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Case Report

Hyperbaric Oxygen for Thermal Burn and Electrical Burn Wound Healing – A Case Report

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Abstract

Contact electrical burns are more severe than others form of contact burn injury. Burns are a difficult treatment challenge and ideally the province of specialized units with high-volume workloads. Such units do not exist in most parts of the world. Early treatment can positively influence the mortality rate. It involves appropriate fluid resuscitation, usually involving the attainment of resuscitation targets using consensus formulas for initial fluid administration and topical agents to control pain, limit direct fluid losses, and slow bacterial growth. Over the past two decades, early closure of full-thickness wounds has improved the outcome from extensive burns by preventing wound colonization and infection. Temporary skin substitutes are widely employed on a similar rationale when formal closure is not an option. Hyperbaric oxygen therapy consists of intermittently administering 100% oxygen at pressures >1 atmosphere in a pressure vessel. This technology has been used to treat various disease states and has been described as helping patients who have sustained burns.

Key words: Hyperbaric oxygen therapy, Electrical injuries, Burns

INTRODUCTION

During the last 30 years, the death rate from burn shock has declined dramatically. The primary concern in managing burns is no longer simply the patient's survival but also includes morbidity and long-term rehabilitation, and reconstructive problems. In deep burns, necrotic skin serves as an excellent culture medium for micro-organisms to increase, and invasive infection will inevitably ensue if the lesion is not promptly resurfaced. In the case of extensive deep burns, after removing the burn wound eschar, it is impossible to cover the exposed wound completely with autografts because of the scarcity of donor sites. A variety of biosynthetic and biological dressings can serve as a temporary wound closure with different acceptability degrees.[1-3] The correlation between burn severity and the magnitude of the impairment of host resistance is well documented.[4-8] An important goal in the course of treatment of the burn patient is to facilitate the outset of the patient's eventual reconstruction and rehabilitation, that is, to return the patient to society as a functional human being is as aesthetically acceptable as possible.[9]

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Hyperbaric oxygen therapy (HBOT) is an adjunctive therapy that has been proposed to improve outcomes in thermal burns. HBOT is the therapeutic administration of 100% oxygen at environmental pressures >1 atmosphere absolute (ATA). Administration involves placing the patient in an airtight vessel, increasing the pressure within that vessel, and administering 100% oxygen for respiration. In this way, it is possible to increase the partial pressure of oxygen to the tissues significantly. Typically, treatments involve pressurization to between 1.5 and 3.0 ATA, for periods between 60 and 120 min once or more daily. It has been suggested since 1965 that HBOT might improve the outcome following thermal burns.[10] HBOT has been shown to reduce edema and preserve microcirculation in many injury models, including burns, vasoconstriction with enhanced oxygen delivery, a direct osmotic effect, and the inactivation of white cell adhesion.[11] HBOT also exerts beneficial effects on infections in hypoxic tissues through a variety of mechanisms.[12] HBOT is associated with some risk of adverse effects, including damage to the ears, sinuses, and lungs from the impact of pressure, temporary worsening of shortsightedness, claustrophobia,

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and oxygen poisoning. Although serious adverse events are rare, HBOT cannot be regarded as an entirely benign intervention.

CASE 1

A 27 years old male patient was admitted with electrical burn involving 50% of total body surface area involving a right upper limb, back, lower limb, and chest. Past medical history reveals no known comorbidities.

The patient was assessed clinically; relevant investigations were done. Opinion from plastic surgeon was obtained before the procedure.

The patient underwent a dorsal slit and cauterization procedure and burns treatment modalities. Two units of blood transfusion done and two units of fresh frozen plasma and four sittings of HBOT were given and continued as indicated. Antiseptic techniques were rigorously followed in dealing with the patient.

CASE 2

A 51-year-old male patient was admitted to our hospital with the chief complaint of a burning sensation over the site of the wound after 5 days of treatment. No previous medical history of diabetes, hypertension, and bronchial asthma or tuberculosis.

On local examination, a 1st degree burn wound was seen in both the right and left lower limb. However, the right lower limb was healed better than the left lower limb, and a hot blister was noted in the left and right lower limb. After first-aid measures in the emergency room, the patient was kept under intensive care to monitor his vital signs. All the necessary investigations were performed and plastic surgeon opinion was obtained.

The patient underwent collagen application under intravenous sedation. Antibiotic and other post-operative medicaments were given. Healing was uneventful. The patient was symptomatically improved and hence discharged. Early oral intake was encouraged and advised to take a high-protein high-calorie diet supplemented with the parenteral administration of intralipid and an essential amino acid formula to reach the calculated daily calorie needs. Parenteral and subsequently oral polyvitamins, minerals and trace element formula were continued. Burn wound debridement with hydrotherapy was initiated and continued with wound flora monitoring. Antiseptic techniques were rigorously followed in dealing with the patient.

Figure 1: Pre-operative wound

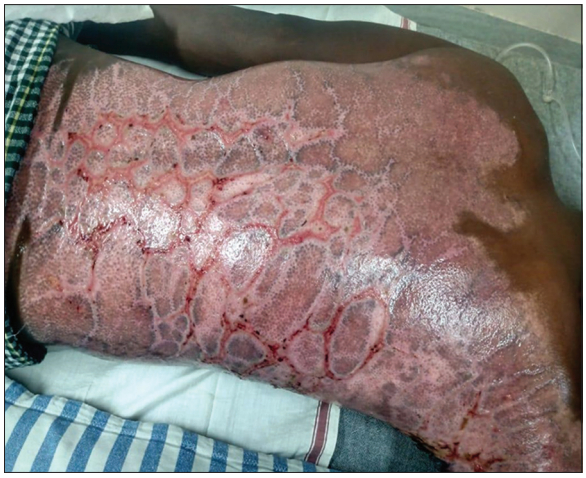

Figure 2: Mid operative wound

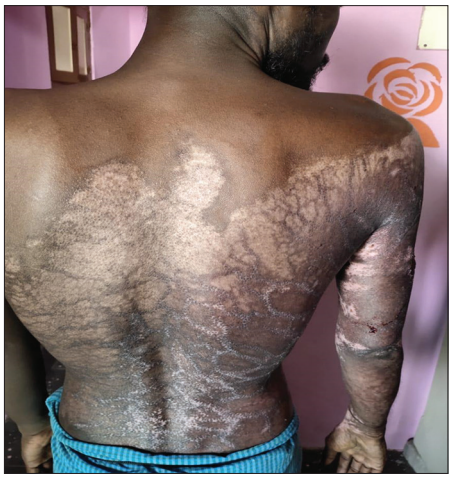

Figure 3: Post-operative wound

DISCUSSION

The burn is one of the most severe types of injuries the human body encounters. Its significant consequences are not only mortality but also the tremendous morbidity and

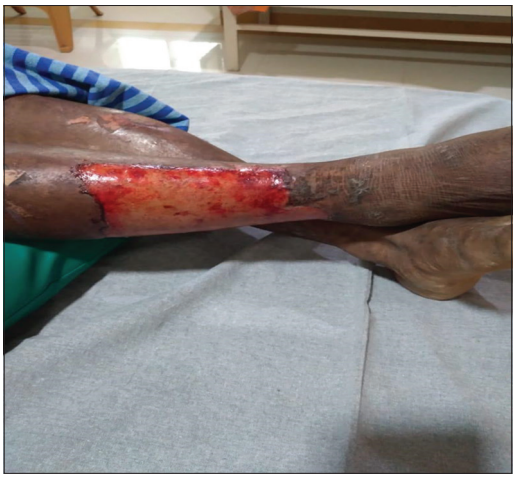

Figure 4: Pre-operative wound

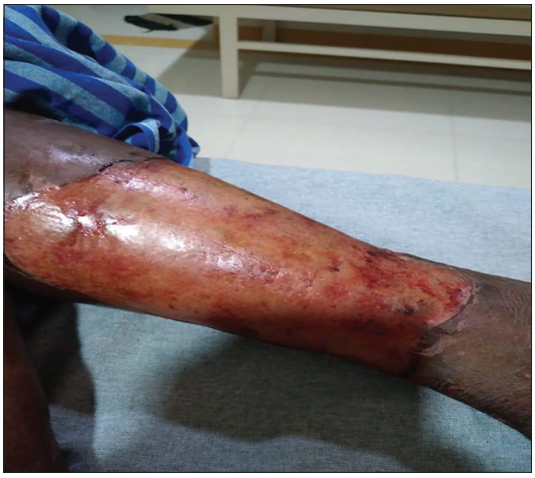

Figure 5: Mid operative wound

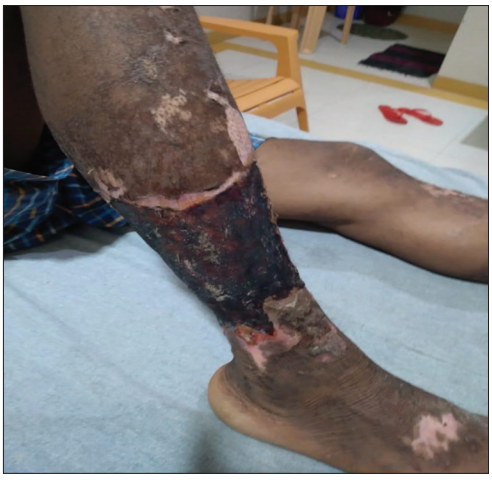

Figure 6: Mid operative wound

the cost factors that are involved. In extensive burns, the health care personnel priorities at the time of injury are survival, functionality, and cosmetics.[13,14]

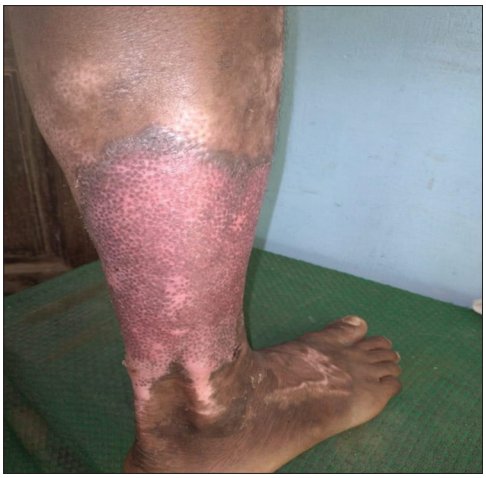

Figure 7: Post-operative wound

The primary rationale for using HBOT is that it increases tissue oxygen tension in hypoxic tissue to higher levels, making the host responses work. With HBOT, arterial blood oxygen contents are increased; plasma and tissue oxygen tension increase 10-fold. HBOT could be effective in fighting against necrosis, infection, and tissue loss in thermal burns.[15] Hence, it could be expected to be effective in electrical burns. However, in thermal burns, some studies have shown little to no benefit with HBO therapy.[16,17]

A Cochrane review was published in 2004[18] that looked at a total of two small randomized trials of HBOT in thermal burns. The main effect is the success of grafts with additional HBOT. It was reported in a low-quality randomized study with a risk ratio of 1.75 (0.53, 5.76) for HBOT.[18]

HBOT has demonstrated utility in the salvaging compromised grafts/flaps,[19] and animal models suggest the benefits of hyperbaric oxygen as a preconditioning stimulus in setting ischemic/reperfusion, including flap preparation to improve survival, by attenuating the inflammatory response and increasing flap perfusion.[20]

Hyperbaric oxygen does have the potential to increase skin grafts success in burns. More studies must be conducted to adopt this therapeutic tool into routine practice, especially in electrical burns. The benefits could have been much more significant if HBOT had started earlier, preferably within the first 24 h following injury[17] and as post-surgical conditioning of amputation and flap coverage.

Current data show that HBOT, when used as an adjunct in a comprehensive program of burn care, can significantly improve morbidity and mortality, reduce the length of hospital stay, and lessen the need for surgery. It has been

demonstrated to be safe in the hands of those thoroughly trained in rendering HBOT in the critical care setting and with appropriate monitoring precautions. Careful patient selection and screening are mandatory [Figures 1-7].

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Case Report

Hyperbaric Oxygen for Post-trauma Wound Healing: A Case Report

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Abstract

In younger patients, compound humerus fractures are usually caused by high-energy trauma, such as traffic accidents or sporting accidents. Surgical wounds are made in optimum conditions with full anesthetic and operating theater support; traumatic wounds are not, and they may be associated with much more serious underlying injury. These wounds need extensive debridement down to viable tissue and should be left open until healthy granulation tissue has formed; repeated debridement may be necessary. Even after extensive debridement, an infection may develop, requiring antibiotic treatment. Case of post wound debridement LRS fixation was treated with HBOT for 10 sitting improved wound healing. HBOT is the use of 100% oxygen at pressures greater than atmospheric pressure. The patient breathes 100% oxygen intermittently while the pressure of the treatment chamber is increased to greater than 1 atmosphere absolute (ATA). Hyperoxia in normal tissues causes vasoconstriction, which reduces post-traumatic tissue edema, contributing to the treatment of crush injuries, compartment syndromes, and burns.

Key words: HBOT, Hyperbaric oxygen therapy, Trauma, Wound healing

INTRODUCTION

Wound healing is a basic and principle factor in medical treatment. The most important mechanism of wound healing is angiogenesis. Growth factor wound cell origin and cellular and biological effects are stimulated, enhancing the accumulation of endothelial cells, which move to the wound and initiate angiogenesis.[1,2] New vessels form and each vessel initiates small branches that connect to other new vessels, forming a new vascular plexus through which blood flows into the wound leading to the remodeling phase of wound healing. During remodeling, vessels differentiate and specialize, becoming arterioles or venules. The granulation tissues, enriched with new vessels, form when the wound is open. In some cases, when the situation of patients is very complicated, including the large size of the acute wound, poor complications, or chronic wound, all relevant factors of wound healing are corrected. Nevertheless, the wound could not be satisfactorily improved. Thus, new adjuvant therapy, which is an alternative treatment for wound healing, is used to treat patients to improve the effectiveness of wound healing. Hyperbaric oxygen increases oxygen supply in the marginally perfused ischemic/hypoxic tissues and improves the cellular metabolism that has been impaired by hypoxia. It relieves the effects of ischemia by promoting angiogenesis and healing.[3-6]

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CASE PRESENTATION

A 20-year-old male patient presented with pain and wound over his right arm following on RTA 3 days before. On examination, there was large 15 × 10 cm wound over anterior distal arm and deformity.Radiograph examination shown Grade 3B compound humerus fracture. Orthopedician opinion was bought and emergency debridement and external fixator were done after doing relevant investigations. Post-operative period was uneventful.

The physician evaluated the patient and finally concluded the treatment plan of HBOT immediately after surgery. Opinion from orthopedician and plastic surgeon was obtained. All vital signs and investigations were normal. Ten sittings of HBOT were given and daily dressing was changed along with antibiotics. We utilize a twice-a-day regimen of 90 min at 2 atmospheres plus descent and

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ascent time. Treatments typically take 105 min. Patients are carefully monitored during initial treatments until stable and as necessary thereafter. Four weeks after HBOT treatment, wound healing was satisfactory.

Supportive medication and nutritional care were taken adjacent. There was a good improvement in the healing of wounds faster after hyperbaric oxygen therapy. The patient was symptomatically improved and hence discharged. Early oral intake was encouraged and advised to take a high-protein high-calorie diet supplemented with the parenteral administration of intralipid and an essential amino acid formula to reach the calculated daily calorie needs. Patients were instructed to change the dressing on alternate days [Figures 1 and 2].

DISCUSSION

Wound healing is a complex process that requires coordinated repair responses, including inflammation,

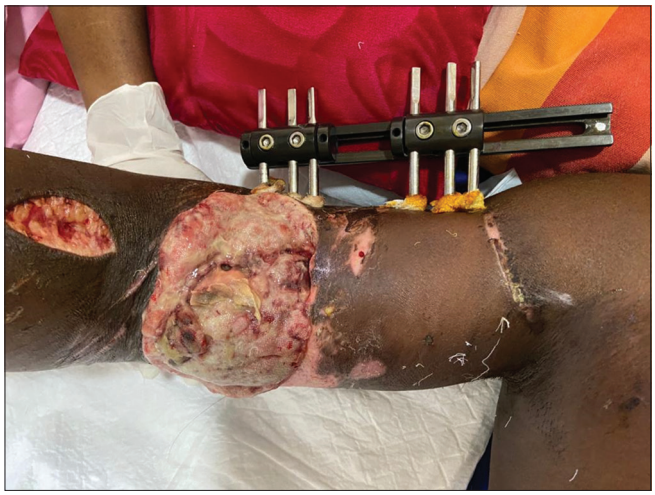

Figure 1: Before HBOT

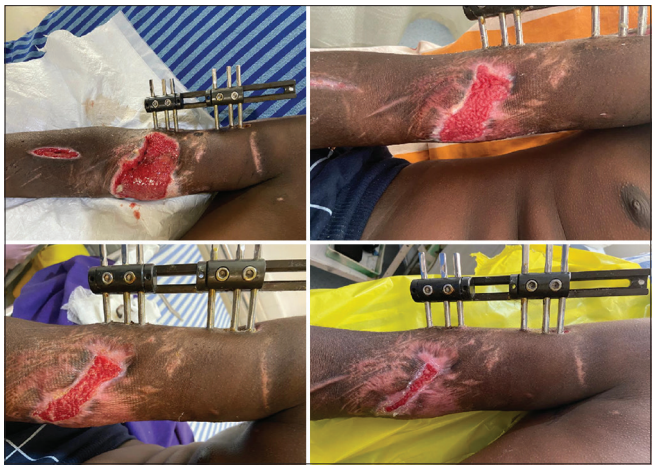

Figure 2: After HBOT

matrix production, angiogenesis, epithelization, and remodeling. Many factors may impair wound healing. Systemic factors such as medical comorbidities, nutrition, sympathetic nervous system activation, and age substantially affect the repair process. Local environmental factors in and around the wound, including bacterial load, degree of inflammation, moisture content, oxygen tension, and vascular perfusion, also profoundly affect healing.[7] Although all of these factors are important, one of the most critical elements is oxygen supply to the wound. Wound hypoxia impairs all the components of healing essentially.[8] Although the role of oxygen is usually thought of in terms of aerobic respiration and energy production through oxidative phosphorylation, in wound healing, oxygen is required as a cofactor for enzymatic processes and also is required for signaling mechanisms. Oxygen is a rate-limiting component in leukocyte-mediated bacterial killing and collagen formation because specific enzymes require oxygen at high partial pressure (at least 40 mmHg).[9,10] The mechanisms by which the other processes are oxygen dependent are less clear. Still, these processes also require oxygen at a concentration much greater than that needed for cellular respiration (though not necessarily a high volume).[11] Wound hypoxia is a common cause of impaired healing, particularly in lower extremity ulcers. Hyperbaric oxygen therapy (HBOT) is a means of correcting wound hypoxia. HBOT usually increases wound oxygen well above the physiologic range (200 mmHg). At these levels, oxygen likely acts like a drug.[12]

Soft-tissue infections, especially of the lower limb, can be difficult to manage with routine therapy, including antimicrobial agents, anti-inflammatory medications, and surgical drainage or lavage. The addition of HBOT may be useful in bacterial killing by leukocytes and improving antimicrobial function in inflamed, hypoxic tissue. A similar effect can be expected in cases of bone infections in which necrotic bone may be preventing adequate penetration and function of antimicrobial agents. While not every wound needs hyperbaric oxygen treatment, some large wounds with hypoxic injury to the skin, underlying tissues, and large skin flaps may benefit from HBOT. The goal is to minimize tissue necrosis and loss from hypoxia to reduce the time for wound healing.[13]

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Original Article

Awareness and Motivation Towards Blood Donation: An Observational Study

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Abstract

Introduction: Even with mankind's advances in science, there is still no substitute for blood. Voluntary blood donation is the safest and most ideal method to meet the current shortage. Increase in the awareness level about blood donation will lead to its acceptance by society, which will be beneficial to all.

Aim: This observational study aimed to analyze the awareness and motivation toward blood donation.

Materials and Methods: This observational study was conducted to assess population awareness toward voluntary blood donation and motivate them to become a regular donor. A total of 50 study people were included in this study. A self-administered questionnaire was prepared for every donor to assess their awareness and misconceptions toward voluntary blood donation.

Results: Out of 50 people, six were between 18 and 20 years, 24 people between 20 and 30 years, 12 people between 31 and 40, and eight people >40 years. Based on education level 14 were at the school level, 26 were at the college level, and ten were professional workers. Based on occupation 14 were self-employed, 20 were students, and 16 were private workers. Based on socio-economic status, 18 were low status, 24 were middle status, and eight were high status. Based on a number of donation, 18 patients were 1st-time donation giving, 22 patients had already given between 2–5 times, and ten patients had donated >5 times.

Conclusion: In our study, most donors were willing to be a regular donor but cannot be due to their lack of awareness and motivation. So by creating awareness and opportunities for blood donation by conducting many blood donation camps may provide a solution for our blood demands.

Key words: Blood, Donation, Awareness, Motivation

INTRODUCTION

Science has advanced in leaps and bounds since the dawn of the 20th century. Blood transfusion has saved millions of lives ever since the discovery of ABO blood groups and advances in preserving collected blood. However, we are yet to find a substitute for this so-called life-giving force that is blood. Hence, blood donation, preferably voluntary donations, is still the only hope of life for the countless people who require blood transfusion every day. It is estimated that donation by 1% of the population is sufficient to meet a nation's most basic blood requirements.[1]

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The supply of safe blood can only be guaranteed with regular, voluntary, and non-remunerated blood donors.[2] It has been found that voluntary non-remunerated blood donation is the safest form of blood donations.[3] These type of donors are considered as safest because it has been seen that the prevalence of transfusion-transmitted infections is lowest among these donors and seropositivity of transfusion-transmitted diseases is greater in replacement blood donors than voluntary donors.[4,5] There are also some medical benefits of blood donation, as the incidence of acute myocardial infarction is lesser in regular voluntary donors.[6] Voluntary blood donation also increases insulin sensitivity and helps maintain the equilibrium of glucose in the body.[7] It has been found that recruiting safe donors, mainly in developing countries, are a more challenging task.[8] Blood donation is motivated by various factors such as altruism, social pressure, and behavior and replacement needs.[8,9] There should be greater consciousness and increased level of a positive attitude about voluntary blood donation. Moreover, these donors

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can self-exclude themselves when they are not fit to donate blood as a regular donor; they are quite aware of donor deferral conditions.

The statistics prepared by the Association of Voluntary Blood Donors' Forum (AVBDF) on the percentage of voluntary blood donation to the total blood collection in individual states in the year 2009–2010 showed a rapid decline in the number of donors throughout India.[10]

According to the WHO, more young people donate blood in low- and middle-income countries, proportionally than in high-income countries. Demographic information of blood donors is important for formulating and monitoring recruitment strategies.[11] In a study in Nepal Medical College, Kathmandu, it was found that more medical students donated blood frequently and were more knowledgeable in all aspects of blood and blood donation related knowledge (*P* values 0.01 or less) than non-medicos.[12]

Aim

This observational study aimed to analyze the awareness and motivation toward blood donation.

MATERIALS AND METHODS

This observational study was conducted to assess the population's awareness of voluntary blood donation at government headquarters hospital, Dindigul. A total of 50 study people were included in this study. Volunteers below the age of 18 were excluded from the study as they would be below the eligible age for blood donation. A self-administered questionnaire was prepared for every donor to assess their awareness and misconceptions toward voluntary blood donation. Data were analyzed and presented in the form of percentages.

RESULTS

Out of 50 people, six were between 18 and 20 years, 24 people between 20 and 30 years, 12 people between 31 and 40, and eight people >40 years [Table 1].

Out of 50 people based on education level 14 were at the school level, 26 were at the college level, and ten were professional workers [Table 2].

Out of 50 people based on occupation, 14 were self-employed, 20 were students, and 16 were private workers [Table 3].

Out of 50 people based on socio-economic status 18 were low status, 24 were middle status, and eight were high status [Table 4].

Out of 50 people based on a number of donation, 18 patients were 1st-time donation giving, 22 patients had already given between 2–5 times, and ten patients had donated >5 times [Table 5].

Out of 50 people, all of them aware that HIV patients cannot donate blood and donate blood at what age. Majority of them do not know how much volume of blood to be donated [Table 6].

The majority were willing to become a regular donor and motivated by social media, relatives, and organization awareness program [Table 7].

DISCUSSION

Escalating demand for safe blood and its availability in our region can be only ensured through enhancing voluntary blood donation. Youngsters' role in voluntary blood donation is crucial to meet the demand for safe blood and youngsters having a better understanding of our country's health-care requirements should come to the forefront. The shortage of blood in India is due to increased demand, with fewer voluntary blood donors. Our study shows a lack of awareness and motivation among our donors regarding the mandatory test done after the blood collection, the amount of blood donated, and whether people could get infected by receiving blood. Hence, there is well need to create awareness among our youngster and replacement donors to become a regular, voluntary donor.

The majority (76%) of the students acquired the information about blood donation from social media such as the internet, while only a few knew from awareness program and relatives. This result is different with the result of a study by Dubey *et al.*[13] where television was considered to be the most effective medium (45.2%), followed by newspapers (39.8%), radio (9.2%), banners (2.8%), pamphlets (2.2%), and SMS (0.8%).

The majority (100%) of them were aware of blood screening for transmissible infection before donation. Around 100% of them had an idea about the spread of major diseases like HIV/AIDS through blood donation which is more than that found in Patel *et al.*[14] (60%) and Kumari *et al.*[15] (62.5%). Again, in the study by Patel *et al.*[14] around 95% of the study participants knew that Hepatitis-B could also be transmitted through blood donation, which was almost similar (100%) in our study.

In the present study, it was observed that 100% of respondents knew about the suitable age group of blood donation (18–65 years). Similar findings were observed in

Table 1: Age distribution

Age group	Frequency	Percentage
18–20	6	12
21–30	24	48
31–40	12	24
>41	8	16

Table 2: Distribution of education level

Education	Frequency	Percentage
School	14	28
College	26	52
Professional	10	20

Table 3: Distribution of occupation

Occupation	Frequency	Percentage
Self-employed	14	28
Students	20	40
Private	16	32

Table 4: Distribution of socio-economic status

Socio-economic status	Frequency	Percentage
Low	18	36
Middle	24	48
High	8	16

Table 5: Distribution of a number of donation

Number of Donation	Frequency	Percentage
1st time	18	36
2–5	22	44
>5	10	20

Table 6: Knowledge about blood donation

Knowledge	Aware	Not aware
Knowledge about donation intervals	12	38
Age to start blood donation	50	0
Can HIV person donate blood	50	0
Required Hb level to donate blood	32	18
The mandatory test was done on the donated blood	28	22
The volume of blood donated	4	46

Table 7: Motivational about blood donation

Motivational of blood donation	Frequency	Percentage
Organization awareness program	18	36
Request for donation by social media	20	40
Relatives	12	24
Willing to become a regular donor	46	92

the study, which was done by Aslami *et al.*[16] (85%), Uma *et al.*[17] (79.4%), and Chopra *et al.*[18] (90%).

In our study, 24% of subjects had the correct knowledge regarding minimum interval of blood donation, which was not similar to the study of Agravat Amit *et al.*[19] (80%). In a similar study, Chopra *et al.*[18] and Aslami *et al.*[16] found that their subjects who had correct knowledge about a minimum interval of blood donation were 48.9% and 45%, respectively.

CONCLUSION

In our study, most donors were willing to be a regular donor but cannot be due to their lack of awareness and motivation. Hence, by creating awareness and opportunities for blood donation by conducting many blood donation camps may provide a solution for our blood demands so that the needy persons can be given the lifesaving blood at the appropriate time.

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Original Article

Comprehensive Analysis of Anesthesia in Coronavirus Disease-19 Positive Patients in a Dedicated Coronavirus Disease Hospital

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Abstract

Background and Aim: To study the clinical characteristics of coronavirus induced disease 19 (coronavirus disease 19 [COVID-19]) patients undergoing anesthesia.

Methods: It was a retrospective study conducted at a dedicated COVID public hospital. All COVID-19 patients undergoing anesthesia were analyzed for anesthesia techniques, peri-operative course, complications, outcome (Intensive Care Unit [ICU] admission, death), and factors associated with perioperative morbidity and mortality. Software EpiInfo version 7.2 was used for statistical analysis.

Results: Total of 269 COVID-19 patients received anesthesia during the study period with 218 (81%) cesarean section and 51 (19%) other surgical emergencies. The most common anesthesia technique was central neuraxial blockade (CNB) in 235 (87.36%), followed by general anesthesia (GA), regional blocks, and monitored anesthesia care. Intraoperative complications in 14 (5.20%) patients were hypotension, bradycardia, hemorrhage, desaturation, and bronchospasm. ICU care needed in 22 (8.18%) patients and significantly associated with age >50 year ($P < 0.001$, odds ratio [OR] 31.73, 95% confidence interval [CI] 10.87–92.62), co-morbidities ($P < 0.00$, OR 9.36, 95% CI 3.61–24.27), GA ($P < 0.00$, OR 7.85, 95% CI 2.99–20.62), and intra-operative complication ($P < 0.001$, OR 295.20, 95% CI 34.87–498.02) and raised inflammatory markers. The most common post-operative complications were pulmonary (Acute respiratory distress syndrome [ARDS], pneumonia, and respiratory failure) and vascular thrombosis. Mortality was (4) 1.49% and significantly associated with advanced age ($P = 0.002$, OR 41.17, 95% CI 4.07–416.08), co-morbidities ($P < 0.001$, OR 10.70, 95% CI 1.09–104.87), SpO_2 <90% ($P < 0.001$, OR 10.70, 95% CI 1.09–104.87), and complications ($P = 0.003$, OR 23.09, 95% CI 2.97–179.23).

Conclusion: We recommend, regional anesthesia mainly CNB for COVID-19 patients whenever feasible and modified rapid sequence induction for GA. COVID-19 severity with hyper-inflammation and pulmonary involvement should be considered for risk estimation. Vigilance for post-operative pulmonary complications and thrombosis is crucial. Identification of risk factors such as advanced age, comorbidities, severe COVID-19 complications (vascular thrombosis, ARDS, multiorgan failure, etc.) and raised inflammatory markers to decrease perioperative morbidity and mortality is vital.

Key words: Anesthesia in coronavirus disease-19, Coronavirus induced disease 19, Severe acute respiratory syndrome coronavirus 2 pandemic

INTRODUCTION

The corona virus induced disease 19 (coronavirus disease [COVID-19]) pandemic is an international public health emergency, which is caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).[1] More than 35.5 million people are affected across the world and almost 1.04 million deaths are observed, in India more than 6.69 million people are infected and more than 1.04 lakhs deaths till date as per COVID-19 tracker and the toll is still rising. Therefore, many hospitals are designated entirely as COVID only hospitals and many routine health-care procedures are being delayed to prioritize treating COVID-19.[1,2] Our tertiary care teaching public institute in a metro city of India was also converted to a

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dedicated COVID hospital (DCH) and nodal center for obstetric care.

COVID-19 patients undergoing anesthesia pose huge challenges due to variety of reasons such as it's a novel, unknown nature, severity, medications, and complications of COVID-19.[2] SARS-CoV-2 is a respiratory system targeting virus with wide spectrum of manifestation from asymptomatic to severe illness with pneumonia, acute respiratory distress syndrome (ARDS), death and specific treatment protocols for managing COVID-19 are still being evolved.[2] Operation theater (OT) and airway procedures are highly aerosol generating. There is limited information about the clinical characteristics of COVID-19 patients undergoing anesthesia, anesthesia techniques, complications, and overall outcome. Furthermore, the effect of surgery and anesthesia on further course of COVID and vice versa is still under investigation. Due to limited evidence, current guidelines for the anesthetic management of COVID-19 patients are based largely on expert opinion and case series.[3-7] A recent meta-analysis concluded that surgical patients with SARS-CoV-2 are at risk of pulmonary complications and mortality.[8]

Our health system is overwhelmed with logistic challenges and limited resources. Therefore, it is crucial to have evidence-based, standard management protocol for anesthesia in COVID patients. Streamlining optimum use of limited resources and prompt management of complications may help to decrease perioperative morbidity and mortality in COVID. Hence, we conducted comprehensive clinical analysis of COVID-19 patients undergoing anesthesia. Our primary objective was to analyze the anesthesia techniques in COVID-19 patients. We also studied the perioperative course with respect to demographic parameters, co-morbidities, complications, severity of COVID-19, and its complications, the need for intensive care unit (ICU) admission, mechanical ventilation, outcome, and the factors associated with ICU admission and mortality.

METHODS

It was a retrospective study conducted at a tertiary care teaching public institute which was converted into DCH after institute's ethics committee approval (ECARP/2020/81). Study period comprised from April 19, 2020 to August 15, 2020. Waiver of consent was obtained. COVID-19 positive case is defined as positive reverse-transcriptase-polymerase chain reaction (RT-PCR) in a diagnostic specimen. All consecutive COVID-19 positive patients undergoing all types of surgery under anesthesia during the study period were included in the study. All the patients were confirmed RT-PCR positive at different stages of COVID-19. Following data were collected from the medical records: Demographics (age, sex, and weight), medical and surgical history, associated co-morbidities, laboratory and biochemical parameters and available investigations, electrocardiogram, available radiological findings from X-ray chest, and computed tomography scan of thorax. The disease severity of COVID-19 was recorded as mild (mild symptoms without radiological and laboratory changes), moderate (fever, cough with <50% radiological involvement), severe (dyspnea, low SPO_2, and lung infiltrates >50%), and critical (severe COVID associated with complications), which was defined according to the management guidelines for COVID-19 and treatment details were recorded.[9]

American Society of Anaesthesiologist Physical Status (ASA-PS) classification, surgical procedure, details of anesthesia technique and duration of surgery were recorded. Vital parameters: Heart rate (HR), systolic and diastolic blood pressure (BP), and oxygen Saturation (SpO_2) were noted as documented in the immediate pre-operative, intraoperative, and immediate post-operative period from records. Perioperative complications (anesthesia, surgical, and COVID related) and need for ICU admission were recorded. In cases of caesarean section (CS), neonatal outcome was noted. In cases of ICU admission, details of ICU intervention and complications developed were noted. Final outcome of the patient was categorized as discharge or death and the cause of mortality was noted.

The data were collected and compiled in MS Excel. Qualitative data such as gender, and co-morbidities were represented in the form of frequency and percentage. Quantitative data such as age, and SpO_2 were represented using percentage, mean ± standard deviation (SD), median, and interquartile range (IQR). Association between variables was assessed by Chi-square test and by Fisher's exact test (small counts). Analysis was two tailed and an alpha value $P < 0.05$ was used as the cutoff for statistical significance. Bivariate analysis for association among various risk factors (variables) and outcome (ICU admission, mortality) was calculated using Odds ratio (OR) and 95% confidence interval (CI). Appropriate statistical software, including but not restricted to MS Excel, EPI info version 7.2 was used for statistical analysis.

RESULTS

Total of 269 COVID-19 patients received anesthesia for various surgical procedures during the study period at DCH. The surgical procedures comprised of 218(81%) CS

and 51 (19%) other surgical emergencies such as general surgical emergencies (exploratory laparotomy for intestinal obstruction and perforation peritonitis, debridement, amputation), check curettage, ectopic pregnancy, suction evacuation, manual removal of placenta, neurosurgery, ophthalmic, and vascular surgery.

Among 218 females undergoing CS, mean age (±SD) was 28.02 (±4.54) years and among 51 other surgical emergencies, mean age was 45.16 (±17.890) years, of which 32 (62.75%) were females and 19 (37.25%) were males [Tables 1 and 2].

In 218 CS patients, 37 (16.97%) had associated comorbidities such as 27 (12.39%) pregnancy induced hypertension (PIH), six (2.75%) gestational diabetes mellitus (GDM), eight (3.67%) thyroid disorders, and eight (3.67%) other conditions such as bronchial asthma (BA), anemia, and pancytopenia. Among 51 other surgical emergencies, 23 (45.10%) patients had comorbidities such as 19 (37.25%) diabetes mellitus (DM), 13 (25.50%) hypertension (HT) and six (11.76%) BA, ischemic heart disease (IHD), chronic kidney disease (CKD), and 13 (25.50%) had more than one comorbidity.

According to disease severity of COVID-19, 245 (91.08%) patients belonged to mild, 20 (7.43%) moderate, three (1.12%) severe, and one (0.37%) critical category. According to the ASA classification, 251 (93.3%) patients were ASA 1, 2, and 18 (6.69%) were ASA 3, 4.

The indications for 218 CS were previous CS 103 (47.25%), fetal distress 65 (29.82%), PIH and eclampsia 21 (9.63%), and other indications such as breech, multiple pregnancy (one triplet and two twins), non-progress of labor, constituted 41 (18.81%). In two severe COVID patients, persistent low SpO_2 was an additional indication.

Among anesthesia techniques administered, central neuraxial blockade (CNB) was used in maximum patients 235 (87.36%) [Figure 1]. GA was given in 4% patients using modified rapid sequence induction (RSI) technique along with viral filter and closed suction. Intraoperative oxygen was administered through nasal prongs in 128 (47.58%) patients, Hudson mask in 30 (11.15%), non-rebreathing reservoir mask in 15 (5.58%), non-invasive mechanical ventilation (NIV) in three (1.12%) patients, and in ten (3.72%) patients by controlled ventilation through endotracheal tube (ETT).

Intraoperative course was uneventful in 255 (94.8%) patients with stable vital parameters and 14 (5.20%) developed complications [Figure 2]. Intraoperative complications were cardiovascular (hypotension and bradycardia) in nine (3.35%) patients, hemorrhage in three (1.49%), desaturation in two (0.74%), and bronchospasm in one (0.37%) patient.

Neonates born to COVID-19 positive mothers by CS had mean APGAR score of 9.87 ± 0.51, mean birth weight 2.77 ± 0.55 kg, and none of them were RT-PCR positive in the first diagnostic specimen.

Postoperatively, 22 (8.18%) patients needed intensive care. We analyzed the risk factors, associated with requirement of ICU care in post-operative period. The

Table 1: Clinical characteristics and quantitative parameters of patients undergoing LSCS

Quantitative parameters	Mean	SD	Min	25%	Median	75%	Max
Age (years)	28.02	4.54	20.00	24.00	28.00	31.00	40.00
Duration of surgery (min)	82.04	15.74	60.00	70.00	85.00	90.00	200.00
Weight (kg)	64.00	7.28	50.00	58.00	62.00	68.00	90.00
Hemoglobin (g%)	10.80	1.25	8.80	10.00	10.90	11.40	14.90
Total leukocyte count (TLC) ($\times 10^9$/L)	9.85	1.58	3.00	9.80	10.00	11.00	14.50
Platelet count ($\times 10^{11}$/L)	1.71	0.51	0.60	1.2	1.75	2.0	3.4
APGAR score	9.87	0.52	7	10	10	10	10

Table 2: Clinical characteristics and quantitative parameters of patients undergoing emergency surgery

Quantitative parameters	Mean	SD	Min	25%	Median	75%	Max
Age (years)	45.16	17.89	18.00	29.00	42.00	62.00	80.00
Duration of surgery (min)	99.51	92.78	20.00	25.00	45.00	180.00	330.00
Weight (kg)	61.57	12.83	30.00	54.00	58.00	65.00	98.00
Hemoglobin (g%)	10.50	0.99	7.30	10.00	10.20	11.00	13.00
Total leukocyte count (TLC) ($\times 10^9$/L)	10.57	4.84	4.50	7.60	9.00	12.00	25.91
Platelet count ($\times 10^{11}$/L)	2.27	0.81	0.97	1.80	2.20	2.40	5.60
C-reactive protein (mg/L)	22.89	20.51	10.00	10.00	10.00	30.00	90.00
Creatine phosphokinase (U/L)	134.31	119.02	32.00	70.00	70.00	122.00	450.00
Interleukin-6 (pg/ml)	291.39	679.03	3.00	3.00	5.00	250.00	3285.00
Serum Ferritin (ng/ml)	168.04	167.24	40.00	40.00	110.00	240.00	550.00
D-Dimer (mg/L)	2.10	2.96	0.20	0.40	0.40	4.00	10.00

significant factors were age more 50 years, presence of co-morbidities, anesthesia technique (GA), and intraoperative complications [Table 3]. In ICU patients, levels of inflammatory markers were significantly elevated such as Interleukin-6 >35 pg/ml ($P < 0.001$, OR 79.20, 95% CI 8.38–748.75, D-dimer >0.8 mg/l), ($P < 0.001$, OR 64, 95% CI 6.96–588.43, Serum ferritin levels >300 ng/ml), and ($P < 0.001$, OR 13.60 95% CI 2.96–62.42). Complications encountered in the ICU were pulmonary complications such as ARDS, pneumonia, respiratory failure, vascular thrombosis in all 22 (8.18%) patients, followed by acute kidney injury (AKI) in six (2.23%), sepsis three (1.12%), multiorgan dysfunction syndrome (MODS) three (1.12%), and pulmonary fibrosis in two (0.74%). Final outcome of the patient was categorized as discharge or death. 265 (98.51%) patients were discharged and four deaths reported with mortality of 1.49%. The risk factors associated with mortality were advanced age, presence of comorbidities, low preoperative oxygen saturation, and presence of ICU complications [Table 4]. Cause of death was severe ARDS and MODS in severe COVID-19.

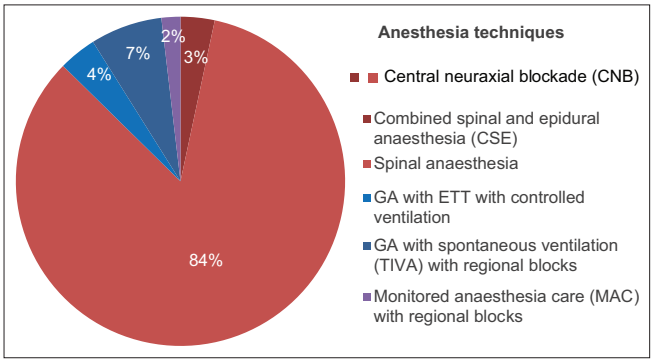

Figure 1: Various anesthesia techniques used in COVID-19 patients. CNB: Central neuraxial blockade, TIVA: Total intravenous anesthesia, MAC: Monitored anesthesia care, GA: General anesthesia

DISCUSSION

Total 269 COVID-19 patients underwent surgical procedure under various types of anesthesia techniques during the study period at DCH. Majority patients belonged to ASA 1, 2 and mild COVID category and had good outcome. ASA 3, 4 and moderate to severe COVID category patients required ICU care and developed post-operative complications; however, six ASA 2 patients developed post-operative COVID related pulmonary complications. Post-operative overt pulmonary manifestations have been reported in COVID due to direct injury to pulmonary epithelium with profound inflammatory response.[8,10] Risk estimation for post-operative outcome may not be accurate using the ASA-PS status alone, COVID disease severity should be considered as an additional index while estimating post-operative outcome.

