teachers on healthy nutrition	26 (9.9)	18 (6.5)	105 (37.9)	128 (46.2)
Teachers should educate pupils on healthy nutrition as part of the school curriculum	5 (1.8)	18 (6.5)	136 (49.1)	118 (42.6)
Parents should be involved in lessons and other activities when nutrition education is provided to pupils	6 (2.2)	41 (14.8)	124 (44.8)	106 (38.3)
Parents should reinforce at home the nutrition education being provided to pupils at school	11 (4.0)	28 (10.1)	123 (44.4)	115 (41.5)
School authorities should provide adequate, safe, clean, and well-maintained spaces and facilities for eating	8 (2.9)	45 (16.2)	90 (32.5)	134 (48.4)
School nutrition services should provide nutritious, appealing, and culturally appropriate school meals for pupils	25 (9.0)	47 (47.0)	124 (44.8)	81 (29.2)
Free or highly subsidized breakfast and lunch should be offered to pupils	16 (5.8)	75 (27.1)	119 (43.0)	67 (24.2)
Inputs should be obtained from pupils about menu choices (e.g., through taste testing)	12 (4.3)	84 (30.3)	139 (50.2)	42 (15.1)
Meals should be served at an appropriate time and pupils should be given enough time to receive and consume their meals	10 (3.6)	38 (13.7)	140 (50.5)	89 (32.1)
School authorities should ensure that foods and beverages sold or served outside of school meal programs meet nutritional standards	10 (3.6)	15 (5.4)	120 (43.3)	132 (47.7)
School authorities should ensure that pupils have access to adequate and safe (potable) drinking water	10 (3.6)	16 (5.8)	68 (24.5)	183 (66.1)
School authorities should take necessary action to prevent or minimize the risk of food-borne illness among pupils	14 (5.1)	12 (4.3)	123 (44.4)	128 (46.2)
Pupils should be trained and actively involved in food environmental activities such as school garden and farm	8 (2.9)	21 (7.6)	135 (48.7)	113 (40.8)

Table 3: Respondents' perception on measures for facilitating physical activity among school pupils

Measures for facilitating physical activity among school pupils	Responses (n=277)			
	Strongly disagree frequency (%)	Disagree frequency (%)	Agree frequency (%)	Strongly agree frequency (%)
School authorities should provide safe and age-appropriate playgrounds and equipment for physical education and physical activity	16 (5.8)	13 (4.7)	117 (42.2)	131 (47.3)
School authorities should ensure that space and facilities for physical activity meet recommended safety standards	2 (0.7)	19 (6.9)	118 (42.6)	138 (49.8)
Provision should be made for physical activity breaks during the school day to enable pupils engage in physical activity	2 (0.7)	25 (9.0)	154 (55.6)	96 (34.7)
Provision should be made for extracurricular programs such as intramurals interscholastic sports that are age-appropriate and safe	10 (3.6)	15 (5.4)	173 (62.5)	79 (28.5)
School authorities should develop, teach, and enforce safety rules in sports	2 (0.7)	20 (7.2)	159 (57.4)	96 (34.7)
School authorities should maintain high level of supervision during structured and unstructured physical activity programs	6 (2.2)	20 (7.2)	136 (49.1)	115 (41.5)
Pupils should be provided with protective clothing (e.g., reflective clothing) and protective equipment (e.g., helmet, face mask, and mouth guards) appropriate for the type of physical activity and environment, and make them use it	8 (2.9)	58 (20.9)	110 (39.7)	101 (36.5)
School authorities should ensure that pupils of all sizes are encouraged to participate in a wide variety of physical activity and avoid policies that single out pupils on the basis of body size or shape	10 (3.6)	31 (11.2)	149 (53.8)	87 (31.4)
The school environment should support pupils with disabilities and chronic health conditions to be physically active	4 (1.4)	33 (11.9)	129 (46.6)	111 (40.1)
School authorities should ensure that injuries sustained during physical activities are healed before allowing further participation	4 (1.4)	15 (5.4)	127 (45.8)	131 (47.3)
School authorities should not use physical activity or withholding from participating in physical activity as punishment for bad behavior	11 (4.0)	66 (23.8)	127 (45.8)	73 (26.4)
School authorities should implement, promote, and advocate for creation of safe routes to school for walk and bicycle to school program	13 (4.7)	81 (29.2)	119 (43.0)	64 (23.1)

Table 4: Promotion of healthy eating and physical activity by respondents

Activity	How often (n=277)			
	Very often frequency (%)	Often frequency (%)	Occasionally frequency (%)	Never frequency (%)
Educate pupils on healthy eating	104 (37.5)	96 (34.7)	72 (26.0)	5 (1.8)
Educate pupils' parents on how to make nutritious foods	67 (24.2)	47 (17.0)	109 (39.4)	54 (19.5)
Participate in ensuring that the school meals meet nutritional standards	74 (26.7)	78 (28.2)	81 (29.2)	44 (15.9)
Educate pupils on the need to engage in regular physical activity/sports and its benefits	96 (34.7)	102 (36.8)	64 (23.1)	15 (5.4)
Engage pupils in physical activities/spots either in the classroom or playground	77 (27.8)	74 (26.7)	100 (36.1)	26 (9.4)

physical activity and not engaging in regular moderate leisure exercise.

Barriers to Healthy Eating and Physical Activity among Respondents

The most commonly cited very important barriers to eating healthy foods by the respondents were lack of information about healthy foods (57.0%), not having money to buy healthy foods (43.7%), and not having the skills to plan, shop for, prepare, or cook healthy foods (41.5%). Other very important barriers to eating healthy foods cited by the respondents are shown in Table 6.

The most commonly cited very important barriers to engaging in regular physical activities by the respondents

were not being motivated to do physical activity, exercise or sports (44.8%), not having the skills to do it (43.3%), and lack of time (42.2%). Other very important barriers to engaging in regular physical activities cited by the respondents are shown in Table 6.

DISCUSSION

This study assessed the perception, promotion, and practice of healthy eating and physical activity among primary school teachers in Sokoto, Nigeria. The strong perception of the need for pupils to have access to adequate and safe drinking water within the school premises by majority, 183 (66.1%) of the 277 respondents in this study appears to be

Table 5: Respondents' dietary habits and physical activity status

Variables	Number of time(s) (n=277)			
	None frequency (%)	Once frequency (%)	Twice frequency (%)	Three or more frequency (%)
Dietary habits				
Eat snacks/fast food items in a week	17 (6.1)	96 (34.7)	80 (28.9)	84 (30.3)
Drink fruit juice in a week	29 (10.5)	49 (17.7)	64 (23.1)	135 (48.7)
Drink carbonated soft drinks in a week	32 (11.6)	102 (36.8)	49 (17.7)	94 (33.9)
Eat fruits in a week	18 (6.5)	22 (7.9)	40 (14.4)	197 (71.4)
Eat vegetables in a week	17 (6.1)	27 (9.7)	17 (6.1)	216 (78.0)
Engagement in physical activity				
Trek to work in a week	86 (31.0)	60 (21.7)	65 (23.5)	66 (23.8)
Ride a bicycle to work in a week	126 (45.5)	34 (12.3)	56 (20.2)	61 (22.0)
Engage in moderate-intensity activity that causes moderate increase in breathing or heart rate such as brisk walking as part of your work schedule in a week	50 (18.1)	76 (27.4)	70 (25.3)	81 (29.2)
Engage in moderate-intensity sports, fitness or leisure activity such as brisk walking, cycling, swimming, and volleyball (lasting between 30 min and 1 h) in a week	53 (19.1)	69 (24.9)	80 (28.9)	75 (27.0)

Table 6: Barriers to healthy eating and physical activity among respondents

Variables	Considered it as very important frequency n=277 (%)
Barriers to eating healthy foods	
Do not have information about healthy foods	158 (57.0)
Do not have motivation to eat healthy foods	114 (41.2)
Do not enjoy eating healthy foods	94 (33.9)
Do not have skills to plan, shop for, prepare, or cook healthy foods	115 (41.5)
Do not have money to buy healthy foods	121 (43.7)
Healthy foods are not available in my school	84 (30.3)
Do not have time to prepare or eat healthy foods because of school commitments	78 (28.2)
No support from the school authority to eat healthy foods	82 (29.6)
No support from my spouse to eat healthy foods	79 (28.5)
No support from friends/relatives to eat healthy foods	72 (26.0)
Barriers to engaging in regular physical activities	
Do not have motivation to do physical activity, exercise, or sports	124 (44.8)
Do not enjoy physical activity, exercise, or sports	77 (27.8)
Do not have the skills to do physical activity, exercise, or sports	120 (43.3)
No support from the school authority to engage in physical activity, exercise, or sports	95 (34.3)
No support from my spouse to engage in physical activity, exercise, or sports	70 (25.3)
No support from friends and relatives to engage in physical activity, exercise, or sports	63 (22.7)
Do not have enough information about how to increase physical activity	97 (35.0)
Do not have access to place to do physical activity, exercise, or sports	94 (33.9)
Not being able to find physical activity, exercise, or sports facilities that are affordable	88 (31.8)
Do not have the time to engage in physical activity, exercise, or sports	117 (42.2)
Feel shy when practicing exercise outdoor	80 (28.9)
The climate is not suitable for practicing exercise	94 (33.9)
Not being able to engage in physical activity, exercise, or sports because of cultural factors	89 (32.1)

a reflection of the general perception of water as a basic necessity of life, considering the fact that less than half of them strongly perceived the need for the other measures for facilitating healthy eating among school pupils. Similarly, less than half of respondents strongly perceived the need for any of the measures for facilitating physical activity among school pupils. These findings suggest gaps in the knowledge of the measures for promoting healthy eating and physical activity in schools, as recommended by the CDC,^[3] and they underscore the need for government and

the management of the Sokoto State Primary School Board to develop and implement healthy eating and physical activity policies and practices in the primary schools across the state (as recommended by the CDC).^[3]

Training of teachers on the benefits of healthy eating and physical activity, and the measures for promoting these practices in schools, as well as the establishment of school environments that support healthy eating and physical activity are crucial to their compliance with the practices and promotion of the practices among their pupils. This is

supported by the findings of a meta-analysis that examined the effectiveness of Health Belief Model (HBM) variables in predicting behavior, which identified perceived benefits as one of the strongest predictors of whether an individual adopted a preventive health measure^[27], and a study conducted among youths by Ashton *et al.* that reported perceived benefits of healthy eating and physical activity as the main motivators for adopting the practices.^[14] It is, therefore, not surprising that only about a third and less of respondents very often promote healthy eating and physical activity among school pupils, while compliance with healthy eating and physical activity by them was suboptimal. Similar to the poor promotion of healthy eating by the respondents in this study, a study among teachers in Minnesota public schools reported that <1/3rd of teachers collaborated with community resources to provide nutrition education, 26% collaborated with the school food services, and 45% tried to involve parents, with the major barriers to nutrition education being lack of training, curriculum materials, administrative support, and time.^[28] These findings reemphasize the need for government and policy-makers to use a coordinated approach to develop, implement, and evaluate healthy eating and physical activity policies and practices in schools as recommended by the CDC.^[3]

According to the HBM, it is believed that messages will achieve optimal behavior change if they successfully target perceived barriers (in addition to benefits, self-efficacy, and threats).^[29] The suboptimal compliance with healthy eating and physical activity by the respondents in this study could, therefore, be related to the barriers reported by them. The findings of the most common barriers to healthy eating among the respondents in this study being lack of information about healthy foods (57.0%), not having money to buy healthy foods (43.7%), and not having the skills to plan, shop for, prepare, or cook healthy foods (41.5%) are similar to the findings in studies conducted among different populations across the world including South Africa,^[30] the United Kingdom,^[31] and Australia.^[32] Similarly, the most common barriers to physical activity among the respondents in this study including lack of motivation (44.8%), not having the skills to do it (43.3%), lack of time (42.2%), and lack of access to facilities for physical activity (33.9%) were the most commonly reported barriers to physical activities in studies conducted in other places including Ghana,^[33] Barbados,^[34] and the United States of America.^[35] These findings reaffirm the submissions of the CDC on the pivotal role of schools in the prevention of obesity and promotion of physical activity and healthy eating through policies, practices, and supportive environment.^[3] The CDC recommends that schools should establish social norms supportive of physical activity, implement school employees' wellness programs (to include healthy eating and physical activity

goals and services), provide a quality school meal program and ensure that students have only appealing healthy food and beverage choices offered outside of the school meal program, implement a comprehensive physical activity program with quality physical education as the cornerstone, and provide community access to facilities for physical activity, particularly at out-of-school times.^[3]

CONCLUSION

This study showed low levels of strong perception of the need for measures for facilitating healthy eating and physical activity and their promotion among school pupils by teachers in Sokoto, Nigeria. Furthermore, a substantial proportion of respondents practice unhealthy eating and live sedentary lifestyle, with the main barriers to healthy eating and physical activity being lack of information, poor motivation, unavailability of healthy foods, and lack of access to facilities for physical activity. These findings underscore the need for the management of Sokoto State Primary Education Board to develop and implement healthy eating and physical activity policies and practices in the primary schools across the state.

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Comparative Study of Unilateral Laminotomy versus Conventional Laminectomy

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Abstract

Introduction: Lumbar canal stenosis and prolapsed intervertebral disc (PVD) have been a major challenging problem of humankind since ages. Many different methods have been evolved for its diagnosis and management. The purpose of this study is to determine the efficacy and safety of unilateral laminotomy for decompression in case of PVD and lumbar canal stenosis compared to conventional laminectomy.

Materials and Methods: A retrospective and prospective study of 40 etrosopes who had undergone surgery for PVD or lumbar canal stenosis at our institute was carried out. They were assigned in the two groups: Group 1 ($n = 20$) consisted of patients who underwent laminotomy for decompression and Group 2 ($n = 20$) consisted of patients treated by decompressive laminectomy. Neurological status of the patients was evaluated by physical examination both pre-land post-operatively. Pain, disability, and other criteria were assessed by Greenough scoring system. Plain anteroposterior and lateral radiographs and magnetic resonance imaging of concerned segment were obtained of every patient. Lumbar flexion-extension films were obtained to assess spinal instability. Minimum follow-up was done at 6 at dhs, and the results were assessed using Greenough scoring system and radiographs at final follow-up.