Various types of anesthesia techniques were administered such as general anesthesia (GA), monitored anesthesia care (MAC), total intravenous anesthesia (TIVA), and regional anesthesia (RA) techniques including central neuraxial blocks (CNB): Spinal, epidural, combined spinal epidural (CSE), and peripheral neural blocks (PNB). Most common technique used was CNB in 235 (87.36%) patients. Anesthesia technique was chosen as per the clinical condition, surgical requirement, COVID-19 severity, lung involvement, hypercoagulopathy, thrombocytopenia, and ongoing COVID medications especially anticoagulants and antivirals. All mild cases received hydroxychloroquine (initial months before obsolete) or favipiravir or doxycycline and ivermectin along with supportive treatment with multivitamins especially Vitamin C and zinc. All moderate to severe COVID-19 patients received LMWH, steroid, and antiviral (favipiravir and remdesivir) medication. CNB was administered as per ASRA guidelines after confirming platelet count, available coagulation parameters (PT, INR, APTT, and D-Dimer) and timing of anticoagulants.[11]

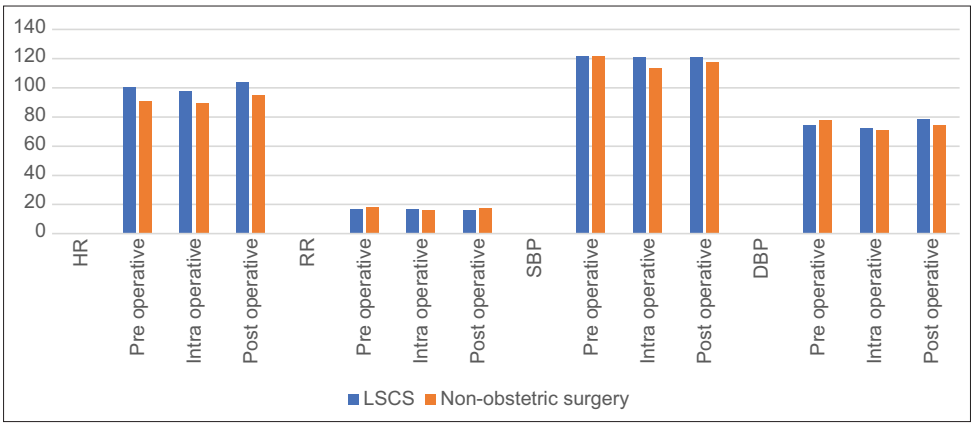

Figure 2: Pre-operative, intraoperative, post-operative trends in vital parameters in COVID-19 patients. Heart rate (HR), respiratory rate (RR), systolic blood pressure (SBP), diastolic blood pressure (DBP)

Table 3: Statistical analysis of different variables with post-operative ICU admission as outcome

Risk factor	ICU admission				Odd's ratio (95% CI) *	*P* value
	Yes (*n*=22)		No (*n*=247)			
	No. %		No. %			
Age						
>50 years	12	54.55	9	3.64	31.73 (10.87–92.62)	<0.001
<50 years	10	45.45	238	96.36		
Comorbidity						
Present	15	68.18	46	18.62	9.36 (3.61–24.27)	<0.001
Absent	7	32.82	201	81.38		
Anesthesia technique						
GA	9	40.91	20	8.10	7.85 (2.99–20.62)	<0.001
Non-GA	13	59.09	227	91.90		
Presence of complications						
Present	12	54.55	1	0.40	295.20 (34.87–498.02)	<0.001
Absent	10	45.45	246	99.60		

* CI: Confidence interval

Table 4: Statistical analysis of variables with post-operative mortality as outcome

Risk factor	Mortality				Odd's ratio (95% CI)†	*P* value
	Yes (*n*=4)		No (*n*=265)			
	No. %		No. %			
Age						
>50 years	3	75.00	18	6.79	41.17 (4.07–416.08)	0.002
<50 years	1	25.00	247	93.21		
Co-morbidity						
Present	3	75.00	58	21.89	10.70 (1.09–104.87)	<0.001
Absent	1	25.00	207	78.11		
Pre-operative SpO2*						
<90	3	75.00	58	21.89	10.70 (1.09–104.87)	<0.001
>90	1	25.00	207	78.11		
Post-operative Complications						
Present	2	50.00	11	4.15	23.09 (2.97–179.23)	0.003
Absent	2	50.00	254	95.85		

*SpO_2: Oxygen saturation; †CI: Confidence interval

Thrombocytopenia has been documented with severe COVID-19.[12]

Pregnant patients may experience non-specific COVID-19 symptoms (myalgia, diarrhea, headache, vomiting, fever, and shortness of breaths) which may be easily attributed to their pregnancy symptoms. Being a referral and DCH center, most of our obstetric patients had been diagnosed RT-PCR positive in their third-trimester antenatal checkup. All received multivitamins including Vitamin C and zinc from the time of diagnosis; however, LMWH and steroids reserved for moderate to severe patients. Although, HCQ was part of COVID-19 management initially, none of pregnant patient received it. Antiviral (remdesivir) drug was started post-LSCS in severe cases. To prevent unnecessary spread of infection most of LSCS was performed electively in indicated patients. CNB was the choice of anesthesia technique in these patients. Severe PIH and GDM patients were well managed by CSE with mild-to-moderate COVID-19 symptoms. Our one severe PIH patients with severe COVID, who was receiving NIV preoperatively was also managed with regional anesthesia successfully with continuation of intraoperative NIV. The choice of anesthesia was depended on risk benefit ratio in every technique in every patient. We observed mild thrombocytopenia in majority of pregnant patients (lowest 60×10^9), drug-induced thrombocytopenia especially steroids and sepsis ruled out. PIH and eclamptic patient with COVID symptoms, who were receiving magnesium, should be of concern as COVID patients are prone to have AKI. Therefore, close monitoring of renal functions was done in these patients. Carboprost and nonsteroidal anti-inflammatory drugs were avoided as it may precipitate bronchospasm and platelet dysfunction, respectively.

All types of anesthesia have been safely reported in COVID patients.[3,13] Recommended technique in whenever possible

is regional anesthesia.[3,6,14,15] GA is preferably avoided as there is always the possibility of exacerbating pulmonary complications, hampering oxygen diffusion across the pulmonary endothelium and respiratory failure which has been reported in advanced pregnancy in COVID.[3,10,16] CNB and other regional blocks (scalp, axillary, and field block) were our first choice whenever possible. During MAC, sedation was avoided or kept minimal to avoid increased oxygen demand and airway manipulation associated with respiratory depression. Oxygen was provided through nasal prongs under a surgical mask. Use of LMA was avoided. Wax *et al*. recommended use of regional anesthesia wherever possible, even if it is outside the usual standard of care.[17] In our study, 29 patients were given GA due to specific indications such as eclampsia, severe thrombocytopenia, hemodynamic instability, requirement of mechanical ventilation due to COVID, and surgical requirement. Special precautions were taken while providing GA to the patients on NIV. Continuous application of NIV till shifting patient to the operation table was practiced. RSI was done with succinyl choline through intravenous induction agents (Propofol was preferred over thiopentone sodium and etomidate, as patients prone to have hyper-reactive airways with hyperimmune response), and avoiding inhalational anesthetics. Vecuronium was preferred over atracurium and cisatracurium except in deranged renal functions. Intraoperative application of positive end expiratory pressure (PEEP) for maintaining saturation and vigilant hemodynamic monitoring was done.

To prevent risk of cross-contamination and risk of viral spread, positive pressure OT was converted to negative pressure design, by the incorporation of a strong low-level exhaust system. Chow *et al*. suggested conversion of OT from positive to negative pressure environment.[18] We strictly followed infection prevention and control policies with emphasis on meticulous hand hygiene.[5,7,13] During GA with ETT, utmost precaution was taken to limit aerosol spread using modified RSI and intubation techniques with video laryngoscope by the most experienced anesthesiologist. Aerosol box or plastic drapes were used for intubation and extubation along with viral filter and closed suction. Intraoperative monitoring in all stable patients was done from distance and minimal personnel was kept in the OT. However, extra staff was kept standby in high risk cases as managing highly dynamic situations in OT, communication and swift functioning in Personal Protective Equipment (PPE) during sudden emergencies were extremely demanding.

Intraoperative course was uneventful and uncomplicated in most of the patients. Hypotension secondary to spinal anesthesia was well within 20–30% of base line and was managed appropriately with fluid and vasopressors and post-CNB noneurological complications were noted. However, in two patients exaggerated hypotension with arrhythmia (ventricular premature complexes and irregular R-R interval) unrelated to anesthesia and surgical causes was noted. Pirzada *et al*. described varied cardiac manifestations in COVID mainly due to Myocarditis.[19] Intraoperative desaturation (86–92%) and bronchospasm were observed in some severe COVID patients which may be attributed to hyperinflammation. Safety of neuraxial procedures in COVID-19 is documented by authors.[20,21] We observed elevated blood sugar in some moderate to severe COVID patients; however, it was not monitored in all the patients. Hyperglycemia in COVID due to pancreatic isletis or stress hyperglycemia is difficult to optimize.[22,23] Therefore, perioperative blood sugar monitoring is advised at regular intervals in COVID.

Amongst the 22 patients who required ICU, 14 were admitted in ICU preoperatively due to moderate-to-severe COVID. Factors which significantly associated with the requirement of perioperative ICU were: age >50 years, comorbidities, raised levels of inflammatory markers (D-dimer, IL-6, Serum ferritin), GA, and presence of intraoperative complications (hypotension, desaturation). Although, technique of anesthesia for GA was not the reason of ICU admission. Higher ASA class, COVID severity, and duration of surgery >2 h were also important factors in ICU admission clinically; however, they were not statistically significant.

Most common post-operative complication was pulmonary (ARDS, pneumonia, respiratory failure, and Pulmonary fibrosis), vascular thrombosis, followed by AKI, sepsis, MODS. Post-operative pulmonary complications were documented in half of patients with perioperative SARS-CoV-2 infection.[8] In some patients with vascular thrombosis, emergency embolectomy was needed. A hypercoagulable state due to uncontrolled immune-thrombotic response has been reported in severe COVID and is associated with poor outcome.[23-25] Hence, it is crucial that in addition to patient, anesthesia and surgical factors, COVID severity with hyperinflammation and pulmonary involvement should be recognized for anticipated ICU care in the post-operative period.

Mortality in the present study was (4) 1.49%, including only one maternal death out of the 218 CS patients and 265 patients were discharged and no neonatal complications were noted. Cause of death was severe ARDS and MODS in severe COVID-19. Good outcomes in pregnant COVID and no neonatal complications were reported.[26] Parameters significantly associated with mortality were advanced age, presence of comorbidities, low SpO_2, and post-operative complications. Similar factors were associated

with mortality in COVID in many studies across the globe.[23,27,28] A recent meta-analysis found that pulmonary complications and 30-day mortality were highest in those who developed lung involvement.[8] In the present study, pulmonary complications and mortality, however, were less as compared to reported literature.

Limitation of this study was being observational, retrospective, and single center study.

CONCLUSION

Thus, the experience from 269 COVID-19 patients with a large obstetric population, highlights, that regional anesthesia can be safely administered mainly to mild-to-moderate COVID patients as well as in some severe COVID patients with extreme vigilance. GA can also be administered safely, if required, using modified RSI and intubation with intravenous induction and use of intraoperative PEEP, viral filter, and closed suction. COVID severity should be considered as an additional index while estimating post-operative risk. Factors associated with ICU admission and mortality were advanced age, co-morbidities, high inflammatory markers, and SpO2<90%, pulmonary complications such as ARDS, pneumonia, and respiratory failure and should be recognized early for better outcome.

During COVID pandemic, we have changed our institutional practice guidelines with many regional techniques as a standard part of our armamentarium. Hence, we recommend regional anesthesia as technique of choice for COVID patients whenever feasible. Identification of risk factors for anticipated ICU care to decrease perioperative morbidity and mortality is vital.

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Original Article

Comparison between the Effects of Dexmedetomidine and Nalbuphine as an Adjuvant to 0.5% Levobupivacaine in Interscalene Brachial Plexus Block – A Prospective Randomized Double-blind Study

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Abstract

Introduction: Regional/peripheral nerve blocks are commonly used nowadays for upper limb orthopedic surgeries as an alternative to general anesthesia, as it provides ideal operating conditions with complete muscle relaxation and stable intraoperative hemodynamics. This study was carried out to compare the effectiveness of dexmedetomidine and nalbuphine as an adjuvant to interscalene brachial plexus block.

Materials and Methods: Sixty adult patients of either sex aged 18–65 years of American Society of Anesthesiologist Physical Status I-II, scheduled for shoulder surgeries which were randomly allocated to Group A (n = 30) receiving 30 ml levobupivacaine plus 50 mg dexmedetomidine and Group B (n = 30) receiving 30 ml levobupivacaine plus 10 mg nalbuphine. The onset and duration of sensory and motor blockade and the duration of post-operative analgesia were studied.

Results: Statistically highly significant difference (P = 0.001) was seen between Group A and Group B, regarding the onset and duration of sensory and motor blockade. Significantly prolonged duration of post-operative analgesia was seen in Group A.

Conclusion: The study concluded that dexmedetomidine is a better adjuvant than nalbuphine in interscalene brachial plexus block as it reduces the onset time for sensory and motor blockade and prolonged the duration of sensory and motor blockade.

Key words: Dexmedetomidine, Interscalene brachial plexus block, Nalbuphine

INTRODUCTION

Pain is an unpleasant phenomenon which has both sensory and affective components.[1] Regional anesthesia can be used alone, either as an anesthetic or can be combined with general anesthesia for perioperative analgesia. Upper limb nerve blocks are used in orthopedic procedures as a substitute to general anesthesia, as it provides good operating conditions and complete muscle relaxation, stable hemodynamics intraoperatively. It also provides associated sympathetic block along with post-operative analgesia. Due to early recovery from anesthesia, it provides less systemic side effects.[2-4] Regional anesthesia has minimum interaction with metabolic process of the body. Hence, it is better to use regional anesthesia in metabolic disorders such as diabetes mellitus, hypertension, cardiovascular diseases, and also in respiratory and renal diseases. It also gives post-operative analgesia.

Interscalene approach provides reliable anesthesia of the shoulder and areas of upper arm. In this technique, the interscalene groove is palpated right at the level of cricoid cartilage and local anesthetic is injected between the anterior and middle scalene muscles. Due to possible

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ulnar nerve sparing and close proximity of carotid artery, its use is restricted to surgeries of upper arm and shoulder.[5] Complications include hoarseness of voice because of blockade of recurrent laryngeal nerve mainly on the right side and Horner's syndrome.

Interscalene block is performed either by conventional, nerve stimulator (NS) guided, or ultrasonography guided. Using NS or ultrasound, we can reduce the complications of interscalene block to minimum. In NS-guided technique, once the needle is in proximity with the plexus, the NS is attached to stimulating needle and a preset current and frequency are delivered. With stimulation of motor fibers, motor twitch is elicited. When the desired twitch is obtained, amplitude is decreased ensuring that muscle twitch is still present.

Drug is usually injected in proximity to lower trunk identified as finger twitch. As motor fibers have a lower electrical threshold than sensory fibers, so the patient need not be subjected to the discomfort of paresthesia when the nerve is stimulated to produce a motor twitch. Applicability of NS-guided blocks in uncommunicative patients due to coma or language barrier provides an extra edge of benefit to the anesthesiologist.

Levobupivacaine is the local anesthetic which can block the transmission of action potential reversibly in both sensory and motor and also in sympathetic nerve fibers. It inhibits the passage of sodium through voltage sensitive ion channel in neuronal membrane. Levobupivacaine is metabolized in liver, primarily by cytochrome P450, specially the CYP1A2 and CYP3A4 isoforms. Clearance reduces when hepatic function is damaged.[6,7]

Adjuvants are pharmacological agents that are added to local anesthetics to enhance the potency and reduce the total dose of local anesthetics needed. Dexmedetomidine is a novel FDA approved (1999) alpha2 adrenergic receptor agonist for short-term sedation and analgesia. It is a category C drug with diverse action. Primary analgesia and potentiation of opioid-induced analgesia results from the activation of alpha 2 adrenergic receptors in the dorsal horn of the spinal cord and further inhibition of the release of substance P. Dexmedetomidine is also a neuroprotective drug.

Nalbuphine belongs to the class of synthetic opioid agonist – antagonist. It belongs to phenanthrene group. Its molecular formula is $C_{21}H_{27}NO_4HCL$ (nalbuphine hydrochloride). It is a potent analgesic basically identical to that of morphine on milligram basis.

We hypothesized that administration of dexmedetomidine as an adjuvant to levobupivacaine will quicken the onset of sensory and motor blockade in interscalene brachial plexus block and lengthen the duration of blockade as compared to nalbuphine as an adjuvant.

MATERIAL AND METHODS

It was a prospective, randomized, double-blind study. Following approval by the Institutional Ethical Committee (Government Medical College, Amritsar, Punjab, India, ECC/TH-03716/05/2019 dated: May 16, 2019), all patients underwent written informed consent (which included the risks, benefits, and explanation of process) to participate in the study. Randomization was performed centrally by a statistician using a random number table generated by Microsoft Excel to ensure proper concealment of the study management from the patients and investigators until the release of final statistical results.

The study was carried out prospectively in 60 patients of American Society of Anesthesiologists (ASA) Grade I and II of age group 18–65 years of either sex, admitted in the orthopedic department of Guru Nanak Dev Hospital, Amritsar, and scheduled to undergo shoulder and arm surgeries under interscalene brachial plexus block with levobupivacaine and dexmedetomidine mixture and with levobupivacaine and nalbuphine mixture. Non-cooperating patients, patients with ASA grade more than II, coagulation disorders, pulmonary and cardiac disease, and morbidly obese and previously brachial plexus injured patients were kept out from the study.

Duration of analgesia was taken as the outcome measure of interest for the purpose of sample size calculation. Sample size was calculated keeping in view at most 5% risk, with minimum 80% power and 5% significance level (significant at 95% confidence interval). Patients were divided into two Groups A and B of 30 each in a random and unbiased manner [Figure 1].

Group A (n = 30): Thirty subjects received 30 mL of 0.5% levobupivacaine plus 50 mg dexmedetomidine.

Group B (n = 30): Thirty subjects received 30 mL of 0.5% levobupivacaine plus 10 mg nalbuphine.

Patients recruited in study were given complete information about the procedure, potential side effects, complications, and alternative techniques. Then, the informed written consent was taken from the patients in their vernacular language. A day before surgery, a thorough pre-anesthetic check-up of all patients was conducted. Assessment of patient airway was done. Patients were instructed to fast for 4–6 h for clear fluids and 6–8 h for semi-solids and solids before the surgery. All basic investigations were carried out

and documented before procedure. The interpretations of visual linear analog scale were explained at the time of pre-anesthetic check-up. The patients were asked to point out the severity of pain experienced at that time in the post-operative period. Rescue analgesia was given if visual analog scale (VAS) score was >4.

In the operating room, 20 G I/V cannula was secured and an IV infusion of ringer lactate started. All the monitors (NIBP, pulse rate, respiratory rate, ECG, and SpO_2) were attached. The baseline readings were noted and were monitored intraoperatively.

The patient was made to lie in supine position, arms by the side, and head turned away toward the opposite side. The interscalene groove was palpated by rolling the fingers posterolaterally from the posterior border of the sternocleidomastoid over the belly of anterior scalene muscles into the groove. Cricoid cartilage palpated and bisecting point of an imaginary line was drawn from cricoid cartilage toward interscalene groove. This was the point of entry. This point lies directly opposite to C6 vertebra. An insulated needle compatible with NS was inserted almost perpendicular to floor of gutter on the superior aspect of transverse process of C6 vertebra that is 45 degrees caudal, posterior, and in medial direction. After inserting the needle, contractions were elicited with the help of peripheral NS starting from 1.2 mA and going down to 0.3–0.4 mA at a frequency of 1–2 Hz. When the contractions were elicited at a current of 0.3 mA, at this point, needle was fixed and local anesthetic solution was injected after repeated aspiration. The assessment of sensory block was done by loss of sensation to pin pricks using 27-gauge blunt hypodermic needle. The degree of motor block was assessed by modified bromage scale. Analgesia was considered satisfactory if score is 3 or less. If score is more than 4, rescue analgesia was given in form of injection diclofenac 75 mg iv. Time to first analgesia and total doses required for post-operative analgesia for 24 h were noted. Oxygen was routinely administered through oxygen mask at 4 L/min.

Bradycardia (heart rate <60 bpm) was treated with I/V atropine 0.4 mg. Hypotension (systolic blood pressure <100 mmHg or 20% less than the base value) was treated with I/V ephedrine 10 mg and additional ringer lactate solution. Ondansetron I/V was given for post-operative nausea and vomiting.

Patients were monitored for 24 h in the post-operative period for total duration of sensory and motor blockade. The patients were monitored for side effects and complications of technique and drugs throughout intraoperative and post-operative period. Side effects and complications such as accidental intravascular injection, pneumothorax, phrenic nerve block, neuropathy, and Horner's syndrome were recorded and if any occurred were followed postoperatively.

Statistical Analysis

Data were recorded in a Microsoft Excel spread sheet and analyzed using Statistical Package for the Social Sciences (SPSS version 24.00). Continuous data were presented as mean with standard deviation. Categorical data were expressed as percentages. Numerical variables were normally distributed and were compared using Chi-square test for non-parametric data and Student's "*t*"-test for parametric data. *P* value was then determined to evaluate the level of significance. The results were analyzed and compared to the previous studies to draw relevant conclusions. The blinding was opened at the end of the study.

RESULTS

Sixty patients were enrolled in the present study in two different groups. No patients were lost in follow-up and excluded from analysis. All the two groups were comparable in terms of demographic parameters [Table 1]. In Group A, the mean onset of sensory block was 9.02 ± 1.07 min. In Group B, the mean onset of sensory block was 10.02 ± 1.21. Group A shows early onset of sensory block as compared to Group B, and it was found to be statistically highly significant ($P = 0.001$).

In Group A, the mean onset of motor block was 9.15 ± 0.98 min. In Group B, the mean onset of motor block was 14.13 ± 1.39 min. Group A showed early onset of motor block as compared to Group B and it was found to be statistically highly significant ($P = 0.001$)

[Table 2 and Figure 2]. The mean duration of sensory block in Group A was 13.32 ± 0.80 h. The mean duration of sensory block in Group B was 12.00 ± 0.65 h. Group A showed prolonged duration of sensory block as compared

Table 1: Demographic parameters

Parameters	Group A	Group B	*P* value
Age (years)	42.10±18.14	38.39±15.87	0.240
Gender (female/male)	14/16	12/18	0.602
Weight (kilograms)	66.08±14.10	64.93±10.95	0.370
ASA (I/II)	27/3	24/6	0.278

Table 2: Onset of blocks

Parameters	Group A	Group B	*P* value
Onset of sensory block	9.02±1.07	10.02±1.21	0.001
Onset of motor block	9.15±0.98	14.13±1.39	0.001

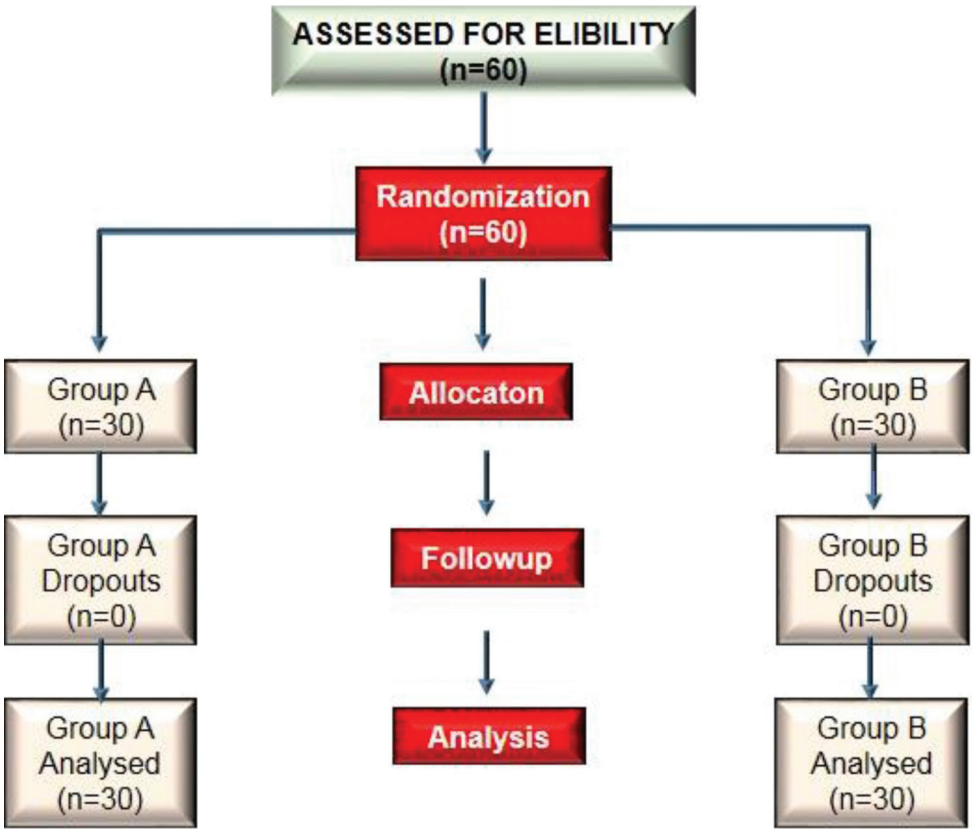

Figure 1: Consort diagram

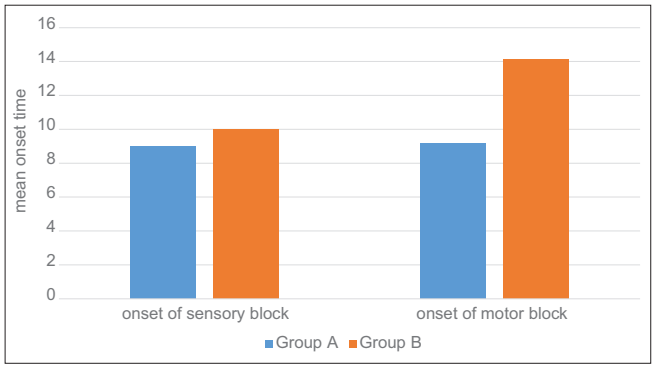

Figure 2: Mean onset time of blocks

to Group B, and it was found to be statistically highly significant ($P = 0.001$).

The mean duration of motor block in Group A was 12.00 ± 0.49 h. The mean duration of motor block in Group B was 7.97 ± 1.05 h. Group A showed prolonged duration of motor block as compared to Group B and it was found to be statistically highly significant ($P = 0.001$)

[Table 3 and Figure 3]. The comparison of VAS for both groups at different time intervals was done. At 8 h, the mean VAS score of Group A was 3.20 and that of Group B was 3.67. It showed statistically significant difference ($P = 0.001$). At 12 h, the mean of Group A was 4.07 and that of Group B was 4.50 and it showed statistically significant difference ($P = 0.03$). At 24 h, the mean VAS score of Group A was 4.50 and that of Group B was 6.07 and it showed statistically significant difference ($P = 0.001$)

[Table 4 and Figure 4]. No adverse effects such as respiratory depression, hypotension, bradycardia, nausea, and vomiting were reported in both the groups in the study.

DISCUSSION

Brachial plexus block has emerged as one of the most popular esthetic technique for upper limb surgeries. This regional technique avoids untoward effects of general anesthesia related to airway instrumentation and poly pharmacy. Ideally, regional anesthesia should have faster sensory onset, differential offset, with an earlier return of motor activities than sensory functions, enabling early ambulation or movements with prolonged analgesia.

Dexmedetomidine, an α2-receptor agonist, with α2/α1 selectivity 8 times than that of clonidine has also been reported to improve the quality of intrathecal and epidural anesthesia when used along with local anesthetics as adjuvant.[8]

Table 3: Mean duration of blocks

Parameters	Group A	Group B	*P* value
Duration of sensory block	13.32±0.80	12.00±0.65	0.001
Duration of motor block	12.00±0.49	7.97±1.05	0.001

Table 4: Visual analog scale score

Time interval	Group A		Group B		t-value	*P*-value
	Mean	SD	Mean	SD		
2 h	1.93	0.64	2.10	0.66	−0.90	0.16
4 h	2.47	0.68	2.53	0.57	−0.36	0.34
6 h	2.83	0.38	2.97	0.56	−1.44	0.14
8 h	3.20	0.61	3.67	0.61	−2.84	0.001
12 h	4.07	0.69	4.50	0.97	−1.90	0.03
24 h	4.50	0.97	6.07	0.91	−6.33	0.001

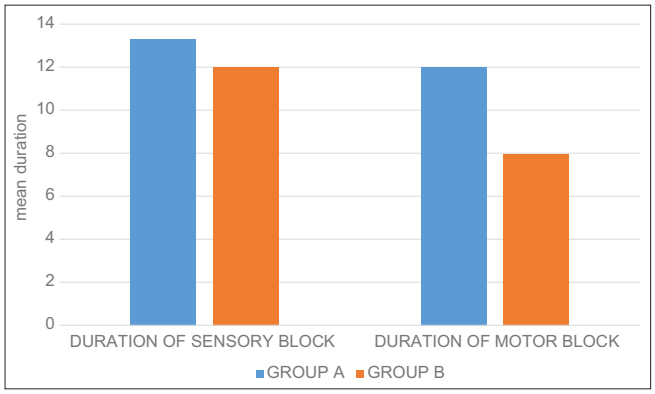

Figure 3: Mean duration of blocks

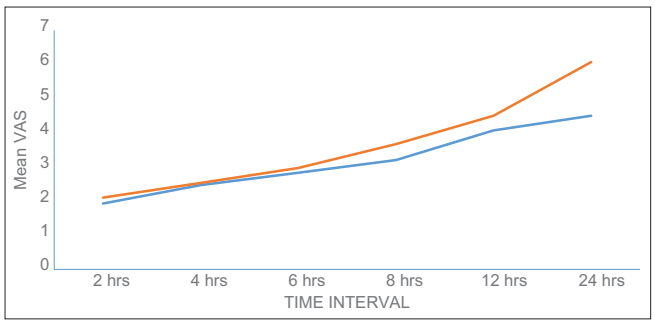

Figure 4: Visual analog scale score

Nalbuphine is a synthetic opioid agonist – antagonist. It is primarily a κ agonist and partial mu antagonist. κ opioid receptors are distributed throughout the brain and spinal cord areas involved in nociception.[9]

In our study, the mean onset of sensory block for Group A was 9.02 min. The mean onset of sensory block for Group B was 10.02 min. Highly significant difference was observed between mean onset time of sensory block among two groups ($P = 0.001$). The findings of our study were in accordance with studies conducted by Esmaoglu *et al.*,[10] Kathuria *et al.*,[11] and Gupta *et al.*[12]

In our study, the mean onset of motor block for Group A was 9.15 min. The mean onset of motor block for Group B was 14.13 min. Highly significant difference was observed between mean onset time of motor block among two groups ($P = 0.001$). The findings of our study were in consistent with studies conducted by Esmaoglu *et al.*,[10] Gupta *et al.*,[12] and Chiruvella *et al.*[13]

The mean duration of sensory block in our study was 13.32 ± 0.80 h (approximately 799.2 min) for Group A and 12.00 ± 0.65 h (approximately 720 min) for Group B. Highly significant difference was observed between duration of both the groups ($P = 0.001$). The results of our study were consistent with studies conducted by Kathuria *et al.*[11] and Chiruvella *et al.*[13]

The mean duration for motor block in our study was 12.00 ± 0.49 h (720 min approximately) for Group A and 7.97±1.05 h (478.2 min approximately) for Grou B. Highly significant difference was observed between both the groups ($P = 0.001$). These findings were in accordance with studies conducted by Kathuria *et al.*[11] and Chiruvella *et al.*[13]

All the hemodynamic parameters were comparable among both the groups. There were no significant differences between the two groups with respect to hemodynamic parameters preoperatively, intraoperatively, and postoperatively. Our observations were in accordance with studies by Kathuria *et al.*[11] and Gupta *et al.*[12]

On comparing the VAS score, significant difference was observed at 8 h, 12 h, and 24 h with mean VAS score of Group B being significantly more than Group A, thus showing that dexmedetomidine is a better analgesic than nalbuphine. The mean VAS score was observed to be 3.2, 4.07, and 4.50 for Group A at 8, 12, and 24 h, respectively, and it was 3.67, 4.50, and 6.07 at 8, 12, and 24 h, respectively, for Group B.

CONCLUSION

From our study, we concluded that the onset of sensory and motor block with dexmedetomidine was significantly earlier as compared to nalbuphine, as an adjuvant. Dexmedetomidine prolongs the duration of sensory block, motor block, and post-operative analgesia.

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Original Article

A Descriptive Study of Clinical, Radiological, and Histopathological Correlation of Sinonasal Masses

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Abstract

Introduction: The nasal masses are most commonly encountered condition in outpatient department of otorhinolaryngology and to evaluate correlation of clinical, radiological, and histopathological diagnosis of various sinonasal masses.

Materials and Methods: This is a hospital-based, descriptive, observational, and cross-sectional study. Total 92 cases of various sinonasal masses were enrolled in the study. They underwent thorough clinical examination, radiological examination in the form of contrast/non-contrast computed tomography scan as per need and histopathological examination (HPE). All of above are correlated with each other to rule out how accurately they correlate with each other.

Results: Average age of study population was 32.52±14.22 years. Male predominance was there. According to final diagnosis, 65 (70.65%) cases had non-neoplastic lesions, 17 (18.47%) had benign tumors, and 10 (10.86%) had malignant tumors. We correlated histopathological diagnosis with clinical and radiological diagnosis and found that in 84 (91.30%) patients histology correlated with clinical diagnosis and in 8 (8.70%) patients histopathology gave final diagnosis in which clinical diagnosis was inconclusive. Similarly, in 86 (93.48%) patients histopathology correlated with radiological diagnosis and in 6 (6.52%) patients histopathology gave final diagnosis in which radiological diagnosis was inconclusive.

Conclusions: We concluded that despite of being a good accuracy sole clinical and radiological diagnosis is not always be a confirmatory one. In some cases, HPE is of utmost importance to approach the diagnosis which can be a game changer in further management. Hence, whenever a sinonasal mass was surgically removed always sent it for HPE.

Key words: Clinical, Correlation, Histopathology, Radiology, Sinonasal mass

INTRODUCTION

Sinonasal masses are a fairly common clinical entity that occurs amongst patients of all age groups and are encountered routinely in ENT outpatient departments. The reported incidence is 1–4% of the population.[1] Their presenting features are diverse and depends on the type, spread, and extent of the primary disease. These lesions can be ranged from simple nasal polyps to malignant lesions.[2]

Sinonasal masses can be divided into two main categories: Non-neoplastic and neoplastic, which, in turn, are further divided into benign and malignant.[3] Benign sinonasal masses are common. They have long clinical history with frequent local recurrence and thus relatively significant morbidity.[4] The prevalence rate of nasal polyp is about 2%. The male:female ratio is about 2:1.[5] Nasal polyps are the most common cause of nasal obstruction.[6]

For malignant sinonasal masses, though the presentation may be nonspecific certain physical finding are often suggestive of the disease spectrum, such as cranial neuropathies, facial swelling, and epistaxis. The average delay between the first noticeable symptom and diagnosis is 6 months.[7]

Presenting complaints of sinonasal masses are quite similar so it is difficult to approach the nature of disease, that is why clinical, radiological, and histopathological assessment play a significant role to supplement the diagnosis.[8] A complete histopathological examination (HPE) is necessary

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to decide the nature of any particular lesion for final diagnosis and management accordingly.[9] Clinical features and imaging techniques help us in reaching a provisional diagnosis but HPE remains the main stay for making a final definitive diagnosis.[10] This study depicts the role of clinical, radiological, and histopathological modalities in diagnosing various sinonasal masses.

MATERIALS AND METHODS

This hospital-based; descriptive, observational, and cross-sectional study was conducted in the Department of Otorhinolaryngology of our institute from June 2018 to December 2019. Total 92 cases attended ENT OPD of our institute with sinonasal masses were included in the study after getting written and informed consent. Those presented with nasal pathology except sinonasal masses, unfit for taking biopsy or for surgery and those who were not willing to participate in the study were excluded from the study.

Patients presented with complaints of nasal obstruction and on anterior rhinoscopy, mass present in nasal cavity were enrolled in the study after confirmation of findings by nasal endoscopy. After applying inclusion and exclusion criteria final sample size achieved. A detailed history was taken with special reference to age, sex, residence, occupation, family history, history, allergic disorders, any addictive habits detailed clinical examination local, and general were made with special reference to nose and paranasal sinuses (PNS). These cases were subjected to routine biochemical and hematological evaluation. Nasal endoscopy, X-ray PNS, computed tomography (CT) scanning non-enhanced/enhanced, magnetic resonance imaging, fine-needle aspiration cytology, and biopsy were conducted. The tissues were routinely processed for histopathological sections of 5 μg thickness and were stained by hematoxylin and eosin stain. Special staining by reticulin, von Giesen, Periodic Acid-Schiff, and Masson's trichrome were undertaken whenever applicable. Immunohistochemical marker studies were done whenever indicated.

After clinical examination, radiological evaluation and HPE statistical analysis were done. Categorical data summarized in the form of rates and proportions. Continuous summarized in the form of mean and standard deviation. The level of significance kept 95% for all statistical analysis. $P = 0.05\%$ taken as significant. Data were analyzed using appropriate statistical tests.

RESULTS

In the present study, the mean age of patients was 32.52±14.22 years with sinonasal masses were most prominent at 2nd, 3rd, and 4th decades of life after that prevalence decreases. There was male predominance with 30 females and 62 males out of 92 patients.

Sixty-five (70.65%) cases had non-neoplastic lesions, 17 (18.47%) had benign tumors, and 10 (10.86%) had malignant tumors. Maximum 22 (33.84%) cases of non-neoplastic lesions were in the age group of 21–30 years. Similarly, maximum 6 (35.29%) cases of benign lesions were seen in 11–20 years age group and the malignant lesions were commonly seen beyond 40 years of age.

The maximum number of non-neoplastic lesions was found to be ethmoidal polyp which was seen in 36 (55.38%) cases, followed by antrochoanal polyp seen in 19 (29.23%) [Figure 1].

In the present study, maximum cases of benign neoplastic lesions to be found were angiofibroma (6/17), followed by hemangioma (3/17). Two cases of inverted papilloma were there, all of them were male. We had one case of ossifying fibroma, two case of nasolabial cyst, one case of squamous papilloma, and one case of ameloblastoma. One case of fibrous dysplasia also encountered. The sex ratio was 3.25:1 [Figure 2].

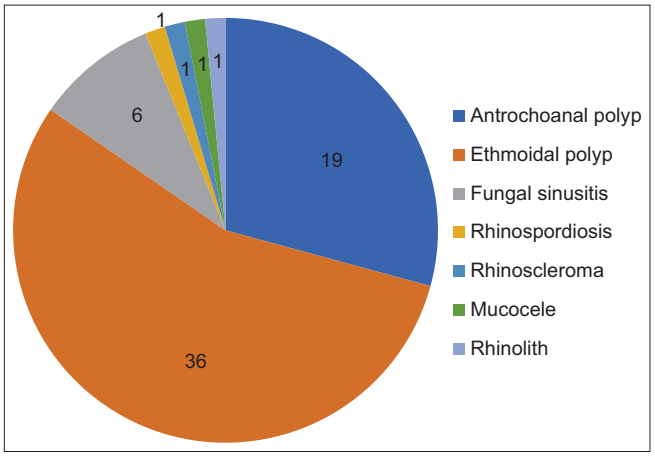

Figure 1: Distribution of non-neoplastic lesions

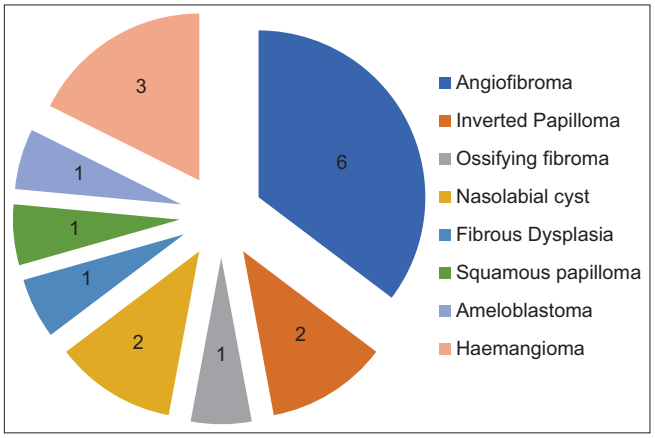

Figure 2: Distribution of benign sinonasal tumors

Squamous cell carcinoma of maxilla was the most common malignant lesion encountered in 4 (40%) out of total ten malignant cases. Other lesions found were adenocarcinoma 2 (20%) and nasopharyngeal carcinomas 2 (20%). We also found one case each of malignant melanoma, esthesioneuroblastoma, and sex ratio was 2.3:1 [Figure 3].

Findings encountered during endoscopy and computerized tomography are shown in Table 1. We also got HPE done and found that nearly 55 patients had inflammatory polyps followed by six patients having angiofibroma [Figure 4].

We correlated histopathological diagnosis with clinical and radiological diagnosis and results obtained are describing in Table 2.

We correlated histopathological diagnosis with clinical diagnosis and radiological diagnosis and found that in 84 patients histology correlated with clinical diagnosis and in eight patient's histopathology gave final diagnosis in which clinical diagnosis was inconclusive. Similarly in 86 patients, histopathology correlated with radiological diagnosis and in six patients histopathology gave final diagnosis in which radiological diagnosis was inconclusive [Figures 5 and 6].

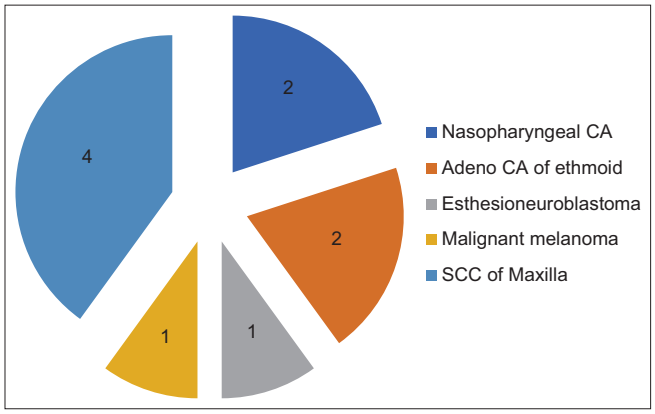

Figure 3: Distribution of malignant sinonasal lesions

DISCUSSION

A wide range of lesions is encountered. The incidence is often stated to be between 1% and 4% of the population.[11] In the present study period, the hospital admission incidence of sinonasal masses was found to be 1.4/1000 admissions in our institute. Sinonasal masses are divided into two major groups, non-neoplastic lesions (inflammatory, polyp, and others) and neoplastic lesions. Neoplastic lesions may be benign or malignant.

Tondon *et al.* in the study of 134 cases presenting with polypoidal lesions in the nasal cavity analyzed that the incidence of inflammatory lesion was 74.61% while those of neoplastic lesions was 25.41%. Among the neoplastic lesions, 73.5% were benign while the malignant were 26.5%.[12]

Dasgupta *et al.* in the analysis of 345 polypoidal masses in nose and nasal sinuses, revealed 175 (50.7%) non-neoplastic lesions and 170 (49.3%) neoplastic lesions. Among the non-neoplastic lesions, there were 110 cases (62.8%) of true nasal polyps including 74 cases (67.3%) of allergic polyps and 36 (32.7%) inflammatory ones.[5]

Diamantopoulos *et al.* in their study on 2021 patients revealed that 1830 (90.5%) patients were non-neoplastic and the remaining 181 (8.9%) were of neoplastic origin. In the non- neoplastic cases, 1570 polyps (77.6% of total) were of allergic, inflammatory or infective origin. In the 181 neoplastic cases, 98 (4.8% of total) were benign while 83 (4.1% of total) were with malignant pathology.[13] Shashin *et al.* reported 193 cases of nasal masses, inflammatory, and tumor such as lesions were 148 (76.68%), benign lesion

Table 1: Nasal endoscopy and computed tomography scan findings of study population

Modality studied	Non-neoplastic lesions	Benign lesions	Malignant lesions
Diagnostic nasal endoscopy			
Unilateral nasal mass	25	17	9
Bilateral nasal mass	40	_	1
Bleeding on touch	2	8	7
Deviated nasal septum	15	3	2
Turbinate hypertrophy	12	2	_
Computed tomography scan			
Unilateral nasal mass	25	17	9
Bilateral nasal mass	40	_	1
Unilateral paranasal sinus mass	21	9	9
Bilateral paranasal sinus mass	40	_	_
Nasopharyngeal mass	21	_	2
Deviated nasal septum	15	3	2
Turbinate hypertrophy	12	2	_
Bone erosion	1	_	7
Neck nodes	_	_	3

Table 2: Correlation of clinical, radiological, and histopathological diagnosis

Clinical diagnosis	*n*	Radiological diagnosis	*n*	Histopathological diagnosis	*n*
Malignant mass	2	Malignant mass	2	Adeno carcinoma	2
sinusitis	3	Allergic fungal sinusitis	3	Allergic fungal sinusitis	3
Maxillary mass	1	Maxillary mass	1	Ameloblastoma	1
Angiofibroma	6	Angiofibroma	6	Angiofibroma	6
Nasal mass	1	Malignant tumor	1	Esthesioneuroblastoma	1
Nasal mass	1	Fibrous dysplasia	1	Fibrous dysplasia	1
Frontal swelling	1	Frontal cystic lesion	1	Frontal mucocele	1
Ethmoid polyp	36	Ethmoid polyp	36	Inflammatory polyp	36
Antrochoanal polyp	19	Antrochoanal polyp	19	Inflammatory polyp	19
Sinusitis	3	Fungal sinusitis	3	Invasive fungal sinusitis	3
Inverted papilloma	2	Inverted papilloma	2	Inverted papilloma	2
Hemangioma	3	Hemangioma	3	Lobular capillary hemangioma	3
Malignant melanoma	1	Septal mass	1	Malignant melanoma	1
Nasolabial cyst	2	Nasolabial cyst	2	Nasolabial cyst	2
Nasal mass	1	Ossifying fibroma	1	Ossifying fibroma	1
Nasal mass	1	Nasal mass	1	Lymphoproliferative disorder	1
Nasal mass	1	Rhinolith	1	Rhinolith	1
Nasal mass	1	Nasal mass	1	Rhinoscleroma	1
Rhinosporidiosis	1	Rhinosporidiosis	1	Rhinosporidiosis	1
Maxillary ca	4	Maxillary ca	4	Squamous cell carcinoma maxilla	4
Nasopharyngeal carcinoma	1	Nasopharyngeal carcinoma	1	Nasopharyngeal squamous cell carcinoma	1
Squamous papilloma	1	Nasal mass	1	Squamous papilloma	1
Total	92	Total	92	Total	92

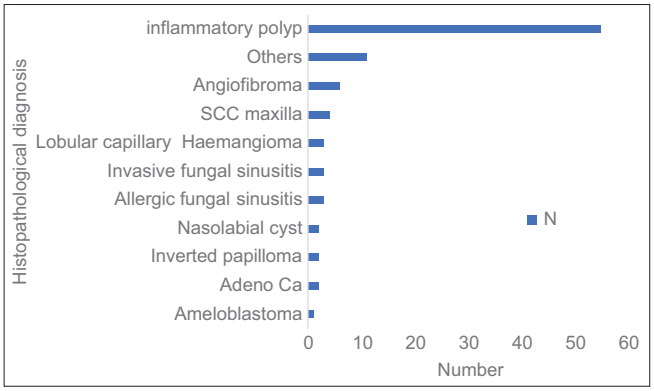

Figure 4: Histopathological findings of study specimen

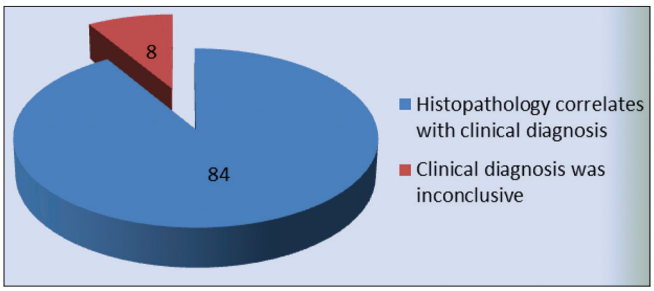

Figure 5: Correlation of clinical and histopathological diagnosis

17 (33.37%), and malignant lesions were 28 (62.28%).[14] Table 3 is showing comparison of various studies including our study based on nature of sinonasal masses.

Maximum number of cases of inflammatory and tumor such as masses was seen in the age group of 21–30 years. Shashin *et al.* reported similar findings.[14] The mean age for benign sinonasal masses was 26 years. We had 17 cases of benign sinonasal lesions. 33.84% of those were of age group of 11–20 years of age. This was due to high number of cases of angiofibromas, a disease affecting adolescent males. Benign lesions are rarely seen above 60 years of age. Our findings closely resembled those of Swamy and Gowda.[15]

Most of the patients of inflammatory masses presented with nasal obstruction (89%) for 2 months-1 year of duration. Nasal discharge was complained by 72% of the patients. These findings were comparable to that of Shashin *et al.*[14] Significant number of the patients had ear findings (8.68%) and alteration of smell (18.47%). Commonly complained ear problem was ear ache and common findings were of serous and adhesive otitis media.

Several studies have provided evidence that CT and symptoms do not necessarily correlate. In a study by Bolger, 42% of asymptomatic patients had mucosal changes on CT scan.[16] In a study, Stankiewicz examined 78 patients meeting chronic rhinosinusitis symptom criteria of which only 47% had evidence of chronic rhinosinusitis on CT.[17] A prospective study of the patients without chronic rhinosinusitis by Flinn reported that 27% had mucosal changes suggestive of chronic rhinosinusitis.[18] In a study of 50 patients of nasal polyps by Chopra, the radiological findings matched with clinical suspicion in only 70% cases. The allergic fungal polyps were the most correctly diagnosed radiological condition in their study. This was

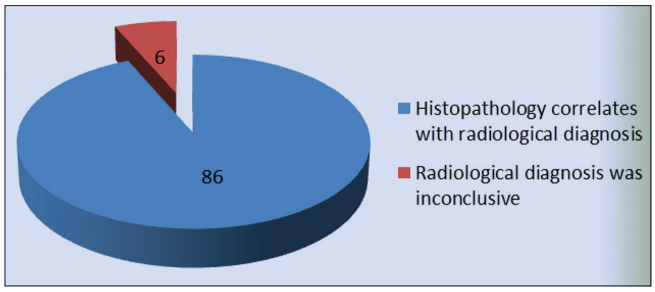

Figure 6: Correlation of radiological and histopathological diagnosis

Table 3: Comparison of distribution of sinonasal masses in various studies based on their nature

Study	No. of cases	Non-neoplastic lesions (%)	Benign tumors (%)	Malignant tumors (%)
Tondon *et al.*	134	74.61	16.8	8.6
Dasgupta *et al.*	354	50.7	31.88	17.4
Diamantopoulos *et al.*	2021	90.5	4.8	4.8
Shashin *et al.*	193	76.68	8.80	13.47
Khan *et al.*	240	60	23.33	16.67
Present study	92	70.65	18.47	10.86

due to the high percentage of hyperdense signal in the sinus cavities (caused by calcium salts) detected on CT scan. The diagnosis of non-specific sinonasal polyps, antrochoanal polyp, and mucormycosis was correctly established in most of the cases.[19] There was a difference of opinion between the clinician and the radiologist in about 20% of non-neoplastic lesions. The correct diagnosis of neoplastic lesions was established in only 22% of cases (two out of nine patients). In most cases, it was inadequate to predict the histological subtype and to differentiate non-neoplastic from neoplastic and benign from malignant lesions. Among 110 cases, nasal polyps were the commonest type of non-neoplastic lesion found in the study conducted by Dasgupta *et al.* in 1997. Allergic nasal polyps were observed in 74 cases and the remaining cases were of inflammatory nasal polyps. There were 64 males and 46 females in the nasal polyp cases. The age range of patients was 8–76 years with a mean of 32.6 years.[5]

Rawat *et al.* conducted a prospective study to evaluate the demographic profile of sinonasal masses, the clinical and radiological findings of sinonasal masses and the correlation of the clinical and radiological findings with the histopathology. They enrolled 264 cases of sinonasal masses, inflammatory, and tumor such as lesions were 68.56 % cases, benign tumors were 22.72% (60 cases) and the malignant were 8.71% (23 cases). The ratio of inflammatory and tumor such as lesions to neoplastic lesions was 2.18:1. They concluded that significant lesions can be missed on either clinical or radiological evaluation and a thorough histopathological evaluation should be done in all cases of nasal polypoidal lesions for accurate diagnosis and management.[20]

CONCLUSION

Sinonasal masses are common problem in today's environment. Sinonasal masses constitute a very wide spectrum of differentiated diagnosis. They have a male predominance and majority are non-neoplastic. Nasal polyps are the most commonly encountered sinonasal masses. HPE still remains the gold standard for diagnosis in most cases. Because of this fact it is essential for otorhinolaryngologists to make the general practitioners aware so that they do not go on treating it as a benign sinusitis. Any sinonasal problem not responding in 6 weeks must be sent to an expert for further evaluation. Correlation of clinical, radiological, and histopathological modalities is most important for accurate diagnosis. A careful histopathological correlation is mandatory for proper diagnosis, accurate, and early management.

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The authors report nothing to declare.

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Original Article

Open Component Separation Technique for Management of Ventral Hernia with Emphasis on Undesirable Outcomes: An Observational Cross-Sectional Analytical Study

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Abstract

Aim and Objective: The aim of the study was to study the surgical details of component separation technique (CST). This includes clinical indication for component separation size of defect, types of component separation, size of mesh used, and time taken for surgery and to compare the association between pre-operative factors and complications of CST.

Introduction: Sir Astely Paston Cooper's words: "No disease of the human body belonging to the province of the surgeon requires in its treatment a better combination of accurate anatomical knowledge with surgical skill than Hernia in all its varieties." A hernia is defined as an area of weakness or disruption of the fibromuscular tissues of the body wall. Often hernia is also defined as an actual anatomical weakness or defect. About 75–85% of abdominal wall hernias are groin hernias. About 15% of males and 5% of female will develop groin hernia The CST was first described by Ramirez *et al*. in 1990. It is very effective for reconstructing large or complex midline abdominal wall defects and it has the advantage of restoring the innervated dynamic abdominal wall integrity without producing undue tension on the repair. It can be performed to reconstruct a large abdominal wall defect without the need for mesh. Recurrence rates after the use of CST ranged from 0% to 30%. Endoscopic-assisted CST was performed to save the perforators of the epigastric arteries and the results were comparable to the open technique.

Discussion: Repair of large ventral hernia is a challenge for even experienced surgeons, as there are large defects with large contents, often with loss of domain. The large defects were bridged by various plastic surgical procedures such as myofascial flaps or free flaps with high recurrences and complications. More often, the bridging was done with artificial prosthesis, leaving the defects open. This was accomplished by either open surgery (onlay, inlay, sublay, or underlay) or laparoscopic intraperitoneal onlay meshes. However, non-closure of the midline had adverse effects on postural maintenance, respiration, micturition, defecation, and biomechanical properties, which have a profound impact on the patients' overall physical capacity and quality of life. CST is a novel answer to the closure of midline with live, active tissues with or without the use of additional prosthesis. Although this technique was originally described in 1990, it has undergone lots of modifications such as perforator preserving CST, endoscopic technique, and posterior component separation.

Conclusion: CST is a novel answer to closure of midline with live, active tissues with or without the use of additional prosthesis. This technique was originally described in 1990 by Ramirez. Lower hernia recurrence rates, restoration of dynamic abdominal wall function, and improvement in back and postural abnormalities have been cited in the Western literature. Major issue with this technique is wound-related com.

Key words: Component separation technique, Hernia, Mesh

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INTRODUCTION

A hernia is a defect in the fascia of the abdominal wall and thus resulting into formation of a hernial sac of peritoneum that contains visceral organ or abdominal contents or other bulges that may appear similar, but are not true hernias. Other abnormalities that present

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as hernia but are not true hernias are diastasis recti and eventration.

Exploratory laparotomy is opening of abdominal cavity for surgical purposes, for the pathologies of abdomen that cannot be dealt with minimally invasive techniques. Abdominal wall comprises musculo-aponeuroses that give the strength to abdominal wall along with skin and fascia. This also functions to keep the abdominal viscera within the cavity. Any incision over the abdominal wall for exploration may result into the weakening of this protective barrier and predisposes for the protrusion of the abdominal wall viscera through the musculo-aponeurotic layers and it presents as a swelling over the wall just beneath the incision scar. This swelling is known as incisional hernia that contributes to significant proportion of post-operative complication in patients who underwent laparotomy.

The incidence of incisional hernia develops after abdominal wall closure range widely from 10 to 23%[1,2] and up to 69% in long-term high-risk patients. Various methods of suture closure (material and technique) and mesh reinforcement (position and shape) have been used to restore abdominal wall integrity and prophylactic treatment of incisional hernia. Primary repair of incisional hernia can be done when the defect is small. Despite advances in early repair, recurrence rates remain unacceptable (12–54%). Larger defect (>2–3 cm) shows higher recurrence rate around 10–15% if closed by primary repair. Recurrence is susceptible to a vicious cycle of morbidity, because early subsequent repair presents greater technical challenges and an increased risk for recurrence and morbidity.[3,4]

Failure of effective and sufficient closure of the abdominal wall after operations leaves the patient at risk for developing hernia. The introduction of prosthesis has become game changer in repair of ventral hernia. To date, few studies have focused on prophylactic management of incisional hernias in index patients which in short decreases the iatrogenic complications secondary to surgical incisional hernia repair.

Ideal mesh positioning is also a topic of study. Till date wound dehiscence and incisional hernia is potentially serious complication following: Abdominal surgery, especially if it is performed through a midline incision. Although, prophylactic reinforcement with mesh has been shown to reduce this risk. Reinforcement of the suture line with a mesh may be an effective way of preventing wound dehiscence. By placing a polypropylene mesh under the aponeurosis along with drain after closure of the midline, the risk for incisional hernia has been shown to be reduced by at least two-thirds.

Enough evidence is now available to advise prophylactic mesh placement (PMP) for routine midline laparotomy in these high-risk cases. However, literature for the use of PMP in emergency midline laparotomy is rather scarce. We conducted this prospective study to examine the safety and efficacy of PMP in Elective Midline Laparotomy.[5,6]

Aims and Objectives

Primary objective

The primary objective of the study was to study the outcome of prophylactic use of mesh in patients undergoing elective exploratory laparotomy.

Secondary objective

The secondary objective of the study was to study the efficacy of PMP in reducing the incidence of incisional hernia in such patients.

MATERIALS AND METHODS

Title

"A prospective study of outcome of prophylactic use of mesh in patients undergoing elective laparotomy in department of general surgery at M.Y. Hospital, Indore."

Study Design

This was a prospective observational study.

Sample Size

The sample size was 50.

Inclusion Criteria

The following criteria were included in the study:

1. Patients >18 years and <70 years
2. Patients who give written informed consent and to follow-up
3. Patient with comorbidities (obesity (body mass index [BMI] <35), chronic obstructive pulmonary disease Smoking (Ceased 1 month before procedure), Diabetes (HbA1C <7).

Exclusion Criteria

The following criteria were excluded from the study:

- Patients not willing to give written consent
- Patients with irregular follow-up
- Age <18 years
- Recurrent hernia (ventral) cases
- Morbidly obese (BMI>35)
- Unable for smoking cessation
- Diabetes (HbA1C>7)
- Immunocompromised cases
- Pregnancy.

Source of Data

All elective cases operated routine Operation Theatre in Department of Surgery, M.G.M Medical College and M.Y Hospital, Indore. The study will include prospective cases for 1 year from date of approval from ethics committee.

Study Period

- One year from date of approval.

Place of Study

The study was conducted at the Department of surgery, M.G.M Medical College and M.Y Hospital, Indore.

Sample Size

The sample size was 50 cases.

Procedure Planned

1. Our study is based on the patients attending the surgical outpatient department of M.Y. Hospital, Indore
2. All patients are to be examined and planned for exploratory laparotomy. An informed consent will be taken from each patient after which the patient will be taken for an elective surgery PMP
3. The patients who developed complications after surgery will be examined clinically and managed as required
4. This study will be conducted after approval from thesis and ethical committee
5. Data will be collected and appropriate statistical analysis will be done. Present study includes 50 cases of laparotomy.

Follow-up

Patient will be discharged and advised to follow-up at

- 1 month
- 3 months
- 6 months
- 1 year.

Routine Investigations

1. Hemogram
2. Renal function tests
3. Liver function tests
4. Serum electrolytes
5. Coagulation study
6. Ultrasonography whole abdomen
7. X-ray chest + electrocardiogram
8. Serology.

RESULTS AND DISCUSSION

We conducted an observational study to see the prophylactic effect of prosthetic mesh in development of incisional hernia after elective laparotomy. The study was conducted in the department of general surgery MGM Medical College Indore from a period of July 2018 to October 2020.

The study is a type of comparative study in which the outcomes after mesh placements were used for comparison with patients developing incisional hernia acting as cases and those not developing act as controls. Furthermore, it compares the variation in the outcomes with the location of mesh, namely, sublay and onlay.

The study comprised 50 elective laparotomy cases done irrespective of the actual pathology involved. The age and gender were not taken as selection criteria. There was no other specific inclusion criteria. Patients who did not give consent were excluded from the study. All emergency laparotomy cases were also excluded from the study.

We had 8 (16.0%) patients in the age group of 18–20 years, 27 (54.0%) patients in the age group of 21–40 years, 12 (24.0%) patients were in the age group of 41–60 years, and 3 (6.0%) patients were in the age group of >60 years. Majority of the patients were in the age group of 21–40 years, followed by 41–60 years.

Patient in 21–40 years age group, 2 in 40–60 years and 1 in >60 years group developed incisional hernia. The association of age with the development of incisional hernia post-laparotomy was found not to be statically significant. We, in our study, were able to establish that age did not have a role as a risk factor in development of incisional hernia in contrast to as described by various surgical literatures based on the fact that human tissue tend to weaken off with ageing.

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Two out of 26 females (7.7%) and two out of 24 males (8.3%) in our study developed incisional hernia. This gender-wise incidence was not statically significant and gender as a risk factor for development of incisional hernia cannot be established in our study.

All four patients developed hernia belonged to obese category as per the WHO criteria for BMI classification. Four out of 24 (16.7%) patient who were obese were associated with this complication. This was, however, not found to be clinically significant but we could not clearly rule out obesity as a risk factor for development of incisional hernia. To clearly establish the relation, we

need to conduct study for greater sample size or in a same cohort.

We placed mesh in all patients in our study. However, the location of mesh placement in different patients was not randomized and was fully on surgeon's discretion. We did sublay mesh placement by retro-rectus dissection in 45 patients and onlay placement in five patients. About 60% (3 out of 5) patient had onlay mesh placement developed incisional hernia. Furthermore, the rate of local wound complications in this group was higher. All five patients developed surgical site infection (SSI) and three progressed to develop seroma and four developing wound dehiscence and burst abdomen.

Table 1: Distribution of Patients According to Post-operative Complications

Post-operative complications	Number	Percentage
Post-operative pain	15	30.0
Hematoma	1	2.0
Seroma	12	24.0
Surgical site infection	13	26.0
Wound dehiscence	6	12.0

Table 2: Distribution of patients according to duration of hospital stay

Duration of hospital stay	Number	Percentage
1–7 days	6	12.0
7–14 days	23	46.0
14–21 days	13	26.0
>21 days	8	16.0
Total	50	100.0

Table 3: Association between age and final outcome

Age	Final outcome (%)			Total (%)
	Hernia	no hernia	Unknown	
18–20 years	0	7	1	8
	0.0	87.5	12.5	100.0
21–40 years	1	24	2	27
	3.7	88.9	7.4	100.0
41–60 years	2	9	1	12
	16.7	75.0	8.3	100.0
>60 years	1	2	0	3
	33.3	66.7	0.0	100.0
Total	4	42	8	50
	8.0	84.0	8.0	100.0

Table 4: Association between location of mesh and final outcome

Location of mesh	Final outcome (%)			Total (%)
	Hernia	No Hernia	Unknown	
Onlay	3	2	0	5
	60.0	40.0	0.0	100.0
Sublay	1	40	4	45
	2.2	88.9	8.9	100.0
Total	4	42	8	50
	8.0	84.0	8.0	100.0

The hospital stay in patients with sublay mesh placement was highly variable with six patients getting discharged before 7 days and 24 staying till 14 days. Eleven patients had stayed for more than 15 days up to 21 days and four patient stayed for more than 21 days. One patient who developed hernia in sublay group had prolonged hospital stay due to development of complications (wound dehiscence). This proves that the sublay mesh placement as such is not associated with increased risk but the wound infection associated with the mesh leads to the hernia formation. Overall sublay mesh placement had lower rate of wound complications with 18% patients developing SSI, 20% developing seroma, and 5% developing wound dehiscence. This, in turn, correlates with lower rate of incisional hernia with sublay mesh placement as compared to that in onlay mesh placement.

In onlay mesh placed cases all five patients had either of the wound complications, that is, SSI, seroma, or wound dehiscence. These complications were related to the prolonged hospital stay in all patients with onlay mesh. One out of five patients had stayed in ward up to 21 days and other four patients had stayed for more than 21 days. Three out of four patients who developed incisional hernia belonged to the onlay mesh placed group. The high rate of hernia in this group hence can be attributed to higher rate of wound complication in these patients.

As compared to previous studies our study showed similar results. In study by Borab *et al.* comparing the suture closure and onlay mesh placement, they found lower rate of incisional hernia with mesh but seroma formation and other wound complications were present. This was consistent with our study. We additionally tried to compare the rate of hernia with onlay and sublay mesh placement but due to lower number in onlay group, we could not establish the clear-cut relationship even though the cases were more after onlay mesh placement. Furthermore, the post-operative pain and development of hematoma are more with the sublay mesh placement than compared with the onlay. This was done in no other previous study of PMP.

In our study, we did not have any patient with intraperitoneal placement as was compared in other studies like that done by Andres Kohler *et al.* and Burns *et al.* Furthermore, the study is limited by the fact that many of the factors directly involved in wound healing such as diabetic status, hemoglobin status of patient, protein status, and technical aspect of closure. Furthermore, our study

did not comment on the deviations with normal suture closure of the abdominal cavity and the type of mesh used [Tables 1-4].

CONCLUSION

From this prospective study following conclusions can be drawn

1. Incisional hernia is an important delayed post-operative complication of abdominal wall surgery
2. Several factors are implicated in occurrence of hernia after abdominal wall closure that includes patient factor and technical factors
3. Wound infections SSI leading to wound dehiscence are a major cause of development of incisional hernia
4. Technique of abdominal wall closure, namely, suture closure and mesh placement respectively have variable impact on the prevention of outcome that is incisional hernia
5. Length of hospital stay depends on the development of wound infection and hence increases the chances of incisional hernia
6. The mesh placement after elective laparotomy while abdominal closure is associated with low occurrence of incisional hernia as compared with the primary suture closure
7. Onlay mesh placement technique has more chances of complications such as seroma and flap infections than sublay due to the fact of more dissection in fatty plane for mesh placement. Furthermore, more superficial location of mesh is easily accessible for bacterial invasion
8. The concept of mesh placement can be successfully applied to selected patients to halt the development a morbid condition of incisional hernia.

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Original Article

Clinical Study of Antithyroid Peroxidase Antibodies in Subclinical Hypothyroidism

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Abstract

Introduction: Subclinical hypothyroidism is an entity based on the laboratory findings of a raised serum thyrotrophin (TSH) concentration and a normal free thyroxine (FT(4)) concentration. Patients with subclinical hypothyroidism who also have antithyroid peroxidase (TPO) antibodies have a higher conversion to overt hypothyroidism than those without.

Objective: The objective of our study is to look for what percentage of patients with subclinical hypothyroidism are TPO antibodies positive as these are the subgroup of patients who need constant follow-up and treatment.

Materials and Methods: The study was conducted on 50 patients attending the OPD or admitted to the wards, Rajarajeshwari Medical College and Hospital, Bengaluru, for patients. All subclinical hypothyroid patients aged above 18 years of both sexes attending OPD, Rajarajeshwari Medical College and Hospital.

Results: Results are tabulated in research paper in the form of tables and graphs giving brief results about our study.

Conclusion: Serum TSH and anti-TPO antibodies analysis are essential in determining the etiology and risk of progression to overt hypothyroidism in patients with subclinical hypothyroidism. Estimation of only TSH would overlook the diagnosis of quite a significant percentage of subclinical hypothyroid patients

Key words: Antibody, Hypothyroid, Thyrotrophin

INTRODUCTION

Subclinical hypothyroidism is more common than overt hypothyroidism. Early diagnosis and treatment of the condition may prevent the onset of overt hypothyroidism. It is defined by isolated elevated serum TSH level in the setting of normal serum T4 level, in the presence or absence of symptoms. The worldwide prevalence of subclinical hypothyroidism ranges from 1% to 10%. The highest age and sex specific rates are in woman over 60 years, approaching to 20%. Patients with subclinical hypothyroidism with high titer of antithyroid peroxidase (anti-TPO) antibodies are more likely to progress to overt hypothyroidism. In one population-based survey with a 20-year follow-up, the progression to overt hypothyroidism was 2.6% per year among patients with elevated TSH and negative anti-TPO antibody and 4.3% per year among those with elevated TSH and anti-TPO antibody positivity.[1-5]

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Aim

The main objective of the study is to evaluate the presence of anti-TPO antibodies among patients with subclinical hypothyroidism.

MATERIALS AND METHODS

Time Period

The study period was from August 2018 to March 2019.

Source of Data

Patients with subclinical hypothyroidism aged above 18 years, attending Rajarajeswari Medical College and Hospital who satisfied the inclusion and exclusion criteria and were willing to give informed consent.

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Study Design
This was a prospective study.

Sample Size
40.

Inclusion Criteria
The following criteria were included in the study:
- Subclinical hypothyroid patients.
- Age above 18 years, both the sexes.

Exclusion Criteria
Females in gestational or postpartum period, patients with thyroid destruction (from radioactive iodine or surgery), and patients receiving medications which may cause thyroid dysfunction (e.g., amiodarone, lithium, and antithyroid drugs) were excluded from the study.

Investigations Required
Thyroid function test.
- Free T3 and T4
- Anti-TPO antibodies

Subclinical hypothyroidism was defined as thyroid stimulating hormone (TSH) >5.0 μIU/ml with normal FT4 (0.60–1.12 ng/dL).

Anti-TPO antibody was assessed by two-step immunoenzymatic assay. TPO antibody was considered positive if the value was more than 9 IU/mL.

Subjects fulfilling inclusion criteria were included in the study after taking informed consent and a detailed history, clinical examination, and relevant investigations were carried out on each subject.

RESULTS

Out of 40 patients included in the study, 30 were female and 10 were male.

Thirty-three participants belonged to the 35–60 age group, 7 in > 60 years age group. The mean age of the subjects was gender distribution across all age group was done,predominantly females with highest percentage of females in the age groups of 35-50 years.

Out of the 40 subjects with subclinical hypothyroidism, 14 were anti-TPO positive and 26 were negative. The corresponding percentage of anti-TPO noted in subclinical hypothyroidism is 35% [Figures 1-3].

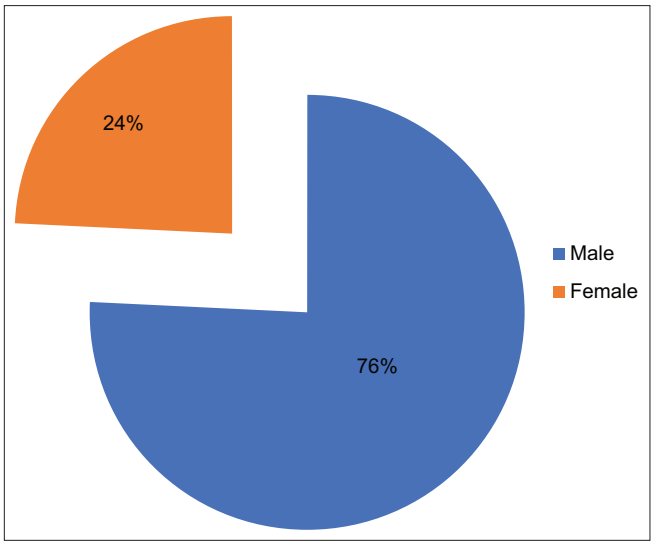


Figure 1: Sex-wise distribution

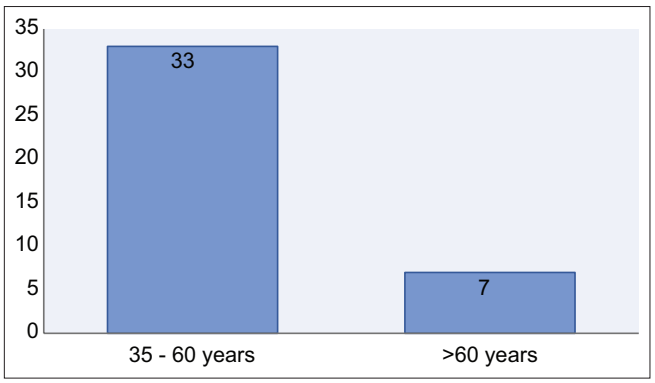
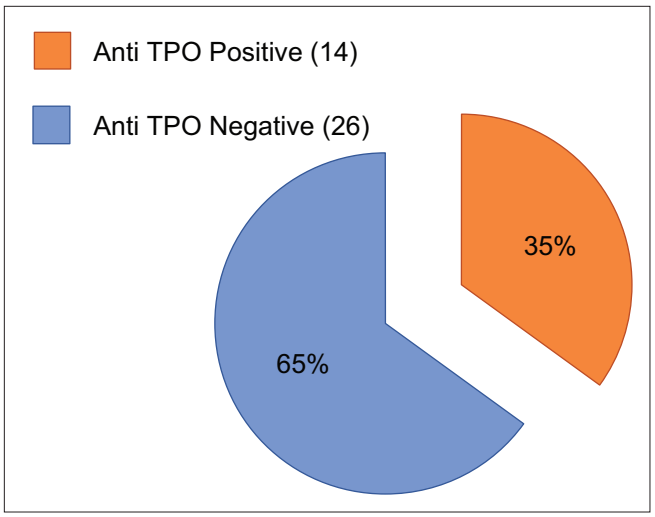


Figure 2: Age-wise distribution



	Male	Female
Anti-TPO positive	2	12
Anti-TPO negative	8	18

Figure 3: Gender-wise distribution of anti-TPO

DISCUSSION

The enzyme thyroid peroxidase (TPO) plays a major role in thyroid hormone synthesis. Measuring the levels of anti-TPO autoantibodies is significant in diagnosing autoimmune thyroid diseases and predicting their clinical course. The prevalence of anti-TPO antibody noted in the current study in patients with subclinical hypothyroidism was 35%.

Similarly, Mohanty *et al.* have showed that 45 of the 61 subclinical hypothyroid patients had elevated anti-TPO (73.78%), thereby suggesting an autoimmune etiology for subclinical thyroid dysfunction and a higher risk of developing overt hypothyroidism in such patients.

Bjoro *et al.*, in a 20-year follow-up study, conducted among Norwegian inhabitants (94,009), have found that the positive anti-TPO levels correlated significantly with thyroid dysfunction and the prevalence of elevated TSH was nearly 10-fold higher in both females and males with positive anti-TPO when compared to anti-TPO-negative subjects.

Lock *et al.* have highlighted the importance of considering anti-TPO antibody testing as an integral part of the clinical investigation for subclinical hypothyroidism.

A rise in prevalence of anti-TPO positivity was noted in the southern part of India in two different studies conducted in Kerala and Chennai with rates 16.7% and 25.81%, respectively.

In the current study, an increased preponderance of autoimmune thyroid disease was seen in women, especially in the age group of 35–50 years.

The study by Ghoraishian *et al.* reported similar findings. The study has demonstrated that the prevalence of anti-TPO antibody in females was about 7 times higher than males.[6-9]

CONCLUSION

Serum TSH and anti-TPO antibodies analysis are essential in determining the etiology and risk of progression to overt hypothyroidism in patients with subclinical hypothyroidism.

Estimation of only TSH would overlook the diagnosis of quite a significant percentage of subclinical hypothyroid patients.

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Original Article

Clinicopathological Features of Colorectal Carcinoma in a Tertiary Care Center of North India – A retrospective study

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Abstract

Colorectal carcinoma(CRC) is the third most commonly diagnosed cancer in males and second in females,with 1.8million new cases and almost 861,000 deaths in 2018 according to the World Health Organisation,rates being substantially higher in males than in females.In India,it is the fourth most common cause of cancer in males and the third most common cause of cancer in females.In Kashmir region,colorectal carcinoma was fourth most common cancer in males and held a third rank among the female population.CRC is the cancer of old age,mostly occur after fifth decade of life.

Key words: Colorectal cancer, Rectal bleeding, Adenocarcinoma

INTRODUCTION

Colorectal carcinoma is the third most commonly diagnosed cancer in males and second in females, with 1.8 million new cases and almost 861,000 deaths in 2018 according to the World Health Organization, rates being substantially higher in males than in females.[1]

In the US, approximately 145,600 new cases of large bowel cancer are diagnosed annually[2] out of which approximately 50,630 Americans die of colorectal cancer (CRC), accounting for approximately 8% of all cancer deaths.

Although colorectal carcinoma is thought to be a rare disease in Asia, an increasing trend in its incidence has been observed lately.[2,3]

Compared to the Western world, the incidence rates of CRC are low in India; but apart from geographical variations, the incidences are rising rapidly in India.[4]

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In India, it is the fourth most common cause of cancer in males and the third most common cause of cancer in females.[2] The age-standardized rates of CRC in India have been estimated to be 4.2 and 3.2/100,000 for males and females, respectively, compared to 35.3 and 25.7, respectively, in the USA.[3,4]

In Kashmir, colorectal carcinoma was fourth most common cancer in males and held a third rank among the female population. It was found overall in 616 (7%) patients, (342 males and 274 females) with a median age of 53 years in males and 50 years for females.[5]

CRC is the cancer of old age, mostly occur after the fifth decade of life.[6] However, the incidence of CRC is increasing in young age, especially in developing countries, which is mainly contributed by change in lifestyle and food habits.[7-10]

In general, colorectal carcinoma is thought to be a malignancy that primarily occurs in patients older than 50 years of age;[11] likelihood, the disease is an unusual in patients under 40 years of age. It has been estimated that between 2% and 3% of CRCs occur in patients younger than the age of 40 years.[12] However, in the past few years, the incidence in younger adults has been on the rise. Changing lifestyle, obesity, physical inactivity, intake of diet

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rich in processed foods with insufficient amount of fruits and vegetables, as well as the lack of screening in the young may be some reasons for this disturbing trend.[13]

CRC is a malignant neoplasm arising from the lining of the mucosa of the colon and rectum. It develops by a multistep process that analyzed can be influenced by hereditary or genetic and environmental or acquired factors. An individual with a history of adenomatous polyps or inflammatory bowel disease has an increased risk of developing CRC compared to an individual with no history of either.[14,15]

The treatment, prognosis, and survival rate largely depend on the stage of disease at diagnosis. Treatment for CRC varies by tumor location and stage at diagnosis. Depending on the stage of the disease, the patient undergoes multimodal treatment, surgery, chemotherapy, radiotherapy, and hormonal therapy. Surgical removal of tumor and nearby lymph nodes is mainstay of the treatment for early stage of CRC. However, with a potentially curative surgery alone, up to 50% of patients will ultimately relapse and die of metastatic disease.[16]

In this study, we aimed to investigate the clinic pathologic features of CRC patients who presented to a tertiary care hospital in Kashmir region of India. Although exact incidence rate cannot be provided by a hospital-based study, the information would be useful in showing patterns of malignancies in our region. This study is designed to describe the distribution of the colorectal carcinoma while considering age, gender, site of tumor, tumor pathology, and other related diseases in a retrospective fashion.

METHODS

All cases of CRC presented to the Department of Radiation Oncology, GMC, Srinagar, between January 2012 and December 2018 were retrospectively reviewed. A total of 199 patients were included in the study. CRC patients were identified through RT numbers in hospital records. The files were reviewed for all medical records in the selected period for collecting the required data. Data were analyzed for age, gender, and district where the patients resided, subsite distribution in the colon, symptoms at the time of diagnosis (early symptoms), type of the CRC, histopathological type, stage of the disease and including metastasis, and treatment received in each case.

Data were presented as frequency and mean plus or minus standard deviation was appropriate. Chi-square test and independent samples *t*-test were performed to examine relationship between different categorical and numerical variables. $P < 0.05$ was considered as statistically significant.

RESULTS

One hundred and ninety-nine cases were included in the present study. One hundred and eleven patients were male (55.8%) and 88 were female (44.2%) with a male-to-female ratio of 1.26:1 [Figure 1]. The youngest and oldest patients were 18 and 83 years old, respectively [Figure 2]. Mean age was 53.42 ± 15.52 years and median was 55 years. The most prevalent age decade was 51–60 years which comprised 26.6% of cases followed by 61–70 years which comprised 25.5% of cases. About 15.1% of patients were in the age group of 41–50 years whereas only 1.5% of cases were below 20 years of age. In our study, 24.6% of patients had age of <40 years and 39.7% of patients had age <50 years, indicating that the percentage of younger colorectal carcinoma patients is rising in this part of India. The exact reasons behind these observations are still not clear. However, it is assumed that the early-onset CRC may be the consequence of genetic mutation. Besides, several other factors such as intake of red

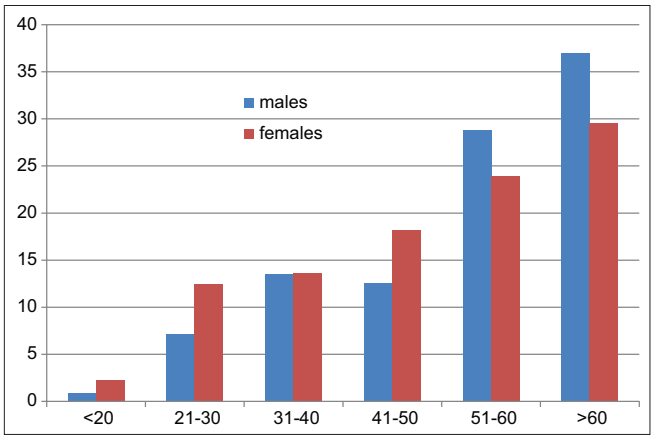

Figure 1: Age distribution of colorectal adenocarcinoma in male and female

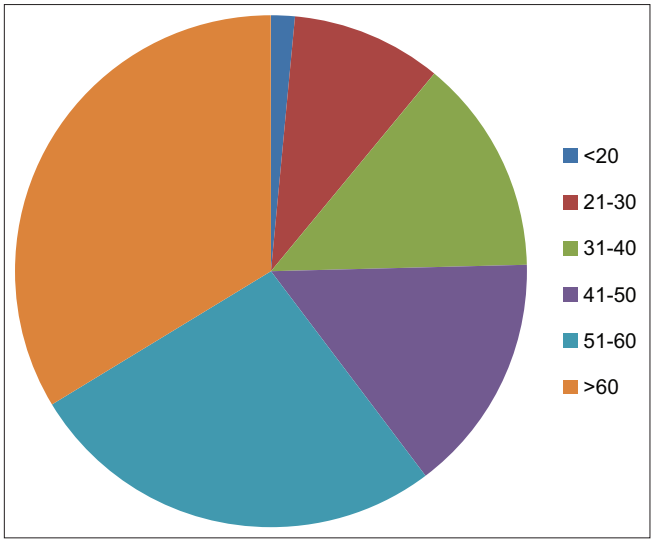

Figure 2: Age distribution of patients

meat, junk foods, uses of tobacco, and lack of exercise have potential risk for such observation.