Result: Excellent-good clinical outcome was obtained in 80% of patients in Group 1 and in 65% of patients in Group 2. Increase in Greenough score was more in Groupe1. Post-operative spinal instability occurred in four patients in Group 2 and none in Group 1. Early rehabilitation and early return to work were more possible in Group 1. There was one surgical complication in each group (dural tear dealt during surgery). Post-operative infection developed in four patients (two in each group), among which one requires surgical debridement in Groupi2. Neurological impairment occurred in one patient in Group 2.

Conclusion: Duration of hospital stay is significantly reduced among the patients operated by unilateral laminotomy compared with laminectomy, and rehabilitation was also faster by starting earlier sitting and thereby reducing morbidity and burden to hospital. Consequent earlier return to normal routine life can be expected. Although overall outcome of the patients at final follow remains mostly unchanged, technique of sparing unilateral paraspinal muscles and thereby sparing supraspinous and interspinous ligaments does help in earlier rehabilitations of the patients, fastens the recovery thereby reducing psychiatric problems related to it, saves many man hours of one to get back to normal routine life.

Key words: Laminotomy, Laminectomy, Lumbar canal stenosis, Prolapsed intervertebral disc

INTRODUCTION

Lumbar canal stenosis and prolapsed intervertebral disc (PVD) have been major challenging problem of mankind since ages. Low back pain, sciatica, is one of the common

problems of patient in orthopedic clinic. It is always seen that the difficulty is encountered by surgeon in arriving at definite diagnosis and haunting for etiology for back pain syndrome. Accurate diagnosis is most important for early recognition of cauda equina syndrome or significant functional illness of a patient, who complains of backache. Various imaging techniques are available nowadays to find the cause of this illness, starting from plain X-ray to the new world of advanced magnetic resonance imaging (MRI) technique. Many different methods have been evolved for its diagnosis and management.

Unilateral laminotomy for the decompression of lumbar canal stenosis was described as subarticular fenestration

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technique in 1988.^[1] Spetzger *et al.* investigated the practical application of unilateral laminotomy for lumbar canal stenosis in a cadaveric study,^[2] and Weiner *et al.* modified and put this technique into practice.^[3] There are many clinical studies on decompression by unilateral laminotomy and other minimally invasive techniques such as bilateral foraminotomies and laminoplasty.^[3-8] Minimally invasive techniques are not the standard surgical treatment modalities for lumbar canal stenosis yet. A minimally invasive technique preserves the structural integrity of the spine and has its own advantage of that. However, decompressive wide laminectomy is still being the most common surgical technique for this condition. Unilateral laminotomy for the decompression of lumbar canal stenosis is the most outstanding of minimally invasive techniques as compared to bilateral foraminotomies, laminoplasty, transforaminal endoscopic surgery, and endoscopic interlaminar canal decompression. Bilateral foraminotomies and laminoplasty require bilateral muscle dissection which makes the procedure disputable. The aim of this study is to investigate the efficacy and safety of unilateral laminotomy for patients of lumbar canal stenosis and PIVD.

MATERIALS AND METHODS

A retrospective and prospective study of 40 retrosps who had undergone surgery for PID or lumbar canal stenosis at our institute was carried out. The study protocol was approved by the institutional ethics committee and scientific committee. 40 committs underwent surgery for lumbar stenosis, and PID refractory to conservative treatment was included.

Inclusion criteria were as follows:

1. Symptoms of neurogenic claudication or radiculopathy;
2. Radiological evidence of lumbar stenosis or PID;
3. Absence of associated pathological entities such as instability and infective etiology;
4. Absence of previous surgery for lumbar spine disorder;
5. Patients who were treated with fixation or fusion in first surgery were excluded.

Forty patients were assigned in the following groups: Group 1 ($n = 20$) consisted of patients who underwent laminotomy for decompression and Group 2 ($n = 20$) consisted of patients treated by decompressive laminectomy.

Pre-operative Assessment

Neurological status of the patients was evaluated by physical examination. Pain, disability, and other criteria were assessed by Greenough and Fraser scoring system^[9] consisting of 13 different parameters. Plain anteroposterior (AP) and lateral radiographs were obtained of every patient. MRI of the concerned segment was also done of each

patient. MRI was the main investigation for diagnosis and surgical planning. Lumbar flexion-extension films were obtained to assess spinal instability. Spinal instability was evaluated as the following criteria:

1. Anterior translation $>8\%$ (L1-2 to L4-5) or $>6\%$ (L5-S1) of the vertebral body width;
2. Posterior translation $>9\%$ (L1-S1);
3. Angular displacement (sagittal rotation) in flexion $>-9.6\%$ (L5-S1) of the vertebral body S1).^[10]

Surgical Procedure

All patients underwent surgery under general endotracheal anesthesia in prone position on bolsters on the radiolucent operative table.

Decompression by Unilateral Laminotomy

Image intensifier was used to localize the involved segment. The skin and fascia were incised in the midline. The paraspinal muscles were dissected free from their bony attachments on the spinous process and the lamina to expose the bony detail. Unilateral laminotomy was performed followed by ipsilateral foraminotomy and facetectomy if required. Adequate decompression was achieved by removing thickened *Ligamentum flavum* and the medial aspects of the facet joints; as well as other structures causing stenosis were resected partially by Kerrison Rongeur for decompression.

Decompressive Laminectomy

The skin and fascia were incised in the midline. The paraspinal muscles were dissected free bilaterally from their bony attachments on the spinous process and lamina to expose the bony detail. The spinous process and the laminae of the involved segment or segments were resected totally; the medial aspects of the facet joints were resected partially if the required, otherwise, facet joint left untouched to prevent the complication of iatrogenic instability.

Post-operative Assessment

The patients were examined neurologically, and Greenough score was assessed at post-operative 1st month and final follow-up. Post-operative AP and lateral radiographs were obtained and flexion-extension films to investigate instability were obtained at final follow-up. Average time of follow-up was 10.3 months (6 months to 2 years). Patients with minimum follow-up of 6 months were included; those not satisfying it were excluded from the study. Patients of all age groups were included in the study.

The safety of surgical techniques both unilateral laminotomy and laminectomy was assessed as surgical complication rate. These complications include neural injury, dural tear, and infection. In Greenough scoring system, total score = SUM (points for all 13 parameters).

Interpretation: Minimum score: 0 maximum score: 75.

Results were graded according to the scoring system into four groups [Table 1].

RESULT

Excellent-good clinical outcome was obtained in 80% of patients in Group 1 and in 65% of patients in Group 2.

There was one surgical complication in each group (dural tear dealt during surgery). Post-operative infection developed in four patients (two in each group), among which one requires surgical debridement in Group 2. Neurological impairment occurred in one patient in Group 2. Post-operative spinal instability occurred in four patients in Group 2 and none in Group 1 [Figure 1].

Improvements in Greenough Scores

The increase in Greenough score was more in Group 1.

DISCUSSION

Difference in mean age of both the groups suggestive of double peak occurs in the lumbar disc disease; first group of patients presents earlier in life due to having risk factors such as trauma or heavy weight lifting or undue exertion, while the second peak occurs after the age of 50 peaks suggestive of degenerative lumbar spine pathology. The difference in sex ratio in both the groups suggests that overall number of operated male persons exceeds far more than females reflecting Indian work distribution. As males are engaged more in heavy outdoor duties and more labored work against females linked to more indoor sedentary duties, thereby males become more prone to traumatic and degenerative lumbar disc disease [Table 2].

In both the groups, almost 50–55% of the patients were associated with the laborious job, suggesting that heavy weight lifting or repeated trauma or undue exertion could be a precipitating factor in early development of lumbar disc disease. History of trauma or exertion is more in laminotomy group patients, suggesting that, in younger age group patients, trauma may act as a precipitating factor and lead to early disc degeneration while older patients have more of age-related degenerative disc disease.

Among the laminotomy group, 70% of the patients were discharged within 10 00% of operation, while in laminectomy operated patients, only 25% of the patients could be discharged within a 10 days, suggesting that overall duration of hospital stay could be reduced with choosing laminotomy as a procedure, and this could be

Table 1: Greenough score outcome

The higher the score, the better the patient's status Score	Status
≥65	Excellent
50–64	Good
30–49	Fair
0–29	Poor

Table 2: Comparison between two groups

Parameters	Group 1 unilateral laminotomy (%)	Group 2 conventional laminectomy (%)
Number of patients	20	20
Male: Female	14:6	10:10
Mean age (in years)	42.4	52.5
Occupation		
Heavy to moderate	55	50
Sedentary	45	50
History of trauma or exertion	55	20
Neurological claudication	55	75
Affected level		
L2-L3	1	1
L3-L4	1	6
L4-L5	11	17
L5-S1	7	8
Number of level operated		
One level	20	10
More than one	0	10
Duration of hospital stay (mean, in days)	9.1	13.85
Pain free sitting (mean in weeks)	3.9	5.6
Return to normal work (mean, in months)	4.5	6.6
Complication		
Major	10	15
Minor	15	10
Improvement in greenough score (mean)	30	24.25

Table 3: Improvement in Greenough scores

Score	Laminotomy (%)	Laminectomy (%)
<20	4 (20)	9 (45)
20–35	6 (30)	7 (35)
>35	10 (50)	4 (20)
Total	20 (100)	20 (100)

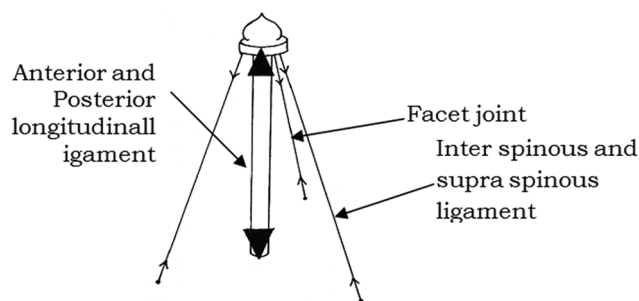
attributed to reduced soft tissue dissection and preventing damage to unilateral paraspinal muscles, supraspinous, and interspinous ligaments in this procedure with minimizing damage and reducing operative time thereby further reducing chances of developing procedure-related complications in perioperative and post-operative period, and thereby patients could be discharged uneventfully.

About 45% of the patients in laminotomy group had started sitting in first 4 rousps with minimum pain as

compared to only 20% of patients in laminectomy group. In laminotomy group, at least 60% of the patients returned to their work within 6 hrs of duration as compared to 25% in laminectomy group. This suggests that the sparing supraspinous and interspinous ligaments with causing minimum damage to paraspinal muscles prevent gross instability and help in early mobilization of the patients and early rehabilitation [Table 3].

Lumbar canal stenosis and PIVD are a common degenerative process of lumbar spine in elder age group patient and may significantly affect the quality of life. Indeed, lumbar canal stenosis is now the most common indication for spinal surgery in patients over 65 of 1s of age.^[7] Extensive laminectomy with medial facetectomy and foraminotomy is commonly used for the treatment of lichen sclerosis (LS). The aim of techniques such as laminectomy or other unroofing procedures is wide decompression, but they may frequently cause spinal instability.^[11-13] Long-term results of decompressive laminectomy for lumbar canal stenosis^[6,13] and a meta-analysis demonstrate that successful short-term results of surgery are not maintained in a substantial percentage of patients.^[14] Loss of midline supraspinous/interspinous ligament complex may lead to a loss of flexion stability, thereby increasing the risk of delayed spinal instability.^[15] Instability with resultant chronic pain syndrome has been suggested as a potential cause of poor outcome.

Anterior longitudinal ligament anteriorly, facet joints on either side laterally, and interspinous and supraspinous ligament posteriorly act as three wires under tension around flagpole. Even if one wire is broken, the stability of the spine is reduced. This is known as “flagpole concept of Evan.”^[16]



Our technique of laminotomy keeps this in mind and preserves spinous process and supraspinous and interspinous ligaments and half the paraspinal muscles along with underlying ALL and PLL, thereby reducing the chances of developing instability.

Mullin *et al.* detected instability in 54% of flexion-extension radiographs of wide decompressive laminectomy patients with long-term follow-up.^[11] The use of wide

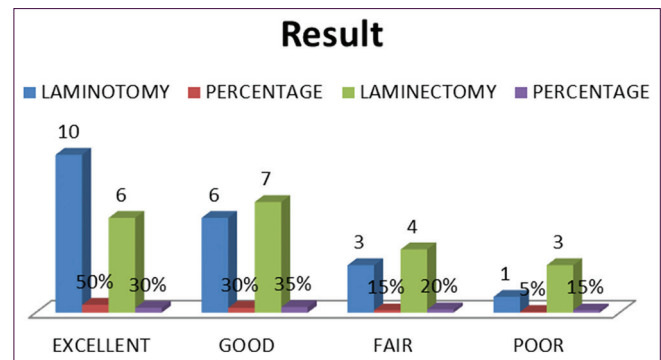


Figure 1: Greenough score comparison

decompressive procedures for lumbar canal stenosis, without regard for the integrity of the laminae and facet joints and without preservation of the spinous processes and interspinous ligaments, may lead to mechanical failure of the spine and a chronic pain syndrome.^[6,12,14,15] According to Rompe, Schultz observed 46 observes after decompressive laminectomy for 3–10 Oamis,^[13] of which 30% developed spinal instability; a correlation between low back pain and instability was found.

The major advantage of performing minimally invasive procedures is in reduction of tissue exposure and soft tissue trauma. As tissue disruption is the most important trigger of the surgical stress response, it is reasonable to modify current practice in favor of minimally invasive procedures.^[5] Despite having this advantage, minimally invasive techniques are still not performed widely. Possible causes of this condition are high-cost hardware, high learning curve for these procedures, and lack of convincing clinical studies on minimally invasive procedures. Among the minimally invasive techniques described for the treatment of lumbar canal stenosis, unilateral laminotomy for decompression is the most outstanding. Although there are many clinical studies reporting affirmative results,^[2-5,7,8,13,17,18] a number of randomized comparative studies on this technique are insufficient.^[8,13,17,18] Studies investigating unilateral laminotomy for decompression do not report post-operative spinal instability.^[2-8,13,17] Mayer *et al.* demonstrated a decrease in paraspinal muscle strength with atrophy after extensive muscle retraction during surgical decompression.^[19] Retraction of multifidus muscle beyond the midpoint of the facet joint tethers the medial branch of dorsal ramus within the mamilloaccessory groove, risking muscular denervation. Unilateral laminotomy for bilateral decompression limits ipsilateral retraction to the level of the medial facet border. Contralaterally, no elevation or retraction of the paraspinal musculature is undertaken, thereby minimizing the risk of iatrogenic muscular trauma.^[3] Unilateral laminotomy for decompression preserves the integrity of both facet and ligament-muscle complex. Bresnahan *et al.* biomechanically evaluated

graded posterior element removal for the treatment of lumbar stenosis.^[20] They suggested that the removal of posterior bony elements associated with laminectomy produces the greatest change in segmental motion during flexion, extension, and left and right axial rotation; while following a minimally invasive procedure, post-operative segmental motion is similar to the intact spine; increased posterior element removal resulted in increased motion when compared to the minimally invasive approach in all loading conditions except for lateral bending; preservation of the posterior spinal elements associated with minimally invasive surgery could minimize rates of developing *de novo* post-operative changes in spinal alignment.^[20] Therefore, this technique is optimal to preserve spinal stability.

We evaluated clinical outcome after surgery using Greenough scoring system. In Group 1, there was excellent-good result in 16, (80%), while 13 (65%) had excellent-good result in Group 2. Although this difference is statistically insignificant, the success rate of unilateral laminotomy is apparently higher than that of laminectomy. Another indicator of clinical outcome after surgery is less hospital stay, early pain-free sitting, and earlier return to work in Group 1 compared to Group 2. There was no post-operative instability in unilateral laminotomy group in this study, while four patients (20%) had post-operative spinal instability in the laminectomy group.

The results of this study show that unilateral laminotomy for the decompression of LS eliminates most of the reasons of failure and seems as an optimal surgical technique. Only one issue remains to be discussed; whether unilateral laminotomy is safe or not. In many studies comparing unilateral laminotomy and laminectomy for the treatment of LS complications, rates differ.^[3,4,7,8,12] Dural tear is the most frequent surgical complication in these surgical procedures whose incidence in one comparative study was 12.5% in unilateral laminotomy group and 20% in laminectomy group.^[17] In our study, the incidence of dural tear was equal in both the groups. Another frequent surgical complication is nerve root injury; fortunately, severe nerve root injury is infrequent in all techniques. In our study, there was no severe nerve root injury in both the groups. These results show that unilateral laminotomy is safe for the decompression of lumbar canal stenosis and PID.

CONCLUSION

Duration of hospital stay is significantly reduced among the patients operated by unilateral laminotomy and decompression as compared with laminectomy, thereby

reducing morbidity and burden to hospital and preventing hospital-acquired complications. Rehabilitation of the patient becomes faster as patient starts earlier sitting, and consequent earlier return to normal routine life can be expected. Complications requiring active interventions are far less in patients operated by laminotomy. Chances of developing instability over the long term are higher in laminectomy group. Although overall outcome of the patients at final follow remains mostly unchanged, technique of sparing unilateral paraspinal muscles and thereby sparing supraspinous and interspinous ligaments does help in earlier rehabilitations of the patients, fastens the recovery from one of the most debilitating disease-disc prolapse and lumbar canal stenosis, and thereby reducing psychiatric problems related to it, saves many man hours as compared with laminectomy, thereby reducing morbidity and burden to hospital.

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Comparative Study of Effectiveness of Short Course versus Long Course Antimicrobial Prophylaxis after Clean Orthopedic Surgery - A Prospective Study of 200 Patients

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Abstract

Introduction: Surgical site infection (SSI) is one of the most devastating complications associated with any surgical procedure. It is associated with prolonged morbidity, disability, and increased mortality. We assess the effectiveness of short-term (<48 h) versus long-term (14 days) antimicrobial prophylaxis therapy in preventing SSI after clean orthopedic surgeries.

Materials and Methods: A random sample of 200 patients admitted for elective orthopedic surgeries performed under all aseptic precautions was divided into two equal groups with Group I given short-term (<48 h) and Group II given long-term (14 days) prophylaxis of the same antibiotic protocol. Both the groups underwent the predetermined protocol of investigations (complete blood count, erythrocyte sedimentation rate, C-reactive protein, BT/computed tomography, liver function tests, renal function test, urine routine, radiographs, and viral markers). They were evaluated on the basis of wound condition as per predetermined criteria on 2nd, 5th, 14th, and 28th days' post-operative procedure.

Results: The mean age of the patients in Groups I and II was 41.68 ± 16.95 years and 40.71 ± 17.22 years, respectively, and the female-to-male ratio in both the groups showed no significant statistical difference ($P > 0.05$). Mean duration of surgery in both the groups showed no significant difference. Two patients (2%) in Group I and three patients (3%) in Group II developed SSI which on statistical comparison showed no significant difference ($P > 0.05$).

Conclusions: There is no benefit of prophylactic antibiotic after 48 h in clean elective orthopedic surgeries with short course antimicrobial prophylaxis being as effective as long course antimicrobial prophylaxis in developing country after clean elective orthopedic surgery.

Key words: Short term, Long term, Antimicrobial, Prophylaxis, SSI, Infection

INTRODUCTION

Infection is one of the most devastating complications associated with any surgical procedure. It is associated with prolonged morbidity, disability, and increased mortality. Of nearly 30 million operations in the United States each year, more than 2% are complicated by surgical site infection

(SSI). Mortality rates are 2–3 times higher in patients in whom SSI develops compared with uninfected patients.^[1] The Centers for Disease Control and Prevention (CDC) considers SSI to include both incisional SSI and organ space SSI. SSI was defined according to the CDC and Prevention.^[2,3,4]

Superficial incisional SSIs must meet the following criteria:

- Infection occurs within 30 days after the operative procedure and involves only skin and subcutaneous tissue of the incision and
- Patient has at least one of the following criteria:
 - a. Purulent drainage from the superficial incision
 - b. Organisms isolated from an aseptically obtained culture of fluid or tissue from the superficial incision

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- c. At least one of the following signs or symptoms of infection.

Pain or tenderness, localized swelling, redness or heat, and superficial incision are deliberately opened by surgeon and are culture-positive or are not cultured (a culture-negative finding does not meet this criterion)

- d. Diagnosis of superficial incisional surgical by the surgeon or attending physician.

Deep incisional SSIs must meet the following criteria:

- Infection occurs within 30 days after the operative procedure if no implant is left in place or within 1 year if implant is in place and
- The infection appears to be related to the operative procedure and involves deep soft tissues (e.g., fascial and muscle layers of the incision) and
- Patient has at least one of the following criteria:
 - a. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.
 - b. A deep incision spontaneously dehisces or is deliberately opened by a surgeon and is culture-positive or not cultured when the patient has at least one of the following signs or symptoms: Fever ($>38^{\circ}\text{C}$) or localized pain or tenderness (a culture-negative finding does not meet this criterion).
 - c. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologic or radiologic examination.
 - d. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

Surgical wounds are stratified into four classes:

- Class I (clean) - An uninfected operative wound in which no inflammation is encountered, and the respiratory, alimentary, genital and urinary tracts are not entered as part of the surgical procedure such as neurological procedure, eye surgery, orthopedic surgery (all closed fracture, arthroplasty, amputation, and removing of old implant), and vascular surgery.
- Class II (clean-contaminated) - Operative wounds in which the respiratory, alimentary, genital, or urinary tracts are entered under controlled, uncomplicated conditions such as any wound open for drainage and reoperation at the same site.
- Class III (contaminated) - Wounds are open, fresh accidental wounds, or incisions made as part of operation, during which major breaks in sterile technique or gross spillage of gastrointestinal contents have occurred such as foreign body in a wound, open fracture, old burns, and open traumatic wounds.

- Class IV (dirty-infected) - Wounds are old traumatic wounds from dirty source or those that involve existing clinical infection or perforated viscera.

Prophylactic antibiotics have been described as antibiotics given for the purpose of preventing infection when infection is not present, but the risk of post-operative infection is present.^[5] The use of prophylactic antibiotic therapy before the induction of anesthesia and continuing it after surgery is an accepted method of avoiding post-operative infection.^[6,7] Essentially, prophylaxis augments the host's natural immune defense mechanism by increasing the amount of bacterial contamination needed to cause an infection.^[8]

While the benefits of preventing surgical infections are apparent, one must also keep in mind the disadvantages of excess antimicrobial use. All infections cannot be prevented by the use of prophylactic antibiotics. Each patient has a unique set of immune defense against the risk of infection. The use of broad-spectrum antibiotics contributes to the development of multidrug-resistant organisms.^[8] Infections due to resistant organisms are associated with a worse clinical outcome for each individual patient. There must be a delicate balance between the use of antimicrobial agents to prevent infection and the overuse of antimicrobial agents, which are associated with the development of multidrug-resistant organisms.^[8] Cephalosporins and other antibiotics are used widely for prophylaxis in India and several reports have compared other antibiotics with cephalosporins.^[7,12]

Patient risk factors thought to increase the chance of SSI include advanced age, poor nutritional status, obesity, smoking, diabetes, altered immune response, length of pre-operative stay, colonization with microorganisms, coexisting infections remote from operative site, setting of the procedure (elective or emergent, clean or contaminated, and others), and other risk factor such as duration of surgery, drain, and blood loss.^[9-11]

The goal of antimicrobial prophylaxis is to achieve serum and tissue drug levels that exceed the minimum inhibitory concentration for the organisms likely to be encountered during the operation.^[6] The idea is not to sterilize tissues but to reduce the microbial burden of intraoperative contamination to a level that cannot overwhelm host defenses.

There is no consensus with regard to the optimal duration of prophylaxis. The standard practice is to administer prophylactic intravenous (i.v.) antibiotics only on the day of surgery in Western countries.^[13-15] However, in Japan, prophylactic i.v. antibiotics are administered for several days postoperatively, and 1 day antibiotic infusion is rare.

A questionnaire survey of Japanese orthopedic surgeons showed that 86% of surgeons administered i.v. antibiotics for 7 days or longer after prosthetic surgery.^[15] Benefits of perioperative antimicrobial prophylaxis need to be balanced against risks. Before the understanding of surgical asepsis and the study and acceptance of the principles of antibiotic prophylaxis, postoperative infections were nearly universal. The benefits of decreased infection rate, length of hospital stay, mortality, and costs have been shown in various populations.^[17]

MATERIALS AND METHODS

A prospective, randomized, comparative study was conducted in 200 patients who were admitted in orthopedic ward of K. J. Somaiya Medical College and Research Centre, Mumbai, for surgery for a period of 1 year.

Participants were randomly allocated to two groups by block randomization method. In each group, equal number of patients, i.e., 100 was included. The patients in Group I were given second-generation cephalosporin (cefuroxime 1.5 g) for 30 min prior to the induction of anesthesia which was continued till 48 h after surgery 12 h apart, then it was discontinued.

The patients in Group II were given perioperative long-term prophylactic i.v. antibiotic second-generation cephalosporins (cefuroxime 1.5 g) 30 min before the induction of anesthesia which was continued for 5 days of the post-operative period 12 h apart then they were further given an oral antimicrobial agent (tab cefuroxime 500 mg) 12 h apart until 14 days.

Patients were admitted a day before surgery. The operative area was cleaned of hairs night before surgery (use of razors over operative area avoided).^[23] The patient took a bath with an antiseptic agent at least once on the night before the operation.^[24]

Routine blood investigations such as complete hemogram, bleeding time, clotting time, erythrocyte sedimentation rate, C-reactive protein, renal function test, and liver function test were done.

Other investigations include:

- Radiographs including chest X-rays.
- Viral markers such as HIV, hemoglobin (Hb) Ag, and HCV.
- Urine routine and microbiology examination.

Aseptic Precautions in Operation Theater

All necessary precautions were followed such as using autoclaved gloves, sterile instruments and drapes, standard

surgical scrub for 5 min before operation, cleaning of operative area with povidone-iodine and spirit,^[25-29] minimal tissue handling, maintaining of adequate hemostasis, and minimal use of cautery, using drains wherever necessary.

Criteria to assess Infection

Our criteria for judging whether or not a wound infection occurred were as follows which has been modified from that of Pavel *et al.*^[37]

1. If a wound drained purulent material irrespective of whether an organism was cultured or not, it was considered infected.
2. When a wound has become red, painful or tender, swollen, and hot for >48 h, the wound was considered infected.
3. When the patient had fever for >48 h and no other cause could be traced, the wound was considered infected.
4. If the patient had a stitch abscess with a small amount of purulence directly around a suture, but without any signs of inflammation or fever, the wound was not be considered infected.

Post-operative Care

All participants were treated by the standard surgical techniques. They were evaluated for the development of wound infections daily until the time of discharge. The wound was clinically observed on 2nd and 5th days after surgery when the dressings were done.

Drain was removed on 2nd post-operative day dressing. Apart from this, the patients were evaluated daily for any signs of wound infection such as local erythema, induration, local rise of temperature, and any discharge, and daily temperature charting was done. The patient was discharged on 5th day after surgery. A clinical follow-up was done on 14th day when the patient's sutures were removed. Surgical site assessment was done for patients who came after suture removal for routine follow-up in OPD on the 28th day.