The clinical presentation was varied including abdominal pain (51.7%), bleeding P/R(50.25%), altered bowel(48.24%), features of intestinal obstruction, weight loss and anaemia. More than one symptom was present in single patient [Figure 3].

Comparison of site and Dukes staging of colorectal cancer in patients below 40 years and above 40 years of age, n (%) is shown in Table 1, whereas location, histology and Dukes staging of colorectal carcinoma according to gender is shown in Table 2. [Tables 1 and 2]. LVI and PNI was available in 178 patients. PNI was positive in 30.7% patients whereas LVI was positive in 42.2% patients.

DISCUSSION

A total of 196 patients were enrolled in our study. Out of these 111 patients were male (55.8%) and 88 were female (44.2%) with a male-to-female ratio of 1.26:1. Mahmodlou *et al* (17). conducted a study in Iran on 546 patients which coincided with our study, wherein 306 (56%) patients were male and 240 (44%) were female.[17] In another study by Aljebreen[18] conducted on a total of 118 patients, 58% of the patients were male and 42% were female. Although in both the studies, there is not a significant difference between the two sexes as compared to the Western study there is significant preponderance of male distribution (male vs. female 2:1).[19,20]

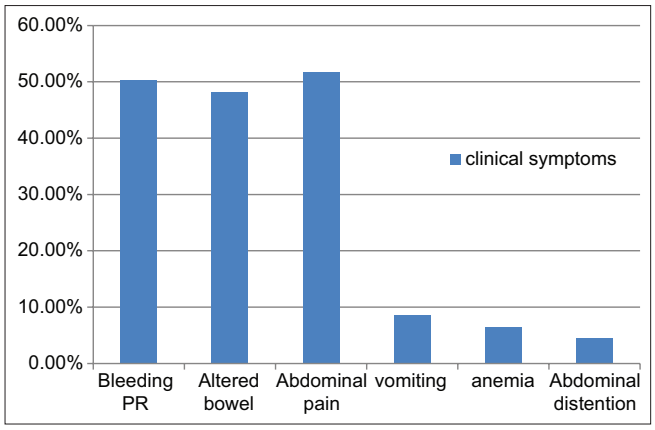

Figure 3: Clinical presentation of patients

Table 1: Comparison of site and Dukes staging of colorectal cancer in patients below 40 years and above 40 years of age, *n* (%)

Patient characteristics	Age<40 years (%)	Age>40 years (%)
SITE (Total – 199 patients)	Total – 49 patients	Total – 150 patients
Rectum (69)	24 (49)	45 (30)
Sigmoid (43)	10 (20.4)	33 (22)
Ileocecal (15)	0	15 (10)
Ascending colon and hepatic flexure (47)	11 (22.4)	36 (24)
Transverse colon (12)	3 (6)	9 (6)
Descending colon and splenic flexure (13)	1 (2)	12 (8)
Staging		
Dukes A (24)	4 (8.1)	20 (13.3)
Dukes B (70)	19 (38.7)	51 (34)
Dukes C (69)	14 (28.5)	55 (36.6)
Dukes D (36)	12 (24.4)	24 (16)

In a study by Suryadevara *et al.*[21] in Bengaluru, India, conducted on 171 patients, the male-to-female ratio in rectal cancers was 1.26:1[a], whereas Elzouki *et al.*[22] in Libya conducted a study on 152 patients where 84 were male and 68 were female with a male-to-female ratio of 1.2:1.0[e] which coincided with our study.

In our study, the youngest and oldest patients were 18 and 83 years old, respectively. Mean age was 53.42 ± 15.52 years and median was 55 years. The most prevalent age decade was 51–60 years which comprised 26.6% of cases followed by 61–70 years which comprised 25.5% of cases. About 15.1% of patients were in the age group of 41–50 years whereas only 1.5% of cases were below 20 years of age. In our study, 24.6% of patients had age of <40 years and 39.7% of patients had age <50 years, indicating that the percentage of younger colorectal carcinoma patients is rising in this part of India.

In a study by Elzouki *et al.*,[22] the ages at diagnosis ranged from 21 to 87 years with a mean age of 57.4 ± 12.92 years. Eighteen (11.8%) patients were below 40 years of age. The

Table 2: Basic data of CRC according to the gender of patients

	Total	Males (%)	Females (%)
Number of patients	199	111 (55.8)	88 (44.2)
Location of CRC			
Rectum	69	36 (32.4)	33 (37.5)
Sigmoid colon	43	21 (18.9)	22 (25)
Ileocecal	15	8 (7.2)	7 (7.9)
Ascending colon	47	29 (26)	18 (20)
Transverse colon	12	6 (5.4)	6 (6.8)
Descending colon	13	11 (9.9)	2 (2)
Histology			
Well-differentiated AC	97	52 (46.8)	45 (51)
Moderately differentiated AC	56	36 (32.7)	20 (22.7)
Poorly differentiated AC	28	14 (12.6)	14 (15.9)
Mucinous Ca	13	7 (6.3)	6 (6.8)
Signet-ring cell Ca	5	3 (2.7)	2 (2.2)
Dukes staging			
Dukes A	24	11 (9.9)	13 (14.7)
Dukes B	70	45 (40.5)	25 (28.4)
Dukes C	69	31 (27.9)	38 (43)
Dukes D	36	24 (21.6)	12 (13.6)
Polyps	34	26 (23.4)	8 (9.1) (*P*=0.008)

CRC: Colorectal cancer

majority of cases (92 patients, 60.5%) were between 50 and 70 years of age.

In another study by Mahmodlou *et al.*,[17] the mean age at diagnosis was 55.2 ± 11.5 years old, 33.6% had an age lower than 50, 43.4% were between 50 and 69 years, and 22.9% had an age higher than 70-years-old. About 23% of patients had an age lower than 40 years old 1[a].

In a study by Hajmanoochehri *et al.*,[23] the youngest and oldest patients were 20 and 90 years old, respectively. Mean age was 57.3 ± 14.7 years and median was 58 years. The most prevalent age decade was 50–59 years which comprised 24.1% of cases. About 12% and 29.2% of patients were under 40 and 50 years old, respectively. About 25.2% and 5.2% of patients were higher than 70 and 80 years old, respectively.

On comparing our data with above-said studies, we found that they tally with our study. In our study, most of the patients presented with abdominal pain (51.7%), followed by bleeding P/R (50.25%), altered bowel (48.24%), features of intestinal obstruction, weight loss, and anemia. More than 1 symptom was present in single patient. Aljebreen[18] study also coincided with ours where they found that most common clinical presentation was bleeding per rectum (62%), followed by weight loss (55%), constipation (50%), melena (14%), and fever and anemia (6%). In an another study by Mahmodlou *et al.*,[17] the presenting symptoms were rectal bleeding (25%), large bowel obstruction (23%), change in bowel habits (14%), weakness and anemia (5%), abdominal mass (4%), and bowel perforation and peritonitis (3%).

In a study by Elzouki *et al.*,[22] the most common presenting symptoms were rectal bleeding and abdominal pain in 71% and the most common sign was palpable abdominal mass found in 13.2% followed by intestinal obstruction in 6.6%. Six patients (3.9%) had a documented history of polyps diagnosed previously and only 2 patients (1.3%) had past long history of ulcerative colitis almost coinciding with our study.

We compared the location of CRC with other studies. In our study, the most common site was transverse colon at 69 sites, 36 (32.4%) in males and 33 (37.5%) in females followed by ascending colon in 47 patients, 29 (26%) in males and 18 (20%) in females, sigmoid colon in 43 patients, ileocecal region in 15 patients, descending colon in 13 patients, and finally, transverse colon in 12 patients. In a study by Abdulkareem *et al.*,[24] the left-sided (distal colon) tumor 261 (62%) were more common than right sided (proximal) ones 58 (14%). More than half of the cases were located in the rectosigmoid region 246 cases (58.6%) followed by cecum 34 cases (9%), ascending colon 24 cases (6%), transverse colon 19 cases (4.5%), and descending colon 15 cases (3.6%) each. In 82 cases (19.5%), the specific site was not indicated. In another study by Xu *et al.*,[25] out of 8172 lesions, 4434 (54.3%) were located in the rectum and 3738 in the colon.

Histopathological data from all the patients were collected and analyzed. Well-differentiated adenocarcinoma comprised 97 cases of which 52 (46.8%) males and females were 45 (51%), moderately differentiated adenocarcinoma in 56 cases in which 36 (32.7%) were male and 20 (22.7%) were female. Poorly differentiated adenocarcinoma comprised 28 cases equally divided in both sexes. Mucinous carcinoma was identified in 13 cases followed by signet cell carcinoma in 5 patients. Elzouki *et al.*[22] while doing a hospital-based study of 152 patients on colorectal carcinoma found that poorly differentiated adenocarcinoma was the most affected site which involved 65 (42.8%) cases of which 29 (42.6%) were male and 36 (42.9%) were female. It was followed by moderately differentiated adenocarcinoma in 52 (34%) of which 23 (3.8%) were female and 29 (34.5%) were male. Well differentiated was seen in 26 (17.1%) followed by undifferentiated carcinoma in 9 (5.9%) patients. Patra *et al.*'s[26] study reported more aggressive histology of tumors in younger in younger patients with CRC, most of the tumor encountered adenocarcinoma and they were subdivided into three grades – well differentiated (9.5%), moderately differentiated (18.3%), and poorly differentiated adenocarcinoma (2.9%).

In our study, the site of involvement and histopathological data were further correlated with two different age groups – younger age group (<40 years) and older age group (>40 years) and the data showed that most common site involved in both the younger and older age groups was rectum, whereas least common site in both the age groups was ileocecal region. Fazeli *et al.*[27] in Iran reported that 22% of patients <40 years had poorly differentiated tumor compared to 5.9% in patients above 40 years. Kakar *et al.*[28] found that all the cancers other than mucinous adenocarcinoma were significantly more prevalent among the middle-aged and older patients and mucinous adenocarcinoma was more prevalent among the young patients. Tumor microsatellite instability has been identified of the genetic basis in most of the younger patients with colorectal carcinoma. The tumor microsatellite instability was suggested for those younger individuals to have a risk for hereditary non-polyposis CRC like mucinous adenocarcinoma.

On staging the tumor according to Duke's classification, majority of patients (n = 19, 38.7%) < 40 years of age were in Stage B, whereas maximum number of patients

(n = 55, 36.6%) > 40 years were in Stage C. Abdulkareem *et al*.'s[24] study showed that most of the patients (52%) were in Stage B.

CONCLUSION

CRC is among the most common malignancies found in this part of the world and percentage of younger patients is rising in this part of the world.Patient stillpresent in advanced stages so the importance of implementing an appropriate screening programme needs to be considered.

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Original Article

Effect of Different Veneer Designs on the Strength of Composite Veneers

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Abstract

Aim: The aim of this *in vitro* study was to evaluate the different designs of composite veneers and their relative strength.

Material and Methods: Thirty extracted, intact, human maxillary central incisors were selected and prepared with three different veneer designs: (1) Feather preparation, (2) bevel preparation, and (3) incisal overlap-palatal chamfer. Restoration was done with composite veneers and failure was recorded at the incisal, gingival, or at both sites after applying appropriate load.

Results: Composite veneers with incisal overlap-palatal chamfer showed highest fracture resistance among the three designs. The mean (SD) fracture loads were as follows: Group 1: 100.4 N, Group 2: 105.3 6.9 N, and Group 3: 123.0 N. The most common mode of failure was debonding for veneers with feather preparation and fracture when incisal edge is reduced. The most frequent localization of fracture was incisal.

Conclusion: The type of preparation has a significant effect on fracture load for composite veneers. This study indicates that using an incisal overlap-palatal chamfer preparation design significantly increases the fracture resistance compared to feather and bevel preparation designs.

Key words: Composite veneers, Fracture resistance, Preparation design

INTRODUCTION

Esthetics, particularly esthetics of the teeth, has become one of the prime areas of concern for the patient in the current times. Now, esthetic issues, such as discolored, broken, chipped teeth, and midline diastemas, can be corrected easily with the advances in technology and materials.[1,2] Composite veneers are one of the best methods to do as they require a simple technology and provide high esthetics. Their high mechanical resistance, low allergy-causing potential, effective cost, and opportunity for clinical repairs increase the use of composite veneers in clinical practice as a contemporary esthetic solution.[3] Therefore, it is necessary to decide the best preparation design for optimum performance. Ideally, the bond should be completely in enamel with the preparation of labial and proximal surface being 0.3 mm–0.5 mm.[4] The preparation's margins must be chamfered. Four possible designs of preparation have been indicated: Window preparation (non-reduced incisal edge); feather preparation (non-reduced incisal edge with the entire labial surface covered by the veneer); bevel preparation (reduced incisal edge with buccopalatal tilt preparation over the entire tooth width); and incisal overlap or palatal chamfer (the reduction of incisal edge with palatal extension preparation). Before starting the preparation, it is important to decide whether to reduce the incisal edge or not. Indirect technique is used to fabricate a restoration in a dental laboratory. Bonding of composite veneers to the teeth is done by adhesive luting procedures. According to Fahl,[5] this type of materials when subjected to heat and in combination with increased exposure to visible spectrum light, pressure or vacuum, and present greater conversion of the resin through increased polymerization. As a result, this conversion results in altered physical properties of the material, such as hardness, mechanical resistance, color stability, and biocompatibility.[6] The aim of this *in vitro* study was to examine the strength of composite veneers (taking fracture load as a guide) using three different preparation designs.

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MATERIALS AND METHODS

Thirty extracted, intact, human maxillary central incisors with similar dimensions were selected for this study. After inspecting them for defects or cracks, calculus and debris were removed by ultrasonic scaling. Selected teeth were stored in normal saline solution at room temperature throughout the study. Teeth were randomly divided into three groups (n = 10) with different preparation designs: Group 1 – feather preparation, Group 2 – bevel preparation, and Group 3 – incisal overlap-palatal chamfer. Impressions of the prepared cavities were taken with identical heavy body and light body impression material and working models were fabricated. Restorations of the cavities were performed with an identical composite material according to the manufacturer's instructions. After polymerization in a curing unit, the veneers were bonded to the teeth using resin cement. After loading the specimens to the failure (cyclic/stress path triaxial system) in a testing machine (TRITECH WF 10056, Wykeham Farrance, Milan, Italy), the fracture strength test was performed at a constant speed of 0.5 mm/min by applying force at a 45° angle to the long axis of the tooth. Data were analyzed by recording failure fatigue of every specimen. The mode of failure was determined as debonding or fracture at the incisal, gingival, or combined level on microscopic visualization (Olympus microscope SZ2-ILST model, Figure 1). The data were statistically analyzed using statistic package–SPSS version 23.

RESULTS

Composite veneers with incisal overlap-palatal chamfer (Group 3) showed highest fracture resistance (123.0 N) and bevel preparation (Group 1) showed minimum fracture resistance (100.4 N). The fracture resistance for feather preparation (Group 2) was 105.3 N. T-test for means shows a statistically significant difference in the fracture resistance of the designs ($P < 0.05$). Most commonly, debonding occurred in samples with feather preparation (80%) while fracture occurred in the other two groups (80%) [Table 1].

DISCUSSION

Clinical studies[7] have confirmed that veneers bonded to mandibular incisors are less susceptible to fractures and most fractures occur on veneers cemented to maxillary incisors.[8] This is due to less destructive nature of the forces of pressure that occur on the incisal edges.[9] This formed the basis for selecting the maxillary incisors as the teeth of choice in our study.

To achieve optimum results with veneers, it is necessary to identify the best design of preparation to achieve the best esthetic and mechanical outcome. Our *in vitro* study eliminated subjective factors such as strength of chewing pressure on mastication and the type of food. However, it is quite difficult to reproduce conditions analogue to those in the mouth. At present, literature assumes complex geometric shape of the veneers to be the cause of failure of composite veneers. Human teeth have strength and elasticity along with bonding characteristics that influence the results of *in vitro* examination.[10,11] In our study, we chose teeth with identical sizes and shape to avoid any bias. Mechanical characteristics are of great importance for successful restoration with veneers. There are many ambiguities and controversies regarding the veneers preparation designs in the literature. Most of the studies in literature have analyzed porcelain veneers as the veneer material and not the effect of the preparation design on the veneer failure.[12] In our study, we have used laboratory processed composite (has high proportion of inorganic fillers in the nanoscale range) resin that offers better handling and superior mechanical resistance and finish than hybrid composite materials. The matrix, based on a urethane dimethacrylate, is recognized for its toughness which is higher than that the frequently used BisGMA.[13,14] As per different studies conducted by Meijering *et al.*[15] and Alghazzavi[12] *et al.*, reduction of incisal edge has no role in the survival rates and mechanical resistance of veneers and there was no statistical difference in fracture strength of the veneer depending of preparation design. However, Mirra and El-Mahalawy[16] had opposite results in an *in vitro* study. Most recommended preparation design for veneer is where the incisal edge is reduced.[17,18] On the other hand, some authors suggest that veneers made with incisal overlap (palatal chamfer) preparation type have the best tolerance of stress distribution.[8,19] The results of our study

Table 1: Relation between force applied and failure of veneers

n	1	2	3	4	5	6	7	8	9	10	Mean
Group 1											
Fracture line (N)	101	112	99	92	103	98	102	107	94	96	100.4 N
Mode of failure	D	D	D	D	F	D	D	D	D	F	
Localization	-	-	-	-	G	-	-	-	-	G	
Group 2											
Fracture line	97	114	110	101	105	104	115	101	102	104	105.3 N
Mode of failure	F	F	F	F	D	F	F	F	F	D	
Localization	I	I	I	I		I	I	I	I		
Group 3											
Fracture line	129	134	117	121	113	128	136	119	118	115	123 N
Mode of failure	F	F	D	F	F	F	F	D	F	F	
Localization	I	I		C	C	I	I		C	C	

C: Combination, D: Debonding, F: Fracture, I: Incisal, G: Gingival

correspond to those of Schmidt *et al.*[20] and Akoglu and Gemalmaz.[21] In the present study, we found a statistically significant difference in the fracture resistance among the three preparation designs. The highest fracture resistance was found in veneers with incisal overlap-palatal chamfer. This was attributed to increased tooth surface available for bonding and enough space and minimum thickness of the composite cement available so that the stress applied to the facets is reduced.[22] The bevel preparation and feather preparation groups do not provide a definite path of placement while cementation of the veneer because of thin incisal edges of the prepared teeth which explains the lower fracture resistance. Our study corroborates previous findings the incisal edge of restoration being the location of the fracture due to the presence of larger stress.[23]

CONCLUSION

This study, though with limitations, concludes that the type of preparation has a significant effect on fracture load for composite veneers. The incisal overlap-palatal chamfer preparation design has the best fracture resistance compared to other designs. The study suggests that for results to be more significant, another *in vitro* study with a much larger sample and/or an *in vivo* study should be carried out.

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Original Article

Insertion Characteristics of Laryngeal Tube Suction-disposable and Laryngeal Mask Airway Supreme in General Surgeries

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Abstract

Background: Laryngeal tube suction disposable and laryngeal mask airway supreme are newly introduced supraglottic airway devices which have an inbuilt drainage channel through which a gastric tube can be passed to allow efflux of gastric fluid and gas. This study was carried out to compare the insertion characteristics, leak pressure, hemodynamic, and ventilatory parameters and post-operative airway morbidity with the use of either of the two devices.

Materials and Methods: Eighty adult patients aged 18–60 years, American Society of Anesthesiology Grades I and II and Mallampati Grades I and II scheduled for surgeries under general anesthesia of <2 h duration, were allocated to Group LTS-D (n = 40) receiving general anesthesia with laryngeal tube suction disposable and Group LMAS (n = 40) receiving general anesthesia with laryngeal mask airway supreme. They were then compared with respect to their insertion characteristics, leak pressure, hemodynamic and ventilatory parameters, and pharyngolaryngeal complications.

Results: Statistically significant difference was seen between the insertion time (P = 0.01), first time success rate (P = 0.002), ease of insertion (P = 0.021), and overall success rate (P = 0.023) between the two groups. Leak pressure, peak pressure, hemodynamic, and ventilatory variables were comparable between the two groups. Patients ventilated with LTS-D had higher incidence of blood staining (P = 0.019), trauma to lip and tongue (P = 0.043), and sore throat at 1 h postoperatively (P = 0.025).

Conclusion: This study concluded that LMAS has better insertion characteristics than LTS-D with low incidence of postoperative pharyngolaryngeal complications.

Keywords: Insertion time, Laryngeal mask airway supreme, Laryngeal tube suction disposable, Pharyngolaryngeal complications, Supraglottic airway device

INTRODUCTION

Supraglottic airway devices (SADs) have been in use in elective surgery and emergency medicine since the introduction of classical laryngeal mask airway (cLMA) into clinical medicine by Archie Brain in early 1980 at Royal London Hospital.[1] The cLMA has undergone various modifications aimed at improving the ease of insertion and patient comfort and safety.[2] Compared to tracheal intubation and extubation, the use of SADs is associated with more stability in hemodynamics,[3] intracranial pressure,[4] and intraocular pressure.[5] Similar results were seen in studies by Dhanda *et al.*,[6] Akhondzade *et al.*[7] who compared use of SADs with endotracheal tube for ventilation and found that hemodynamic parameters were found to be better with use of SADs.

Newer SGAs have an inbuilt drainage channel to facilitate the efflux of gastric fluid and gas and allow the insertion of a gastric tube.

The newly introduced laryngeal tube suction is a further development of the laryngeal tube which allows better

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separation of the respiratory and alimentary tracts. The LTS is a dual-lumen silicone tube without latex, in which one lumen is used to ventilate and the other is used to decompress, suction, and position a gastric tube. It consists of a proximal cuff which seals the oropharynx and a distal cuff which blocks the esophagus and reduces gastric insufflation. It is color coded for immediate identification of the size.

The laryngeal mask airway supreme (LMAS) is a new disposable airway device that combines features of the LMA Proseal (PLMA and gastric access) and LMA Fastrach (curved shaft to ease insertion) and has been available since April 2007.[8] It allows rapid passage of higher volume of gas through the airway and can be inserted rapidly and in a safe manner due to its advanced cuff and airway tube design.

Both are second generation, single use, and supraglottic airway devices provided with a gastric access which can be used for both spontaneous and mechanically ventilated patients.

In our study, we compared LTS-D and LMAS with respect to insertion characteristics, leak pressure, hemodynamic and ventilatory parameters, gastric tube placement, and airway morbidities.

MATERIALS AND METHODS

After approval from the Institutional Ethics Committee, Government Medical College Amritsar, a prospective randomized, and comparative study was conducted on 80 patients of ASA Grade I or II in aged 18–60 years posted for elective general surgeries. Sample size was calculated in consultation with the statistician taking mainly the parameters of insertion characteristics and leak pressure and based on previous study to get the power of study more than 85%.

The surgeries included were cholecystectomy, fibroadenoma, lumpectomy, incision and drainage, dilation and curettage, gynecomastia, axillary swelling, skin grafting, and submandibular swelling. Inclusion criteria were as follows: Age 18–60 years, ASA Grade I or II, Mallampati Grade I or II, and elective surgical procedures of <2 h duration. Exclusion criteria were as follows: ASA Grade III or IV, Mallampati Grade III or IV, BMI > 30 kg/m^2, known risk of pulmonary aspiration, and known or predicted difficult airway.

The demographic data collected for each patient was as follows: Age, gender, height, weight, type, and duration of surgery.

Pre-anesthetic check-up, including detailed history and thorough general physical examination of patient, was carried out a day before surgery and was recorded.

The patients were divided into two groups (each group containing 40 patients) who were posted for surgery under general anesthesia using laryngeal tube suction disposable (LTS-D) and laryngeal mask airway supreme (LMAS). After selection of the patients, a written informed consent from every selected patient was taken in their vernacular language.

The patients were kept NPO after 12 midnight and tablet alprazolam 0.5 mg was given at 6 am in the morning before surgery with a sip of water.

A standard anesthesia sequence was followed. On arrival in theater, the patient was connected to standard monitoring devices, including electrocardiogram, non-invasive blood pressure (NIBP), heart rate (HR), end tidal carbon dioxide ($EtCO_2$), and oxygen saturation (SpO_2) and the baseline values, were recorded. All emergency airway equipment's and emergency drugs were kept ready. After removal from its sterile packet, the integrity and function of the LTSD and LMAS were checked.

Anesthesia was induced in supine position after preoxygenating the patient for 3–5 min. Premedication i.v midazolam (1 to 2 mg), i.v butorphanol (1 to 2 mg), was given on the OT table before induction. Preservative free lignocaine 2 % (2 mL) was given to attenuate the pain from propofol injection. Induction was done with i.v propofol (1.5 to 2 mg/kg body weight), i.v vecuronium (0.08 mg/kg body weight), and anesthesia, which was maintained with oxygen: Nitrous oxide (50:50) with isoflurane (MAC value of 1.15). All patients were ventilated manually for 3–4 min before insertion of either of the two supraglottic airways.

A senior anesthetist who was experienced in placement of SGA was the one placing either of the two devices. A size 3/4/5 LTS–D and size 3/4/5 LMAS were used according to manufacturer's recommendations. The devices were lubricated with a water-soluble jelly before their insertion.

After insertion, the cuff was inflated with the minimum amount of air required to achieve an effective seal. The recommended intracuff pressure was not allowed to exceed 60 cmH_2O measured using cuff pressure gauge. The time taken to insertion of the device from the time of picking up of the device to the appearance of first capnograph trace was recorded. In case, a difficulty was encountered during insertion of either of the two devices, manoeuvers such as jaw thrust manoeuver or hyperextension of the neck were done to ease insertion. Ease of insertion was

graded as very easy, easy, difficult (additional manoeuvers such as jaw thrust and hyperextension of neck) and very difficult (failure). Additional propofol increments were given if coughing, gagging or body movements occurred during device insertion to increase the depth of anesthesia.

Correct position with proper ventilation was confirmed by: (a) End tidal carbon dioxide between 35 and 45 mmHg, (b) a square wave capnograph, (c) good chest expansion on manual ventilation, (d) auscultation over both lungs, and (e) no audible leak from the drain tube on positive pressure ventilation when peak airway pressure was kept at 20 cmH_2O.

The initial ventilation was started using TV (tidal volume) of 8 ml/kg, RR of 12–14 /min, and I:E ratio of 1:2.

Failed insertion of SGA was considered if: (a) Inability to position the device within 60 s, (b) any air leak observed through the drainage channel during positive pressure ventilation despite corrective manoeuvers (deeper insertion or up and down manoeuver), and (c) inability to maintain an end tidal carbon dioxide between 35 and 45 mmHg.

In case of failure of insertion of one of the two devices following two attempts, endotracheal intubation was done for proper ventilation of the patient.

After proper taping of the airway device when it was secured in position, an appropriate sized gastric tube was passed through the suction channel of either of the device after proper lubrication. Correct placement of gastric tube was confirmed by epigastric auscultation of air injected by a 10 ml syringe. Gastric tube placement was graded as easy, difficult, or unable to pass.

Following insertion, the ventilatory variables (leak pressure and peak pressure), hemodynamic parameters (NIBP and HR), and ventilatory parameters (SpO_2, $EtCO_2$, ITV, and ETV) were recorded at regular intervals.

The leak pressure was determined after confirmation of correct placement of the device in supine position. Under the manual control ventilation mode, the APL valve (adjustable pressure limiting valve) in the breathing circuit of the anesthesia machine was closed, and the fresh gas flow was adjusted to 3 L/min to elevate the pressure in the breathing circuit until the airway pressure was stabilized, that is, the leak airway pressure (OLP/airway sealing pressure).[9] Leakage was defined as air escape audible with a stethoscope placed on the larynx and leak pressure was defined as the airway pressure at which leakage was first detected. Expiratory valve was released completely once the pressure exceeded 40 cmH_2O. In patients in whom the airway pressure reached 40 cmH_2O, the leak was interrupted and a value of 40 cm H_2O was recorded.

On completion of surgery, all anesthetic gases were stopped and patient ventilated with 100% oxygen. The patient was brought to spontaneous respiration and muscle paralysis reversed with neostigmine (0.05 mg/kg) and glycopyrrolate (0.5 mg). After oral suctioning, the SGA was removed on return of protective airway reflexes. The shape and blood staining of the device were checked thoroughly after removal. Tolerance during removal was graded as good (comfortable patients), moderate (coughing, retching, and biting of device), and poor (vomiting or vagal rection).

Patients were asked for any sign of airway morbidity such as swelling of tongue, sore throat, dysphagia, or dysphonia at first hour postoperatively and then again at 24 h.

OBSERVATIONS AND RESULTS

Patients were divided into two groups LTS-D and LMAS of 40 each in a random and unbiased manner.

Group LTS-D (n = 40): Forty patients received general anesthesia using laryngeal tube suction disposable.

Group LMAS (n = 40): Forty patients received general anesthesia using laryngeal mask airway supreme.

There were no fallouts from the study.

In Table 1, there was no statistical difference between the demographic and surgical data between the two groups with $P > 0.05$

The difference in the duration of insertion between both the groups was found to be statistically significant with $P = 0.01$ [Table 2 and Figure 1].

Table 1: Comparison of demographic and surgical data

	Group LTS-D	Group LMAS	*P* value
Age (years)	37.73±9.63	36.03±9.23	0.211 (NS)
Sex (F/M)	24/16	26/14	0.644 (NS)
Weight (Kg)	62.90±7.26	60.57±8.29	0.090 (NS)
Height (cm)	160.25±8.23	160.20±8.28	0.170 (NS)
ASA (I/II)	23/17	28/12	0.245 (NS)
Duration of surgery (min)	61.12±23.83	68.25±24.24	0.185 (NS)

Table 2: Comparing insertion time

	Group LTS-D		Group LMAS		*P*-value
	Mean	SD	Mean	SD	
Insertion time (Seconds)	14.35	3.34	10.08	3.16	0.01 (S)

The first-time success rate, number of attempts, and ease of insertion were found to be better with use of LMAS than LTS-D such that the difference came out to be statistically significant with $P < 0.05$ [Table 3].

The overall success rate was 100% with use of LMAS as opposed to 87.5% seen with use of LTS-D which was found to be statistically significant with $P = 0.023$ (S).

The difference between leak pressure and peak pressure between the two groups came out to be statistically non-significant ($P > 0.05$) [Table 4].

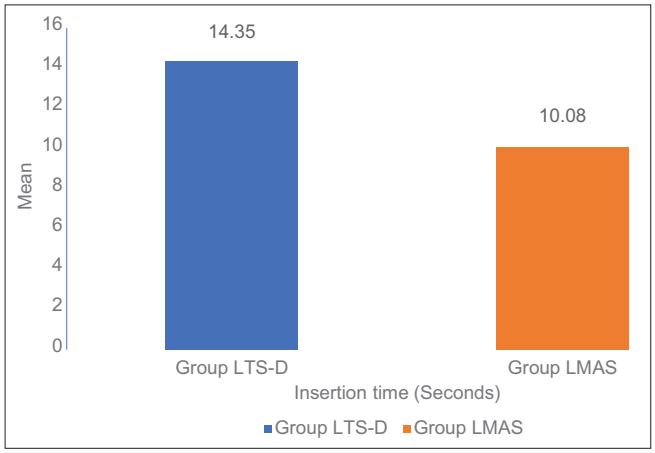

Figure 1: Comparing insertion time

Table 3: Comparing first time success rate, number of attempts, ease of insertion and overall success rate

Variables	Group LTS-D		Group LMAS		*P* value
	No.	%	No.	%	
First time success rate	27	67.50	38	95.00	0.002 (S)
No. of attempts					
1	27	67.50	38	95.00	0.023 (S)
2	8	20.00	2	5.00	
Ease of insertion					
Very easy	4	10.00	8	20.00	0.021 (S)
Easy	18	45.00	29	72.50	
Difficult	13	32.50	3	7.50	
Very difficult (Failure)	5	12.50	0	0.00	
Overall success rate	87.5%		100%		0.023 (S)

Table 4: Comparison of leak and peak pressure

Variables	Group LTS-D		Group LMAS		*P*-value
	Mean	SD	Mean	SD	
Leak pressure (cmH_2O)	20.88	2.77	20.38	2.15	0.098 (NS)
Peak pressure (cmH_2O)	22.63	2.22	21.95	1.95	0.080 (NS)

There was seen statistically significant difference between the two devices with more incidence of blood staining, trauma to lip, and tongue and sore throat seen with use of LTS-D [Figures 2 and 3].

DISCUSSION

The demographic and surgical data were found to be comparable between the two groups in our study.

In our study, we found that the insertion characteristics of LMAS are better than LTS-D. The mean duration of insertion of laryngeal tube suction disposable in Group LTS-D was 14.35 ± 3.34 s and of laryngeal mask airway supreme in Group LMAS was 10.08 ± 3.16 s with $P = 0.01$. First time, success rate ($P = 0.002$) and ease of insertion ($P = 0.021$) were better with use of LMAS than LTS-D. Our findings are comparable with the study by Russo *et al.*,[10] in which the insertion time was found to be 11 ± 9 s for LMA supreme and 14 ± 10 s for LTS-D ($P = 0.173$) and the insertion success rate of LMAS was 95% as compared to LTS-D of 70%.

The mean insertion time was found to be more for LTS-D as compared to LMA supreme since more manoeuvers such as jaw thrust manoeuver and hyperextension of neck were required to be done during the insertion of LTS-D as compared to LMA supreme. This is supported by study by Somri *et al.*[11] who found that jaw thrust manoeuvers were required in 11 patients in LTS-D and three patients in LMAS to achieve an effective airway during spontaneous ventilation in 80 patients.

The unique elliptical airway tube of laryngeal mask airway supreme allows for the easy and fast insertion of the device with less resistance and no kinking. It also keeps the device stable *in situ*.

Similarly, in a study by Schalk *et al.*,[12] the time required for successful insertion of LTS-D was shortest in the FIT/JT group (23 ± 6s), and significantly longer in the SIT/JT (42 ± 29s, $P < 0.001$) and SIT groups (51 ± 29s, $P < 0.001$) (FIT = Frontal Insertion Technique, SIT = Standard Insertion Technique, and JT = Jaw Thrust). Performing jaw thrust enhances the retropharyngeal space and increases the insertion success rate of the LTS-D from 49 to 100%.

In our study, we found that the mean leak pressure for LTS-D was 20.88 ± 2.77 cmH_2O and for LMAS was 20.38 ± 2.15 cmH_2O such that the difference was statistically non-significant with $P = 0.098$.

The oropharyngeal leak pressure quantifies the efficacy of airway sealing in supraglottic airway devices. A higher

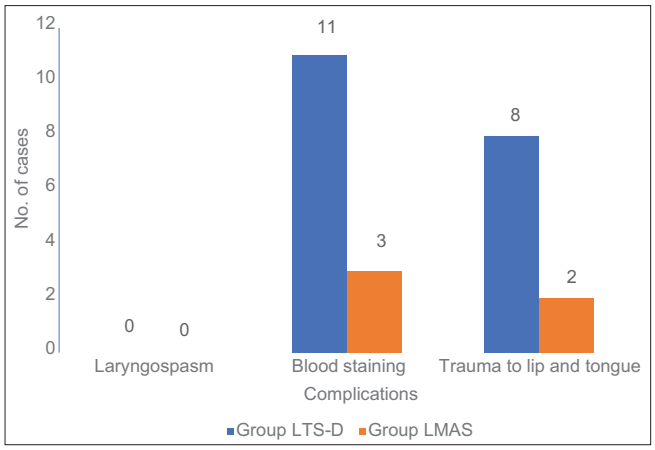

Figure 2: Comparing peroperative complications

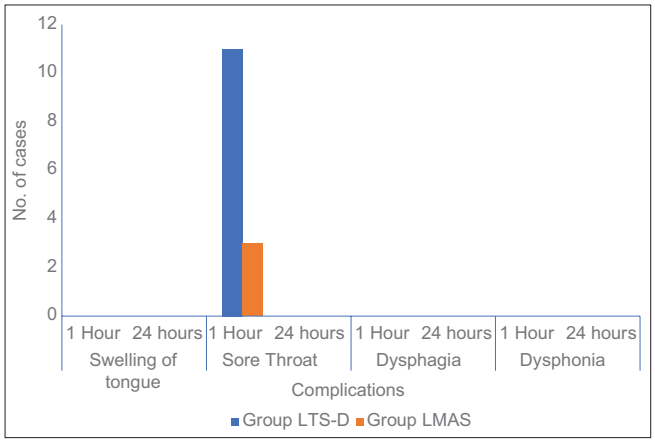

Figure 3: Comparing postoperative complications

oropharyngeal leak pressure indicates that safe controlled ventilation can be carried out at higher airway pressure if required.[13] The large pre-curved cuff of LMAS contributes in providing an effective seal.

In a study by Zhang *et al.*[14] conducted on 40 patients to determine, the oropharyngeal leak pressure of LMAS at different intracuff pressures, the mean OLP obtained at cuff pressure of 60 cmH_2O was 20.7 cmH_2O (18.9 to 22.5 cmH_2O) which is comparable with our study.

Damodaran *et al.*[15] conducted a study comparing the oropharyngeal leak pressure of Air-Q, I gel, and LMAS in 75 patients of ASA Grade I/II between the age group of 18–60 years and found that the OLP for LMAS was 24.80 ± 4.78 cm H_2O. Our findings are comparable with this study.

In the study by Russo *et al.*,[10] no difference in the leak pressure between LTS-D and LMAS was seen with the $P = 0.184$ which is non-significant and, thus, supports the result of our study.

The difference between hemodynamic and ventilatory parameters between the two groups was found to be statistically non-significant.

The incidence of airway morbidity during insertion as well as after removal of the device has been found to be more with the use of LTS-D as compared to LMAS in our study.

There were seen 11 (27.50%) cases of blood staining of the device and 8 (20%) cases of trauma to lips and tongue with use of LTS-D as opposed to 3 (7.50%) cases of blood staining and 2 (5%) case of trauma to lips and tongue with the use of LMAS such that the difference was found to be significant ($P > 0.05$).

Post-operative pharyngolaryngeal complications such as laryngospasm, swelling of tongue, dysphagia, and dysphonia were not seen in either of the two groups in our study.

There was no incidence of aspiration or regurgitation with use of either of the two devices.

Both the devices were tolerated well during their removal.

The incidence of sore throat was higher in group LTS-D at 1 hour with 11 (27.50%) patients showing the same as compared to 3 (7.50%) cases in group LMAS and the difference came out to be significant with $P = 0.025$.

Higher incidence of airway morbidity with use of LTS-D may be due to more of additional manoeuvers and increased number of attempts required during its insertion.

Similar results were seen in a study by Russo *et al.*[10] and Henlin *et al.*,[16] in which rate of complications was found to be more with use of LTS-D than LMAS.

A gastric tube of appropriate size was successfully passed through the gastric channel of both the devices after proper lubrication. In our study, we found that 16Fr and even 18Fr sized gastric tubes could be easily passed through the gastric channels of LTS-D as opposed to mostly 16Fr or a size smaller could be passed through the drainage channel of LMAS. Thus LTS-D presents an advantage over LMAS when evacuation of large gastric contents needs to be carried out.

The results are supported by the study done by Somri and Vaida *et al.*[17] Correct placement of the gastric tube ensures correct placement of the device.

CONCLUSION

In conclusion, during elective general surgical procedures of less than two hours duration, both laryngeal tube suction

disposable and laryngeal mask airway supreme can be used since they provide an effective airway with minimal alterations in hemodynamic variables. LMAS is better than LTS-D since it can be inserted with ease with less time taken for insertion, less requirement of additional manoeuvers and has less rate of failure. Furthermore, the incidence of post-operative airway morbidities is less with use of LMAS, thus making it a more suitable device than LTS-D.

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Original Article

Comparison of Intrathecal Nalbuphine and Dexmedetomidine as Adjuvants to Levobupivacaine in Infraumbilical Surgeries

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ABSTRACT

Background: Various intrathecal adjuvants have been clinically tried for the prolongation of intraoperative and post-operative analgesia. This study aims at evaluating the effects of intrathecal nalbuphine and dexmedetomidine as adjuvants to isobaric levobupivacaine in subarachnoid block.

Materials and Methods: Sixty patients scheduled for elective infraumbilical surgeries were allocated into two groups of 30 each to receive 15 mg of 0.5% isobaric levobupivacaine with either 0.8 mg nalbuphine (Group LN) or 5 μg dexmedetomidine (Group LD) intrathecally. Characteristics of spinal anesthesia in terms of sensory analgesia and motor blockade were noted. Hemodynamic parameters and adverse effects if any were recorded. Data obtained were compiled and statistically analyzed with appropriate tests.

Results: Onset of sensory and motor blocks was faster in Group LD (2.31 ± 0.66 and 6.24 ± 0.45 min) compared to Group LN (4.33 ± 0.66 and 7.00 ± 0.45 min). Total duration of effective analgesia (402.50 ± 9.79 vs. 294.63 ± 8.95) and total duration of motor block (289.67 ± 5.94 vs. 251.87 ± 8.48 min) were significantly prolonged in Group LD than in Group LN. There was no significant difference in hemodynamic changes and adverse effects between the groups.

Conclusion: The addition of 5 μg dexmedetomidine to intrathecal 0.5% isobaric levobupivacaine as adjuvant is associated with prolonged sensory and motor blockade with better perioperative analgesia compared to 0.8 mg nalbuphine.