Observations

Majority of patients were male, i.e., 63% and 68% in Groups I and II. We also found equal number of female cases, i.e., 37% in Group I and 32% in Group II. Statistical comparison of both the groups showed no significant difference ($P > 0.05$). Mean age 41.68 ± 16.95 in Group I and 40.71 ± 17.22 in Group II showed no statistical significant difference ($P > 0.05$). Thus, we can say that both the groups were found to be comparable with each other. Mean body mass index (BMI) of all the cases was 23.21 ± 1.9 in Group I and 23.04 ± 3.0 in Group II.

We noted that laboratory investigations of both the groups are compared with each other, thus showing no statistical

difference among them ($P > 0.05$). Mean duration of the operation in the present study of all the cases was 65.27 ± 29.21 in Group I and 66.50 ± 25.11 in Group II. Statistical comparison of the duration of surgery of both the groups was found to be statistically non-significant ($P > 0.05$). A maximum number of patients were non-smoker, i.e., 76% in Group I and 73% in Group II. Only 24% and 27% of cases were found to be with smoking habits in Groups I and II, respectively. Statistical comparison of smoking habits of both the groups showed no significant difference ($P > 0.05$). Two patients (2%) developed SSI infection in Group I and three patients (3%) developed in Group II. On statistical comparison, we found no significant difference between the two groups ($P > 0.05$). We did not find any case of deep SSI in any of the groups in our study. Two cases in Groups I and two cases in Group II in the age group of >60 years having superficial SSI. On statistical comparison, we found no significant difference between the two groups ($P > 0.05$). Equal number of male, i.e. two cases each was found in both the groups and no female in Group I and 1 female in Group II suffered with infection. On statistical comparison, we found no significant difference between the two groups ($p > 0.05$). One case in Group I and one case in Group II infected with SSI with BMI range from 18.5 to 24.9, and one case in Group I and two cases infected with SSI with BMI range from 25 to 29.9. On statistical comparison, we found no significant difference between the two groups ($P > 0.05$).

DISCUSSION

Post-operative wound infections have been shown to significantly increase morbidity, extend patients hospital stay, drastically increase the cost of medical system, and cause severe physical limitations that diminish the quality of life. Decreasing the incidence of SSI is a matter of utmost interest to both patient and surgeon.

The use of prophylactic antibiotics is one of the most important factors in decreasing infection, and there is wide variability in the duration of their use.^[18,22] Available literature recommends the use of prophylactic antibiotics for 24 h only.^[39,44] Administration of prophylactic antibiotics for longer than 24 h has not been demonstrated to be effective and may actually lead to superinfection with drug-resistant organisms.^[31,33]

The present study was conducted in K. J. Somaiya Medical College and Research Centre, Mumbai, with an aim to find optimal duration of prophylactic antibiotics in elective orthopedic surgeries.

A total of 200 patients who were undergoing clean elective orthopedic procedures were selected. These were

divided into two groups of 100 patients each by block randomization method. The patients in the first Group received same i.v. antibiotic protocol as in the Group II for 48 h, then it was discontinued. The patients in Group II received perioperative long-term prophylactic i.v. antibiotic second-generation cephalosporins (cefuroxime 1.5 g) 30 min before the induction of anesthesia, which continued for 5 days of the post-operative period 12 h apart then they were further given an oral antimicrobial agent (tab cefuroxime 500 mg) 12 h apart till 14 days.

Cephalosporins and other antibiotics are used widely for prophylaxis in India and several reports have compared other antibiotics with cephalosporins.^[7,12] The trend in Western literature is to use second-generation cephalosporins (cefuroxime) prophylactic antibiotics 30 min to 1 h before skin incision and preferable for 24 h to 3 days in i.v. infusion postoperatively.^[21] Cefuroxime has high bioavailability in tissue and serum after a single dose and is efficacious for preventing perioperative infection.^[34,36] Yeap *et al.*^[16] studied antibiotic prophylaxis in state-level hospitals and found out that 1st generation antibiotics as advised were not practiced in any of patients. Second-generation followed by third-generation cephalosporins were most popular antibiotics, with trend using third-generation antibiotics in arthroplasty patients. Cephalosporins are by far the most popular choice of antibiotics for prophylaxis.

In our study, of 200 patients, 131 (65.5%) were males and 69 (34.5%) were females. 4 (3.05%) of 131 males developed SSI compared to 1 (1.58%) of 63 females developed SSI. Shrestha *et al.*^[19] found that infection rate among males was nearly twice that of females.

In this study, of 200 patients, 55 (27.5%) patients were more than 50 years of age group and 145 (72.5%) were below 50 years. Of 55 patients above 50 years, 5 patients (9.09%) developed infection. Chhabra *et al.*^[39] found that patients aged more than 50 years most commonly developed SSI. Increasing age was found to be a significant influence on the rate of infection in this study; this is keeping with other studies.^[32] Increased infection rates among the elderly may be attributed to low healing rates, malabsorption, and low immunity.^[37]

In this study, smoking was associated with higher incidence of SSI. 51 patients (25.5%) were smokers and 149 (74.5%) were non-smokers. Of 51 patients who were smokers, 4 (7.84%) developed SSI and 1 (0.67%) of 149 non-smokers developed SSI. Masood *et al.*^[38] showed 25% infection rates among smokers in their study. Smoking has detrimental effect on tissue oxygenation, impairing reparative process of wound healing, and neutrophil defense against surgical pathogens.^[30]

In our study, average BMI in long duration group was $23.21 \pm 1.9 \text{ kg/m}^2$ and short duration group was $23.04 \pm 3.0 \text{ kg/m}^2$. Of 200, 31 (15.5%) patients had BMI >25 and 169 (84.5%) had BMI <25 . Three patients (9.6%) of 31 patients with BMI >25 developed SSI compared to two patients (1.18%) of 169 with BMI <25 . Masood *et al.*^[38] in their study, found out BMI $>40 \text{ kg/m}^2$ to be associated with higher rate of SSI.

In our study, we found that mean Hb in long duration group was 11.128 ± 1.79 , whereas mean Hb in short duration group was 11.069 ± 1.69 . About 67 (33.5%) patients had Hb $<10 \text{ g/dl}$, of which 5 (7.46%) developed SSI, whereas 143 (71.5%) patients with Hb $>10 \text{ g/dl}$, of which no patient had developed SSI which was comparable to study done earlier. Masood *et al.*^[38] found that higher incidence of SSI was noted in low pre-operative Hb ($<10 \text{ g/dl}$) group. It may be due to poor oxygen and nutritional delivery to tissues.

In this study, of total 200 patients, 30 (15%) had TLC more than reference range, i.e. $11,000/\text{mm}^3$. Four (13.33%) of these 30 developed SSI. Of 170 (85%) patients with TLC $<11,000$, one (0.59%) developed SSI. Guohua *et al.*^[36] found that pre-procedural white blood cell count $>10 \times 10^9/\text{L}$ was identifiable risk factor for SSI.

Average duration of surgery in long-term antibiotics group was $65.27 \pm 29.21 \text{ min}$ and that of short-term antibiotics was $66.50 \pm 25.11 \text{ min}$. 13 surgeries lasted more than 2 h, of which 1 (7.6%) developed SSI, whereas of 187 surgeries lasting $<2 \text{ h}$, 4 (2.1%) developed SSI. Samuel *et al.*^[40] found increased rates of infection in surgeries lasting longer than 2 h. Masood *et al.*^[38] found that the rate of SSI was increased in surgeries lasting longer than 150 min.

We observed that the average cost of short course treatment amounted to Rs.800 per patient as compared to Rs. 2900 per patient for prolonged combinational regimens. Mathur *et al.*^[20] found that shorter courses of perioperative antimicrobials reduce cost, toxicity, and development of drug resistance. Prolonged courses of prophylactic antimicrobials have tremendous economic consequences for health-care facilities. In developing nations, such resource saving can be utilized for purchase of other life-saving drugs/devices. Since perioperative prophylaxis contributes a significant proportion of in-hospital antimicrobial use, its judicious use will also curtail the cost of hospital treatment.^[38-41]

In our study, SSI among long-term group was 2% and short-term group was 3% which was statistically insignificant. Similar results have been quoted by Mathur *et al.*^[20] who found out that there is no significant difference between short course of injectable antibiotic cefuroxime 12 hourly

for 48 h and long course of same injectable antibiotic for 5 days and then oral antibiotic cefuroxime 12 hourly until suture removal. He also found that the incidence of SSI was comparable in both the groups, i.e., 2% (2 of 100 patients) in short duration group and 2.06% (2 of 97 patients) in long duration group. Williams and Gustilo^[41] retrospectively compared outcomes for 1341 joint arthroplasties who had received prophylaxis for 3 days with 450 patients undergone similar procedure and received antibiotics prophylaxis for 1 day. Infection developed in 8 (0.6%) of 1341 patients in Group I compared with 3 (0.67%) of 450 patients in Group II.

CONCLUSIONS

In our study, there was no statistical difference between the rate of infection among those who received 48 h i.v. antibiotics and those who received antibiotics for 14 days. It was concluded that there is no benefit of prophylactic antibiotic after 48 h in clean elective orthopedic surgeries. Short course antimicrobial prophylaxis is as effective as long course antimicrobial prophylaxis in developing country after clean elective orthopedic surgery. There are many risk factors associated with SSI such as age >50 years, male sex, Hb $<10 \text{ g/dl}$, pre-operative TLC $>11,000$, BMI $>25 \text{ kg/m}^2$, smoking, and duration of surgery $>2 \text{ h}$.

Prophylactic administration of antibiotics for short term can decrease post-operative morbidity, shorten hospitalization, reduce the overall cost attributable to infection, prevent unnecessary use of antibiotics for longer periods, and reduce the risk of resistance of antibiotic in clean orthopedic surgery. However, since the sample size was less, larger and multicentric studies covering different regions of the country are required to substantiate the role of short-course prophylaxis in our country.

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Study of Incisional Hernia in Relation to Specific Risk Factors

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Abstract

Background: Incisional hernia is a serious post-operative complication of laparotomy. Its incidence following abdominal surgery ranges from 2% to 11%, and it accounts to 15–20% of all abdominal wall hernias. A number of predisposing factors have been identified which may be related to specific patient characteristics and underlying pathological process or iatrogenic factors.

Materials and Methods: This prospective study was conducted in 40 cases of incisional hernia in isolation or in various combinations of specific risk factors such as sex, obesity, diabetes mellitus, history of previous wound infection, the site and type of incision used, and indication for previous operations admitted in surgical unit of Mahatma Gandhi Memorial Hospital, Kakatiya Medical College, Warangal, Telangana State, India, from June 2015 to December 2017. The results were analyzed.

Results: The total number of cases studied in the series is 40. In this series, incisional hernia is found to be common in third and fourth decades with 80% of females and 20% of males and female-to-male ratio is being 4:1, showing a clear predilection toward female sex. 75% of incisional hernias followed operations on female pelvic organs. 5% followed after unspecified laparotomy (lump abdomen) and 20% of cases followed after acute abdominal procedures. 75% of incisional hernias occurred through subumbilical midline incisions.

Conclusion: The highest incidence of incisional hernia in the present series is between the age group of 21 and 30 years. Most of our patients were females. Multiple predisposing factors are noticed to the occurrence of incisional hernia. Operations on the female pelvic organs were the most common procedures preceding the development of incisional hernia. Obesity is a common predisposing factor. Post-operative wound infection at previous surgery seems to be a common predisposing factor. Lower midline incision appears to have a special predilection toward incisional hernia. All these factors are interrelated. The presence of more than one factor in a patient shows increased predisposition to the incidence of incisional hernia. Obese female has an increased predilection toward incisional hernia. Obesity is associated with more risk of post-operative wound infection and both resulted in an increased incidence of incisional hernia.

Key words: Incisional hernia, Lax abdominal muscles, Subumbilical midline incision

INTRODUCTION

Hernia is a protrusion of a viscus or part of a viscus through an abnormal opening in the wall of its containing cavity. An incisional hernia is any herniation of anterior

abdominal wall that occurs through a previous surgical incision. It is a type of ventral hernia.

A post-operative ventral abdominal or incisional hernia is the result of failure of the fascial tissues to heal and close the following laparotomy.^[1]

Incisional hernia is a serious post-operative complication of laparotomy. Its incidence following abdominal surgery ranges from 2% to 11%.^[1]

Moreover, it accounts for 15–20% of all abdominal wall hernias.^[2]

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A number of predisposing factors have been identified which may be related to specific patient characteristics and underlying pathological process or iatrogenic factors.

This study is undertaken to review the various factors and circumstances, leading to the development of incisional hernia in each case, and hence may be able to minimize its occurrence Table 1.

MATERIALS AND METHODS

The study is a prospective study carried at Mahatma Gandhi Memorial Hospital, Warangal, between June 2015 and December 2017. A total number of 40 cases were studied. The study aims to determine the association of incisional hernia in isolation or various combinations of specific risk factors such as sex, obesity, diabetes mellitus (DM), history of previous wound infection, the site and type of surgical incision used, and indication for previous operations.

This study includes cases spread over a period from June 2015 to December 2017.

Patients were selected randomly.

There was a detailed history with specific reference to previous surgery/surgeries, and the post-operative period is elicited from the patient and verified with the previous records which are available with the patient. The following risk factors are studied.

- Sex,
- Obesity - body mass above 30 is taken as obesity in this study,
- DM,
- Wound infection: History of any percentage discharge

Table 1: Age and sex distribution

Age group	Sex		Total number of cases (%)
	Male	Female	
<20	0	1	1 (2.5)
21–30	1	11	12 (30)
31–40	2	9	11 (27.5)
41–50	1	7	8 (20)
>50	4	4	8 (20)

Table 2: Site of previous incision

Type of incision	Number of cases (%)
Subumbilical Midline	30 (75)
Mc. Burney's	2 (5)
Mid midline	1 (2.5)
Upper midline	5 (12.5)
Pfannenstiel	1 (2.5)
Paramedian	1 (2.5)

(serosanguinous/pus) from the wound is considered as wound infection,

- Site and type of incision used for previous surgery,
- Indication for previous surgery.

The association of incisional hernia with these risk factors both independently and in combination is studied. After pre-operative workup, patients were operated by a method, most suited for the individual. Post-operative management comprised of antibiotics, intravenous fluids, and Ryles tube aspiration in cases where peritoneum has opened. The subcutaneous drain kept on the wound is removed after serous discharge has decreased. Sutures are removed on 9th post-operative day, and prophylactic abdominal corset is advised for each patient post-operatively for 3 months. Patients are advised to desist from strenuous work for about 3 months.

RESULTS

The total number of cases studied in the series is 40. In this series, incisional hernia is found to be common in third and fourth decades with 80% of females and 20% of males and female-to-male ratio is being 4:1.

Showing a clear predilection toward female sex Table 2.

75% of incisional hernias occurred through subumbilical midline incisions (SUMLs).

Wound infection is present in 18 cases amounting to 45% of incisional hernias Table 3.

Seventyfive percent of incisional hernias followed operations on female Pelvic organs. 5% followed after unspecified laparotomy (lumpabdomen) and 20% of cases followed after acute abdominal procedures.

Table 3: Initial operative procedure

Procedure	Number of cases (%)
Hysterectomy	14 (35)
LSCS	10 (25)
Tubectomy	6 (15)
Acute abdomen	8 (20)
Unspecified laparotomy	2 (5)

LSCS: Lower segment Cesarean section

Table 4: Obesity and SUML

Obese / Non-obese	SUML	Other incisions	Total	Incidence (%)
Obese	21	3	24	87.5
Non-obese	9	7	16	56.25
Total	30	10	40	

SUML: Subumbilical midline incision

In our study, 60% of patients with incisional hernia were found to be obese. Among the obese people, 62.5% had wound infection during previous surgery. In our study, obese people with DM show the significant correlation between obesity, DM, and incidence of incisional hernia Table 4.

In our study, the obese people with SUML constitute 87.5%.

DISCUSSION

Incisional hernia is commonly seen in third and fourth decades. In this series, peak incidence of Incisional hernia is seen in the 3rd decade. In this study, 80% were females and female-to-male ratio is being 4:1. High incidence of incisional hernia is seen in young- and middle-aged females, whereas the same incidence was not seen in males. This can be explained by multiparity and repeated surgeries on female pelvic organs. In our study, 75% of the incisional hernias occurred following operations on female pelvic organs. Harikrishnan and J.K.Karr have also found operations on female pelvic Organs were being the commonest surgeries which lead to the development of Incisional hernia 77.8%.^[3] Agarwal in his series found 87% of incisional hernia were after female pelvic organ surgeries. E A Agbak Wuru J.K.Olabanji et al identified, women pelvic organ surgeries plays major role, specially incisional hernia following emergency caesarian section 59%.^[5] Maximum incidence of hernia is seen with midline incisions that too with infraumbilical incisions. Ponka JL found 36% of incisional hernia through the midline infra Umbilical incision^[4] EA Agbak (2009) also found that 81.9% incisional hernias occur through The midline infraumbilical incision.^[5]

This may be because of:

- Intra-abdominal hydrostatic pressure is higher in the lower abdomen compared to the upper abdomen in erect position, i.e., 20 cm of water and 8 cm of water, respectively.
- Absence of posterior rectus sheath below arcuate line.
- This incision is used for mostly gynecological surgery inpatients who have poor abdominal wall musculature.

In the present study, 20% of patients with incisional hernia are found to have DM.

Among this, 75% of diabetic patients are obese, and about 50% of diabetic patients developed wound infection post-operatively following first surgery.

Obese patients with diabetes are more prone to wound infection, which acts as a cumulative risk factor for the development of incisional hernia.

CONCLUSION

- Highest incidence of incisional hernia in the present series is between the age group of 21 and 30 years.
- Most of our patients were females.
- Multiple predisposing factors are noticed to the occurrence of incisional hernia.
- Operations on the female pelvic organs were the most common procedures preceding the development of incisional hernia.
- Obesity is a common predisposing factor.
- Post-operative wound infection at previous surgery seems to be a common predisposing factor.
- Lower midline incision appears to have a special predilection toward incisional hernia.
- All these factors are interrelated. The presence of more than one factor in a patient shows increased predisposition to the incidence of incisional hernia.
- Obese female have an increased predilection toward incisional hernia.
- Obesity is associated with more risk of post-operative wound infection and both resulted in an increased incidence of incisional hernia.
- Lower midline incision in obese people have a predilection for incisional hernia.
- Diabetic patients are more prone to post-operative wound infection and both result in an increased incidence of incisional hernia.

Regarding Management Aspects

1. In elective operations:
 - a. Obesity must be reduced; it should start at least 2 months before surgery.
 - b. In patient with lax abdominal muscles, physiotherapy of muscles should be done.
 - c. Hypertension and diabetes must be controlled effectively before surgery.
 - d. Improvement of nutritional status has to be done.
 - e. Anemia and vitamin deficiency should be corrected.
2. During surgery:
 - a. Plan anatomical incisions.
 - b. Perfect hemostasis must be achieved.
 - c. Minimal handling of tissues should be done.
 - d. For closure, use non-absorbable suture material which must be non-toxic, pliable, strong, durable, and resistant to fatigue such as polypropylene and polyamide.
 - e. Suture should be taken 1cm from the edge and

spaced at interval of 0.5 cm from one another.

- f. Always drain whenever oozing, serous discharge is anticipated to prevent wound infection.
3. Prophylactic abdominal corset is advised to be applied after the post-operative period for 3 months in high-risk cases.
4. Patients must be advised not to resume strenuous work, especially manual laborers.
5. As all types of repair have equally good prognosis, the method should be selected according to the individual merits and best suited for the patient.

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Comparative Study of the Effectiveness of Three Techniques of Insertion of Proseal Laryngeal Mask Airway in Adults Posted For Elective Surgery

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Abstract

Background: ProSeal laryngeal mask airway (PLMA) (Laryngeal Mask Co. limited, Mahe, Seychelles) introduced by Dr. Archie Brain, as a modification of the classic laryngeal mask airway (LMA) designed for positive pressure ventilation, has increasingly become the mainstay of anesthesia practice in a variety of settings. The dorsal cuff and drain tube broaden its application. However, it was found to be relatively difficult to insert as compared to classic LMA.

Aim: The aim of the present study was to assess the ease of insertion and correct placement of PLMA using three different techniques, namely Gum elastic bougie (GEB), insertion with an aid of introducer tool (IT), and digital (D) technique in adults undergoing elective surgeries requiring general anesthesia.

Materials and Methods: A total of 150 adult patients of age group 18–60 years of either sex of American Society of Anesthesiologists (ASA) Class I and II, undergoing elective surgery for various procedures requiring general anesthesia with PLMA were included in this study. The study subjects were divided into three groups, namely GEB where insertion of PLMA is aided using a GEB, IT where insertion of PLMA is aided using an introducer, and D where PLMA is inserted using conventional D technique. These techniques were then correlated with each other in terms of ease of insertion, correct placement, time to insert PLMA, and unwanted adverse effects if any. Data are presented as the mean \pm standard deviation. Fisher's exact test and the Chi-square test were applied for the statistical analysis. Results having $P < 0.05$ were considered statistically significant.

Results: Insertion time for the 1st attempt was similar in all the three groups but was significantly less in GEB group the incidence of visible blood staining of the device was significantly less in GEB group. The GEB-guided insertion technique is more frequently successful than the D or IT techniques and suggested that GEB-guided technique may be a useful backup technique when the D and IT techniques fail.

Key words: Anesthesia, Gum elastic bougie, ProSeal laryngeal mask airway

INTRODUCTION

ProSeal LMA (PLMA) (Laryngeal Mask Co. limited, Mahe, Seychelles) introduced by Dr. Archie Brain, as a modification of the classic LMA designed for positive pressure ventilation

(PPV), has increasingly become the mainstay of anesthesia practice in a variety of settings.^[1] The dorsal cuff and drain tube broaden its application.^[1-3] However, it was found to be relatively difficult to insert as compared to classic LMA.^[4] The aim of the present study was to assess the ease of insertion and correct placement of PLMA using a gum elastic bougie (GEB)^[5] and compare it with an introducer tool (IT) and digital (D) technique in adults undergoing elective surgeries.

MATERIALS AND METHODS

After obtaining Institutional Ethical Committee approval and informed consent, 150 patients of ASA physical status

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A and unwanted adverse effects i–60 years scheduled to undergo elective surgeries under general anesthesia were randomly allocated in our study performed over a period of 6 months.

Exclusion Criteria

Patients were excluded if they had any of the following criteria:

- i) Aged younger than 18 years or older than 60 years.
- ii) Previously known/predicted difficult airway.
- iii) History of any pathology of neck, upper respiratory tract/upper alimentary tract.
- iv) Having cardiovascular disease, bleeding disorders.
- v) Mouth opening <2.5 cm.
- vi) Body mass index greater than 25 kg/m².
- vii) Had a high risk of aspiration.
- viii) Recent history of a sore throat.

Randomization

Patients were randomized using a computer-generated random number table into three groups GEB, IT, and D as per the choice of the technique of insertion of PLMA in each group ($n = 50$).

- Group GEB - GEB group
- Group IT - IT group
- Group D - D group.

All the patients were monitored as per the ASA standards of monitoring.

After taking informed consent, all the patients were examined on the previous day, and necessary investigations for general fitness were done. Patients were kept nil per oral for 6 h. Randomization was done before surgery during the preanesthetic checkup.

Premedication was given 30 min before surgery with glycopyrrolate 0.2 mg iv and midazolam 1 mg iv and standard monitors attached. Preoxygenation for 3 min with 100%O₂ followed by induction with sleep dose of propofol and fentanyl at a dose of 1.5–2 mcg/kg iv was administered. Neuromuscular blockade was achieved with 0.5 mg/kg iv atracurium as the first dose followed by top-ups. PLMA was inserted by an experienced anesthesiologist with different techniques (GEB technique, IT technique, and D technique).

D technique: The D technique involved the use of the index finger to press the PLMA into and advancing it around the palatopharyngeal curve [Figure 1].

IT guided technique: In IT technique, introducer was attached to the PLMA, a single-handed technique was used to press the PLMA into and advancing it around the palatopharyngeal curve and the tool was then removed while the PLMA was held in position [Figure 2].

GEB guided technique: The GEB-guided technique involved the following steps: (1) Drain tube of PLMA was primed with lubricated GEB with its straight end first; (2) under gentle laryngoscope guidance, the distal portion of the GEB was placed into the esophagus while the assistant held the PLMA and the proximal portion [Figure 3]; (3) the laryngoscope was removed; (4) the PLMA was inserted using the D insertion technique while the assistant applied



Figure 1: Conventional PLMA insertion using digital technique



Figure 2: PLMA insertion using Gum elastic bougie



Figure 3: Gentle laryngoscopy during Gum elastic bougie guided PLMA insertion

jaw thrust [Figure 4]; and (5) the GEB was removed while the PLMA was held in position [Figure 5].

After the PLMA was inserted, gastric tube was placed into the stomach through the gastric channel. The effective airway was judged by the normal thoracoabdominal movement, bilateral air entry by auscultation, waveform of capnogram trace, oropharyngeal leak pressure <30 cm H₂O, bubble test, suprasternal notch tap, and passage of gastric tube.^[6-8] In case, the effective placement is not achieved, the device was removed and reinserted to a maximum of three attempts, and even then if the placement remains unsuccessful after three attempts, the patient was intubated. Ease of insertion including number of attempts and time required to insert the PLMA was recorded. The time to insert PLMA was recorded between picking up the laryngoscope or prepared PLMA (cuff deflated, lubricated, and IT attached) and its successful placement. Ease of the placement of gastric tube was also recorded.

Anesthesia was maintained with intermittent PPV with 1:1 O₂ in the air with sevoflurane maintaining minimum alveolar concentration between 1.2 and 1.4 and intermittent doses of iv atracurium.

Anesthesia was discontinued at the conclusion of surgery, and the patient was reversed with a standard dose of neostigmine (0.05 mg/kg iv) and glycopyrrolate (0.01 mg/kg iv), and the PLMA was removed once the patient was awake. Blood staining of the device and tongue, lip and dentition were recorded. Any adverse reaction in the post-anesthesia care unit within the next hour was recorded.

Statistics

In our study, we compared three different techniques of insertion (GEB technique, IT technique, and D technique) of LMA-ProSeal for the ease of insertion including insertion attempts, time to insert, airway sealing pressure, blood staining of device, dental and soft tissue injury and bronchospasm/laryngospasm, and any post-operative complication.

The sample size was calculated based on a previously published study.^[9] Student t-test was used to compare the demographic data and the time for insertion. The number of insertion attempts (success rates), the presence of the blood on the PLMA, and the occurrence of complications were compared using Chi-square analysis and Fisher exact test. $P < 0.05$ was considered significant.

Demographic parameters for age and weight in all groups were statistically not significant [Table 1]. The first attempt success rate was better with GEB technique (100% successful) as compared to IT (86%) and D groups (84%), which was found to be statistically significant.

Insertion time for the 1st attempt was similar in all the three groups but was significantly less in GEB group (27.12 se) compared to other groups (31.71 sec in D group and 31.45 s in IT group) when overall insertion time was considered [Table 2].

Airway sealing pressure was similar, Group D 31.86 cm/H₂O, Group IT 31.71cm/H₂O, and Group GEB 31.54 cm/H₂O and was not statistically significant [Table 3].