Key words: Dexmedetomidine, Infraumbilical surgeries, Levobupivacaine, Nalbuphine

INTRODUCTION

Subarachnoid block is the most common anesthesia technique used to conduct lower limb surgeries and lower abdominal surgeries among all methods. It has a big role in anesthesia because of its advantages in the form of reducing the metabolic stress, less blood loss, lower incidence of venous thromboembolism, reduction in pulmonary complications, early return of bowel function, and shorter admission-discharge interval. However, the limited duration of action is one of its disadvantages. Levobupivacaine has emerged as popular local anesthetic for central neuraxial blocks in this century. It is a pure s-enantiomer of bupivacaine and is a safer alternative for regional anesthesia than its counterpart with lower toxicity.[1]

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Local anesthetic drugs used alone for spinal anesthesia do not prolong post-operative analgesia. Various adjuvants, for example, opioids, midazolam, alpha-2 agonist, and ketamine, have been used along with the local anesthetics for prolongation of post-operative analgesia in neuraxial blockade, reduction of local anesthetic dose, and thereby side effects.[2]

Opioids are an important modality of post-operative pain management. They blunt the neuroendocrine stress response

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to pain. Nalbuphine is a synthetic, mixed agonist-antagonist opioid analgesic with agonistic action at kappa receptor and antagonism at mu receptor. Nalbuphine, whenever used as adjuvant to bupivacaine, it was found to improve the quality of perioperative analgesia with comparatively lesser side effects and nil neurotoxicity.[3,4]

Among non-opioids, dexmedetomidine is a highly selective α2-agonist, which is used as neuraxial adjuvant as it provides stable hemodynamic conditions, good quality of intraoperative and prolonged post-operative analgesia with minimal side effects.[5] Dexmedetomidine has been approved by Food and Drug Administration (FDA) as a short-term sedative for mechanically ventilated intensive care unit patients. The present study was designed to evaluate the sensory and motor block characteristics, hemodynamic changes, and any adverse effects of nalbuphine and dexmedetomidine when used as adjuvants to 0.5% isobaric levobupivacaine in patients undergoing elective infraumbilical surgeries under subarachnoid block.

MATERIALS AND METHODS

After obtaining the approval from the research ethics committee and informed written consent from the patients, 60 patients between the age 18 and 60 years, American Society of Anesthesiologists Grade I and II, scheduled for infraumbilical surgeries under spinal anesthesia were enrolled in the present study. Patients with a history of allergy to local anesthetics, local infection at the site of the block, coagulopathies, pregnancy, previous neurological deficit in lower limb, spinal deformity, and those who refused the technique were excluded from the study [Figure 1].

Careful pre-anesthetic check-up was carried out in all patients with detailed clinical history, general and systemic examination. Patients were explained about the visual analog scale (VAS) and its use for measuring the post-operative pain and advised fasting for 6 h. All patients were pre-medicated with tablet alprazolam 0.25 mg a night before surgery, injection glycopyrrolate 0.2 mg intravenous (IV), and injection midazolam 0.04 mg/kg iv just before the procedure. In operating room, all routine monitors were attached and IV fluid (IV) ringer lactate (R.L.) 10–15 ml/kg was started. Baseline hemodynamic parameters, heart rate (HR), oxygen saturation (SpO_2), systolic blood pressure (SBP), diastolic blood pressure (DBP), and mean blood pressure (MBP), were noted. Spinal anesthesia was induced with the patients in lateral position. Under all aseptic conditions, L3–L4 interspace was chosen and the overlying skin was anaesthetized by means of local infiltration with xylocaine 2%. Lumbar puncture was performed in the midline using a 23 G Quincke spinal needle. After the needle was passed into the subarachnoid space and the appearance of clear cerebrospinal fluid, the intrathecal local anesthetic was injected.

Group LN patients received 3 ml of 0.5% of levobupivacaine + 0.8 mg of nalbuphine comprising a total volume of 3.5 ml

Group LD patients received 3 ml of 0.5% levobupivacaine and 5 μg dexmedetomidine comprising a total volume of 3.5 ml.

Patients and anesthesiologist (the outcomes assessor) who recorded the perioperative data were blinded to the study drugs.

Assessment of sensory block was done by loss of sensation to pinprick using a 27 G hypodermic needle. When T10 sensory blockade level was achieved, surgery was allowed. Testing was carried out every 2 min till 10 min, every 5 min up to 30 min, every 15 min up to 60 min, half hourly up to 180 min, and thereafter hourly till the 12th h and every 3 hourly till 24 h of surgery in both the groups. The onset of sensory block (when patient does not feel pinprick at T10 level), the highest level of sensory block achieved, time to maximum sensory block, regression of sensory block to L5, and total duration of sensory block (regression to S1 dermatome) were noted. Degree of motor block was assessed by modified Bromage scale. The time needed for the onset of motor block (Bromage 1), time taken for maximum motor block, and total duration of motor block (time taken for complete motor recovery to Bromage 0) were also noted. Hemodynamic parameters such as HR, SBP, DBP, mean arterial blood pressure (MAP) and respiratory rate, and Spo2 were monitored every 2 min for the first 10 min, every 5 min for the next 30 min every 15 min up to 60 min, half hourly up to 180 min and thereafter hourly till the 12th h, and every 3 hourly till 24 h of surgery in both the groups. The quality of surgical analgesia was assessed as per operating surgeon and graded as excellent, satisfactory, and unsatisfactory. Adverse effects such as hypotension, bradycardia, vomiting, shivering, pruritus, respiratory depression, and urinary retention were observed. Hypotension was defined as a fall in SBP to <90 mmHg or more, and bradycardia was defined as a HR of 60 or less. Perioperative hypotension, bradycardia, and nausea/vomiting were treated with injection ephedrine, atropine, and ondansetron, respectively.

Pain was measured using VAS rated from 0 to 10 subjectively with 0 for no pain and 10 for maximum pain. Rescue analgesia was given when the VAS was >3 in both the groups. Inj. diclofenac 75 mg was given as rescue analgesia and if needed, inj. tramadol 2 m/kg iv was given. Time to

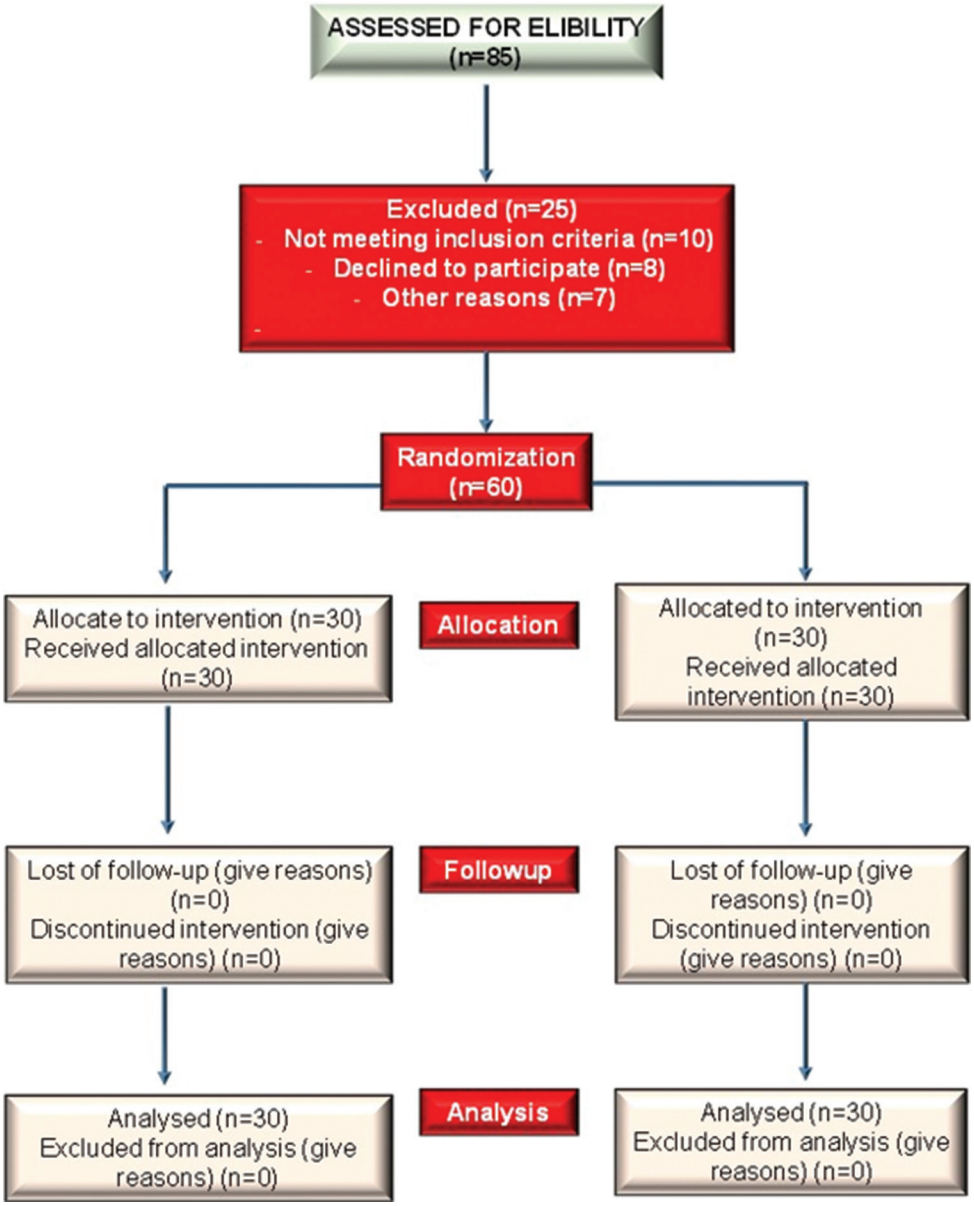

Figure 1: Consort flow diagram

first rescue analgesia (total duration of analgesia) and total number of doses of rescue analgesia were also noted.

Statistical Analysis

Data were entered into MS Excel and analyzed in SPSS V22. Descriptive statistics for qualitative data were represented with frequencies and percentages, whereas for quantitative data, descriptive statistics were represented with mean and standard deviation. Chi-square and *t*-test were applied for finding significance between the groups in qualitative and quantitative data, respectively. $P < 0.05$ was considered as statistically significant.

The mean time taken for onset of sensory block and the time to maximum sensory block were significantly lesser in Group LD ($P = 0.001$). The median maximum sensory level reached was T6 in both groups. Time to achieve maximum motor block was also lesser in Group LD as compared to Group LN ($P = 0.001$). The median maximum motor block achieved in both the groups was mBromage 2. Regression of sensory block to L5 dermatome was significantly prolonged in Group LD ($P = 0.000$). The total duration of sensory and motor block was also significantly more in Group LD as compared to Group LN ($P = 0.001$). Motor and sensory block parameters are shown in Tables 1 and 2. The total duration of effective analgesia was significantly longer in Group LD when compared to Group LN ($P = 0.001$). The total number of doses of rescue analgesia required in 24 h was also significantly less in Group LD as compared to Group LN ($P = 0.001$) [Table 1]. The

Table 1: Sensory block characteristics (Mean±SD)

Sensory block data	Group LN	Group LD	*P* value
Time of onset of sensory block to T10 (min)	4.33±0.66	2.31±0.35	0.001 (HS)
Median maximum sensory level	T6	T6	1.00 (NS)
Time to achieve maximum dermatomal level (min)	7.33±1.25	6.63±0.80	0.001 (NS)
Time to regression to L5 sensory level (min)	269.10±8.68	372.93±7.83	0.000 (HS)
Total duration of effective analgesia (min)	294.63±8.95	402.50±9.79	0.001 (HS)
Total number of doses of rescue analgesia	2.73±0.44	1.76±0.42	0.001 (HS)

HS: Highly significant, *P*<0.01; NS: Not significant, *P*<0.05

Table 2: Characteristics of motor blockade (Mean±SD)

Motor blockade data	Group LN	Group LD	*P* value
Mean maximum motor block achieved (mBromage scale)	2	2	_
Time to achieve maximum motor block (min)	7.00±0.43	6.24±0.45	0.001 (HS)
Total duration of motor block (min)	251.87±8.48	289.67±5.94	0.001 (HS)

HS: Highly significant, *P*<0.01; NS: Not significant, *P*<0.05

Table 3: Comparative incidence of adverse effects

Side effects and complications	P		LD		Total	
	No.	% age	No.	% age	No.	% age
Hypotension	3	10.00	2	6.67	5	8.33
Bradycardia	2	6.67	0	0.00	2	3.33
Nausea	2	6.67	2	6.67	4	6.67
Shivering	2	6.67	1	3.33	3	5.00
No side effect	21	70.00	25	83.33	46	76.67
Total	30	100.00	30	100.00	60	100.00

Table 4: Demographics and duration of surgery (Mean±SD)

Variable	Group LN (Mean±SD)	Group LD (Mean±SD)	*P* value
Age (in years)	37.63±13.20	36.57±13.23	0.380 (NS)
Sex (M/F)	M=21 (70%) F=9 (30%)	M=23 (76.67%) F=7 (23.33%)	0.551 (NS)
ASA I and II	I-25 (83.33%) II-5 (16.67%)	I-24 (80%) II-6 (20%)	0.739 (NS)
Weight (in kg)	67.63±6.04	67.83±6.05	0.450 (NS)
Duration of surgery (in min)	54.50±6.99	52.67±6.80	0.160 (NS)

HS: Highly significant, *P*<0.01; NS: Not significant, *P*>0.05

quality of surgical analgesia was excellent in both groups as none of the patient required supplementary analgesia intraoperatively. Regarding hemodynamic changes, there were no significant alterations in the measured parameters between the two groups ($P > 0.05$) at various time intervals, as shown in Figures 2-4. Hypotension was observed in 3 (10%) patients in Group LN and 2 (6.67%) patients in Group LD while bradycardia was seen in 2 (6.67%) patients in Group LN and 0 (00%) patients in Group LD. The incidence of nausea was similar in both groups, that is, 2 (6.67%) patients. Shivering was recorded in 2 (6.67%) patients in Group LN and 1 (3.33%) patient in Group LD [Table 3]. Other side effects such as urinary retention, pruritis, headache, backache, local anesthetic toxicity, and respiratory depression were not recorded in any of the patients in both the groups.

RESULTS

There was no statistically significant difference in patient's demographics and duration of surgery [Table 4].

DISCUSSION

Adequate pain management has become essential part in surgical patients to facilitate rehabilitation, accelerate functional recovery, and enabling patients to return to their normal activity more quickly. Spinal anesthesia is a safe and reliable method of anesthesia for abdominal and lower limb surgery, with the advantages of rapid onset of action, economical and easy to administer, and a relatively low side effects rate and shorter post-anesthesia care unit stay.[6,7] However, these advantages may be offset by the limited duration of action, or an increased likelihood of motor power recovery delay, thus delaying ambulation and prolonged hospital stay. To improve the quality of blockage and prolong the duration of analgesia, and reduce the required dose of local anesthetics, thereby reducing the incidence of side effects caused by the use of high-dose local anesthetics, such as late and severe bradycardia, hypotension, nausea, and vomiting, appropriate adjuvants are commonly used with intrathecal local anesthetics.[8,9]

The appropriate dose of intrathecal nalbuphine has been debated. It has been used as an additive with bupivacaine intrathecally in several clinical settings in doses ranging from 0.8 mg to 2.4 mg. Studies were done to evaluate the subarachnoid block characteristics with different doses of nalbuphine with bupivacaine for spinal anesthesia. It was concluded that addition of 0.8 mg of nalbuphine to 0.5% bupivacaine for subarachnoid block provides excellent analgesia with long duration of action.[10,11] Hence, based on these studies, we have chosen 0.8 mg nalbuphine for our study like various researchers.[12-14]

Various authors have studied different doses of dexmedetomidine intrathecally and concluded that better prolongation of analgesia and motor block with minimal hemodynamic changes and sedation are seen when 5 μg

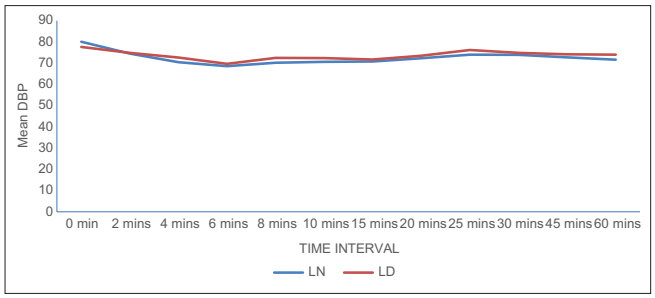

Figure 2: Systolic blood pressure in two groups at different time intervals during the intraoperative period

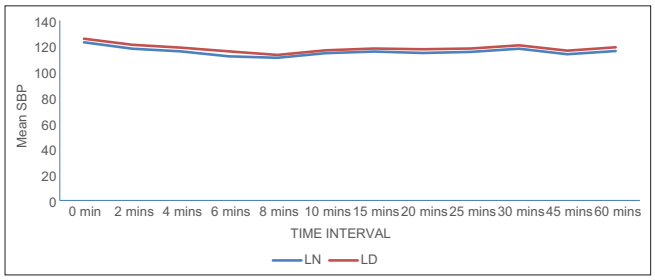

Figure 3: Diastolic blood pressure in two groups at different time intervals during the intraoperative period

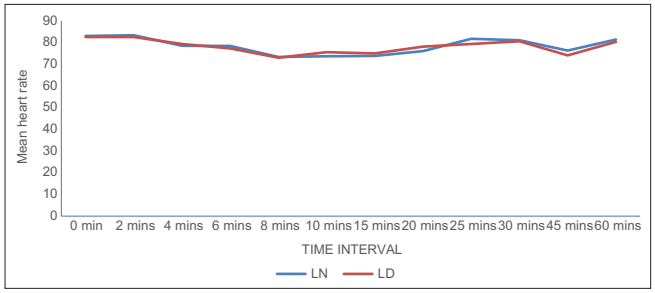

Figure 4: Heart rate in two groups at different time intervals during the intraoperative period

dexmedetomidine was used.[15-17] Based on these studies, we chose 5 μg dexmedetomidine for our study.

In our study, the onset of sensory block and motor block and time taken to achieve peak sensory level were faster in LD group compared to LN group. However, the maximum sensory level attained was comparable and statistically not significant in both groups. Srinivasan *et al.*[12] evaluated the efficacy of 3 ml of 0.5% of levobupivacaine with 0.8 mg of nalbuphine and observed that mean time to onset to T10 was 6.03 ± 1.21 min (4.33 ± 0.66 min in LN group). Shalini *et al.*[18] when evaluated the effect of 15 mg of 0.5% isobaric levobupivacaine with 1 mg nalbuphine intrathecally in patients undergoing infraumbilical surgeries observed that the mean time taken to reach maximum sensory level was 6.0 ± 2.49 min (7.33 ± 1.25 min in Group LN), time to achieve maximum motor block was 5.40 ± 2.42 min (7.00 ± 0.43 min in LN group), total duration of motor block was 235.6 ± 29.5 min (251.87 ± 8.48 in LN group), and total duration of effective analgesia was 292.1 ± 40.9 min (294.63 ± 8.95 min in LN group of the present study). Hence, the sensory and motor block characteristics of the present study are almost comparable to the above studies.

In Group LD, the onset of sensory block to T10 occurred in 2.31 ± 0.35 min. Time to maximum motor block was 6.24 ± 0.45 min and total duration of motor block was 289.67 ± 5.94 min. Duration of analgesia was 402.50 ± 9.79 min. Similar findings were observed in previous studies also. Abd Elhamid *et al.*[17] who investigated the effects of 5 μg dexmedetomidine as adjuvant to 15 mg of 0.5% levobupivacaine under spinal anesthesia observed that mean time to onset to T10 was 2.58 ± 3.25 min, total duration of motor block was 319.7 ± 92.2 min, and mean time for administering rescue analgesia was 365.4 ± 96.4 min. Kataria *et al.*[19] studied the efficacy of 3 ml (15 mg) of 0.5% levobupivacaine with 3 μg dexmedetomidine and observed that the mean time taken to maximal sensory and motor blockade (6.63 ± 0.80 min and 6.24 ± 0.45 min) was almost similar to LD group of our study.

Hemodynamic parameters revealed no statistically significant difference. Incidence of adverse effects was comparable between the groups. There was no incidence of pruritus, respiratory depression, and desaturation in both the groups. In Group LN, hypotension was observed in 3 (10%) patients and bradycardia was observed in 2 (6.67%) patients. Similar findings have been seen in a study done by Shalini *et al.*[18] using 1 mg nalbuphine as adjuvant where 10% of patients had hypotension and no patient had bradycardia. In Group LD, hypotension was seen in 2 (6.66%) patients and bradycardia was seen in 0 (0.00%) patient. Similar findings were also observed by Abd Elhamid *et al.*[17] and Elshalakany *et al.*[15] using levobupivacaine and dexmedetomidine intrathecally. Other side effects observed were nausea and shivering which were comparable in both groups.

Limitations of Study

1. Our study was done on patients of age groups of 18–60 years of age.
2. Physical Status I and II patients were included only. Hence, results may not be extrapolated to ASA Physical Status III and IV patients. Further studies are needed to know the effect of studied drugs on comorbidities such as diabetes or hypertension.
3. Measuring nalbuphine with an insulin syringe should also be meticulous as a slight mistake would alter the dosage.
4. Moreover, adding adjuvants will not only increase the sensory block duration alone but also will increase

the duration of the motor block duration which is considered as a limitation to the drug itself (not to the study) and may lead to prolonged recovery or hospital stay.

CONCLUSION

On the basis of the results of our study, we conclude that addition of 5 μg of dexmedetomidine to intrathecal 0.5% isobaric levobupivacaine as adjuvant is preferable to 0.8 mg of nalbuphine, as it provides comparatively more prolonged sensory and motor blockade with better perioperative analgesia.

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Original Article

Comparative Study between Distal Femoral Locking Plate and Retrograde Femoral Nail in Surgical Management of Supracondylar Fracture of Femur

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Abstract

Introduction: This study provide an update on the management of supracondylar femur fractures by distal femoral locking plate and Retrograde femoral nail. The purpose of this study is to evaluate the results of supracondylar fracture of femur, treated by close/ open reduction and internal fixation using retrograde intramedullary nail and locking plate and analysis of their results.

Material and Methods: This is a prospective study with Simple Random Sampling of patients treated with plate fixations or distal femoral nailing for supracondylar femur fractures. Total 40 patients were taken in which 20 cases each for plate fixation and distal femoral nailing.

Results: Distal femoral nail has shorter union time than Distal femoral locking Plate but total range of motion and extensor lag is same. Functional results are same.

Conclusion: This study concluded that results are better with both the techniques,provided done correct surgically. The plate can be adapted to all fractures, while retrograde nailing is better adapted to extra-articular fractures

Key words: Distal femoral locking plate, Distal femoral nail, Supracondylar femur fracture femur

INTRODUCTION

In the early 1960s, there was a great reluctance toward operative management of this fracture because of high incidence of infection, non-union, malunion, inadequate fixation and lack of proper instruments, implant as well as antibiotics. Then, the traditional management of displaced supracondylar fracture of femur was along the principle of Jones[1] and Charnley.[2] This comprised skeletal traction, manipulation of fracture, and external immobilization in the form of casts and cast bracings. These methods, however, met with problems such as deformity, shortening, prolonged bed rest, knee stiffness, angulation, joint incongruity, malunion, quadriceps wasting, knee instability, and post-traumatic osteoarthritis.

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The trend of open reduction and internal fixation has become evident in the recent years, with good results being obtained with the AO blade plate, dynamic condylar screw, and other implant systems such as intramedullary supracondylar nails and recently locking compression plate (LCP). During application of AO blade plate or dynamic condylar screw, creates rotational movement at the fracture site that causes pulling off the blade plate or condylar screws leading to fatigue fracture of the plates. Furthermore, the presence of osteoporotic bone leads to fixation failures with screws and plates cutting of the soft bone.

During application of distal femoral plate, the shaft of femur is often pulled laterally displacing the line of weight bearing, lateral to the anatomical axis of condyle. The obvious advantage of an intramedullary device is that it aligns the femoral shaft with condyles reducing the tendency to place varus movement at the fracture site but

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at the same time entry from the intra-articular site causes knee stiffness. LCP has the advantage of combination of conventional compression plating and locked plating techniques which enhances the plate osteosynthesis.

The advantage of an intramedullary device is that it maintains the anatomical axis, and because the bending movement of an intramedullary device is substantially reduced, failure of fixation in osteoporotic bone should be less. In addition, a retrograde intramedullary supracondylar nail has got distinct advantages of preservation of fracture hematoma, decreased blood loss, minimal soft-tissue dissection, less operative time, and reduced rate of infection. LCP has anatomically pre-contoured built reduces soft-tissue problems and acts as internal external fixator. In addition, a LCP has got distinct advantages of uni-cortical fixation and least chance of plate back out as the screw gets locked to the plate. Further, minimal soft-tissue injury occurs when closed reduction is done and minimal invasive plate osteosynthesis technique is used. The purpose of this study is to evaluate the results of supracondylar fracture of femur, treated by close/open reduction and internal fixation using retrograde intramedullary nail and locking plate and analysis of their results.

MATERIALS AND METHODS

A prospective, double-blinded, longitudinal, single cohort study with simple random sampling of patients treated with plate fixations or distal femoral nailing for supracondylar femur fractures. Twenty cases each for plate fixation and distal femoral nailing. There were 40 cases in this study. The study was conducted at the Department of Orthopaedics, NIMS Medical College and Hospital, Jaipur, Rajasthan, India. We studied our patients who fitted our criteria for the study. A written consent was obtained from all the patients. The study was done after obtaining clearance from our institutional ethical committee before the subjects are recruited and recommended.

Parameters to be studied are:

1. Assessment using standard radiographic criteria for time of union, incidence of infection, and knee function with a functional knee score.
2. Incidence of complication after surgery, namely, implant failure, wound infection, and delayed union.
3. Quality of life and pain status at follow-up.

Inclusion criteria are skeletally mature patients, fracture of supracondylar femur without intra articular extension, fracture requiring operative treatment amenable to either distal femoral nailing or locking plate, and informed consent obtained. Exclusion criteria are fracture of the supracondylar femur with intra-articular extension, open fracture involving supracondylar femur, pathological fracture, known metabolic bone disease, existing deformity in the affected limb that would complicate plating or distal femoral nailing, and immunocompromised patient. Pre-operative preparation – fractures were classified with the help of radiographs according to the AO-ASIF classification. Pre-operative calculation was done on radiographs to ascertain the length of supracondylar nail, maximum possible diameter, and lengths of interlocking bolts after subtraction of the magnification factor. After induction of patient with regional or general anesthesia, a bolster was kept underneath the knee so that knee is in 50° to 60° flexion. A cotton padding was always placed to prevent neurovascular insult.

Operative Procedure

For intra-medullary nailing – a midline incision of 4 cm was taken from inferior pole of patella up to tibial tuberosity. A straight bone awl was inserted into the joint through the split tendon and positioned against the inter-condylar notch. The femoral attachment of Posterior Cruciate Ligament is palpated and the bone awl is kept just anterior to the Posterior Cruciate Ligament attachment. The bone awl was then removed and Guidewire passed through the entry point. The fracture was reduced under image intensifier control and Guidewire passed in proximal fragment. The nail was then inserted over the guide wire through the entry point made previously through distal and then proximal fragment. Either single or both holes were locked proximally. Similarly, the distal holes were locked in one, two or three numbers.

The important step in the evolution of plating distal femur fractures was the introduction of locking plates. Distal femoral locking plates are anatomically contoured and have multiple locking screw options distally to allow for secure fixation in the typical short condylar segment. When using the plate as a reduction aid, the compression screw draws the bone toward the plate and uses the contour of the plate to reduce the fracture in the coronal plane. Reduction of the fracture was assisted keeping folded pillow below the knee which prevented posterior angulation of distal fragment with manual traction. Once the fracture is reduced, supplemental locking screws were then added to create a fixed-angle construct.

RESULTS

In our study, 40 supracondylar femoral fractures were treated. All cases were fresh, 35 patients were males and five patients were females. The median age was 47 years ranging from 28 to 70 years. Thirty-five of the fractures

were caused by road traffic accidents three were due to fall and two were due to assault. Twenty-eight patients were with fracture on right side and 12 on left side.

Average knee flexion in this study was 104° with more than 50% patients having knee range of motion more than 110°. Out of 40 patients, three patients had shortening, two patients with shortening of 15 mm, and one patient with shortening of 10 mm. In this study, very few patients had significant varus/valgus mal-alignment with two patients had deep infection which was treated with debridement and antibiotics. The duration of follow-up was 12 months.

Group of patients with distal femoral locking plate has union time of 18.4 ± 1.23 weeks while distal femoral nail has union time of 15.2 ± 4.83. $P = 0.007$ is significant. This value shows that distal femoral nail has shorter union time. The total amount of knee flexion in distal femoral locking plate is 104.75 ± 8.19, while in distal femoral nail is109.5 ± 11.46. $P = 0.14$ is not significant. Hence, both the technique has equal amount of knee flexion. The total amount of extensor lag in both the groups is also same as distal femoral locking plate has extensor lag of 5.7 ± 4.31 while distal femoral nail has extensor lag of 5 ± 6.28. $P < 0.05$ is not significant.

Neer rating[3] (0–100 Points) is done for both the groups, with distal femoral locking plate having 79.15 ± 12.05 while distal femoral nail has 76.45 ± 11.27. Results are found to be not significant. Functional outcome was not significant in both the groups.

DISCUSSION

Fractures of the distal femur often pose challenges to the trauma surgeon because of the proximity to the knee joint. In the younger age group, the injury is usually a result of high velocity vehicular crashes. In older patients with osteoporotic bone, it is often due to low energy injuries especially falls. In either case, the fracture is usually comminuted. Treatment requires skill and meticulous technique for good outcome. A variety of devices have been used in the treatment of supracondylar femoral fractures. The locking plate relies on the principles of open reduction, absolute stability and inter-fragmentary compression to achieve union. The technique of retrograde nailing uses indirect reduction of the metaphyseal fracture component, offering relative stability, and a less invasive approach.

Internal fixation of supracondylar femoral fractures using distal femoral locking plate produces good results in most cases. However, the incidence of bone infections is high. In case of distal femoral nail, there is a trend for patients undergoing retrograde nailing to complain of more pain and to require revision surgery for removal of implants. There seems to be a tendency toward progression to arthritis particularly in fractures treated by distal femoral nail. The quality of the surgical technique is the primary factor, and the only guarantee of obtaining good radiological and clinical results in supracondylar femoral fractures. Mini-invasive treatment (nailing or plates) seems to provide better results.

Markmiller *et al.*[4] prospectively compared the outcome of condylar blade plate and retrograde intramedullary nail. At 12 months, no statistically significant differences were noted with non- union, fixation failure, infection, and secondary surgical procedure.

Hierholzer *et al.*[5] confirmed these results in a retrospective series of 115 fractures comparing retrograde nailing ($n = 59$) and mini-invasive locking plate ($n = 56$). The authors describe the indications for each technique: The plate can be adapted to all fractures, while retrograde nailing is better adapted to extra-articular fractures. They emphasize that high quality results are more dependent on the surgical technique than the choice of implant.

Hartin *et al.*[6] did not observe any difference in functional recovery in a randomized comparison of the treatment of extra-articular fractures by retrograde intramedullary nailing and blade plate. The only element observed was more frequent pain in the knee in the retrograde nailing group, so that fixation material had to be removed in 25% of the cases.

For Thompson *et al.*, statistical results for the rate of surgical revision and the rate of malunion are better for retrograde intramedullary nailing. The rates of infection and nonunion were higher in the open internal fixation group. Zlowodzki *et al.*[7] compared LCP, blade plates, and retrograde nailing in extra-articular fractures. Strength under axial compression was better with the LCP system than with the blade plate or nailing, by 34–13%, respectively, but strength under torsion was reduced.[8-12] The authors observed better distal fixation with the LCP system with loss of distal fixation in only one LCP plate (6%), three blade plates (38%), and eight losses with retrograde intramedullary nailing (100%).[13,14]

CONCLUSION

The goal of this study was to provide an update on the management of these fractures by two modalities of treatment. The technical details and the indications of both the surgical treatments are described and from our study

it can thus be concluded that results are better with both the techniques. The surgical technique must be rigorous and the biomechanical qualities of both the implants must be understood to prevent the development of major complications. The plate can be adapted to all fractures, while retrograde nailing is better adapted to extra-articular fractures. They emphasize that high quality results are more dependent on the surgical technique than the choice of implant. On the other hand, results comparing retrograde nailing and classic open internal fixation are clear.

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Original Article

A Study of Epidemiology and Analysis of Outcome of Facial and Scalp Burns by Satisfaction Smiley Score in a Tertiary Burn Care Center in South India

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Abstract

Background: Face is a symbol of beauty. Facial burn is a major blow to the burn victim, as it not only causes skin changes esthetically but also affects function. Government Kilpauk Medical College Hospital has a tertiary burn care center catering to all types of burns.

Aim: This study aims to do an epidemiological survey of facial and scalp burns in all the surviving inpatients and to do a follow-up analysis using satisfaction score of patient and surgeon with referral to the various treatment modalities done for the reconstruction of facial and scalp burns injuries.

Materials and Methods: A retrospective study of facial and scalp involvement in all burn victims who were admitted from January 2018 to December 2019 in the Department of Burns, Plastic, and Reconstructive surgery, Government Kilpauk Medical College Hospital, Chennai, was done. All surviving patients with burns in face and scalp were included in this study. A total of 697 patients included in this study were analyzed for the distribution of facial and scalp burns and the various treatments carried out. Among these 697 patients, 274 (39.3%) participated in the study for outcome analysis.

Discussion and Results: Different etiologies of burns cause varying depth of burn, hence, management can be conservative or surgical. Superficial burns can be managed conservatively. Deeper burns depending on depth, wound can be covered with skin graft or flap. Outcome was analyzed after doing smiley face scoring by patient and assessor based on function, anatomical integrity, and esthetic outcome.

Conclusion: The incidence of face and scalp burn in different age groups, total burn surface area of burns, and the outcome of different procedures done in the acute phase and follow-up with satisfaction scores of patient and plastic surgeon was analyzed and presented.

Key words: Anterolateral thigh flap, Burn outcome score, Burn survivor, Facial and scalp burns, Total body surface area

INTRODUCTION

Face is a symbol of beauty. Facial movements are needed for expression of feelings. Lip seal is required to avoid drooling of saliva and eyelid closure is essential for prevention of corneal ulceration. Facial burn is a major blow to the burn victim, as it not only causes skin changes esthetically but also affects function. Our hospital has a tertiary burn care center catering to all types of burns.

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Burn injuries pertaining exclusively to the face and scalp are quite rare. They are usually associated with burn over other areas also. The final outcome of the facial and scalp burns depends on the burn injuries occurring over other regions, total body surface area (TBSA) involved, degree of the burns, inhalational burns, the time of arrival to burn center, the associated comorbidities, and finally, the patient's and his/her attendee's cooperation in the management of the burns.

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Aim

The aim of the study was as follows:

- To study the epidemiology of facial and scalp burn involvement in surviving burn patients.
- To statistically analyze the satisfaction of treatment provided.

Literature Review

There are various articles that deal with facial burns. Friedstat *et al.* and Bagby deal with the acute management of facial burns.[1,2] Handling of facial burns in an emergency set up was discussed in one editorial article.[3] Treatment of second-degree facial burns with allografts was quoted in a study by Horch *et al.*[4] Long-term survival of human skin allografts in patients with immunosuppression was discussed by Wendt *et al.*[5] Topical management of facial burns were discussed in a review article by Leon-Villapalos *et al.*[6] In another study, the protocol for the use of Biobrane dressing for the facial burns in children was introduced by Rogers *et al.*[7] The motor movements and facial mimic in patients with head-and-neck burns were evaluated by a team in Brazil.[8] Epidemiology of burns throughout the world was dealt with by Peck.[9] A systematic review about recent trends in burn epidemiology worldwide was done by Smolle *et al.*[10] A retrospective multicenter study was done for epidemiology and outcome analysis of facial burns by Tian *et al.*[11]

MATERIALS AND METHODS

All the surviving burn patients in all age groups involving facial and scalp burns who were admitted during the period of January 2018–December 2019 for 2 years were included in the study. This study was a retrospective study done in the department of burns, plastic, and reconstructive surgery in our institute. Epidemiology and various modalities of the treatment given during acute stage of the facial and scalp burns regions were analyzed.

Among these survivors, persons who gave consent for follow-up study of outcome analysis were followed up for minimum of 9 months, and at the end of follow-up, a smiley scoring study was done. This part was prospective study. Both the concerned person, and assessor who is the plastic surgeon other than the one who has operated the case did the scoring and these were compiled and analyzed statistically.

Observations

The total number of burn victims who were admitted during the years 2018 and 2019 includes 1622 and 1504, respectively. The numbers of deaths due to burns were 752 and 688 during the years 2018 and 2019, respectively. Hence, the case fatality rate for burns was 46.07% for the 2 years.

The total number of burn survivors with facial and scalp burns during the years 2018 and 2019 was 379 and 318, respectively. Among the survived 1686 burn victims admitted in the hospital, about 697 (41.3%) patients were found to have facial and scalp burns during the period of 2 years from January 2018 to December 2019 [Table 1].

Considering the age of the burn victims, facial and scalp burns in victims aged between 12 and 50 years were highest with 414 cases (59.4%). The facial and scalp burns in pediatric age group <12 years were about 172 cases (24.7%), and 15.9% of cases were in the age group of more than 50 years (111 cases) [Figure 1].

Among the 697 burn victims with facial and scalp burns for the 2 years duration, 420 patients were male (including male children of about 112), and 277 patients were female (including female children of about 60) [Figure 2]. Four hundred and twenty male patients (42.3%) of 993 survived male burn patients had facial and scalp burns. Two hundred and seventy-seven female patients (40%) of 693 survived female burn patients had facial and scalp burns [Table 2].

According to the mode of injury, analyzing distribution of facial and scalp burns for the 2 years 2018 and 2019, accidental involvement was predominant with 561 patients

Table 1: Total number of facial and scalp burns among the survived total burn patients admitted during the year of 2018 and 2019, and its percentage

Year	Total burns patients admitted	Total burns patients survived among admission	Total number of facial and scalp burns patients (%)
2018	1622	870	379 (43.6)
2019	1504	816	318 (39)
Total	3126	1686	697 (41.3)

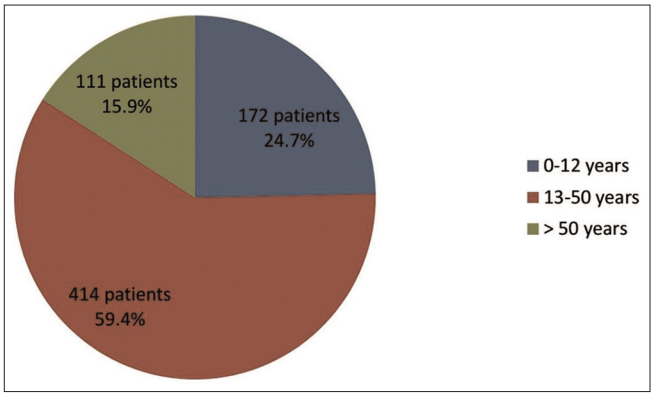

Figure 1: Number of facial and scalp burns victims according to the age

(80.5%). Suicidal involvement was in 116 (16.6%) patients with facial and scalp burns. Homicidal patients were the least with 20 patients (2.9%) [Figure 3].

Among the various etiologies of the burns, flame burn with 52.8% was the primary reason for the facial and scalp burns followed by scalds with 27.1% [Figure 4]. About one-third (32.3%) of survived total burns from scalds had facial and scalp burns [Table 3].

Involvement of face and scalp can vary from 1% to 19% TBSA depending on the area affected and age group. The number of burn victims with 3–6% facial and scalp burns was 419 (60.1%), which was the highest. The least affected were in the group with <2% burn involvement of face and scalp [Table 4]. The number of patients with facial and scalp burns included in this study with 11–40% TBSA burns was highest with 421 patients (60.4%) followed by those with more than 40% TBSA burns with 193 patients (27.7%) [Table 5].

Table 2: Total number of survived burn patients and total number of facial and scalp burn patients in male and female category

Gender	Total number of burn patients admitted	Total number of survived burn patients	Total number of facial and scalp burns patients (%)
Male	1573	993	420 (42.3)
Female	1553	693	277 (40)
Total	3126	1686	697 (41.3)

Table 3: Total number of facial and scalp burns among the total number of survived burn victims and percentage in different etiologies

Etiology of burns	Total number of survived burn victims	Total number of facial and scalp burn victims (%)
Flame burns	845	368 (43.6)
Scalds	585	189 (32.3)
Electrical burns	147	66 (44.9)
Chemical burns	40	26 (65)
Cracker burns	43	34 (79)
Rescue burns	26	14 (53.8)
Total	1686	697 (41.3)

Table 4: Distribution of number of patients having different range of percentage of facial and scalp burns

Percentage of facial and scalp burns	Year 2018	Year 2019	Total
1–2%	48	45	93
3–6%	238	181	419
7% and above	93	92	185

Most of the patients with facial and scalp burns in this study were treated conservatively with 418 patients (60%) followed by those treated with skin graft with 147 patients [Figure 5].

Outcome Satisfaction Analysis

Among the 697 facial and scalp burn victims for the 2 years 2018 and 2019, 274 patients (39.3%) participated in the outcome analysis. They were followed for minimum of 9 months. A smiley face score from 1 to 6 was provided [Table 6]. The smiley score was given by the patient

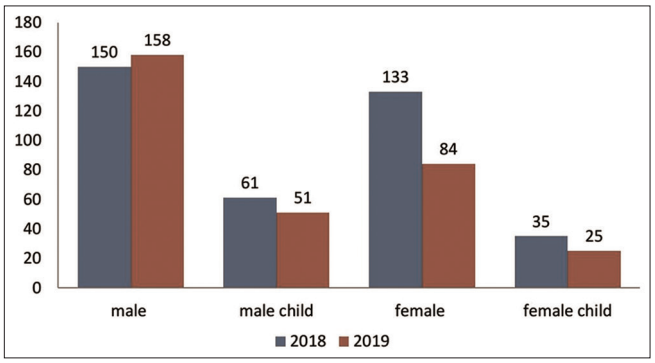

Figure 2: Sex distribution of facial and scalp burns for 2 years 2018 and 2019 (Y-axis shows the number of affected individuals)

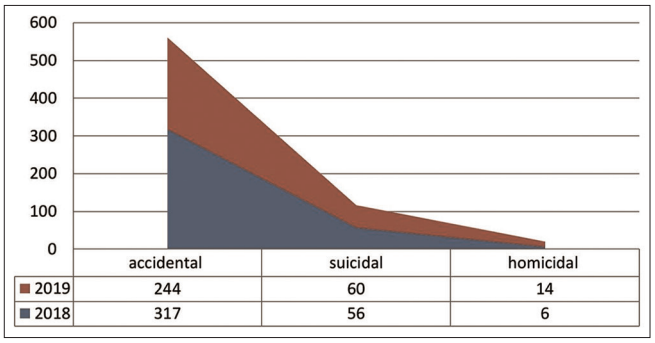

Figure 3: Distribution of cases according to the mode of injuries (Y-axis shows the number of affected individuals).