The incidence of visible blood staining of the device was significantly less in the GEB group (6%) compared to the

Table 1: Demographic profile of the patients (mean±SD) among the three groups

	Group			P value		
	D	IT	GEB	D and IT	D and GEB	IT and GEB
	Mean±SD	Mean±SD	Mean±SD			
Age (in years)	36.02±12.69	40.12±13.14	39.88±12.87	0.116	0.134	0.927
Weight (in Kg)	59±4.25	58.22±4.61	58.82±4.78	0.381	0.843	0.524
Height (in cm)	160.76±4.71	160.4±4.66	160.32±4.81	0.702	0.645	0.933
BMI (Kg/mts ²)	22.81±1.06	22.61±1.13	22.85±0.99	0.344	0.857	0.250

SD: Standard deviation, GEB: Gum elastic bougie, IT: Introducer tool, D: Digital

Table 2: Insertion attempts comparing the three groups

Attempts	Group				P value		
	D (%)	IT (%)	GEB (%)	Total	D and IT	D and GEB	IT and GEB
1 st attempt (n)	42 (84.00)	43 (86.00)	50 (100.00)	135 (90.00)	0.779	0.003	0.006
2 nd attempt (n)	5 (10.00)	4 (8.00)	0 (0.00)	9 (6.00)	0.727	0.022	0.041
3 rd attempt (n)	2 (4.00)	2 (4.00)	0 (0.00)	4 (2.70)	1.000	0.153	0.153
Failure (n)	1 (2.00)	1 (2.00)	0 (0.00)	2 (1.30)	1.000	0.315	0.315

SD: Standard deviation, GEB: Gum elastic bougie, IT: Introducer tool, D: Digital

other groups (26% and 24%, respectively, in Group D and IT). *P* value between D and GEB was 0.006 and between IT and GEB is 0.12, both being significant. The incidence of trauma was similar in all the groups [Table 4]. There was no incidence of bronchospasm/laryngospasm in any of the groups [Table 5].

DISCUSSION

The first attempt success rate was significant with GEB technique as compared to D and IT technique. The principal cause of failed insertion was malposition of PLMA as detected by suprasternal notch tap test and the cause of malposition was impaction of PLMA at the back of the mouth which resulted in failed passage into the pharynx or folding over of the distal cuff, or the distal cuff being directed into glottic inlet rather than the hypopharynx. Several studies conducted on adult and pediatric patients confirm this finding. The higher first attempt success rate with GEB technique was due to the fact that the incidence of distal cuff folding over is reduced when PLMA is primed with GEB.

Other advantage of GEB technique was that the overall insertion time was less due to higher first attempt success rate. The potential disadvantages of GEB technique were potential for airway stimulation and pharyngoesophageal trauma as GEB was stiff and was not meant for esophageal placement. However, there was no case of bronchospasm or laryngospasm using this technique. Furthermore, blood

staining of the device was significantly less in GEB guided technique. The further potential disadvantage was that of the assistance that was required more often than D and IT technique.

In the year 2004, Brimacombe *et al.*^[9] compared the three different techniques of the introduction of ProSeal LMA which included standard D technique, IT technique, and GEB guided technique.^[9] They concluded that the GEB-guided insertion technique is more frequently successful than the D or IT techniques and suggested that GEB-guided technique may be a useful backup technique when the D and IT techniques fail. They found that the first attempt success rate in GEB group was 100% compared to 87% and 84% in D and IT group, respectively, which was similar to our study finding of GEB (100%), Group D (84%), and Group IT (86%). They reported that the time required for single insertion attempt in all the three groups were comparable but due to failure to pass the PLMA in single attempt in Groups D and IT; they had a significant difference in overall insertion time in comparison with GEB group. Oropharyngeal leak pressures were similar in all the three groups. We have found there is a significant difference in visible blood staining of the device between GEB groups from rest of the groups.

Eschertzhuber *et al.*^[10] compared three techniques of introducing PLMA in patients with simulated difficult laryngoscopy using a rigid neck collar, and they found out that the GEB guided insertion technique was far superior

Table 3: Insertion time (mean±SD) among the three groups

	Group			<i>P</i> value		
	D	IT	GEB			
	Mean±SD	Mean±SD	Mean±SD	D and IT	D and GEB	IT and GEB
Insertion time 1 st attempt (sec)	26.96±1.63	27.06±1.8	27.12±1.7	0.769	0.632	0.867
Insertion time overall (sec)	31.71±12.66	31.45±12.67	27.12±1.7	0.918	0.013	0.019

SD: Standard deviation, GEB: Gum elastic bougie, IT: Introducer tool, D: Digital

Table 4: Airway sealing pressure (mean±SD) among the three groups

	Group			<i>P</i> value		
	D	IT	GEB			
	Mean±SD	Mean±SD	Mean±SD	D and IT	D and GEB	IT and GEB
Airway sealing pressure/oropharyngeal leak pressure (cmH ₂ O)	31.86±2.27	31.71±2.26	31.54±2.57	0.756	0.517	0.721

SD: Standard deviation, GEB: Gum elastic bougie, IT: Introducer tool, D: Digital

Table 5: Adverse events during different techniques of insertion

Adverse Events	Group				<i>P</i> value		
	D (%)	IT (%)	GEB (%)	Total	D and IT	D and GEB	IT and GEB
Blood staining of the device (visible blood only) (n)	13 (26.00)	12 (24.00)	3 (6.00)	28 (18.70)	0.817	0.006	0.012
Tongue, lip, dental trauma (n)	1 (2.00)	4 (8.00)	2 (4.00)	7 (4.70)	0.169	0.558	0.400



Figure 4: Gum elastic boogie guided PLMA insertion technique showing one assistant giving jaw thrust



Figure 5: PLMA inserted using Gum elastic bougie

to the D or the IT techniques.^[10] They found that in all the cases PLMA could be inserted in the very first attempt using GEB (100%), it was successful only in 64% cases with D technique and 61% with IT technique and our finding was quite distinct from their study where we found 84% first-pass success in Group D and that of 86% in Group IT though it was the same 100% in Group GEB. This difference might be due to the exclusion of predicted difficult airway cases from our study. However, the success rate of insertion after three attempts and also visible blood staining of the device in our study was consistent with their study. They found that all failed insertions with the D and IT techniques were subsequently successful with the guided technique. However, in our study, we intubated the cases after three failed insertion attempts rather than opting for an alternative technique. However, the above-mentioned study did not compare the values of airway sealing pressure.

Nileswar and Goyal^[11] compared insertion and placement of ProSeal LMA using a IT and GEB in patients undergoing minor surgical procedures.^[11] They supplemented the condition of insertion with a comparison of actual views through each lumen using fiber-optic bronchoscope. They also found that the success rate of the insertion of PLMA

was higher in GEB group (96.67%) compared to IT group (80%), our study result is also similar to their study in that respect but with respect to insertion time, our study showed no difference in the first attempt insertion time among the groups which was inconsistent with their study finding, where they found that the insertion time for GEB group (40.8 s) was comparably higher than IT group (19.8 s). This might be due to the fact that we assigned only experienced anesthiologist for PLMA insertion.

Kuppusamy and Azhar^[12] compared bougie-guided insertion of PLMA with D technique in the adult. They found that the GEB-guided, laryngoscope aided insertion of PLMA is an excellent alternative technique to D technique in adults. They found that bougie-guided insertions of PLMA took longer time, but they helped achieve higher oropharyngeal leak pressures (30.63 cm H₂O vs. 23.13 cm H₂O) which were quite distinct from our study finding. Again the reason might be the difference in the expertise or might be due to difference in sample size (our study $n = 50$ in each group, their study $n = 30$ in each group).

However, there are also some limitations of the present study:

- All insertions were by an experienced user and may not necessarily apply to the less experienced user.
- We did not measure the hemodynamic response and possibly GEB-guided insertion technique is associated with greater response.
- Data were collected by unblinded observers.

CONCLUSION

From the outcome analysis of our study, we can conclude that compared to the D and IT PLMA insertion technique, GEB-guided PLMA insertion is an easier, reliable, having higher first-pass success rate and relatively atraumatic technique through all techniques have similar airway seal and ease of insertion of the gastric tube. Hence, GEB-guided insertion technique of PLMA can act as a better alternative to standard D and IT technique.

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Demographic Corelation of Fibro-osseous Lesions Prevailing in Uttar Pradesh - A Review

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Abstract

Fibro-osseous (FO) lesions are a group of lesions in which normal bone is replaced initially by fibrous connective tissue, and over a period of time, the lesion is infiltrated by osteoid and cementoid tissue. The concept of FO lesions has evolved over the last several decades and now including entities such as fibrous dysplasia, ossifying fibroma, juvenile ossifying fibroma, desmoplastic fibroma, osteoid osteoma, cemento-osseous dysplasia (COD), focal COD, and cement-ossifying fibroma. This article is thereby made to review the various FO lesions and their variance among the different groups prevailing in Uttar Pradesh. Besides, the fact there are various groups in these lesions, group of ossifying fibroma is found to be at a higher incidence rate.

Key words: Fibro-osseous lesions, Cement-osseous dysplasia, Focal cemento-osseous dysplasia

INTRODUCTION

Fibro-osseous (FO) lesions are a group of disorders that are characterized by replacement of normal bone by fibrous tissue that contains a newly formed mineralized product. FO lesions encompass a wide range of processes that may vary from bony to fibrous or inflammatory to neoplastic in nature. They can affect any part of the body and can vary from the innocuous to the extremely debilitating and potentially life threatening.

Demographic data on FO lesions over the years show that the general data regarding the epidemiology of FO lesions, the site of FO lesions varies but has been estimated that these lesions occur more in the mandible than in maxilla; however, in children, it is frequently seen in the maxilla. It is seen that there is a huge gender-wise differences. Higher male predominance is seen to occur in

FO lesions while in children, there is no sex predilection. In general, FO lesions occur at any age-group. As such, there is no age preponderance. However, in adults, these lesions occur between 3rd and 4th decade of life whereas in children it is seen to occur more within 2nd decade of life. According to Muwazi and Kamulegeya,^[1] among these group of lesions, fibrous dysplasia (56.1%) is one of the most prevalent followed by ossifying fibroma (32.9%) and osseous dysplasia (10.9%). This group of lesions is more prevalent in the mandible than in the maxillary region in higher age-groups. However, a marked predilection was also noted in females in case of the children with a mean age of 11–14 years of age in the maxilla according to Yadavalli.^[2] Clinical findings suggest that there is increasing pain and enlarging soft tissue mass with swelling in the hard tissue suggesting a malignant change. The lesion is generally asymptomatic until the growth becomes prominent with a mild deformation in either of the jaws; displacement of teeth with varying degree of mobility. Furthermore, there are both buccal and palatal expansions of the cortical bone with overlying mucosa intact. Radiographically, in the early stages FO lesions appear as a radiolucent area, but as the lesion progresses, this radiolucency exhibit some calcifications which interpret as radio-opacities at certain areas. Displacement of teeth becomes more evident with the progression of the lesion.

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Over the years, there have been numerous attempts at classifying FO lesions. Among the earliest of them is the one proposed by Charles Waldron. This classification system segregates FO lesions into fibrous dysplasia, FO lesions (cemental origin), and FO lesions of unknown origin. The benefits of this classification are that it clearly briefs out the lesions out of its origin while its shortcomings are the lack of subjective headings of each lesion. In addition to Waldron's classification, there have been other classifications proposed by Malek *et al.*, Slootweg and Muller *et al.*, Eversole, etc., the WHO classified FO lesions into osteogenic neoplasms, non-neoplastic bone lesions, cherubism, central giant cell granuloma, aneurysmal bone cyst, and solitary bone cyst. The one uniform thread which can be noted in all these systems is that FO lesions encompass a wide range of diseases, from developmental and reactive to neoplastic. It is, therefore, of utmost importance that these disorders are diagnosed accurately so that appropriate treatment can be initiated.

With the multitude of lesions and presentations possible in case of these disorders, it is no surprise that comprehensive reviews of the same are few and far between. This is especially true in the case of our study population, where no or very limited epidemiologic data are available in this regard. Hence, the present study charts the demographic and clinic pathologic characteristics of FO lesions reported at our institution over a period of 7 years.

MATERIALS AND METHODS

A cross-sectional analysis was designed over a period of 14 years from January 2002 to December 2016. The data were collected from patient records, and histologically diagnosed cases of FO lesions were taken from the archives of Oral Pathology and Microbiology, Kothiwal Dental College, Moradabad, Uttar Pradesh, India. A total of 25 histologically confirmed cases of FO lesions were included in the study. Sociodemographic variables, clinical features, and radiographic findings were obtained from the patient's records. Hematoxylin and Eosin stained slides and blocks were retrieved from the archives and re-analyzed for all cases. Poorly documented cases or patients lost to follow-up were excluded from the study. The data obtained were tabulated, and relevant comparisons were drawn and analyzed.

RESULTS

Incidence Rate

FO lesions that have been detected so far, we have investigated 3 cases was of fibrous dysplasia (i.e., 12%), 5 cases were of ossifying fibroma (i.e., 20%), 3 cases were of juvenile ossifying fibroma (i.e., 12%), 1 case detected

with desmoplastic fibroma (i.e., 4%), 1 case found with osteoid osteoma (i.e., 4%), 2 cases was of cemento-osseous dysplasia (COD) (i.e., 8%), 1 case of focal COD (i.e., 4%), and 2 cases of cemento-ossifying fibroma (i.e., 8%). These values have been depicted in the following Graph 1:

Age and Gender

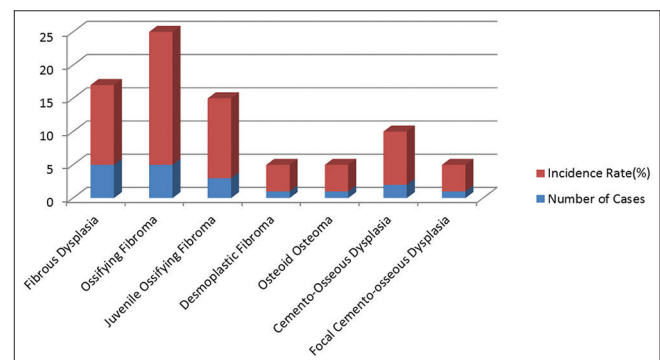
Out of all the 25 biopsy cases ($n = 25$), 14 cases were found in males (i.e., 56%) and 11 cases in females (44%) with a ratio of 3:1. From the above-mentioned cases: In case of:

- Fibrous dysplasia: The mean age lies between 17 and 30 years of age out of which 40% is found in females and 60% in males.
- Ossifying fibroma: The mean age is 35 years where there is an equal incidence in both females and males (20%).
- Juvenile ossifying fibroma: The mean age is 19 years and found only in females (33.33%).
- Desmoplastic fibroma: The mean age is 52 years and found in females (100%).
- Osteoid Osteoma: The mean age is 21 years and found in females (25%).
- COD: The mean age is 32–45 years of age out of which 66% is found in males and 33% in females.
- Focal COD: The mean age is 40 years and is found in males (100%).
- Cemento-ossifying fibroma: The mean age is 35 years with equal sex predilection (i.e., 20% in both females and males).

The following Table 1 is enumerated with Age and Gender distribution:

Site

Out of overall biopsied cases, 84% of cases are seen mandible, and 16% are seen in maxillae. The following cases with a variety of FO lesions are enlisted as: (a) Fibrous dysplasia occurs in the posterior part of mandible, (b) ossifying fibroma occurs in the ramus of mandible while medio-laterally, the lesion extended from the lateral part



Graph 1: Depicts the incidence rate of various fibro-osseous lesions

Table 1: Age and gender distribution

Lesion	Age (years)	Gender	In percentage
Fibrous dysplasia	17–30	Female+Male	40 and 60
Ossifying fibroma	35	Female	20
Juvenile ossifying fibroma	19	Female	33.33
Desmoplastic fibroma	52	Female	52
Osteoid osteoma	21	Female	21
COD	32–45	Male+Female	66 and 33
Focal COD	40	Male	100
Cemento-ossifying fibroma	35	Female+Male	20

COD: Cemento-osseous dysplasia

of the nasal cavity up to the maxillary buttress covering the maxillary sinus, (c) focal COD occurs in the lingual surface of the anterior portion of the mandible, (d) osteoid osteoma is seen to occur in the lower border of mandible, (e) juvenile ossifying fibroma extends from midline to 2 cm ahead to the angle of the mandible, (f) and desmoplastic fibroma occurs posteriorly at the ramus angle region.

Clinical Presentation

Among all the above-mentioned cases, (a) fibrous dysplasia clinically presents as intraoral swelling present in the right side of the mandible which is approximately 2 cm × 3 cm in diameter. There is an expansion of buccal and lingual cortical plates. Mandibular obliteration is seen with the displacement of premolars and molars. (b) Cemento-ossifying fibroma presents as a bony hard swelling in 43–45 region which is non-tender and fixed to underlying structures. Furthermore, there was seen buccal and lingual cortical plates expansion (c) COD presents with an oro-antral fistula developed along with pus discharge where there is buccal and lingual cortical plates expansion. Moreover, palatal expansion can also be seen up to the midline. (d) Focal COD presents with hard swelling in both the arches (i.e., maxilla and mandible), (e) osteoid osteoma occurs gradually with swelling of 3 cm × 2 cm in dimension along with buccal and lingual cortical plates expansion, (f) juvenile ossifying fibroma exhibits extra-oral swelling in the right lower jaw since 2 years lesion extended from midline to 2 cm ahead of angle of the mandible and (g) desmoplastic fibroma exhibits firm to hard intraoral swelling involving buccal and lingual cortex which measures 3 cm × 2 cm in diameter extending from 35 to 37 region.

Radiographic Presentation

The radiographic presentation of FO lesions helps us to differentiate among each lesions.

(a) In fibrous dysplasia, both the maxillary and mandibular cases interpret radio-opaque and radiolucent areas with the displacement of teeth which gives rise to ground-glass appearance, (b) in 1 case of ossifying fibroma, mixed

radio-opaque, and radiolucent areas are seen w.r.t 43–45 region, (c) in the case of desmoplastic fibroma, features like well-delineated areas of unilocular radiolucencies can be seen, and (d) another case of juvenile ossifying fibroma, the affected lesion presents as radio-opacity with multiple root resorption and thinning of the cortical plates w.r.t 35–37 region.

DISCUSSION

Knowing the epidemiological data and incidence rate of FO lesions, these group of lesions varies from one another. Each of these lesions has a unique entity to some extent, but most of them were found to arise from the similar location. According to this present study, the age limit of fibrous dysplasia is between 17 and 30 years. This study is in accordance to studies performed by Weerakkody *et al.* which stated that the highest incidence of fibrous dysplasia was found before the age of 30 years. Similar studies by Shreedhar and Kamboj mentioned in a case report fibrous dysplasia of the palate where they have mentioned that the craniofacial form of fibrous dysplasia occurs 10–14 years of age.^[3] In this study, the highest incidence rate of COD is 32–45 years and according to a study by More and Shirolkar the maximum age limit is 4th decade.^[4] The mean age of occurrence in juvenile ossifying fibroma in this present study is 19 years. Similar results are in accordance with a study by Kumar and Paul titled psammomatoid variant of juvenile ossifying fibroma involving mandible where the mean age of occurrence is 17.7 years.^[5] The maximum age limit of cement-ossifying fibroma is 35 years, and these results are similar to studies by Tapas and Soni^[6] Osteoid osteoma has a mean age of occurrence in jaw bones (mandible) is 21 years, and these results are in accordance to study by Karandikar *et al.* where the age limit of osteoid osteoma falls within a 2nd decade.^[7]

According to the studies by Bhattacharya and Mishra *et al.*, both fibrous dysplasia and CODs have almost the same prevalence in both males and females. The data from our study also show that there is no particular gender predilection in the case of these two entities. Both the lesions such as ossifying fibroma and cemento-ossifying fibroma have the highest female predilection, and these results are in accordance to studies by Tapas and Soni mentioned in a clinicopathological case report. According to studies reported by Singh and Solomon,^[8] osteoid osteoma occurs more in females than males which was published in a case report. These observations are similar to our study. Desmoplastic fibroma occurs in females, and these results are similar to Hovinga and Ingenhoves in a review article.^[9]

However, in this present study, FO lesions had a similar location (i.e., mandible) and these results are in accordance to various authors such as Alves and Oliveira *et al.* in a proposed case report of monostotic fibrous dysplasia in jaws.

In one of the case report presented as recurrent monostotic fibrous dysplasia of mandible, fibrous dysplasia occurs as swelling over the right hemi mandibular region and malocclusion of the teeth, pain, distortion of facial contour, and alveolar abscess associated with displacement of teeth, similar results were observed in our present study where there was intraoral swelling present in the right side of the mandible. In this study, cemento-ossifying fibroma presents as a bony hard swelling in 43–45 region which is non-tender and fixed to underlying structures. Furthermore, there was seen buccal and lingual cortical plates expansion which is similar to a study by Naik and Sujata^[10] mentioned in a case report of Giant cemento-ossifying fibroma of the mandible and its features are alike to this study and are justified. COD in our present study illustrates mild buccal and palatal cortical plate expansion and this very much similar to study by Yildirim *et al.* Yadav in their study illustrates that juvenile ossifying fibroma as an extraoral diffuse swelling was present on the right lower side of face, approximately 10 cm × 6 cm in size, extending anteroposteriorly 2 cm away from the midline on the left side until right angle of mandible and superoinferiorly from a line connecting angle of mouth to angle of the mandible until 2.5 cm below the lower border of mandible. Moreover, these results are in accordance to our present study. Another case report by Anand *et al.*^[11] where desmoplastic fibroma of mandible instantiated as cortex is perforated at some areas with associated soft tissue mass, and these results are similar to our present study where desmoplastic fibroma showed perforation of the buccal and lingual cortex with intra-oral swelling.

In a series of cases by Nitya *et al.* 19 cases showed a mixed radiolucent-radiopaque appearance, of which 4 cases showed a non-discernible pattern, and these results are similar to these present study in cases of fibrous dysplasia.

In case of ossifying fibroma, radiographically it can present with different patterns depending on the degree of mineralization, ranging from an immature, radiolucent and cyst-like lesion with scattered radiopaque foci to mature dense sclerotic lesions. The borders are well-defined, and usually, a thin radiolucent line representing a fibrous capsule separates the lesion from the surrounding bone as stated by Kumaraswamy *et al.* in one of his case report. These results are similar to this present study. Another case report by authors Sumer and Sumer radiographically,^[12] a radiolucent destruction area was observed between the mandibular left lateral incisor and canine teeth in panoramic and periapical radiographs in case of desmoplastic fibroma, and these findings were very much similar to our present reviews where unilocular radiolucency was observed. However, up till now cases regarded so far in the literature mixed radio-opaque and radiolucencies could be observed in juvenile ossifying fibroma while in this study, juvenile ossifying fibroma presents with only radio-opacities radiographically.

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Aneurysmal Bone Cyst Mimicking Ameloblastoma: A Rare Case Report

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Abstract

Aneurysmal bone cyst (ABC) is rare benign lesion of bone which is infrequent in craniofacial skeleton. ABCs are characterized by rapid growth pattern with resultant bony expansion and facial asymmetry. Clinical presentation of the ABC varies from expansile, destructive lesion causing pain, swelling, deformity, and perforation of the cortex to the relatively innocuous type which may not produce any clinically evident bone expansion. As the radiologic and clinical presentation of ABC is extremely variable, histopathologic examination has a great emphasis for the diagnosis. We describe a case of ABC in a 22 years male patient affecting the buccal and lingual cortical plates with expansion on the lower border of mandible. Treatment consisted of hemimandibulectomy of the lesion. A yearlong follow-up revealed complete healing of the involved site with restoration of acceptable esthetics and no recurrence.

Key words: Aneurysmal bone cyst, Pseudocysts, Mandible

INTRODUCTION

Aneurysmal bone cyst (ABC) has been recognized since 1983 when it was described as an ossifying hematoma by van Arsdale. Jaffe and Lichtenstein suggested that the ABC is a bone benign injury, recognized as a solitary clinical-pathological entity.^[1-3]

The aneurysmal term is used to describe the balloon-shaped distension of part of the affected bone that results in characteristic radiographic appearance frequently viewed.^[4] Shear and Speight mention a case where an injury was observed near the orbit's floor and another one near the zygomatic arch.^[5] The radiograph presents a uni- or multi-locular radiolucent injury; cortical bone expansion is described as a balloon-shaped stretching of the affected bone. The teeth can be found displaced, and their roots might have resorption. In the computerized

tomography, an image compatible with uni- or multi-locular cyst with cortical expansion is observed, with periosteal reaction or the appearance of moth-eaten shape.^[6] There are several pathologic identities that mimic the same image such as the ameloblastoma, myxoma, central giant cells granuloma, the odontogenic cysts, and the central bone hemangioma.

The pathogenesis of the ABC is controversial, and several theories were postulated to explain it. It has been proposed that a trauma, a malformation, or a neoplasia could disorganize the local bone microvasculature resulting in an abnormal vascular condition that is the ABC.^[7]

Macroscopically during the operation, it is common to note an intact periosteum and a very thin layer of bone covering the cyst. When this is removed, several hidden blood vessels can be seen. The bleeding can be profuse and hard to control until the pseudocyst is removed.

CASE REPORT

A 22-year-old male patient had reported to the department of oral and maxillofacial surgery with a chief complaint of pain and swelling in the right side of jaw for 5–6 months.

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On Clinical Examination (C/E), there was hard tissue swelling over the buccal and lingual cortical plates with expansion on the lower border of mandible. On palpation, the swelling was firm to hard in consistency with positive crepitation in relation to 43–47 [Figure 1].

Orthopantomogram showed multilocular radiolucency over the right mandible extending from 43 to 47 region with well-defined margins [Figure 2]. A computed tomography scan was requested which showed injury on the right mandible body approximately 4 cm × 5 cm in dimensions [Figure 3].

Based on the clinical findings and radiological findings, a provisional diagnosis of multicystic ameloblastoma of the mandible with resorption of molar roots was given. Differential diagnosis of myxoma, central giant cell granuloma, odontogenic cysts, or central hemangioma of the bone was given.



Figure 1: Pre-operative photograph of patient. Arrow pointing the swelling

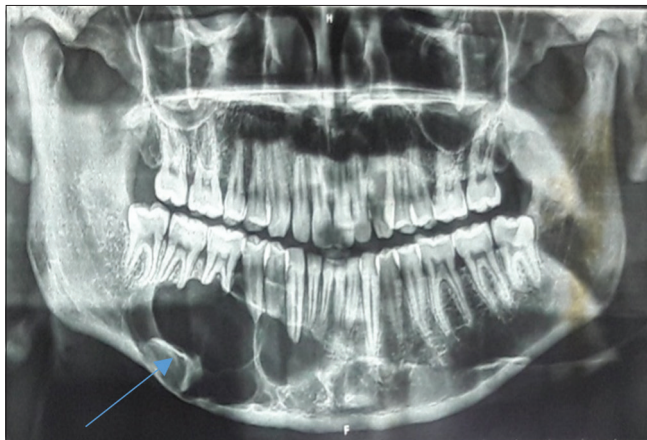


Figure 2: Orthopantomogram showing multilocular radiolucency over the right mandible extending from 43 to 47 region with well-defined margins

The case was referred to the department of oral and maxillofacial surgery. After routine blood examination, the lesion was approached under general anesthesia. The buccal flap was raised, thin cortical border was exposed and the tumor was excised along with the tooth and sent for histopathological examination [Figure.4].

The hematoxylin and eosin stained section (×10) revealed the presence of fibrocellular connective tissue stroma. The stroma shows blood-filled spaces and abundant young fibroblasts [Figure 5]. The stroma contains few inflammatory cell infiltrate, numerous dilated blood vessels, and calcified areas.