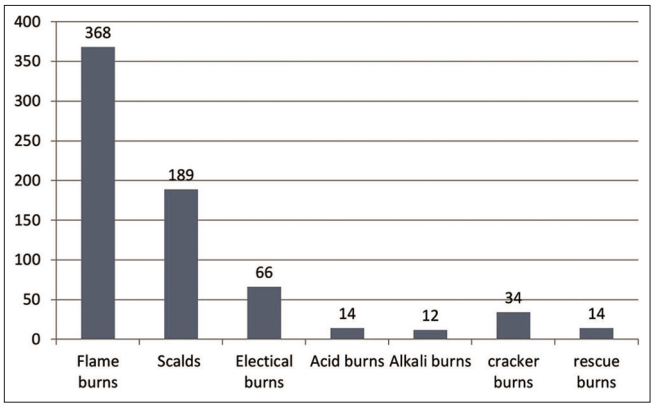

Figure 4: Various etiologies of facial and scalp burns for the 2 years (Y-axis shows the number of affected individuals).

himself/herself or by the patient's parents for children. The smiley score was also given by plastic surgeon who has not operated/treated the patient. The parameters which were considered in calculating smiley score by the assessor include function, anatomical integrity, and esthetic outcome.

Among the 274 patients who participated in the outcome satisfaction analysis, only 27 (10%) patients had same smiley score given by patient and surgeon. These patients were categorized into two groups – (a) satisfied group having smiley score 4 and above and (b) not satisfied group having smiley score 3 and below.

Outcome satisfaction was analyzed statistically by McNemar test under various categories which were tabulated. Based on depth of wounds, based on the mode of treatment, and based on region involved, the outcome satisfaction analysis was done.

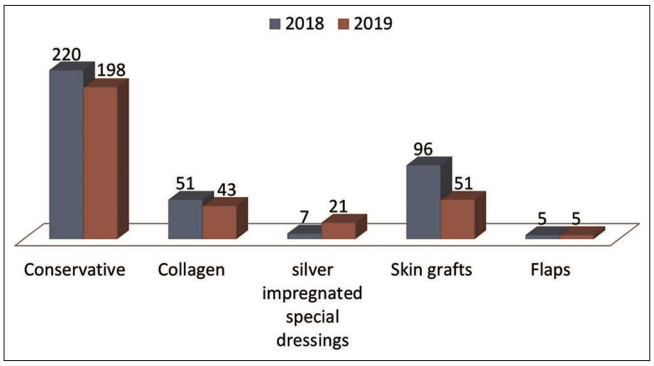

Figure 5: Number of facial and scalp burn victims who had undergone various treatments in this study for 2 years.

Table 5: Number of patients with facial and scalp burns having different TBSA burns percentage for the 2 years 2018 and 2019

TBSA percentage of burns	Year 2018	Year 2019	Total
10% and below	47	36	83
11–40%	229	192	421
>40%	103	90	193

TBSA: Total burns surface area

Table 6: Smiley score for outcome satisfaction analysis of facial burns

Outcome satisfaction	Smiley face	Score
Satisfied completely		6
Moderately satisfied		5
Satisfied		4
Unsatisfactory		3
Moderately unsatisfactory		2
Not satisfied completely		1

DISCUSSION

Out of 1686 burn survivor in the study period of 2 years from January 2018 to December 2019, 697 patients had facial and scalp burns. Hence, the incidence in survivor was 41.3% [Table 1]. The incidence of burns on the head and neck was found to be 65.63% in a retrospective multicenter study from 2011 to 2015 in China, but in this study, it included all burn victims including death.[11]

Face and scalp involvement in burns was noted in a baby of 8 days (youngest) and the oldest burn patient was 91 years with facial and scalp burns in this study. Maximum number of burn victims with facial and scalp burns were noted in the age group of 13–50 years with 414 patients contributing to 59.4%. One hundred and seventy-two patients with facial and scalp burns (24.7%) were in the age more than 50 years. The pediatric age group with <12 years was the least in number with 111 patients (15.9%) [Figure 1].

Contrary to popular belief, in this study, males predominated female in having facial and scalp burns with 1.52:1 and even in pediatric age group <12 years, male children predominated female children in having facial and scalp burns with 1.87:1 [Figure 2]. However, on analyzing the total number of survived burn patients and total number of facial and scalp burns in both genders, male had 42.3% and female had 40% of total survived burn patients [Table 2]. The increased survival among males caused increased number of male burn patients having facial and scalp burns. Predictors of facial burns were described in a retrospective study of facial burns and they have inferred male sex, work-related burns, flame burns, increased TBSA, and full-thickness burns were more prone to higher incidence corresponding to our finding.[11]

There are various modes of burn injury to face and scalp – accident, suicide, or homicide. In this study, accidental burn injuries to face and scalp were common with 80.5% followed by suicidal burn injuries with 16.6% and homicidal burn injuries with 2.9% [Figure 3].

Coming to the etiology of the burns to face and scalp, it could be due to flame burns, scalds, cracker burns, chemical burns – acid/alkali burns, and electrical burns. In retrospective multicenter study for 4 years, injuries due to flame were the most common cause of facial burns.[11] Scalding was the most common mechanism of burn (53.9%) in a retrospective study of burns conducted in Beirut, Lebanon, but here they included burns involving all regions.[12] In our study, flame burns to face and scalp were common with 52.8% of cases, followed by scalds with 27.1%, electrical burns with 9.4%, cracker burns with 4.8%, and chemical burns including acid and alkali burns with 3.7% [Figure 4]. On comparing the total number of survived burn victims admitted with the number of burn victims with facial and scalp burns, 43.6% of survived total burns from flame burns had facial and scalp burns. About 44.9% of survived total burns from electrical burns had facial and scalp burns. About 79% (almost $4/5^{th}$) of survived total burns from cracker burns had facial and scalp burns, which is obviously due to cracker injuries by flower pot or due to bursting crackers without safety precautions. About two-third (65%) of survived total burns from chemical burns had facial and scalp burns due to vitriolage [Table 3].

The treatment of acute thermal burns of the face in burn center starts with management of airway, circulation, and pain control.[13-15] Involvement of facial and scalp burns is prone to inhalational burns and respiratory burns. This leads to respiratory embarrassment eventuating to mechanical ventilation by oral endotracheal tube or tracheostomy.[16-19] In our study, only those patients who recovered from all these initial complex problems and who survived were included in the study.

The nutritional requirement is higher due to increased metabolic rate in burns and is dependent on the extent of burns determined by TBSA calculated by various formulas such as Wallace, Lund, and Browder chart. In this study, burns percentage calculation was done by following Lund and Browder chart. According to Lund and Browder chart, face and scalp contribute to 7% in adults, 9% in 15 years, 11% in 10–14 years, 13% in 5–9 years, 17% in 1–4 years, and 19% in infants <1 year. In this study, it was found that for the 2 years 2018 and 2019, the patients having facial and scalp burns with 3–6% were the highest with about 419 patients out of 697 (60.1%), followed by those with 7% burns and above which was found to be 185 patients (26.6%), and those with 1–2% facial and scalp burns were the least with 93 patients (13.3%) [Table 4].

In this study, it was also found that 421 patients with facial and scalp burns had 11–40% TBSA burns out of 697 patients for 2 years 2018 and 2019 contributing to 60.4%. One hundred and ninety-three patients (27.7%) with facial and scalp burns had more than 40% TBSA burns. This less number of patients in this category was due to decreased survival in patients having more than 40% TBSA burns. Eighty-three patients with facial and scalp burns (11.9%) had 10% and below TBSA burn [Table 5].

The facial and scalp burns are treated conservatively by doing simple non-adherent paraffin dressing in case of first-degree burns and second-degree burns. If the burn is found to be second-degree superficial burns particularly due to scalds, collagen dressing would be ideal. Collagen dressing was applied in these cases particularly in pediatric age group, as it does not require dressing changes which is painful and requires anesthesia. In case of mixed burns with second-degree superficial and second-degree deep burns, silver impregnated dressings can be tried in selected cases and it depends on the availability due to its high cost. Third-degree burns involving full thickness of skin require skin grafts. Resurfacing the burn injuries over face with graft is based on the esthetic subunits of face to prevent secondary contracture.[20] Early excision of burn wound and resurfacing with skin graft particularly over face gives early healing of wound and better esthetic outcome.[21-28] Fourth-degree burns exposing bone, vessels, and other vital structures require flap cover. The above protocol of treatment was followed in this study. In this study, conservative management predominated with 418 patients due to rich vascularity of face and scalp, followed by skin grafts with 147 patients, and collagen dressing in 94 patients [Figures 5 and 6]. Silver-impregnated special dressings were tried in 28 patients. In only 10 patients with burn wound over face and scalp, flap cover was required primarily [Figure 5]. Among these 10 patients, two patients with scalp defect were treated with scalp rotational flaps, four patients with scalp defect were treated with scalp transposition flaps, one patient with scalp defect was treated with bipedicled scalp flap, two patients with defect over face exposing mandible were treated with free anterolateral thigh flap, and one pediatric patient with nasal defect was treated with pedicled forehead flap [Figure 7]. These flap patients were advised to have further surgical correction such as flap thinning and tissue expansion for scalp to improve the cosmetic appearance, and some of them deferred due to personal reasons. Overall, 157 patients out of 697 facial and scalp patients (22.5%) were treated surgically with skin graft and flap.

After healing of burn wounds, patients were followed for minimum of 9 months regularly for physiotherapy, oil massage, and compression garments to prevent hypertrophic scar. In some patients, secondary surgical procedures such as flap thinning, flap adjustments, ectropion of eyelid, and lip correction were required to

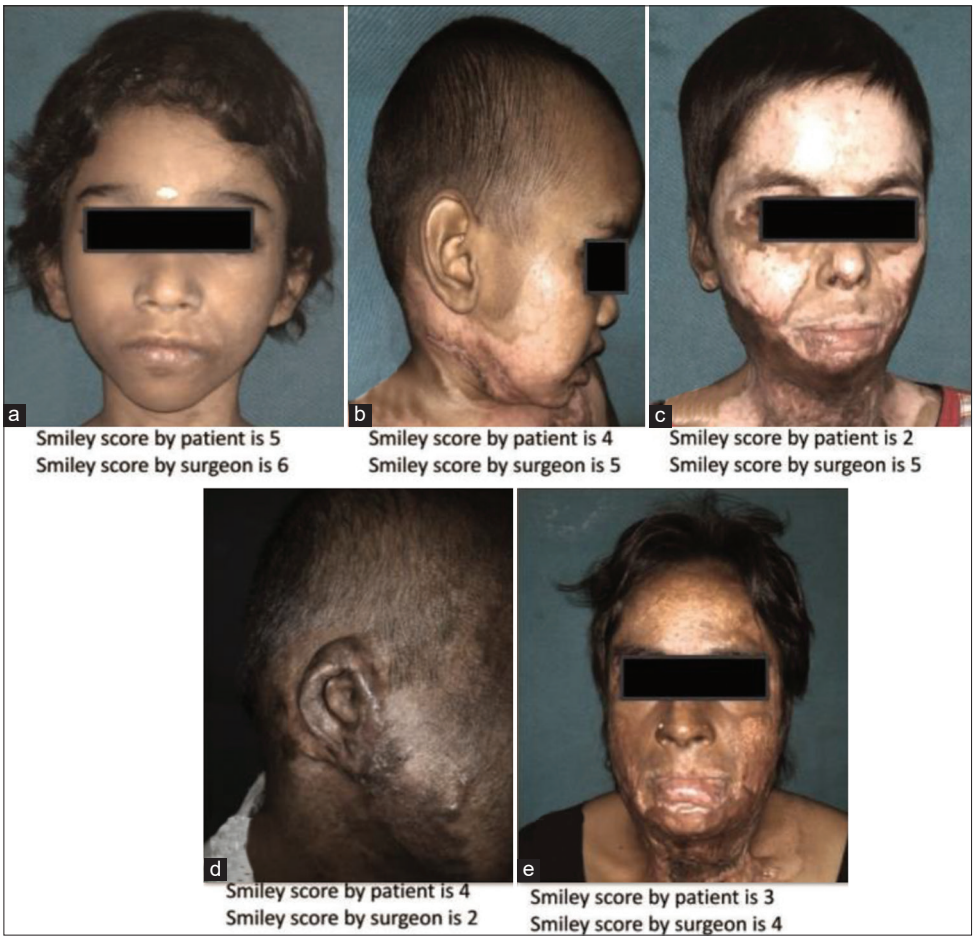

Figure 6: Five patients with the smiley scores, one patient with facial burn who was treated conservatively (a), other one was treated with collagen (b), the third one was treated with skin graft (c), fourth one with ear burns (d), and fifth one with second degree deep burns with hypertrophic scar (e)

Figure 7: Three patients, one patient with scalp defect following electrical burns exposing parietal and temporal bone which was covered with scalp transposition flap (a), another patient with facial burns, with injury to left eye, ectropion of left eyelid and deformity of mouth exposing mandible which was treated with free anterolateral thigh (ALT) flap (b) and another patient with electrical burns which was treated with pedicled seagull forehead flap for the reconstruction of nose and skin graft for the cheek (c)

correct the deformities caused by burn scar contracture, which was done as and when required.

Outcome Satisfaction Analysis

Satisfaction of outcome of all burn cases included in this study was analyzed. It was found that the proportion of agreement between surgeon and patient satisfaction is 46.4%. While analyzing the results statistically by McNemar test, $P<0.0000001$ (<0.05) is statistically significant. Here, the perception about the satisfactory outcome by the patient and assessor was the same in 127 (115+12) patients (46.4%). In remaining 147 patients, surgeon was satisfied,

but patient was not satisfied in 107 patients, and surgeon was not satisfied, but patient was satisfied in 40 patients. Since the P value is statistically significant, the difference of opinion about their satisfaction by the surgeon and patient is valid and not occurred by chance [Table 7].

These 274 patients were divided into two groups based on depth of burns. Superficial burn group included patients with first-degree burns and second-degree superficial burns and, it was found that 76 patients were in this group. Deep burn group included patient with second-degree deep burns and third-degree burn and, it was found that 198 patients were in this group. While analyzing the superficial burn group, *P* value by McNemar test is 0.13361 (>0.05) which is statistically not significant [Table 8]. This implies the difference of opinion about their satisfaction by the surgeon and patient is not valid and occurred only by chance. While analyzing the deep burns group, $P = 0.00$ (<0.05) is statistically significant. Here, the perception about the satisfactory outcome by the patient and assessor was the same in 47 (35+12) patients (23.7%). In remaining 151 patients, surgeon was satisfied, but patient was not satisfied in 107 patients, and surgeon was not satisfied, but patient was satisfied in 44 patients. Since *P* value is statistically significant, the difference of opinion about their satisfaction by the surgeon and patient is valid rather than by chance [Figure 6]. Hence, in 76.3% of the patients, what the surgeon perceived about the satisfactory outcome was not the same as the patients [Table 9].

Two hundred and seventy-four patients were further categorized into three groups based on the mode of treatment – non-surgical, skin graft, and flaps. Among these 274 patients, 156 patients were treated conservatively, 108 patients were treated with skin grafts and 10 patients with flaps. On analyzing the outcome satisfaction of patients treated non-surgically, $P = 0.0175$ (<0.05) is statistically significant. Here, the perception about the satisfactory outcome by the patient and assessor was the same in 80 (76+4) patients (51.3%). In remaining 76 patients, surgeon was satisfied, but patient was not satisfied in 52 patients, and surgeon was not satisfied, but patient was satisfied in 24 patients [Table 10]. On analyzing the outcome satisfaction of patients treated with skin graft, $P = 0.0026$ (<0.05) is statistically significant. Here, the perception about the satisfactory outcome by the patient and assessor was the same in 36 (28+8) patients (33.3%) [Table 11]. This implies that difference of opinion about their satisfaction with those treated conservatively and those treated with skin graft is valid [Figure 6]. However, those treated with flaps, outcome satisfaction is not valid since $P = 0.24821$ (>0.05) is statistically not significant [Table 12].

While analyzing the burns region wise, 31 patients were found to have scalp burns and $P = 0.72367$ (>0.05) is

Table 7: Statistical analysis of outcome satisfaction of all facial and scalp burns patients

Surgeon \ Patient	Satisfied	Not satisfied	Total
Satisfied	115	107	222
Not satisfied	40	12	52
Total	155	119	274

The proportion of agreement between surgeon and patient satisfaction is 46.4%. The *P* value by McNemar two-tailed test is<0.0000001 (<0.05) – statistically significant

Table 8: Statistical analysis of outcome satisfaction of superficial burns patients

Surgeon \ Patient	Satisfied	Not satisfied	Total
Satisfied	72	4	76
Not satisfied	0	0	0
Total	72	4	76

McNemar test statistic value is 2.25. *P*=0.13361 (>0.05) – statistically not significant

Table 9: Statistical analysis of outcome satisfaction of deep burns patients

Surgeon \ Patient	Satisfied	Not satisfied	Total
Satisfied	35	107	142
Not satisfied	44	12	56
Total	79	119	198

The percentage agreement is 23.7%. McNemar test statistic value is 25.45695. *P*=0.00 (<0.05) – statistically significant

Table 10: Statistical analysis of outcome satisfaction of patients treated non-surgically

Surgeon \ Patient	Satisfied	Not satisfied	Total
Satisfied	76	52	128
Not satisfied	24	4	28
Total	100	56	156

The percentage agreement is 51.3%. McNemar test statistic value is 9.59211. *P*=0.0175 (<0.05) – statistically significant

Table 11: Statistical analysis of outcome satisfaction of patients treated with skin graft

Surgeon \ Patient	Satisfied	Not satisfied	Total
Satisfied	28	52	80
Not satisfied	20	8	28
Total	48	60	108

The percentage agreement is 33.3%. McNemar test statistic value is 13.34722. *P*=0.0026 (<0.05) – statistically significant

Table 12: Statistical analysis of outcome satisfaction of patients treated with flaps

Surgeon \ Patient	Satisfied	Not satisfied	Total
Satisfied	7	3	10
Not satisfied	0	0	0
Total	7	3	10

The percentage agreement is 70%. McNemar test statistic value is 1.33333. *P*=0.24821 (>0.05) – statistically not significant

Table 13: Statistical analysis of outcome satisfaction of patients with scalp burns

Surgeon \ Patient	Satisfied	Not satisfied	Total
Satisfied	23	4	27
Not satisfied	4	0	4
Total	27	4	31

The percentage agreement is 74.2%. McNemar test statistic value is 0.125.
P=0.72367 (>0.05) – statistically not significant

Table 14: Statistical analysis of outcome satisfaction of patients with ear burns

Surgeon \ Patient	Satisfied	Not satisfied	Total
Satisfied	0	0	0
Not satisfied	36	2	38
Total	36	2	38

The percentage agreement is 5.3%. McNemar test statistic value is 34.02778.
P=0.00 (<0.05) – statistically significant

statistically not significant [Table 13]. Thirty-eight patients were found to have ear burns and here it was found that assessor was not satisfied in all 38 patients, but 36 patients were satisfied with their final outcome. While analyzing the satisfaction outcome by those with ear burns, it was found that $P = 0.00$ (<0.05) is statistically significant [Table 14]. This shows that the difference of opinion about the satisfaction in those with ear burns is valid rather than by chance [Figure 6].

In burn surgery, the form and function in more important, but in esthetic surgery, esthesis is of utmost importance. It is not possible to give 100% satisfaction to the patient based on the esthesis, since burn surgery is entirely different from esthetic surgery.

Limitations

Accidental victims usually will have more burns over extremities and trunk, and suicidal victims will have more burns over face and scalp. However, in this study, accidental victims with facial and scalp burns (80.5%) were more compared to suicidal victims (16.6%). This could be due to higher mortality in suicide burns or due to hiding the suicidal facts by the patients and their attenders and changing their statement from suicidal to accident as mode of injury. This could be subjective variance by patient and their attenders to events. The outcome analysis was done by the patient and assessor. Hence, there could be subjective variance by the patient.

CONCLUSION

Adult male burn survivors have higher incidence of face and scalp involvement. Accidental flame burns have shown higher involvement of face and scalp burns. Survival is better in inpatients with <40% TBSA burns. The incidence of facial and scalp burns in survivor was 41.3%.

The final outcome of satisfaction is based on the patients' perception about themselves. The views about satisfactory outcome done by smiley score are valid in patients with deep facial and scalp burns, and those treated conservatively. Perception of satisfaction or unsatisfaction about outcome of treatment both by surgeon and patient is significant when skin grafting has been done or when ear burn has been managed. Overall, perception of outcome by surgeon and patient is the same in about 46.4% of the patients included in this study.

The yardstick of satisfaction may have to be tilted differentially by the burn surgeon from an esthetic surgeon, while dealing with patients having facial and scalp burns. This mindset self-motivates the burn surgeons and this will help the burn surgeons to improve their skills.

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Original Article

Is Pre-operative Screening of Cultures of Urine and Nasal Swab is Useful in Patients Undergoing Total Knee Arthroplasty?

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Abstract

Background: Infection is a major complication after total joint arthroplasty. The urinary and nasal tract is a possible source of surgical site contamination but the role of asymptomatic bacteriuria before elective surgery and subsequent risk of infection is poorly understood.

Aim: This study aims to identify a correlation between pre-operative screening of urine and nasal culture/sensitivity and prosthetic joint infections postoperatively in patients undergoing total knee arthroplasty (TKA).

Methods: Patients undergoing TKA from July 2015 to March 2016 were reviewed in our center for a period of 6 months. In all cases, a urine sample and a nasal sample were cultured. Symptomatic urinary tract infection and patients with significant growth (>1 lac colony counts/ml) were treated with sensitive antibiotics for 7 days. Patients with asymptomatic bacteriuria or colony counts <1 lac/ml were not treated with any antibiotics. Patients were followed up for 6 months.

Results: A total of 624 patients were enrolled in the study. In 35 (0.056%) patients, urine routine was positive for pus cells (>=10 pus cells/hpf) and out of them 25 (0.04%) patients were positive for urine culture. The study was undertaken over 6 month period, and only 2 patients (0.003%) developed a wound site infection, however, these case were negative for pus cells in urine routine as well as urine culture examination. None of the patients had a positive growth in their nasal cultures. All urine cultures returned Gram-negative infections with the exception of one being a fungal infection.

Conclusion: The role of pre-operative nasal swab and urine cultures and the presence of asymptomatic bacteriuria are independent of the causation of prosthetic joint infections and are not warranted in our population.

Key words: Bacteriuria, Total knee arthroplasty, Urine cuture

INTRODUCTION

Infection is one of the most serious complications after total knee arthroplasty (TKA). Revision of TKA because of infection is associated with long hospitalization, many operations, and with a current mortality rate of 1–2.7%.[1-5] Although its reported incidence now is <1%, its treatment is among the most expensive of orthopedic procedures. The importance of prevention is critical because of the devastating clinical and economic consequences.

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Urinary tract infection (UTI) is a common nosocomial infection creating potential bacteremia.[6,7] The presence of a urinary catheter is the main risk factor for UTI[8-10] and can precipitate bacteremia.[11-15] In orthopedic surgery, UTI as a source for joint infection is the subject of controversy.[16] Some authors suggest that UTI should be treated before the joint arthroplasty[6] whereas others have stated that there are no well-documented data to support the association between UTI and joint infection.[17,18] Some authors report an association between post-operative bladder catheterization and subsequent joint infection.[12,15,16] However, these data are from case reports or case series[12,15,16] and their validity is questionable.[7]

We, therefore, asked whether a treated pre-operative UTI or asymptomatic bacteriuria increases the risk of joint

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infection and whether the organisms are the same when UTI and joint infection occur in the same patient.

The urinary and nasal tract is a possible source of surgical site contamination but the role of asymptomatic bacteriuria before elective surgery and subsequent risk of infection is poorly understood. Whether patients with asymptomatic bacteriuria in nasal swab and urine should be investigated and treated before elective total knee replacement (TKR) remains controversial.

Many orthopedic surgeons do not routinely test urine and nasal swab. The American Academy of Orthopaedic Surgeons recommends urine analysis only for patients with a history of frequent urinary infections,[17] but other organizations[18] and authors[19-28] avoid definitive guidance. A postal survey in the United Kingdom reported that two-thirds of orthopedic surgeons would treat asymptomatic bacteriuria before TKR, but 70% had no evidence to cite as a reason for this practice.[8]

Our present study is to identify a correlation between pre-operative screening of urine and nasal swab culture and sensitivity and prosthetic joint infections postoperatively in patients undergoing TKA.

Aims and Objectives

This study aims to identify a correlation between pre-operative screening of urine and nasal swab culture and sensitivity and prosthetic joint infections postoperatively in patients undergoing TKA.

MATERIALS AND METHODOLOGY

Ethics committee approval was taken from the Institutional Review Board (IRB), Ganga Hospital and Research Pvt. Ltd., Coimbatore, Tamil Nadu, India.

In this study, we did urine routine examination, urine culture, and nasal swab culture in every patient, undergoing TKA. In patients with significantly positive culture (>1 lac colony counts/ml), 1 week antibiotic treatment was given according to the culture and sensitivity. Patients underwent TKA with regional anesthesia and pre-operative antibiotics, inj. ceftriaxone 1.5 g and inj. amikacin 1 g. i.v., were given followed by two doses of inj. ceftriaxone 1.5 g. postoperatively. Plain bone cement (without antibiotic) was used. Most patients had only a subcutaneous drain. Aspirin and mechanical devices were used for DVT prophylaxis.

Patients with post-operative urinary retention were catheterized by Foley's catheter which was removed after ambulation. Patients with symptomatic UTI were started on empirical antibiotic and switched on other antibiotic according to culture and sensitivity. All these patients were followed for a period of 6 months.

Design of the Study

This was an observational study.

Data Collection

Prospective.

Sample Size and Study Duration

Patients undergoing TKA from July 2015 to March 2016 were reviewed in our center for a period of 6 months in Ganga Hospital, Coimbatore, Tamil Nadu.

In all cases, a urine sample and a nasal sample were cultured. Symptomatic UTI and patients with significant growth (>1 lac colony counts/ml) were treated with sensitive antibiotics for 7 days. Patients with asymptomatic bacteriuria or colony counts <1 lac/ml were not treated with any antibiotics.

Patients were followed up for 6 months postoperatively asking for details of signs and symptoms of prosthetic joint infection, any eventual pathogens, and any related treatment with antibiotics.

RESULTS

A total of 624 patients (male 205 [32%] and female 419 [62%]) were studied, who undergone TKR in Ganga Hospital for a period of 6 months between July 2015 and March 2016.

The mean age of the patients was 69.1 years and, all were followed up postoperatively 6 months for potential prosthetic joint infection of urinary or nasal or both origins. One hundred and thirty-one patients (20%) were diabetic.

Out of 624 TKR patients, 224 (35%) patients required post-operative catheterization which remained *in situ* for more than 12 h.

In 35 (0.056%) patients, urine routine was positive for pus cells (>=10 pus cells/hpf) and out of them 25 (0.04%) patients were positive for urine culture.

Organism was found in urine culture in the following numbers of patients:

- *E. coli* – 21
- *Klebsiella* – 2
- *Proteus* – 1
- *Candida* – 1.

Fifty-seven (0.09%) number of patients were treated by antibiotics for an average of 1 week.

However, nasal swab culture was negative in all patients.

There were only 2 (0.003%) cases who developed wound site infection after 6-week follow-up, out of them one patient becomes negative for wound infection after 3-month follow-up.

However, the cases developed wound site infection was negative for pus cells in urine routine as well as urine culture.

DISCUSSION

These results support the hypothesis that the pre-operative urine and nasal swab culture before elective joint replacement surgery are not mandatory and add to unnecessary cost. The study was undertaken over a 6-month period, and only 2 patients (0.003%) developed wound site infection, however, these cases were negative for pus cells in urine routine as well as urine culture examination.

Fortunately, in daily practice, chronic bacteriuria almost never provokes UTI. Thus, not even patients who undergo renal transplantation require the eradication of asymptomatic urinary colonization preoperatively.[18] Infection of a joint replacement presumably requires the urinary infection to become bacteremia, which is a relatively rare event even in neglected lower UTIs. Theoretically, the very rare occurrence of urinary incontinence might secondarily infect a freshly implanted TKR due to direct contamination of the wound.[23]

Review of relevant orthopedic literature supports our findings. Koulouvaris *et al*.,[12] in a retrospective study involving 20,000 patients, found no association between the pre-operative UTI (odds ratio, 0.341; 95% confidence interval, 0.086–1.357) and post-operative UTI (odds ratio, 4.222; 95% confidence interval, 0.457–38.9) and wound infection which is also supported by other reports.[10,25]

A retrospective analysis by Uçkay *et al*. between 1996 and 2008 revealed 71 infected replacements and none could be attributed to a urinary infection.[27]

A recent study of 471 patients randomized to receive or not to receive systemic antibiotics for 7 days, based on a cutoff of 105 colonies/ml in pre-operative urine cultures, found no infected THRs of urinary origin and concluded that 25,000 asymptomatic bacteriuria would need to be treated to prevent one joint replacement infection.[5]

CONCLUSION

The pre or post-operative assessment of the urine in asymptomatic patients who undergo joint replacement generates modest but unnecessary cost and may lead to inappropriate use of antibiotics. If symptomatic infection occurs, there is sufficient time for targeted antibiotic treatment to prevent urinary sepsis and hematogenous spread to a joint replacement.

The role of pre-operative nasal swab[16] and urine cultures and the presence of asymptomatic or symptomatic bacteriuria are independent of the causation of prosthetic joint infections and are not warranted in our population.

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Original Article

Correlation of High-resolution Ultrasound Sonography Findings in Anterior Abdominal Wall Lesions with Surgical and Histopathological Findings

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Abstract

Background: There are wide ranges of pathology affecting the anterior abdominal wall which range from simple fluid collection to hernias as well as complex neoplasms.

Objective: The objective of the study was to assess the precision of high-resolution sonography in the diagnosis of anterior abdominal wall lesions with corroboration of post-operative histopathological study

Materials and Methods: Fifty cases of anterior abdominal wall lesions that were evaluated consecutively by high-resolution ultrasound sonography (HRUSG), followed by gold standard investigation.

Results: The precision was 97.7% in detecting anterior abdominal wall lesions with 40% correctly diagnosed as inguinal hernia.

Conclusion: HRUSG is a noninvasive, easily available and cost-effective method with minimal patient discomfort.

Key words: Anterior abdominal wall lesion, Hernia, High resolution sonography, Precision

INTRODUCTION

The abdominal wall is a layered structure, consisting of skin, superficial fascia, subcutaneous fat, muscle layer, transverse fascia and a layer of extraperitoneal fat. The skin is echogenic. Subcutaneous fat is usually hypoechoic. Muscles reveal mid-level echoes with a laminar pattern of muscle fibers.

Scanning technique

The examination of the anterior abdominal wall does not require special preparation on the part of the patient.

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The transducer placed over the surgical wounds can be applied with a plastic membrane to avoid contamination. The highest possible frequency should be used that allows penetration into the areas of interest.

Anatomy

In physically fit people, the navel is at the level between the L3-L4 intervertebral disc; halfway between the xiphoid process and the pubic symphysis. The linea alba divides the anterior abdominal wall into the right and left halves. Linea semilunaris indicates the lateral border of the rectus abdominis muscle. Most of the abdominal wall is muscular and runs between the rib cage and the bony pelvis. There are four major muscle pairs in the anterior abdominal wall. The flat muscles are crossed in such a way (similar to a three-layer corset) to reduce the risk of protrusion of the viscera between the muscle bundles.

Pathology

Although most abdominal wall hernias are asymptomatic, they may develop acute complications that necessitate

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emergent surgery. Prompt diagnosis is desirable because delay is associated with greater morbidity.[1] Often patients with chronic abdominal pain need an examination of the abdominal wall, especially when a positive Carnett's sign suggest the cause of pain to be in the abdominal wall.[2] Most commonly abdominal wall pain is related to cutaneous nerve root irritation or myofascial irritation. The patient is asked to cough or perform a Valsalva maneuver while scanning over the suspected site is performed, and with an increase in abdominal pressure, there will be better appreciation of hernia sac, site, and size of the defect and also contents of the hernia. On ultrasound, where the lesion is of homogeneous fat echogenicity, diagnosis of a simple lipoma can be made with relative certainty.[3] Desmoid often develops from the previous surgical scar and is more common in female patients than in male patients.[4] Seroma occurs after surgical procedures with well-defined anechoic lesion with irregular margins and internal echoes with posterior acoustic enhancement.[5] Below the arcuate line, hematoma can extend across along the midline, as there is no midline aponeurosis.[6] Endometriosis of the abdominal wall usually develops as complication of uterine surgery, due to seeding of functional endometrial tissue outside the uterine cavity with showing color uptake on Doppler.[5]

Aims and Objectives

The objectives are as follows:

1. To assess the spectrum of anterior abdominal wall lesions (localization and characterization) by high-resolution ultrasound sonography (HRUSG)
2. To correlate the sonographic finding with post-operative and pathological findings
3. To assess the efficacy of high resolution sonography in the diagnosis of anterior abdominal wall lesions.

MATERIALS AND METHODS

Study time

The study was from July 2019 to June 2020.

Study place

This study was conducted at Nil Ratan Sircar Medical College and Hospital.

Inclusion Criteria

The following criteria were included in the study:

1. All cases with clinical manifestations of the anterior abdominal wall lesions
2. Cases of all age group.

Exclusion Criteria

The following criteria were excluded from the study:

1. All cases with acute abdominal wall trauma
2. Pregnant mother.

Institutional review board approval for conducting this study was obtained and informed consent of all those 50 patients was taken. They underwent anterior abdominal wall ultrasonography using 7–12 MHZ high frequency linear array transducer coupled with color Doppler equipment (Philips HD 7 series). This was followed by surgical or histopathological confirmation whenever needed.

Technical Consideration

They were initially scanned in the supine position and then examined in the upright position. The examination of the inguinal region has been described in the literature.[7] Inferior epigastric artery is identified where it passes under the lateral border of the rectus abdominis muscle. From there it can be followed inferiorly to its origin from the external iliac artery. The Valsalva maneuver should be liberally used to detect hernias. Scanning patients in the supine and in the upright position may facilitate detection. The anterior abdominal wall can be incrementally scanned from the epigastrium to the symphysis pubis.

Statistical Methods

Diagnostic efficacy of the anterior abdominal wall lesion using HRUSG will be determined by comparing with post-operative and histopathological findings, by performing diagnostic validity tests like positive predictive value.

Test	Disease present	Disease absent
USG positive	TP	FP
USG negative	FN	TN

Positive predictive value=Tp/(Tp+Fp)

RESULTS AND ANALYSIS

Our study showed high prevalence of anterior abdominal wall lesions in patients of the age group of > 40 years (60%), with male predominance (30 out of 50). Among 50 clinically suspected anterior abdominal wall lesions, most common indication for high resolution sonography was inguinal hernia followed by incisional hernia and abdominal wall lump which was relatively a non-specific clinical diagnosis [Table 1], which later turned out to be different lesions on high-resolution sonography as well as in histopathology. Most common USG findings in our study was hernias (inguinal, incisional, and ventral) [Figure 1], followed by lipoma, abscess, and desmoids tumor.

Others here include two cases of Abscess, one each of external oblique pyomyositis and rectus sheath hematoma. As the lesions were small in size, they were left for follow-up without any intervention [Table 2]. On statistical analysis ,it was found that HRUSG had 97.7% positive predictive value (PPV))[Figure 2].

DISCUSSION

Anterior abdominal wall lesions often mimic intra-abdominal conditions and frequently presents as a palpable mass. This is more common with patients who have thick anterior abdominal wall with a large layer of fat. Pathological process that may involve the anterior abdominal wall occasionally raises diagnostic challenge because of the low specificity of the physical findings. Because of introduction of newer ultrasonography techniques with higher frequency probes and newer software such as tissue harmonic imaging, it has led to the better characterization and diagnosis of the lesion. The purpose of this study was to provide an overview of sonographic appearances of different anterior abdominal wall lesions and to compare it with histopathological/post-operative findings. Literature on this type of study is sparse in Indian literature and such study have not highlighted on incidence and prevalence of anterior abdominal wall lesions. Our study also emphasized on the diagnostic efficacy of high-resolution sonography in detection of anterior abdominal wall lesions. Our study showed a high prevalence of anterior abdominal wall lesions in the age group of >40 years (60%), where in majority of cases were various types of inguinal and incisional hernias [Figure 3]. The higher prevalence of anterior abdominal wall lesions in the age group of >40 years probably explains the patients seeking medical/surgical attention more frequently than other age group due to various reasons this is in conformity with Spangen[8] and others (1990, 2003), who have reported hernia to be the second most common abdomino-pelvic surgery after caesarean section and its incidence increases with age.[9] In study done by Ruhl and Everhart, the cumulative incidence of inguinal hernia was higher among men (13.9%) than among women (2.1%)[10] as similarly shown in our study also where a higher incidence

Table 1: Various clinical diagnosed of anterior abdominal wall lesions

Clinical diagnosis	No.	%
Inguinal hernia	20	40
Incisional hernia	10	20
Ventral hernia	4	8
Abdominal wall lump	8	16
Lipoma	2	4
Abscess	2	4
Hematoma	1	2
Post-operative collection	1	2
Lipoma/Neurofibroma	1	2
Others	1	2
Total	50	100

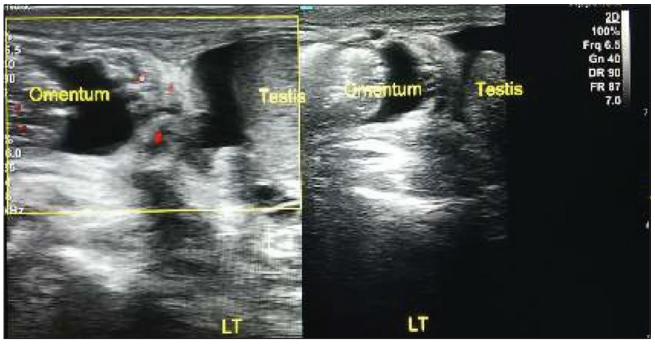

Figure 1: Direct inguinal hernia extending into the scrotal sac

Table 2: Over all Usg, post-operative, and histopathological correlation

No. of cases	USG findings	Post-operative findings	Histopathological findings
20	Inguinal hernia	Bowel loops and Mesentery noted	-----
10	Incisional hernia	Defect in Fascia transversalis' external oblique muscle	------
4	Ventral hernia	Linea alba defect	------
4	Lipoma	Circumscribed soft encapsulated mass excised	Mature adipocytes with no cellular atypia
1	Neurofibroma/Lipoma	Circumscribed but not encapsulated soft mass excised	Non-encapsulated with proliferation of Schwann cells and collagen Consistence with neurofibroma
2	Desmoid tumor	Firm gritty texture, on cut surface glistening white and coarsely trabeculated	Sweeping fascicles with spindle cells and long thin walled parallel vessels with adjacent infiltration S/O-desmoid tumor
1	Abdominal wall sarcoma	Small firm TAN colored with whorled appearance	Well-circumscribed, non-encapsulated sheets of large moderately differentiated spindle shaped cells with pleomorphism and atypia S/O- Sarcoma
1	Scar Endometriosis	Excision of endometrial tissue from surrounding tissue	Endometrial glands and stroma with areas of hemorrhage
1	Swelling with no obvious defect	Linea alba defect	------
1	Hematoma	On aspiration blood material noted	-------
1	Abscess	Pus drained	-------
1	Seroma	Clear serous fluid drained	------
4	Others	No intervention done	

Others here include 2 (Two) cases of Abscess, 1 (One) each of External Oblique Pyomyositis and Rectus Sheath Hematoma. As the lesions were small in size, they were left for follow-up without any intervention

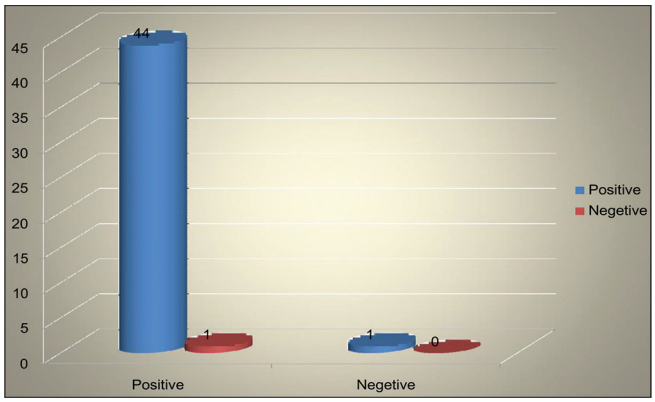

Figure 2: Diagnostic validity of high-resolution sonography

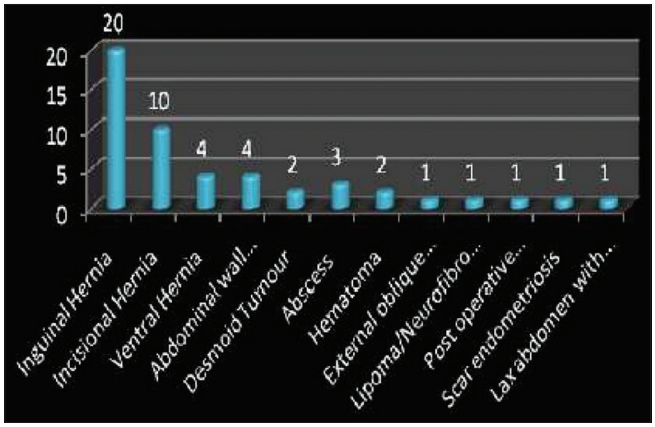

Figure 3: Spectrum of anterior abdominal wall lesions detected by high-resolution ultrasound sonography

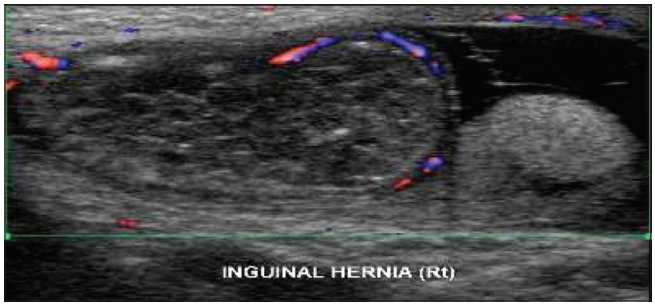

Figure 4: Inguinal hernia extending into the scrotal sac

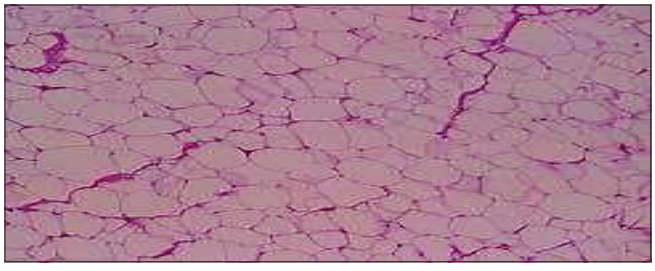

Figure 5: Sections shows mature adipose tissue. The fat contains few small capillaries within thin fibrous strands

of anterior abdominal wall lesions was shown in males, that is, as many as 30 cases (60%).

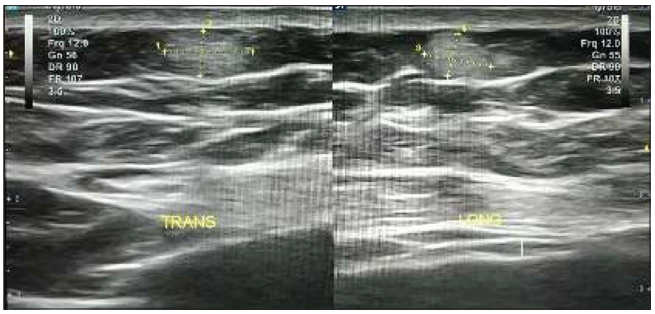

Figure 6: Ant. Abdominal wall hyperechoic sol

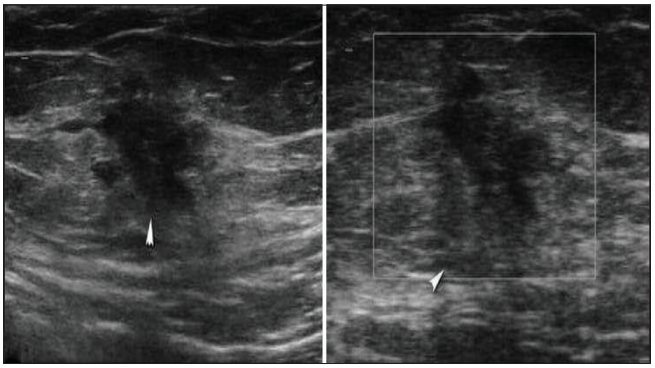

Figure 7: High-resolution sonogram shows heterogenous solid mass in a post-operative case of TAH and BSO

Table 3: Various histopathological/post-operative diagnosis of anterior abdominal wall lesions

Diagnosis	No.	%
Bowel loops/omentum/mesentery	30	60
Not done	4	8
Lipoma	4	8
Desmoids tumor	1	2
Linea alba defect	4	8
Abdominal wall sarcoma	1	2
Abscess	1	2
Neurofibroma	1	2
Endometriosis	1	2
Hematoma	2	4
Post-operative seroma	1	2
Total	50	100

Table 4: Diagnostic validity of high resolution sonography

Test	Positive	Negative	Total
Positive	44	1	45
Negetive	1	0	1
Total	45	1	46

PPV=TP/(TP+FP)=97.7%

In the study conducted by Devareddy *et al.*,[11] incisional hernia was the most common diagnosis with female predominance but in our study inguinal hernia was the most common and accurately diagnosed lesion with male predominance. The reason could be less number of cases in our study. With application of color Doppler sonography[10]

differentiation between strangulated and non-strangulated hernias can be made out [Figure 4]. In one case of ventral hernia, although swelling was present, defect could not be found out. The patient was very uncooperative and obese and the defect was small in size, so we could not detect it in USG, patient later underwent surgical repair of the defect. Anterior abdominal wall lesion other than hernias which were common in our study was anterior abdominal wall lipomas four cases (8%), all four cases correlated with histopathological findings [Figure 5 and Table 3][12] all cases of anterior abdominal wall lipomas showed similar sonographic findings, that is, well defined round to ovoid, iso to slightly hyperechoic echotexture as compared to the adjacent muscles along with a thin echogenic capsule [Figure 6]. It is in conformity with the description of lipomas in the study conducted by Stroung *et al.* and others in 1993 2 cases out of 50 cases (4%). Sonographic diagnosis of both desmoids tumor was not 100% accurate, where in one case was ill defined lobulated hypoechoic soft-tissue mass which came out to be a case of anterior abdominal wall sarcoma on histopathology. Desmoids tumor appeared as a hypoechoic soft-tissue masses with smooth, well defined margins [Figure 7] and variable vascularity on color Doppler. Casillas *et al.* in a case series study of 15 patients of desmoid tumors also found similar findings on USG.[4]

We showed overall comparison of high resolution sonographic findings with post-operative and histopathological findings which correlated accurately with a positive predictive value (efficacy) of 97.7% [Table 4]. Devareddy *et al.*[11] had reported that the high resolution sonographic findings correlated with surgical or histopathological findings with a positive predictive value (efficacy) of 97.4% which closely resembles to our study findings. Dynamic USG improved the morphological appearance of the lesion. In all cases, it improved the visualization of the hernia and gave clarity of the content and as well as the blood supply, thereby aided in determining the viability. Dynamic USG also helped to accurately measuring the diameter of the neck of the sac, which aided the surgeon in his assessment during surgery especially while repairing the hernia.[13]

CONCLUSION

Clinical signs and symptoms are not very specific. High-resolution sonography in correlation with clinical findings and proper clinical history of the patient helps in reaching a proper diagnosis. Ultrasound can differentiate a fluid filled mass from a soft-tissue lesion and also can demonstrate the site of hernia with its content very accurately. In correlation with post-operative findings and histopathological study, it is a reliable method of investigation. It is a noninvasive, easily available, and cost-effective method with minimal patient discomfort. Hence, we emphasize on using this modality in evaluation of anterior abdominal wall lesions.

ACKNOWLEDGMENTS

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MASTER CHART

S. No.	Name	Age (years)	sex	Clinical diagnosis	Sonological features	Radiological diagnosis	Histopath/surgical findings
1.	S. Khatoon	28	F	Incisional Hernia	Defect in the paramedian region with herniation of bowel loops	Incisional hernia (bowel loops and Omentum)	Defect noted in rectus sheath with bowel loops
2.	D. Sarkar	65	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Bowel loops noted
3.	M. Sk	55	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of left side	Indirect inguinal hernia	Bowel loops noted
4.	D. Mondal	51	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of left side	Indirect inguinal hernia	Bowel loops noted
5.	R. Kuila	48	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Bowel loops noted
6.	K. Sing	54	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Bowel loops noted
7.	U. Bauri	50	M	Lipoma	Well-defined hypoechoic lesion with no vascularity	Lipoma	Lipoma
8.	S. Das	29	M	Abdominal wall lump	Ill-defined collection with internal debris around suture line	Sutural abscess	Removal of suture
9.	M. Kar	55	F	Incisional hernia	Defect in the fascia transversalis with herniation of bowel loops	Incisional Hernia (bowel loops and Omentum)	Defect noted in rectus sheath with bowel loops and omentum
10.	K. Mondal	52	F	Incisional hernia	Defect in the rectus sheath with herniation of omentum	Incisional Hernia (Omentum)	Gap noted in the rectus muscle with herniation of omentum
11.	K. Pal	18	F	Abdominal wall abscess	Mixed echogenicity lesion with debris, surrounding fat, and muscle inflamed	Abscess	Not done
12.	A.Chatterje e	75	F	Ventral hernia	Defect in the linea alba in the midline, through which omentum and gut loops herniated	Ventral hernia (omentum and gut loops)	Linea alba defect with bowel and omentum herniation
13.	A.Samad	61	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of Left side	Indirect inguinal hernia	Bowel loops noted
14.	K. Sk	18	M	Abdominal pain swelling	Left internal oblique muscle appear hypoechoic and enlarged with anechoic collection, surrounding fat and muscle appears inflamed	Pyomyositis	Not done
15.	M.Banerjee	29	F	Abdominal wall lump	Well defined hypoechoic lobulated lesion with internal vascularity	Desmoid tumor	Features suggestive of desmoid tumor
16.	J.Ghosh	36	F	Lower abdominal swelling at the site of previous TAH with rt SO surgery	Focal iso to hypoechoic nodules at previous scar site with collection in the adjoining area and debris	Endometriosis	Endometrial tissue found
17.	S. Rana	29	F	Abscess/abdomen al wall lump	Thick walled anechoic collection with internal debris in the right iliac region	Abscess	Pus drained
18.	S.Basak	35	M	Lipoma/ neurofibroma	Well-defined hypoechoic lesion with no vascularity	Lipoma/ neurofibroma	Neurofibroma
19.	N.Alam	36	M	Abdominal wall lump	Ill-defined mixed echogenic lesion with areas of necrosis and with internal vascularity	Desmoid tumor	Abdominal wall sarcoma
20.	P.Tripathi	31	F	Abdominal wall lump	Well-defined ovoid iso to hypoechoic encapsulated lesion with no internal vascularity	Lipoma	Lipoma

(*Contd*...)

S. No.	Name	Age (years)	sex	Clinical diagnosis	Sonological features	Radiological diagnosis	Histopath/surgical findings
21.	R.Bibi	33	F	Lipoma	Well-defined ovoid iso to hypoechoic encapsulated lesion with no internal vascularity	Lipoma	Lipoma
22.	K.Sarkar	27	F	Abdominal wall lump	Well-defined ovoid iso to hypoechoic encapsulated lesion with no internal vascularity	Lipoma	Lipoma
23.	P.Paswan	43	F	Incisional hernia/ abdomen l wall lump in a case of post-operative cholecystectomy	Defect in the rectus sheath with herniation of omentum	Incisional hernia (omentum)	Gap noted in the rectus muscle with herniation of omentum
24.	M.Kar	56	F	Abdominal lump with changing in posture Ventral hernia	Thinned out of linea alba just above the umbilicus but no herniation noted	Lax abdominal wall	Small defect noted in the linea alba
25.	U.Maity	61	F	Ventral hernia	Defect in the rectus sheath in right paramedian region with herniation of bowel loops	Ventral hernia	Linea alba defect with bowel and omentum herniation
26.	J.Biswas	50	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Omentum noted
27.	A.Ali	49	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of the right side	Indirect inguinal hernia	Omentum noted
28.	J.Majumda r	51	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of the left side	Indirect inguinal hernia	Bowel loops noted
29.	S.Das	53	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Omentum noted
30.	E. Ali Sk	55	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Omentum noted
31.	K. Sk	46	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Omentum noted
32.	A.Das	48	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Bowel loops noted
33.	S.Roy	18	F	Post-operative collection/lump	Ill-defined hypoechoic collection under the scar line	Hematoma	Collection with clot
34.	S.Parveen	13	F	Post-operative collection/lump	Ill-defined hypoechoic collection under the scar line	Post-operative seroma/collection	Not done
35.	A.BiBI	52	F	Ventral hernia	Defect in the linea alba in the midline, through which omentum and gut loops herniated	Ventral hernia	Linea alba defect with bowel and omentum herniation
36.	N.Sk	46	M	Incisional hernia	Defect in the paramedian region with herniation of bowel loops	Incisional hernia (bowel loops)	Defect noted in rectus sheath with bowel loops and omentum
37.	P.Bhowmik	31	F	Incisional hernia	Defect in the paramedian Region with herniation of bowel loops	Incisional Hernia (bowel loops)	Defect noted in rectus sheath with bowel loops and omentum
38.	A.Paswan	51	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Bowel loops noted
39.	A.Sing	49	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Bowel loops noted
40.	Sk Idris Ali	49	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Omentum noted

(*Contd*...)

S. No.	Name	Age (years)	sex	Clinical diagnosis	Sonological features	Radiological diagnosis	Histopath/surgical findings
41.	K.Ali	52	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Omentum noted
42.	R.Bibi	54	F	Ventral hernia	Defect in the linea alba in the midline, through which omentum and gut loops herniated	Ventral hernia	Linea alba defect with bowel and omentum herniation
43.	M.Sk	50	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Bowel loops noted
44.	A.Roy	50	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Omentum noted
45.	S.Chudhury	39	M	Inguinal hernia	Herniation of bowel loops lateral to the IEA of right side	Indirect inguinal hernia	Bowel loops noted
46.	L.Bauri	48	M	Incisional hernia	Defect in the paramedian Region with herniation of bowel loops	Incisional Hernia (bowel loops)	Defect noted in rectus sheath with bowel loops and omentum
47.	D.Thakur	39	M	Incisional hernia	Defect in the rectus sheath with herniation of omentum	Incisional hernia (omentum)	Gap noted in the rectus muscle with herniation of omentum
48.	K.Sing	39	F	Incisional hernia	Defect in the rectus sheath with herniation of omentum	Incisional hernia (omentum)	Omentum noted
49.	Md Salauddin	35	M	Incisional hernia	Defect in the paramedian region with herniation of bowel loops	Incisional hernia (bowel loops)	Bowel loops noted
50.	B. Das	38	M	Abdominal lump	Ill-defined collection with internal debris	It sided rectus abdominis hematoma	Not done

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Original Article

Pain Perception Young Adult versus Aged Using Visual Analog Rating Scale

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Abstract

Aim: Pain is the most common complaint in most of the patients in post-operative period. The elderly frequently suffer from discomfort or are not cared. It can be difficult to measure pain accurately in the elderly. The elderly may present pain atypically particularly if the cognition is impaired. Rather than admitting to the presence of pain, they may use the terms such as aching and hurting.

Methods and Statistics: Keeping in view the problems faced by the elderly in expressing pain intensity, a study was carried out comparing pain scores between young adults and the elderly. Patients between 17 and 67 years of age undergoing surgery of any kind were randomized into two groups. Group 1 consists of young adult between 17 and 27 years of age and Group 2 consists of aged adult between 47 and 67 years. Each group was divided into 50 patients each of ASA Grade 1 and 2 and both the groups were statistically compared at varying intervals, for example, 1st h after surgery, 4 h, 8 h, 24 h, 36 h, 48 h, and at 72 h.

Observation and Results: It was found that pain score was more in young adults as compared to the elderly and the difference in pain score was statistically significant, $P < 0.001$, which showed that the elderly feel less pain, reason can be multifactorial.

Conclusion: Our study showed that young patients were more perceptible to acute pain as compare to older patients.

Key words: Age, Pain, Numerical rating scale, Visual analog scale

INTRODUCTION

Pain perception is a subjective phenomenon influenced by age and gender of the person. Hence, there should be an appropriate pain assessment scoring system which exactly measures the severity of the pain measuring scales validated over the years such as visual analog scale (VAS), verbal rating scale (VRS), numerical rating scale (NRS), and many more. The well-known VAS and NRS assessment of pain intensity agree well and are equally sensitive in assessing acute pain after surgery and they are both superior to a 4-point verbal categorical rating scale (VRS). They function best for the patient's subjective feeling of the intensity of pain right now – present pain intensity. Age difference in pain perception is less consistent, some studies show that older patients are more sensitive to pain then young adults, whereas other studies show a decrease in pain sensitivity in older patients.[1] The development of these scales is done with the active participation of the patients by the health professionals.[2] Pain assessment tools help health professionals to quantify a subjective phenomenon into objective terms to inform and evaluate pain management within the context, the presence of severe unresponding pain is often regarded as one of the most common and devastating threats to health-related quality of life.[3] Recent epidemiologic studies indicate that more than 50% of older persons suffer from some form of persistent pain. The older person face many threat to quality of life, including a marked increase in incidence of disease, high level of fractional disability, loss of lifetime partner or friends and family support networks, reduction in economic resources, and the foreboding prospect of institutional placement with an associated loss of independence.[4,5]

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However, several studies suggest that older adults report a low intensity of post-operative or procedural pain when compared with younger adults.[6,7] Although such findings are not universal, investigations also indicate that verbal reports of pain trend to decrease as cognitive impairment increases[8] and may depend on the age range of the sample and type of the scale used to measure it.[9]

Many physicians believe that older people feel less degree of pain than younger, it may probably be due to their loss in ability to perceive pain.[10] However, some feel that an increase in the incidence of severity of pain is seen with age until the seventh decade, this may, however, could be due to the fact that older patients suffer from conditions as dementia, which affect how they express themselves or simply that then life experience has made them view then pain differently.[11]

Acute pain can reliably be assessed, both at rest (important for comfort) and during movement (important for function and risk of post-operative complications), with one-dimensional tool such as numeric rating scales or VAS. Both are better when it comes to pain level changes than a VRS. They are more effective. In acute pain trials, assessment of baseline pain must ensure sufficient pain intensity for the trial to detect meaningful treatment effects.[12]

Most papers reported good correlation between scales, particularly so between NRS and VAS. In case of discrepancy, NRS scores were considered to be higher than the equivalent VAS scores, especially the verbal NRS scores.[13] One study found that more than 75% of the patients provided ratings that were not mathematically equivalent on NRS and VAS.[14]

Relatively little investigative or clinical attention has been paid to the assessment of pain in the geriatric population when compared with the general population. This is shocking because population-based statistics shows that pain in people over 60 (250 per thousand) is twice their incidence relative to those under 60 years of age (125 per thousand).[15-17]

The elderly will use words such as doling and hurting, rather than accept the presence of suffering. Communication and cognitive disturbances are additional barriers to such assessment.[18]

Pain has been described as the fifth "vital sign," and therefore, physician should regularly enquire about the presence of pain in elderly patients. Pain can be assessed even in those with dementia, using simple questions and screening tools.[19]

Sample Size Calculation

Sample size was calculated keeping in view at most 5% risk, with minimum 85% power and 5% significance level (significant at 95% confidence interval).

MATERIALS AND METHODS

After taking permission from ethic committee of Govt. Medical College, Amritsar, we have conducted a prospective randomized study in the Department of Anesthesiology and intensive care unit in which 100 patients were taken and distributed in Groups I and II. Group I included 50 young adults of the age between 17 and 27 years of sexes and Group II included 50 older patients of both the sexes aged between 47 and 67 years. The patients with chronic pain and those with intoxication were excluded from the study. All patients belonged to ASA Grade 1 and 2. To measure the pain score, NRS was used. Patients were kept in the hospital for day 1 (on the day of surgery), day 2 (post-operative day), and day 3 (post-operative day) and their pain score was measured 1 h, 4 h, and 8 h after surgery on day 1, then in the morning at 9 o'clock and in the evening at 9 o'clock at day 2nd and again pain score was measured in the morning at 9 o'clock and in the evening at 9 o'clock at day 3rd. The pain scores were measured, analyzed, and statistically compared. All patients in the post-operative period were given only one type of rescue analgesia in the form of inj. diclofenac sodium (IM) and who do not relieved with diclofenac were given inj. tramadol (IV).

Observations

Age and sex distribution

Mean age in Group I was 24.3 years and mean age in Group II was 58.7 years. In Group 1, there were 24 males and 26 females while in Group 2, there were 27 males and 23 females. Hence, the sex distribution was insignificant while comparing both the groups.

Pain Scoring after Surgery

[Table 1, Graph 1] On day 1, in Group I, pain score using VAS scoring method was 70 mm in 25 patients each, 80 mm in 15 patients each, and 90 mm in 10 patients each. Hence, total scoring was 3850 mm in 50 patients and mean was 77 mm and SD±7.88. In Group II, pain score was 60 mm in 24 patients each, 50 mm in 16 patients each, and 70 mm in 10 patients each, total scoring in 50 patients was 2940 mm, with mean of 58.8 and SD±7.18.

[Table 2, Graph 2] Four hours after surgery: Total score in Group I was 3880, mean 77.6 and SD±7.25. While in Group II, total score was 3260, mean 65.2 and SD±6.46.

[Table 3, Graph 3] Eight hours after surgery: In Group I, total score was 2790, mean 55.8 and SD±4.44. While in Group II, total score was 2430, mean 48.6 and SD±7.28.

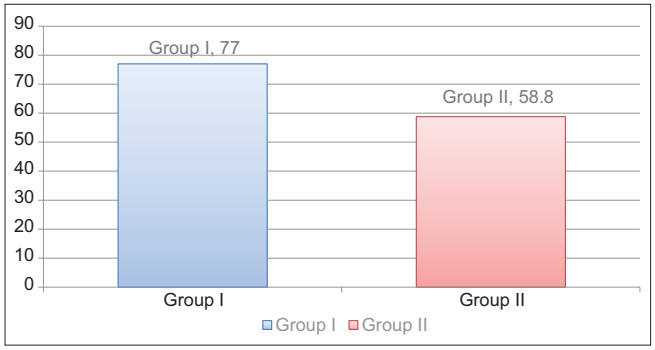
[Table 4, Graph 4] On day 2, at 24 h: In Group I, total score was 3260 mm, mean 65.2 mm and SD±5.20, while in Group II, total score was 2794, mean 54.48 and SD±7.88.

[Table 5, Graph 5] Twenty-four hours: In Group I, total score was 3212. Mean was 64.24 and SD±3.76, while in Group II, total score was 2488, mean 49.76 and SD±3.76.

[Table 6, Graph 6] At 48 h, in Group I, total score was 1864 mm, mean 37.28 mm and SD±6.92. While in Group II, total score was 1486 mm, mean 29.72 mm and SD±3.60.

Table 1: Comparing Group I (young) with Group II (aged) 1 hour after Surgery

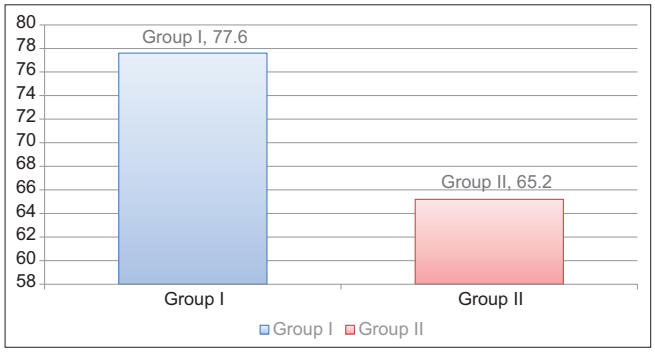
Group I			Group II		
No. of patients	Pain score in mm	Mean±S.D	No. of patients	Pain score in mm	Mean±S.D
25	70	77.0±7.88	24	60	58.8±7.18
15	80		16	50	
10	90		10	70	
50	3850		50	2940	



Graph 1: Comparing Group I (young) with Group II (aged) 1 hour after Surgery

Table 2: Comparing Group I (young) with Group II (aged) 4 hour after Surgery

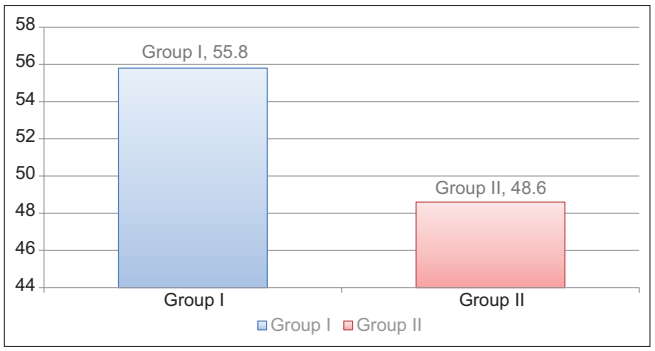
Group I			Group II		
No. of patients	Pain score in mm	Mean±S.D.	No. of patients	Pain score in mm	Mean±S.D.
20	70	77.6±7.25	18	70	65.2±6.46
22	80		28	60	
08	90		04	80	
50	3880		50	3260	



Graph 2: Comparing Group I (young) with Group II (aged) 4 hour after Surgery

Table 3: Comparing Group I (young) with Group II (aged) 8 hour after Surgery

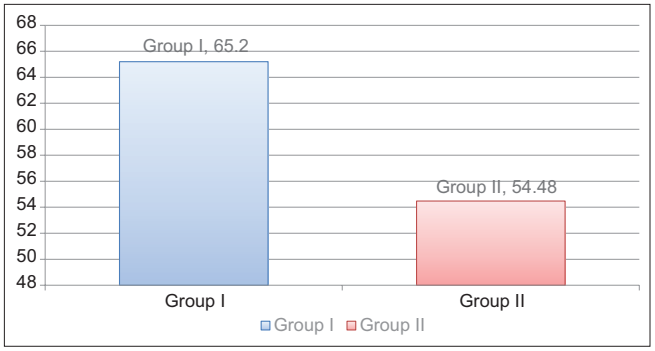
Group I			Group II		
No. of patients	Pain score in mm	Mean±S.D.	No. of patients	Pain score in mm	Mean±S.D.
24	60	55.8±4.44	23	50	48.6±7.28
16	50		17	40	
10	55		10	60	
50	2790			2430	



Graph 3: Comparing Group I (young) with Group II (aged) 8 hour after Surgery

Table 4: Comparing Group I (young) with Group II (aged) 24 hour after Surgery

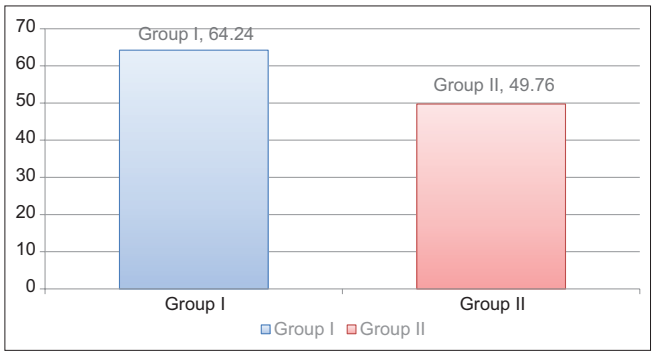
Group I			Group II		
No. of patients	Pain score in mm	Mean±S.D	No. of patients	Pain score in mm	Mean±S.D
20	60	65.2±5.20	20	52	54.48±7.88
20	66		08	40	
10	74		22	62	
50	3260		50	2794	



Graph 4: Comparing Group I (young) with Group II (aged) 24 hour after Surgery

Table 5: Comparing Group I (young) with Group II (aged) 36 hour after Surgery

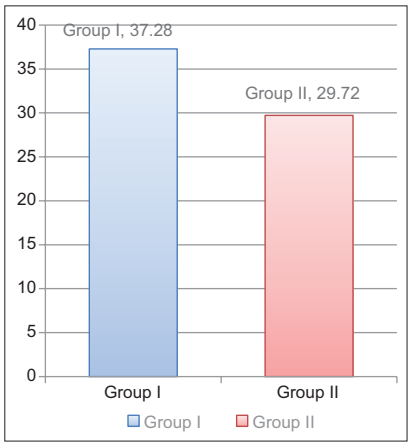
Group I			Group II		
No. of patients	Pain score in mm	Mean ± S.D.	No. of patients	Pain score in mm	Mean ± S.D.
20	60	64.24 ± 3.76	22	48	49.76 ± 3.76
22	66		20	54	
08	70		08	44	
50	3212		50	2488	



Graph 5: Comparing Group I (young) with Group II (aged) 36 hour after Surgery

Table 6: Comparing Group I (young) with Group II (aged) 48 hour after Surgery

Group I			Group II		
No. of patients	Pain score in mm	Mean±S.D.	No. of patients	Pain score in mm	Mean±S.D.
26	42	37.28±6.92	28	32	29.72±3.60
14	38		20	28	
10	24		02	15	
50	1864		50	1486	

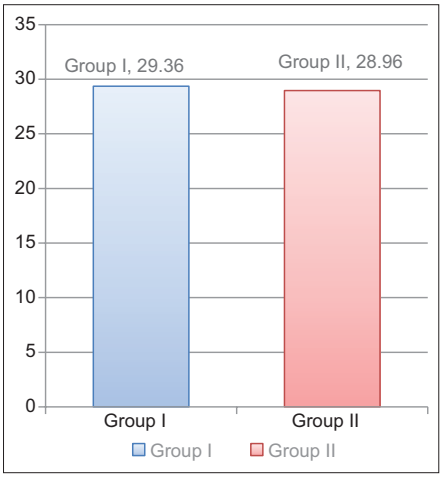


Graph 6: Comparing Group I (young) with Group II (aged) 48 hour after Surgery

[Table 7, Graph 7] At 72 h, in Group I, total score was 1468 mm, mean 29.36 mm and SD±3.16. While in Group II, total score was 1448 mm, mean 28.16 mm and SD±3.08.

Table 7: Comparing Group I (young) with Group II (aged) 72 hour after Surgery

Group I			Group II		
No. of patients	Pain score in mm	Mean±S.D.	No. of patients	Pain score in mm	Mean±S.D.
20	32	29.36±3.16	22	32	28.96±3.08
18	30		18	28	
12	24		10	24	
50	1468		50	1448	



Comparing Group I (young) with Group II (aged) 72 hour after Surgery

DISCUSSION

On comparing pain score using VAS scoring method, it was found that young patients had more mean pain score one hour after surgery, four hour after surgery, eight hour after surgery, on the day 1, and in the morning and evening on the day 2nd, again in the morning on the day three as compare to older patients and the difference in pain perception was very significant, $P < 0.001$. While in the evening of day 3, the perception of pain in both the groups was insignificant, $P = 0.52$. Our results are consistent with studies conducted by Gagliese *et al.*,[19] and Taverner *et al.*[20] and Hallingbye *et al.*[21]

CONCLUSION

Our study showed that young patients were more perceptible to acute pain as compare to older patients. Reason may be much factorial, it may be due to their loss of pain receptors, it may be due to psychological factor that older patients were unable to express due to loss of cognitive function and also they were more tolerant to acute pain.

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Original Article

Morphometric Measurements of Cadaveric Anterior Cruciate Ligament and Hamstring Tendons Graft among Indian Population

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Abstract

Introduction: Anatomical graft placement is important for the best clinical outcome of anterior cruciate ligament (ACL) reconstruction. The objectives were to study the dimensions of the ACL, the quadrupled hamstring tendon graft and reveal the correlation between the size of the ACL native and transplant quadrupled hamstring tendon of the Indian population.

Materials and Methods: In this study, 44 cadaveric knees from 22 cadavers (13 males and 9 females) were included for measuring the dimensions of the ACL and hamstring tendon graft. The measurement of ACL was taken using Vernier calipers. The length was taken from the main axis of the insertion zone and the width was taken perpendicular to the longitudinal axis of the widest point.

Results: Average diameter and cross-sectional area of the ACL were found to be 6.6 mm and 34.35 mm^2, respectively. The average diameter and cross-sectional area of the hamstring tendon graft are 7.2 mm and 41.28 mm^2, respectively. The average tibial cross-sectional area of ACL was 129.63 mm^2, femoral insertional area was 97.23 mm^2. The quadruple transplant hamstring tendon is 20.17% larger than the ACL midsubstance. The difference was statistically significant ($P = 0.0207$).

Conclusions: There is a good correlation between the cross-section of midsubstance of the ACL and quadrupled hamstring tendon graft in Indian population. With the use of graft quadrupled hamstring tendon for reconstruction of the ACL, the graft is oversized to the average of 20.17%. With the use of the current reconstruction using hamstring quadrupled tendon graft technique, it is unlikely to reproduce the footprints of the ACL.

Key words: Anterior cruciate ligament, Cadaveric study, Quadrupled hamstring graft

INTRODUCTION

Injury of the anterior cruciate ligament (ACL) is rising due to the increased participation in sporting activities in the recent years. As knee is majorly stabilized by ACL in extreme balancing, climbing, and gymnastic exercises, there is increased demand from patients for repair or reconstruction of ACL injuries. ACL is primary restraint to anterior translation of the tibia and secondary restraint to internal rotation of the knee.[1] Arthroscopic reconstruction of the ACL is one of the most frequently performed procedures in knee surgery in recent years. ACL reconstruction has been performed using bone-patellar tendon-bone graft (BPTB) or using Hamstring tendon graft.[2] Anatomical graft placement is important for the best clinical outcome of ACL reconstruction[3] and non-anatomical graft placement in bone tunnel is the main cause of graft failure in the ACL reconstruction.[4] Reconstruction surgery of ACL presents as challenge even for experienced surgeons. Therefore, the surgeon must have complete knowledge of the anatomy of the knee ligaments, graft used for reconstruction and normal biomechanics to reduce operative time, and improve postoperative functional

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outcome.[1] Length and diameter of the native ACL play an important role in the selection and preparation of the graft for reconstruction.

With the new techniques of reconstruction of the ACL, the main objective was to reproduce the impression of the native ACL to restore the kinematics and improve functional outcome. However, it is also important to consider that there is a design of the graft relative to the native ACL midsubstance to avoid the risk of encroachment of the graft. The impact on the graft causes tearing, which leads to joint laxity and failure of the graft transplant.[5]

In recent years, studies have been conducted to reveal the biomechanics of the knee joint and the establishment of the tunnel in graft reconstruction.[6,7] However, there are little data available on the dimensions of the ACL graft and hamstring tendons used for reconstruction of the ACL in the Indian population. There were questions about the discrepancy between the size of the ACL and tendon graft hamstring used for reconstruction. This study reveals the details of the dimensions of the ACL and its footprints, hamstring quadruple graft used for reconstruction surgery.

The objectives were to study the dimensions of the ACL, the quadrupled hamstring tendon graft and reveal the correlation between the size of the ACL native and transplant quadrupled hamstring tendon of the Indian population.

MATERIALS AND METHODS

In this study, 44 cadaveric knees from fresh frozen 22 cadavers were included for measuring the dimensions of the ACL and hamstring tendon graft. Adults from the age group 18–70 years were included for the study. The ethical committee approval was taken. The uninjured, unoperated knee and unwounded joint with intact ACL were included in this prospective study. Decomposed cadavers, cadavers with previous knee surgeries, torn ACL, and osteophytes in the notch (tibia and/or femur) were excluded from the study. There were 13 males and 9 females. The average storage time of death to dissection was 40 days. Full extension was possible in all knees, while flexion ranges from 120 to 135.

The body was placed in supine position, knee was opened by paramedian incision. The subcutaneous tissue and retinaculum were incised, the capsule has been cut and the patella was everted so as to expose the ACL [Figure 1]. Anterior and posterior bundles and foot prints were visible all the time. The measurement of ACL was taken using Vernier calipers before cutting the ligament so as to maintain the native ligament tension. Soft tissue including synovial membrane around the ACL has been removed. The diameter was taken with a digital Vernier caliper in two different axes and the average of both was taken [Figure 2].

The ACL was released from its tibial and femoral insertion. Sites of femoral and tibial insertion were stained, the length and width were taken. The length was taken from the main axis of the insertion zone and the width was taken perpendicular to the longitudinal axis of the widest point.

The incision was extended until the insertion of the semitendinosus and gracilis on the center upper part of the tibia shaft and the semitendinosus and gracilis tendon was removed with tendon stripper. The graft was cleaned and prepared as four tendon grafts and the diameter of cross-section was taken with a digital caliper by tensioning with 25 g weight.

Cross-sectional area and the diameter were calculated using the geometric calculation used to calculate the surface of the cylinder and ellipse as

$$\text{Area of the circle pie} \times = (\text{diameter}/2)\ 2$$

Field of the ellipse pie × = length of the major axis (length) × length of the minor axis (width)/4. All continuous data are expressed as mean (SD). Z test was used to calculate *P* value. $P < 0.05$ was considered statistically significant. Coefficient of correlation (R) of Karl Pearson coefficient was used to evaluate the correlation between different parameters.

RESULTS

The study was conducted on 44 knees of 22 human cadavers including 13 males and 9 females. The results are summarized in Tables 1 and 2.

ACL

Average diameter of the ACL was found to be 6.6 mm (range from 5.7 to 7.4 mm) and the average cross-sectional area of the ACL was 34.35 mm^2 (range from 25.53 mm^2 to 43.03 mm^2). Average ACL diameter in male was 6.77 (range from 6.2 mm to 7.4 mm) and in female 6.36 mm (5.7 mm to 6.8 mm). Average ACL diameter in right was 6.64 mm (range from 5.8 mm to 7.4 mm) and on left was 6.56 mm (range from 5.7 mm to 7.3 mm). Cross-sectional area in male was 36.10 mm^2 (range from 30.3 mm^2 to 43.03 mm^2) and in female 31.81 mm^2 (range from 25.53 mm^2 to 36.33 mm^2). Cross-sectional area of the ACL on right side was 34.72 mm^2 (range from 26.43 mm^2 to 43.03 mm^2) and on left was 33.97 mm^2 (range from 25.53 mm^2 to 41.87 mm^2) [Figure 3].

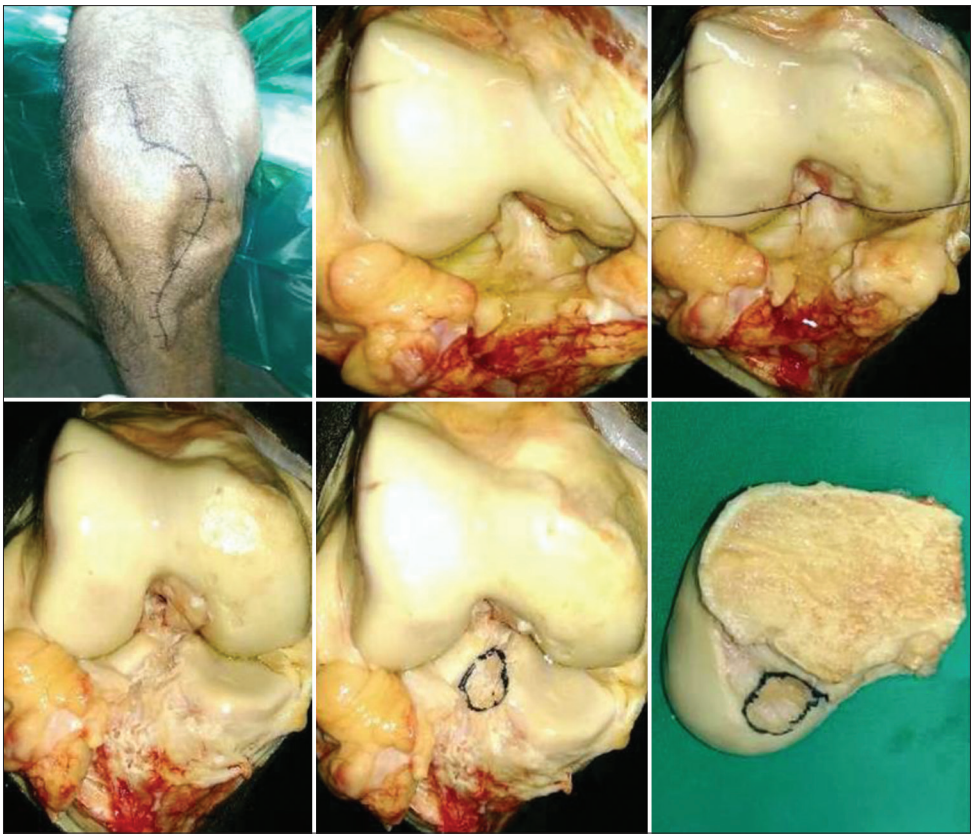

Figure 1: Stepwise measurement of anterior cruciate ligament cruciate ligament dimensions and its footprint

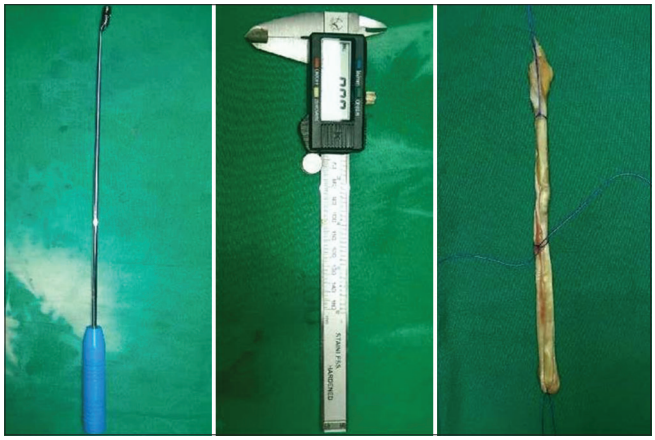

Figure 2: Tendon stripper, Vernier caliper, and harvested tendon graft

Quadrupled Hamstring Tendon Graft

The average diameter of the hamstring tendon graft was 7.2 mm (range from 6.3 mm to 8.5 mm). The average cross-sectional area of the hamstring tendon graft was 41.28 mm^2 (range from 31.19 mm^2 to 56.77 mm2). The diameter of the hamstring tendon graft in male was 7.46 mm (range from 6.7 mm to 8.5 mm) and in female was 6.8 mm (6.3 mm to 7.5 mm). The diameter of the hamstring tendon graft on the right side was 7.26 mm (range from 6.4 mm to 8.5 mm) and on the left side 7.19 mm (6.3 mm to 8.4 mm). The cross-sectional area of the hamstring tendon graft is male was 43.94 mm^2 (range from 35.27 mm^2 to 56.77 mm^2) and in female was 37.43 mm^2 (range from 31.19 mm^2 to 44.23 mm^2). The cross-sectional area of the hamstring tendon graft on the right side was 41.70 mm^2 (range from 32.18 mm^2 to 56.77 mm^2) and on the left side is 40.86 mm^2 (range from 31 mm^2 to 55 mm^2).

Tibial Insertional Area

The average tibial insertional length is 14.31 mm (range from 11.8 mm to 16.6 mm) and width was 11.47 mm (range from 9.7 mm to 13 mm). The average tibial cross-sectional area was 129.63 mm^2 (range from 99 mm^2 to 169.56 mm^2). The average tibial cross-sectional area in male was 140.83 mm^2 (range from120.03 mm^2 to 169.56 mm^2) and in female was 113.46 mm^2 (99 mm^2 to 146.49 mm^2). The average tibial insertional area on the right side was 131.10 mm^2 (100.1 mm^2 to 169.56 mm^2) and on the left side was 128.16 mm^2 (99 mm^2 to 164.94 mm^2).