DISCUSSION

ABC develops mostly in maxillofacial bones depending on high venous pressure and high marrow content. Therefore, it is rarely seen in the skull bones where there is low venous pressure. The mandible is affected 3 times more when

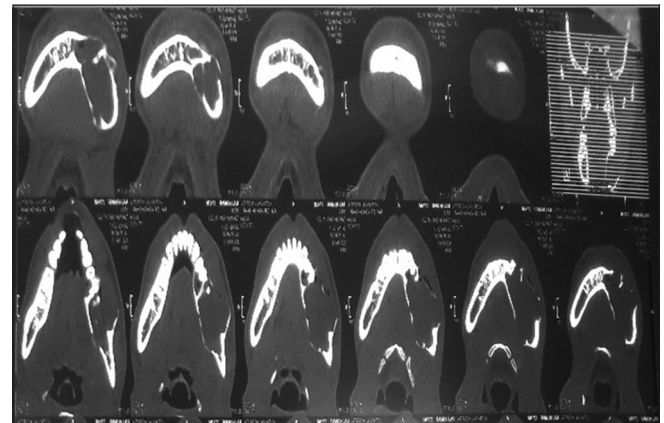


Figure 3: A computed tomography scan showed injury on the right mandible body approximately 4 cm × 5 cm in dimension



Figure 4: The formalin fixed hard tissue specimen with dimension 4 cm × 5 cm and was brownish-gray in color



Figure 5: The hematoxylin and eosin stained section (×10) revealed the presence of fibrocellular connective tissue stroma. The stroma contains blood-filled spaces and abundant young fibroblasts

compared to the maxilla. It is frequently observed at the molar and ramus regions of the mandible.^[1] ABC was first described in the literature by Jaffé and Lichtenstein in 1942. The term “aneurysmatic” emphasizes on expansion of the affected bone, which is called the “blowout effect.” The etiology of ABC is controversial. Increased venous pressure and repletion of the vascular bed in the transformed bone caused by the alteration of local hemodynamics were related to resorption, connective tissue replacement, and osteoid formation by Jaffe and Lichtenstein. Matsuura *et al.* had reported that the development of ABC is related to a history of trauma and subperiosteal hematoma formation.^[8] In the present case, pain and swelling or facial asymmetry were observed. The radiological features of the ABC in the jaws are variable; the expanded bone appears cystic resembling a honeycomb or soap bubble. Destruction or perforation of the cortex and a periosteal reaction can be also seen. In our case, the ABC represented a multilocular

radiolucency causing expansion of the cortical plates. Histologically, the ABC reveals the presence of fibrocellular connective tissue stroma. The stroma contains blood-filled spaces and young fibroblasts abundantly. The stroma contains few inflammatory cell infiltrate, numerous dilated blood vessels, and calcified areas. Recurrence rates range from 20% to 30% in different groups and it occurs most frequently within the 1st year after surgery.^[9] Several authors recommend immediate reconstruction of the defect with autogenous grafts in cases of esthetic deformity and in cases with high risk of fractures and loss of mandibular continuity. In the present case, treatment of choice was initiated from curettage of the mass to complete excision.

CONCLUSION

As the radiologic and clinical presentation of ABC is extremely variable, a great emphasis is placed on histopathologic examination for the diagnosis.

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A Rare Case of Bilateral Adrenal Hemorrhage

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Abstract

Bilateral adrenal hemorrhage is a rare condition that may lead to acute adrenal crises, shock, and death, if untreated. It is associated with a 15% mortality rate and 55–60% mortality, if secondary to Waterhouse–Friderichsen syndrome.^[4] It can present with non-specific clinical and laboratory findings; hence, early recognition and treatment is mandatory. We report a 57-year-old female who presented with abdominal pain and vomiting found to have urosepsis causing bilateral adrenal hemorrhage.

Key words: Bilateral adrenal hemorrhage, Urosepsis, Acute Adrenal crisis

INTRODUCTION

Adrenal hemorrhage is a life-threatening condition that can present with non-specific symptoms such as abdominal pain, nausea, vomiting, and fatigue.^[1,2] Rarely, adrenal hemorrhage can be picked up as an incidental finding on imaging, without any symptoms. Examination findings are fever (most frequent), tachycardia, skin hyperpigmentation, and shock in severe bilateral adrenal hemorrhage.

Most cases are caused by acute, stressful illness (e.g., infection, acute coronary syndrome, heart failure, Waterhouse–Friderichsen syndrome - meningococcal septicemia, etc.). Other causes include blunt trauma and thromboembolic diseases such as antiphospholipid antibodies (APLA), anticoagulant use,^[3] thrombocytopenia, pregnancy complications,^[7] ACTH use, tuberculosis and rarely acute pancreatitis.^[6] A multicentric case–controlled study was done to study the major risk factors associated with bilateral adrenal hemorrhage. Thrombocytopenia, sepsis, and heparin use were identified as major risk factors.

CASE REPORT

A 57-year-old female, who is a known case of systemic hypertension on treatment, came with complaints of abdominal pain for 1 week, which was dull aching type of pain, non-localized. She also complaints of vomiting, non-bilious, non-projectile, and multiple episodes per day contains food particles for the past 1 week. Patient did not give any history of fever, burning micturition, or substance abuse. There was no history of any anticoagulant use, tuberculosis or trauma.

On examination, the patient was conscious, oriented to time, place, person, vitals stable, and afebrile. There was no skin hyperpigmentation or rashes present. Per abdomen, there was no organomegaly, epigastric tenderness was present. CNS examination revealed no focal neurological deficits.

All laboratory investigations were done which showed sodium -110, potassium - 4.2, chloride - 79, bicarbonate - 21. Serum osmolality-223, urine spot sodium-100, serum cortisol was 1.85. Echocardiogram done showed no regional wall motion abnormality with an ejection fraction of 64%. Ultrasound abdomen was done, which showed bilateral mild hydronephrosis, after which a CT whole abdomen was done which showed splenomegaly and bilateral adrenal haemorrhage (figure-1). CT thorax done showed minimal left pleural effusion. Urine culture showed Klebsiella. A diagnosis of bilateral adrenal hemorrhage due to urosepsis was made and the patient was managed

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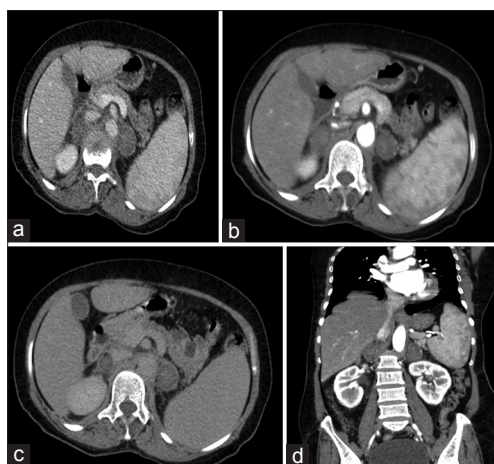


Figure 1: (a-d) CT abdomen showing bilateral adrenal haemorrhage

in ICU. APLA workup was done and was found to be negative. ANA/double-stranded DNA was negative. The patient was treated with injection meropenem 1 g IV BD, injection hydrocortisone, and other supportive measures in ICU. The patient improved symptomatically and was shifted back toward. The patient was discharged with T. Hisone 10 mg 1-0-1/2 and was advised to follow-up.

DISCUSSION

Bilateral adrenal hemorrhage can be caused by a number of conditions. In our patient, the underlying cause was urosepsis. The underlying mechanism in a non-traumatic adrenal hemorrhage is unclear. Adrenal gland has a poor venous drainage, but the arterial supply is rich. During stress, there is increased ACTH secretion which causes increases arterial blood flow, exceeding the venous drainage capacity causing adrenal hemorrhage. Adrenal vein thrombosis is another proposed mechanism, which occurs in association with primary APLA, sepsis, and heparin-induced thrombocytopenia. For the hormone deficiency to be clinically evident, 90% of the adrenal tissue must be destroyed. Hence, minor adrenal hemorrhage may go unnoticed.

CT abdomen is the investigation of choice in diagnosing adrenal hemorrhage. Hyponatremia, hyperkalemia, and hypoglycemia are presented in most cases; however, their absence does not exclude the diagnosis. High ACTH and low cortisol are diagnostic of primary adrenal insufficiency.

Acute adrenal insufficiency is a medical emergency. Supportive care is essential which includes fluid and electrolyte correction, monitors and stabilizes blood pressure and blood transfusion in case of severe hemorrhage.

If acute adrenal insufficiency is clinically suspected, hydrocortisone should be given without delay (100 mg bolus injection, followed by 200 mg per 24 h either as a continuous infusion or 50 mg every 6 h) along with intravenous fluid resuscitation, after withdrawing samples for cortisol assay, without waiting for the results. Treating the underlying cause is essential to the management of adrenal haemorrhage

CONCLUSION

Adrenal hemorrhage is a serious condition, which can present with non-specific signs and symptoms; hence, prompt diagnosis and treatment is required. It could be due to a number of causes. In our patient, the underlying etiology was urosepsis.

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Varied Presentations and Management of Symptomatic Meckel's Diverticulum

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Abstract

Meckel's diverticulum is a true diverticulum arising from the antimesenteric border of the distal ileum. It is a remnant of vitellointestinal duct present. Majority of the population with Meckel's diverticulum are asymptomatic, with diverticulum being an incidental finding during laparoscopy/laparotomy. Majority of the population with Meckel's diverticulum are asymptomatic, with diverticulum being an incidental finding during laparoscopy/laparotomy.

Key words: Meckel's diverticulum, Complications, Treatment

INTRODUCTION

Meckel's diverticulum is a true diverticulum arising from the antimesenteric border of the distal ileum. It is a remnant of vitellointestinal duct present in 0.3–2.9% of population.^[1,2] It was first described by Fabricius Hildanus and later named after Johann Friedrich Meckel, who described the embryological origin of this type of diverticulum in 1809.^[3] Majority of the population with Meckel's diverticulum are asymptomatic, with diverticulum being an incidental finding during laparoscopy/laparotomy. We present here two cases of acute abdomen that were admitted on two consecutive days that were later found out to be due to complications of Meckel's diverticulum.

CASE REPORT

Case 1

A 24-year-old male was admitted with 2-day history of central abdominal pain, vomiting, and constipation. He was tachycardia with a heart rate of 102 beats/min and respiratory rate of 26 breaths per minute. The abdomen

was distended and was diffusely peritonitic. Routine blood investigations were within normal limits. Plain X-ray of the abdomen showed multiple small bowel air-fluid levels and contrast-enhanced computed tomography (CECT) abdomen showed transition point in distal ileum with angulation of about 4 cm of ileum [Figure 1]. The patient was taken up for emergency laparotomy and was found to have an adhesive band from the Meckel's diverticulum to the parietal wall with a loop of bowel coiled around it. The Meckel's diverticulum was gangrenous and a stricture was noted next to it. Resection and anastomosis of small bowel containing the gangrenous Meckel's was performed, and the patient made an uneventful recovery. Histopathology did not reveal any ectopic tissue.

Case 2

Admitted on the next day of admission of Case 1, a 35-year-old male complained of abdominal pain and vomiting for 15 days. The pain was intermittent and colicky with bowels working. The patient was hemodynamically stable, and abdominal examination revealed palpable bowel loops during episodes of pain. Plain X-ray of the abdomen was unremarkable, and CECT abdomen showed ileocecal intussusception with a possible polyp as the lead point. Blood investigations showed a Hb of 19 g/L with peripheral smear unremarkable except for increased red cell mass. After repeated venesections to optimize Hb, the patient was taken for exploratory laparotomy. The patient was found to have an ileocecal intussusception and on reduction was found to have an inverted Meckel's as the lead point [Figure 2].

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Figure 1: Contrast computed tomography of case 1 showing transition point in distal ileum with Meckel's diverticulum



Figure 2: Operative specimen of resection and anastomosis of small bowel with intussusception due to Meckel's diverticulum

Resection and anastomosis of the ileum with Meckel's were performed and the patient made an uneventful recovery. Histology showed ulceration in the tip of Meckel's with no ectopic tissue.

DISCUSSION

Abdominal emergencies would form a considerable caseload of General Surgical work. Complications arising from Meckel's diverticulum would form <1% of abdominal emergencies.^[4] In a series of Meckel's diverticulum, 74.5% of cases were asymptomatic with intestinal obstruction and bleeding being the major complications.^[5] The main management of asymptomatic Meckel's diverticulum would be to leave it alone. Operative resection and anastomosis of the small bowel containing the diverticulum or wedge resection of asymptomatic Meckel's is recommended in patient age younger than 50 years, male sex, diverticulum length >2 cm, and ectopic or abnormal features within a diverticulum.^[6]

It is quite uncommon to have admission on 2 consecutive days of acute abdomen with Meckel's as the cause. The first case warranted an emergency laparotomy due to bowel obstruction and peritonitis. Meckel's diverticulum was identified as the cause preoperatively. In the second case, an intussusception in the ileum was identified. However, due to accompanying polycythemia, we had a suspicion that the accompanying diverticulum could be due to reticuloendothelial malignancy in the small bowel or due to a polyp. After the peripheral smears showed normal cells and multiple venesections, a laparotomy was performed, and a long and inverted Meckel's as the lead point was identified.

Had these Meckel's found as incidental findings during laparotomy for some other reasons, we would have resected the Meckel's in both the cases, as in the first case there was a band from the Meckel's, and the second Meckel's had a long length.^[6]

In this day and age of minimal access surgery, Meckel's could be resected laparoscopically with the extracorporeal division of small bowel and re-anastomosis with staplers being quite popular.^[7-9] Minimal access surgery reduces the morbidity rates in the post-operative period and ensures an early return to daily activity.^[10] It remains to be seen that with minima access surgery, management would change for incidentally found Meckel's diverticulum.

CONCLUSION

Complications arising from Meckel's diverticulum should be considered in every case of acute abdomen and should be dealt with appropriately. Further studies are warranted to decide if asymptomatic Meckel's could be treated laparoscopically.

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