Femoral Insertional Area

The average femoral insertional area of the ACL was 97.23 mm^2 (range from 56.57 mm^2 to 144.63 mm^2). The femoral insertional area of the ACL in male was 110.78 mm^2 (range from 80.21 mm^2 to 144.63 mm^2) and female was 77.66 mm^2 (range from 56.57 mm^2 to

Table 1: Mean diameter of ACL, quadrupled hamstring tendon, and mean cross-sectional area of ACL midsubstance, hamstring tendon

Parameters	Mean diameter of the ACL midportion in mm	Mean diameter of the quadrupled hamstring tendon graft in mm	Mean cross-sectional area of the ACL midportion in mm²	Mean cross-sectional area of the quadrupled hamstring tendon graft in mm²
Mean	6.6 (±0.39)	7 (±0.55)	34.35 (± 4.09)	41.28 (±6.53)
Male	6.77 (±0.35)	7.46 (±0.56)	36.10 (±3.80)	43.94 (±6.78)
Female	6.36 (±0.31)	6.89 (±0.33)	31.81 (± 3.09)	37.43 (±3.65)
Right	6.64 (±0.39)	7.26 (±0.56)	34.72 (± 4.13)	41.70 (±6.67)
Left	6.56 (±0.39)	7.19 (±0.55)	33.97 (± 4.12)	40.86 (±6.49)

ACL: Anterior cruciate ligament

Table 2: Tibial and femoral insertional area dimensions

Parameters	Tibial insertional length/width (mm)	Tibial insertional area (mm²)	Femoral insertion length/width (mm)	Femoral insertional area (mm²)
Mean	14.31 (±1.31)/11.47 (±0.9)	129.63 (±20.71)	12.76 (±1.62)/9.55 (±1.24)	97.23(± 24.37)
Male	14.83 (±1.09)/12.06 (±0.56)	140.83 (±15.58)	13.7 (±1.17)/10.22 (±0.94)	110.78(± 19.23)
Female	13.55 (±1.26)/10.62 (± 0.56)	113.46 (±15.78)	11.41 (±1.18)/8.57 (±0.95)	77.66 (±16.51)
Right	14.37 (±1.34)/11.55 (±0.92)	131.10 (±21.32)	12.79 (±1.63)/9.57 (±1.26)	97.68 (±24.67)
Left	14.25(±1.31)/11.39 (±0.9)	128.16 (±20.47)	12.73 (±1.65)/9.52 (±1.25)	96.78 (±24.63)

ACL: Anterior cruciate ligament

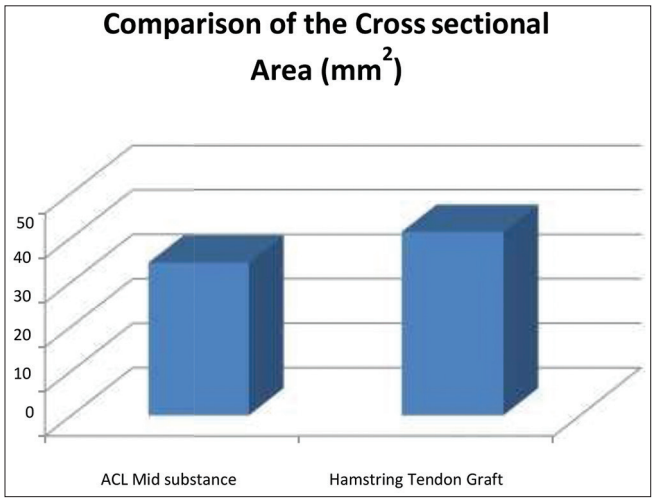

Figure 3: Comparison between the cross-sectional area of the anterior cruciate ligament midsubstance and hamstring tendon graft

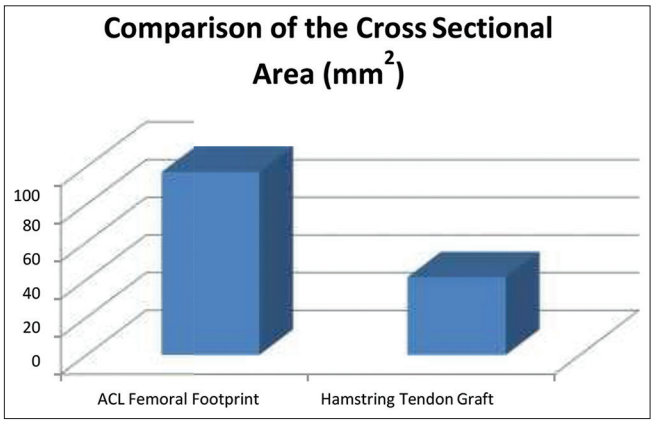

Figure 4: Comparison between the cross-sectional area of the anterior cruciate ligament femoral footprint and hamstring tendon graft

104.19 m²). The femoral insertional area on the right side was 97.68 mm² (range from 56.57 mm² to 144.63 mm²) and on the left side was 96.78 mm² (56.37 mm² to 142.49 mm²) [Figure 4].

The quadruple transplant hamstring tendon is 20.17% larger than the ACL mid substance. The difference was statistically significant (P = 0.0207). Although there is a significant difference in size (20.17%) between the hamstring tendon graft and ACL midsubstance, it always showed the highest correlation (coefficient correlation Karl Pearson (R) 0.92), which is considered a good correlation [Table 3, Figure 5]. ACL femoral and tibial footprint also has a correlation with hamstring tendon graft but midsubstance has the highest correlation amplitude (coefficient of Karl Pearson correlation R was 0.92).

DISCUSSION

ACL is most commonly injured in internal derangement of knee. ACL reconstruction is important because it restores back the stability of the knee and prevents the development of osteoarthritic changes in the knee joint. Various grafts are used for ACL reconstruction, BPTB graft and quadrupled hamstrings tendon graft are commonly used for the graft ACL reconstruction. However, graft quadrupled hamstring tendon is more popular and commonly used in Indian subcontinent. The reconstruction of the ACL is passed by the evolution of open ACL reconstruction to reconstruction under

Table 3: The correlation between ACL tibial, femoral footprint, and midsubstance

Parameters	Karl Pearson's coefficient of correlation (R) Wrt hamstring tendon graft
ACL tibial footprint area	0.85
ACL femoral footprint area	0.89
ACL midsubstance cross-sectional area	0.92

ACL: Anterior cruciate ligament

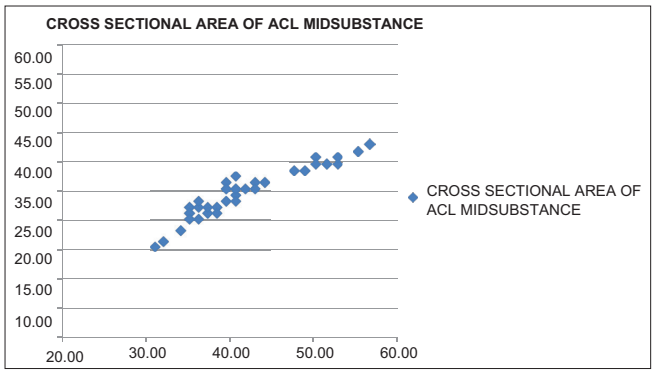

Figure 5: Scattered diagram showing the correlation between cross-sectional area of hamstring tendon graft and anterior cruciate ligament midsubstance

assisted arthroscopy. The reconstruction of assisted arthroscopic ACL has become more popular after 1980. In the first technical time, transtibial tunnel was used for ACL reconstruction. However, it has the disadvantage of a more vertical position and non-anatomical graft that undermines the rotation stability.[8] Nowadays, it is replaced by the establishment of the anterior graft tunnel, anterolateral tunnel technique is useful for anatomical placement graft.[9] ACL is the primary restraint against anterior translation of the tibia. Therefore, the anatomical placement of the graft is important to prevent the development of osteoarthritic changes in the knee joint and prevent the encroachment of the graft in the intercondylar notch.[10]

The purpose of this study is to investigate the dimensions of the ACL and quadruple hamstring tendon graft used for ACL reconstruction.

In our study, the statistical analysis shows that: (a) There is a good correlation between the middle part of the ACL and quadrupled hamstrings tendon graft of the Indian population. (b) There is a correlation between the hamstring tendon graft, tibial and femoral ACL footprint. However, the magnitude of the correlation is less compared to the midsubstance ACL. With the tendon graft quadrupled hamstrings, the femoral and tibial footprints of the ACL could not be reproduced.

In our study, we measured the dimensions of the middle portion of the ACL intact unlike other studies in the past and Dargel *et al.*,[11] where measurements were carried out after removal of ACL knee. In this study, the dimensions of the ACL were taken after the removal of the synovial membrane to obtain the most accurate dimensions. The results obtained by this method are comparable to those obtained after removal of the synovial membrane.[12-14]

According to the previous studies, the area of the ACL femoral ranges from 83 mm^2 footprint to 198 mm^2 and of the tibial footprint from 114 mm^2 to 229 mm^2.[12,15-19] The area of quadrupled hamstring tendon graft ranges from 20 mm^2 to 50 mm^2 and the surface of the middle portion of the ACL ranges from 20 mm^2 to 38.9 mm^2.[20] The findings of the present study are similar to the previous studies. The tibial footprint is substantially greater than the footprint of the femur, middle part, and quadrupled graft tendon hamstrings.

As described by Mochizuki *et al.*[21] and Hara *et al.*,[22] the ACL is attached to the femoral origin as a fan-shaped structure on the side wall of the intercondylar notch of the femur. Therefore, insertional area at the femoral footprint is larger than the midsubstance of the ACL. These results are similar to the present study.

The technique of double-bundle and bone-patellar tendon-bone graft can reproduce footprints of ACL, but the reconstructed graft must be as large as and as close as the native ACL. The major problem with the use of larger graft and so as to mimic the footprint is the transplant impingement. The tibial and femoral footprints are significantly larger compared to the average cross-sectional area of the ACL. Therefore, it is important to evaluate the graft, which must imitate reconstructed cross midsubstance ACL to avoid impingement. In this study, we found a good correlation between the graft and ACL midsubstance.

The arthritic knees are not included as osteoarthritic changes can alter the dimensions of the ACL and transplant hamstring tendon. The main limitation of the study is that the assessment is done by macroscopic examination only. There could be human error and prejudice. The measurement of the size of the ACL was manually taken with digital calipers. However, as the ACL is three-dimensional structure,[16] better dimensions have been obtained with the three-dimensional camera or computer graphics. Some took with dimensions X-ray and magnetic resonance imaging.[23]

For the clinical relevance, there is a good correlation between the ACL and the medial part of the ACL, but the correlation between the footprints of the ACL and

hamstring tendon graft is four-fold less in amplitude. Therefore, it is unlikely to reproduce with the graft tendon hamstring quadrupled the femoral and tibial footprint of the ACL. Furthermore, Bedi *et al.*[24] said, in its study, that the restoration of the footprint of the ACL in reconstruction is paramount.

CONCLUSIONS

There is a good correlation between the cross-section of midsubstance of the ACL and quadrupled hamstring tendon graft in Indian population (coefficient of Karl Pearson correlation (R) 0.92). With the use of graft quadrupled hamstring tendon for reconstruction of the ACL, the graft is oversized to the average of 20.17%. The ACL dimensions are more in men than women ($P < 0.05$). With the use of the current reconstruction using hamstring quadrupled tendon graft technique, it is unlikely to reproduce the footprints of the ACL.

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Original Article

Patients Satisfaction about Services Provided by Smoking Cessation Clinic at Armed Forces Hospital in AL-Jubail

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Abstract

Background: Health-care providers can help in achieving live tobacco-free which will reduce smoking-related disease, disability, and death. It has been documented that most quit attempts are unsuccessful, despite of that, half of smokers who have tried to quit are no longer smoking, which means that those who trying to quit can succeed.

Objectives: The objectives of the study were to assess the level of satisfaction of patients attending the smoking cessation clinic regarding provided services and identify factors association with that satisfaction.

Subjects and Methods: A cross-sectional study was conducted at the smoking cessation clinic, Armed Forces Hospital in Jubail, Saudi Arabia. It included all patients attending the clinic, throughout the period from September 1, 2019, to March 31, 2020. A self-administered questionnaire comprised 19 questions was utilized to assess their satisfaction with services, in addition to demographic and smoking-related characteristics.

Results: The study included 171 males. The age of about one-fourth of them (24.6%) ranged between 20 and 29 years whereas that of 21.1% was 50 years or above. Regarding the provided services, Champix treatment was the most common (50.8%), followed by counseling (34.5%). Majority of the participants reported previous attempts to quit smoking (86.5%); mostly once (46.2%). One-third of the participants reported a history of smoking relapse. Overall, more than half of the participants (53.8%) were satisfied with services offered by the smoking cessation clinic. Low satisfaction was reported regarding the written information provided by the medical staff and having calls from the smoking cessation clinic before appointment to encourage them to attend treatment. None of the demographic, smoking-related, and smoking-cessation clinic related factors was associated with the level of satisfaction with the offered services.

Conclusion: A considerable proportion of smoking cessation clinic male attendees in Armed Forces hospital, Al-Jubail is satisfied with offered services, with no difference between them according to demographic, smoking-related, and smoking-cessation clinic-related characteristics.

Key words: Satisfaction, Services, Smoking cessation clinic, Smoking quitting, Smoking relapse

INTRODUCTION

Background/Literature Review

Tobacco smoking is the single preventable risk factor for death-related caner as it is proved to be a risk factor for numerous types of cancer.[1,2] In addition, tobacco smoking is a major risk factor for cardiovascular diseases (CVDs) and it is associated with almost 12% of all deaths due to CVDs.[3] Furthermore, tobacco smoking continues to be the fundamental reason of premature death and a major cause of medical costs and lost productivity.[4]

One cigarette contains more than 5000 harmful chemical substances that can damage all body systems.[5] According to a recent (2018) report of the World Health Organization (WHO), approximately 7 million individuals die yearly because of tobacco smoking worldwide, off them, 6 million die by direct use of tobacco whereas about 1 million die due to secondhand smoking.[6]

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In the Kingdom of Saudi Arabia (KSA), the overall prevalence of tobacco smoking was 12.1%; 23.7% among males, and 1.5% among females.[7] More dramatically, this rate was increasing in the last few decades making KSA on the top ten worldwide concerning cigarette smoking.[8]

Ministry of Health in KSA declared that smokers consumed around 15 billion cigarettes per year which costs around 690 million Saudi Riyals (SR).[7,9] In addition, 5 billion SR were spent on the health costs due to smoking health problems annually.[10]

It has been documented that the habit of smoking is hard to stop once begin as the cigarettes contain substances like nicotine which have addictive characteristics. Inside the body circulation, they produce neurotransmitters, mainly dopamine which improve working capacity, memory, attention, as well as pleasure and improve mood,[11,12] therefore, on stopping smoking, the levels of neurotransmitter decrease making the smokers develop what is called "withdrawal symptoms" such as anxiety, irritability, lack of attention, and restlessness."[11,13]

Water pipe tobacco smoking is a form of tobacco smoking present in various flavors and gaining popularity in our area.[14] Banning smoking in all forms in closed and public areas as well as prohibiting advertising of tobacco products and derivatives were issued by the Council of Arab Ministers of Health.[15]

Health-care providers can help in achieving live tobacco-free which will reduce smoking-related disease, disability, and death.[16] It has been documented that most quit attempts are unsuccessful,[17] despite of that, half of smokers who have tried to quit are no longer smoking, which means that those who trying to quit can succeed.

According to the Centers for Disease Control and Prevention (CDC), primary care visits should be a chance to educate smokers about facilities available to them to quit smoking. However, counseling for quitting represent only 20–50% of physician visits and cessation medications are ordered minority of them (<8%).[16,18]

Few studies were conducted worldwide investigating patients' satisfaction with services provided at smoking cessation clinics. In Saudi Arabia, no study was cited investigating the patients' satisfaction with services provided at smoking cessation clinics. However, few studies investigated the physician's knowledge, attitude, and practice of smoking cessation counseling which could impact the patients` satisfaction through indirect way. The following is summary of these studies.

Al-Jdani *et al.* (2018) evaluated the knowledge, attitude, and practices of primary health-care physicians and dentists regarding smoking cessation counseling in Jeddah. Their main source of smoking cessation counseling was the internet (21.3%), followed by postgraduate studies (19.4%). The level of knowledge regarding smoking cessation counseling was poor. However, the level of attitude was good and that of practice was average. There was a significant association between participants' title and knowledge, attitude, and practice ($P < 0.001$).[19]

AlAteeq *et al.* (2016) carried out a survey to assess the attitude and practice of primary healthcare physicians toward providing smoking cessation advice to their smoker patients in a military community in Riyadh. More than half of the physicians (56%) did not attend a smoking cessation educational program in the last year. Most of them (75%) had a positive attitude and 64.4% had favorable practice. Positive attitude was significantly associated with higher educational level. Favorable practice was significantly associated with higher experience and positive attitude.[20]

In Bahrain, Hamadeh *et al.* (2017) carried out a cross-sectional study to estimate the smoking quit rates among male attendees of quit tobacco clinics and define associated factors. More than half of male smokers (56.5%) had quit all forms of tobacco after attending the quit tobacco clinics. Shisha smokers were more successful in quitting than cigarette smokers. Majority of them (93.0%) received nicotine replacement treatment accompanied with counseling sessions. Factors significantly associated with successful quitting were more than three visits to the clinics and previous quit attempts (≥21 months). Most participants were satisfied with the services provided by the clinics. The majority wanted an increase in the working days of the clinic.[21]

In USA, Quinn *et al.* carried out a study to explore the extent of compliance of physicians with the guideline's treatment model known as "5A's" (Ask, Advise, Assess, Assist, Arrange). Smokers were inquired about tobacco-cessation treatments received during primary care visits in the last year. Majority of smokers (90%) were asked about smoking, 71% of them were advised to quit smoking, 56% were assessed for their willingness to quit it, 49% received assistance interventions, and 9% had arranged follow-up arranged. Treatment was provided more often to smokers who asked for help and/or intended to quit. Only modest associations were found between patient characteristics and receipt of 5A's cessation services. Smokers who received treatment were more satisfied with health-care services.[22]

Solberg *et al.* (2001) carried out a study to assess the impact of receiving smoking cessation information during health

visits on the satisfaction with the smoking cessation among current cigarette smokers. Smokers were either very satisfied (12%) or satisfied (25.3%) with physician counseling. Patients who had been asked about tobacco use or advised to quit it during the latest visit were more likely to be satisfied with services compared to their counterparts. Smokers reported no interest in quitting at the time of the latest visit expressed greater satisfaction with physician help.[23]

Conroy *et al.* (2005) evaluated the smoking intervention through the five-step algorithm (5A's) among patients attending primary care centers. About two-thirds of them (65.9%) reported that they smoked at the time of the visit. They reported high levels of satisfaction with their tobacco-related care. Patient-reported receipt of each 5A step was significantly associated with greater patient satisfaction with tobacco-related care. Satisfaction with overall healthcare increased as counseling intensity increased. Patient reports of smoking cessation interventions delivered during primary care practice are associated with greater patient satisfaction with their healthcare, even among smokers not ready to quit.[24]

Sipos *et al.* (2018) carried out a cross-sectional study to assess the effectiveness of general practitioners' smoking cessation support, in the form of brief intervention, pharmacological and non-pharmacological support, on a sample of regular smokers aged 18 years or over in Hungary. The smoker's factors significantly associated with providing general practitioners' mediated smoking cessation support were high school education, chronic obstructive pulmonary, disease, and CVDs.[25]

Halladay *et al.* investigated interaction between smokers and health-care providers at primary care settings to explore the resources needed to support quit attempts and to better determine important outcomes among smokers through a focus group composed of patients (current smoker or having quit within 6 months). They concluded that smoking cessation counseling requires seeking the patient voice early in the process. Participants preferred honest, consistent, and pro-active discussions and actions.[26]

Study Rationale

- Tobacco smoking is the most modifiable risk factor that increases morbidity and mortality rates
- Patients' satisfaction with provided care is an essential indicator of the adequacy of the quality of healthcare
- The outcome of this study may help physicians better understand the patients' needs to quit smoking
- Up to the researcher's knowledge, very few studies were carried out worldwide, none-of them in Saudi Arabia discussing this important issue

Aim of Study

The aim of the study was to improve patients` satisfaction about services provided at smoking cessation clinic at armed force hospital.

Objectives

The objectives are as follows:

1. To assess the level of satisfaction of patients attending the smoking cessation clinic at Al-Jubail Military hospital regarding provided services
2. To identify factors associated with patients' satisfaction with services provided at smoking cessation clinic at Al-Jubail Military hospital.

METHODOLOGY

Study Design

This study was a cross-sectional study.

Study Area and Setting

This study was conducted at Al-Jubail city, which situated in the Eastern province on the Arabian Gulf coast of Saudi Arabia. Jubail Industrial City is the largest civil engineering project in the world today. According to 2011 census, there are 800.949 individuals in Al-jubail (73% of them were Saudis).[27] At the smoking cessation clinic, Armed Forces Hospital in Jubail, the study was specifically implemented. This clinic launched on 2015.

Study Population

All patients attending the smoking cessation clinic at Armed Forces Hospital in AL-Jubail, through the study period (September 1, 2019–March 31, 2020) constituted the target population for the study.

Sampling

All patients attending the smoking cessation clinic at Armed Forces Hospital in AL-Jubail, throughout the period from September 1, 2019 to March 31, 2020 were invited to participate in the study by filling in the study questionnaire. In 2018, almost 300 patients visited the clinic.

Study Tool

A self-administered questionnaire that comprised 32 questions was utilized. Permission to use the questionnaire was obtained from the corresponding authors through e-mail communication.

The questionnaire composed of two sections:

1. The first section: Was adopted from a recent study carried out in Bahrain:[21] It included demographic characteristics of the participants (age, gender, educational level, marital status, and employment status), in addition to details of smoking history

(Duration, average number of cigarettes/shisha/day, age at starting smoking). Number of visits to smoking cessation clinic in the past 12 months, history of previous quitting/relapse, provided services at the smoking cessation clinic and overall smoker's satisfaction. Quit smoking was considered if the smoker stopped smoking of any tobacco product for at least 6 months after attending the clinic whereas relapse in tobacco smoking was defined as resuming smoking after a complete abstention for at least a month.[28]

2. The second part: Stop Smoking Service client satisfaction survey tool which designed for all clients visiting smoking cessation clinics. It included three key items; "Overall how satisfied were you with the support you received to stop smoking"; response options were on a Likert scale: 1 (very satisfied), 2 (satisfied), 3 (unsure), 4 (unsatisfied), and 5 (very unsatisfied). "Would you recommend this service to other smokers who wanted to stop smoking": 0 (no), 1 (unsure), and 2 (yes) and "Have you smoked since your last appointment with the service?": 1 (No, not a single puff), 2 (Yes, just a few puffs), 3 (Yes, 1–5 cigarettes), and 4 (More than 5 cigarettes). The complete questionnaire (19 items) included the three key items assess overall client satisfaction with the smoking cessation services.[29] We include the 32 questions in our questionnaire. The questionnaires were scored in the way that the high the satisfaction with smoking cessation service, the higher the score. Total score was computed for each participant and the median value was computed (it was 53). Participants scored below the median value were considered "unsatisfied" whereas those scored at the median value and above were considered "Satisfied."

Data Collection Technique

The researcher distributed the self-administered questionnaire during the waiting of patients for their clinic visits. Care was taken to not disturb the working schedule. A help in collecting data from female site were requested by a trained nurse. The researcher was available to clarify any issue and the questionnaires were collected in the same day. The data were verified by hand then coded and entered to a personal computer.

Pilot Study

A pilot study was conducted on ten smokers. The results of this pilot study helped to set the study in their final applicable forms. The results were added to the final report sine there was no significant difference from final results.

Data Analysis

The Statistical Package for the Social Sciences (SPSS version 25) was used for data entry and statistical analysis. The descriptive statistics were calculated. Chi-square test was utilized to test for the association between satisfaction with services offered by smoking cessation clinic and factors affecting it. Statistically significant differences were considered at $P < 0.05$.

Definitions

Relapse

Resuming smoking after a complete abstention for at least a month.

Administrative Considerations

All the necessary official permissions will be fully secured before data collection. Collected data will be kept strictly confidential and will be used only for research purposes.

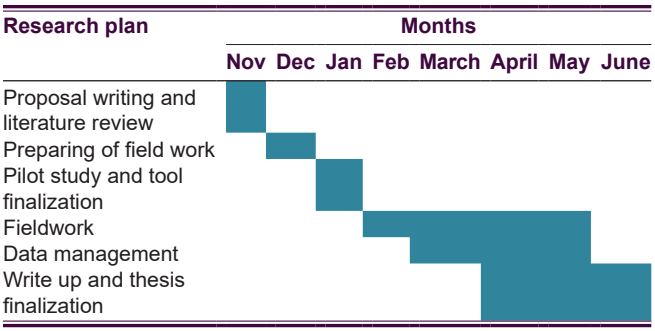
Ethical Considerations

Before start of the study, the researcher will fulfill all the necessary official approvals by the Research and Ethics committee. Before data collection, all participants will be clearly and briefly informed about the objectives of this study. A written consent form will be signed by every participant in the study before conducting the interview. All participants will be assured regarding the full confidentiality of any collected data.

Budget

This study was funded by the researcher.

Timetable



RESULTS

The study included 171 males. The age of about one-fourth of them (24.6%) ranged between 20 and 29 years whereas that of 21.1% was 50 years or above. Almost half of them (49.7%) were secondary school graduated whereas 36.8% were university graduated. Slightly more than half of them (51.5%) were married and 61.4% were working Table 1.

Smoking Related Characteristics

From Table 2, it is shown that more than half of the participants smoked for more than 10 years (54.4%), on an average of 1–2 packets per day among 59% of them and at least one shish per day among 35.7% of them. Regarding

Table 1: Socio-demographic characteristics of the participants

Socio-demographic characteristics	Frequency	Percentage
Age (years)		
<20	19	11.1
20–29	42	24.6
30–39	39	22.8
40–49	35	20.5
≥50	36	21.1
Educational level		
Below secondary school	23	13.5
Secondary school	85	49.7
University	63	36.8
Marital status		
Single	58	33.9
Married	88	51.5
Divorced/widowed	25	14.6
Employment status		
Working	105	61.4
Retired	31	18.1
Not working	35	20.5

Table 2: Smoking-related characteristics of the participants

Smoking-related characteristics	Frequency	Percentage
Duration of smoking before visiting the smoking cessation clinics (years)		
<5	48	28.1
5–10	30	17.5
>10	93	54.4
Average amount of cigarettes/Shisha smoked per day before visiting the smoking cessation clinics		
One packet of cigarettes	53	31.0
Two packets of cigarettes	48	28.0
≥thee packets of cigarettes	9	5.3
One Shisha	32	18.7
Two or more Shisha	29	17.0
Age at stating any type of tobacco smoking		
<18	40	23.4
18–20	56	32.7
20	36	21.1
>20	39	22.8

the age at starting any type of tobacco smoking, almost one-third of them (32.7%) started smoking between 18 and 20 years whereas 22.8% started it after 20 years.

Information Related to Smoking Cessation Clinics Visits

Among almost half of the participants (49.7%), the current visit was the first one to the smoking cessation clinic in the last 12 months whereas it more than the third among 17.6% of them. Regarding the provided services, Champix treatment was the commonest (50.8%), followed by counseling (34.5%) Table 3.

Majority of the participants reported previous attempts to quit smoking (86.5%); mostly once (46.2%) as illustrated in Figure 1. Among quitters, the longest duration exceeded 1 month among 45.9% of them as shown in Figure 2.

Table 3: Information related to smoking cessation clinics visits among the participants

Information related to smoking cessation clinics visits	Frequency	Percentage
Number of clinic visits in the last 12 months		
First	85	49.7
Second	39	22.8
Third	17	9.9
>Third	30	17.6
Provided services at the clinics		
Nicotine replacement therapy (gum-patch)	22	12.9
Champix treatment	87	50.8
Counseling cessions	59	34.5
Traditional herbal medicine	3	1.8

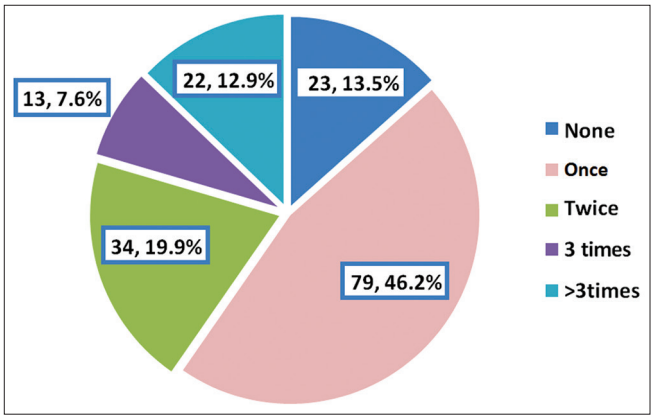


Figure 1: History of previous quitting among the participants

One-third of the participants reported a history of smoking relapse which means resuming smoking after a complete abstention for at least a month Figure 3.

Satisfaction with the support received to stop smoking'

Most of the participants were either satisfied or very satisfied with the support received to stop smoking (60.8%) and the support of the medical staff (65.6%). Furthermore, 60.8% of the participants agreed that the information and advice provided by the medical staff during their appointment was either helpful or very helpful while less than half of them (48.6%) described the written information provided by the medical staff as very helpful/helpful. Most of the participants agreed to recommend smoking cessation service to other smokers who want to stop smoking (64.3%), will be back to the clinic, if start smoking again to help stop smoking (63.1%), will be welcomed back if go back to the clinic for help stopping smoking in the future (56.8%), contact the smoking clinic easily when decided to stop smoking (59.6%) and when they contacted the clinic, they asked them they have to wait (67.2%); this waiting was 1 day or less among 52.5%) of the participants. Majority of the participants were offered support with child care costs (91.9%), agreed that the amount of time they had to wait for first appointment was acceptable (77.8%), the place for appointments was convenient (73.1%), and the appointment times given were convenient (71.9%)

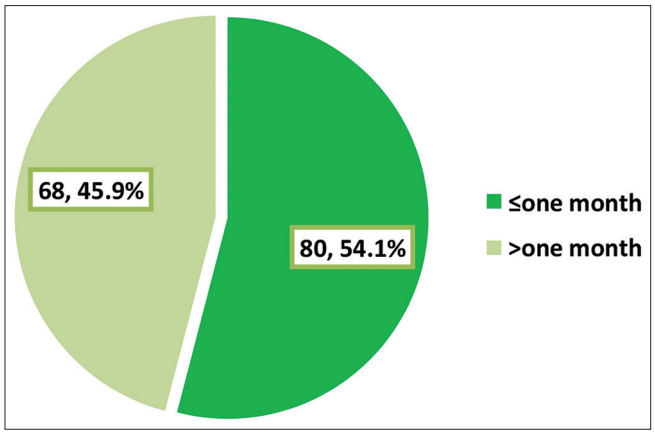


Figure 2: The longest duration of quitting among smoking quitters (n=148)

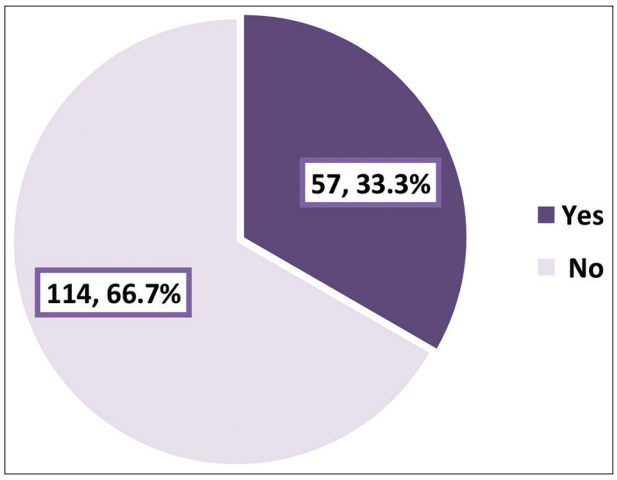


Figure 3: History of smoking relapse among the participants

whereas only 33.9% reported a call from the smoking cessation clinic before appointment to encourage them to attend treatment. More than half of the participants (57.3%) have smoked since their last appointment with the service.

Overall, more than half of the participants (53.8%) were satisfied with services offered by the smoking cessation clinic, Armed Forces Hospital, Al-Jubail city, as illustrated in Figure 4.

Factors Associated with Satisfaction with Smoking Cessation Services

Socio-demographic characteristics

As shown in Table 5, none of the studied socio-demographic factors (Age, educational level, marital status, and employment status) was significantly associated with satisfaction of the participants with services offered by smoking cessation clinic.

Smoking-related characteristics

Smoking-related characteristics (duration of smoking before visiting the smoking cessation clinics, average

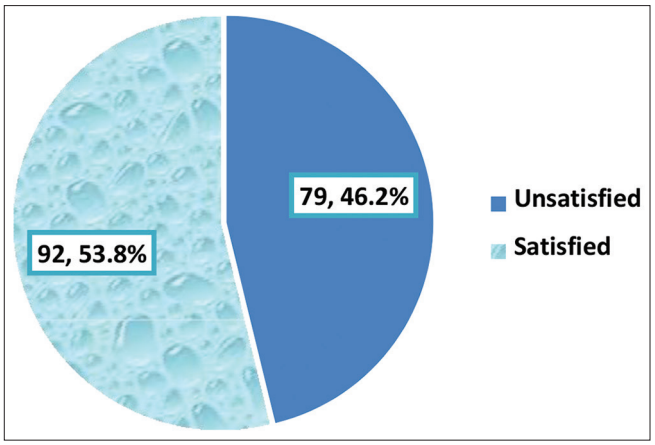


Figure 4: Overall satisfaction of the participants with smoking cessation services at the clinic, Armed Forces hospital, Al-Jubail city

amount of cigarettes/Shisha smoked per day before visiting the smoking cessation clinics, and age at stating any type of tobacco smoking) were significantly associated with satisfaction of the participants with services offered by smoking cessation clinic Table 6.

Information related to smoking cessation clinics visits

Number of clinic visits in the past 12 months and type of provided services at the clinics were not significantly associated with satisfaction of the participants with services offered by smoking cessation clinic, Table 7.

History of quitting attempts

Neither history of previous quitting among the participants nor the longest duration of quitting was significantly associated with satisfaction of the participants with services offered by smoking cessation clinic, Table 8.

History of smoking relapses

There was no statistically significant association between history of smoking relapse and satisfaction with services offered by smoking cessation clinic among the participants, Table 9.

DISCUSSION

Tobacco cessation clinics are essential to help smokers quit, through offering services to them. These services are provided free of charge in the KSA, including consultation as well as full course of nicotine replacement therapy.[10] Despite of that, just a little more than half of the smokers reported having been advised by their health-care professional to quit smoking.[30]

Up to the best of our knowledge, no previous efforts have been made to investigate how valuable are the smoking

Table 4: Satisfaction of the participants with the support received to stop smoking at smoking cessation clinic, Armed Forces hospital, Al-Jubail city

Satisfaction of the participants with support received clinic	Very satisfied *n* (%)	Satisfied *n* (%)	Unsure *n* (%)	Unsatisfied *n* (%)	Very unsatisfied *n* (%)
Satisfaction with the support received to stop smoking'	56 (32.7)	48 (28.1)	19 (11.1)	25 (14.6)	23 (13.5)
Satisfaction with the support of the medical staff	55 (32.3)	57 (33.3)	11 (6.4)	31 (18.1)	17 (9.9)
Satisfaction of the participants with information received clinic	**Very helpful *n* (%)**	**Helpful *n* (%)**	**Unsure *n* (%)**	**Unhelpful *n* (%)**	**Very unhelpful *n* (%)**
How useful is the information and advice provided by the medical staff during your appointment?	56 (32.7)	48 (28.1)	13 (7.6)	36 (21.1)	18 (10.5)
How useful is the written information provided to you by the medical staff? (*n*=105)	32 (30.5)	19 (18.1)	17 (16.2)	23 (21.9)	14 (13.3)

Participant recommendation with the services provided in the clinic	No *n* (%)	Not sure *n* (%)	Yes *n* (%)
Do you recommend smoking cessation service to other smokers who want to stop smoking	32 (18.7)	29 (17.0)	110 (64.3)
If starting smoking again, will be back to the clinic to help stop smoking	41 (24.0)	22 (12.9)	108 (63.1)
If you go back to the clinic for help stopping smoking in the future, do you think you will be welcomed back?	30 (17.5)	44 (25.7)	97 (56.8)
It was easy to contact the smoking clinic when you decided you wanted to stop smoking	34 (19.9)	35 (20.5)	102 (59.6)
When you contacted the clinic were you given an appointment date or told how long you would have to wait?	36 (21.1)	20 (11.7)	115 (67.2)
How long should you wait a head? (*n*=115) ≤1 day		60 (52.5)	
2–<7 days		28 (24.3)	
≥7 days		27 (23.2)	
Was the amount of time you had to wait for your first appointment acceptable to you?	24 (14.0)	14 (8.2)	133 (77.8)
Was there a call from the smoking cessation clinic before your appointment to encourage you to attend treatment?	75 (43.9)	38 (22.2)	58 (33.9)
Are the appointment times you were given convenient for you?	26 (15.2)	22 (12.9)	123 (71.9)
Is the place where you go for your appointments convenient for you to get to?	15 (8.8)	31 (18.1)	125 (73.1)
Have you been you offered support with child care costs?	10 (5.8)	4 (2.3)	157 (91.9)
Were you given a choice of an individual appointment or a group?	35 (20.5)	40 (23.4)	96 (56.1)
The information given to me about choosing the drug was helpful	38 (21.1)	28 (16.4)	107 (62.5)
It was easy to stick and hold on to the medication by simply choosing the medication I am going to use to try to stop smoking	63 (36.8)	35 (14.6)	83 (48.6)
Have you smoked since your last appointment with the service?		73 (42.7)	
No		44 (25.7)	
Yes, just a few puffs Yes, 1–5 cigarettes		27 (15.8)	
Yes, more than 5 cigarettes		27 (15.8)	

cessation clinics in the KSA and in particular the Eastern Region. Therefore, this study was conducted to assess the level of satisfaction of patients attending the smoking cessation clinic regarding provided services and identify factors association with that satisfaction as the findings of this study would be of importance for health policy makers in their smoking control efforts.

In the current study, majority of the participants reported previous attempts to quit smoking (86.5%), which is encouraging; among 45.9% of them. The longest duration exceeded 1 month. In a study carried out in Bahrain,[21] the tobacco-quit rate was 56.5%. However, in the present study, one-third of the smoking cessation clinic attendees reported a history of smoking relapse, which is very close to what has been observed in Bahrain.[21] Therefore, these clinics could contribute effectively to the tobacco control efforts and reduce the health burden of tobacco smoking, through providing services that initiate and maintain quitting.

The present study revealed that most of smoking cessation clinic' attendees were satisfied with support received to stop smoking as well as the support of the medical staff. Furthermore, most of them agreed that the information and advice provided by the medical staff during their appointment was helpful to them while almost half of them described the written information provided by the medical staff as helpful. Previous Saudi study indicated that physicians' level of knowledge regarding smoking cessation counseling was poor; however, the level of attitude was good and that of practice was average[19] Furthermore, in another study carried out in Riyadh, more than half of the physicians did not attend a smoking cessation educational program in the last year, however, most of them had a positive attitude and favorable practice regarding smoking

Table 5: Association between socio-demographic characteristics and satisfaction with smoking cessation services among the participants

Association between socio-demographic characteristics and satisfaction with smoking cessation services	Satisfaction with smoking cessation services		*P*-value*
	Unsatisfied *n*=79 *n* (%)	Satisfied *n*=92 *n* (%)	
Age (years)			
<20 (*n*=19)	6 (31.6)	13 (68.4)	
20–29 (*n*=42)	20 (47.6)	22 (52.4)	0.307
30–39 (*n*=39)	23 (59.0)	16 (41.0)	
40–49 (*n*=35)	14 (40.0)	21 (60.0)	
≥500 (*n*=36)	16 (44.4)	20 (55.6)	
Educational level			
Below secondary school (*n*=23)	13 (56.5)	10 (43.5)	0.242
Secondary school (*n*=85)	34 (40.0)	51 (60.0)	
University (*n*=63)	32 (50.8)	31 (49.2)	
Marital status			
Single (*n*=58)	29 (50.0)	29 (50.0)	0.526
Married (*n*=88)	37 (42.0)	51 (58.0)	
Divorced/wido (*n*=25) wed	13 (52.0)	12 (48.0)	
Employment status			
Working (*n*=105)	53 (50.5)	52 (49.5)	0.365
Retired (*n*=31)	12 (38.7)	19 (61.3)	
Not working (*n*=35)	14 (40.0)	21 (60.0)	

*Chi-square test

Table 6: Association between smoking-related characteristics and satisfaction with smoking cessation services among the participants

Association between smoking-related characteristics and satisfaction with smoking cessation services	Satisfaction with smoking cessation services		*P*-value*
	Unsatisfied *n*=79 *n* (%)	Satisfied *n*=92 *n* (%)	
Duration of smoking before visiting the smoking cessation clinics (years)			
<5 (n=48)	17 (35.4)	31 (64.6)	0.210
5–10 (n=30)	15 (50.0)	15 (50.0)	
>10 (n=93)	47 (50.5)	46 (49.5)	
Average amount of cigarettes/Shisha smoked per day before visiting the smoking cessation clinics			
One packet of cigarettes (*n*=53)	21 (39.6)	32 (60.4)	0.521
Two packets of cigarettes (*n*=48)	21 (43.8)	27 (56.3)	
≥thee packets of cigarettes (*n*=9)	6 (66.7)	1 (33.3)	
One Shisha (*n*=32)	17 (53.1)	15 (46.9)	
Two or more Shisha (*n*=29)	14 (48.3)	15 (51.7)	
Age at stating any type of tobacco smoking			
<18 (*n*=40)	17 (42.5)	23 (57.5)	0.400
18–20 (*n*=56)	23 (41.1)	33 (58.9)	
20 (*n*=36)	21 (58.3)	15 (41.7)	
>20 (*n*=39)	18 (46.2)	21 (53.8)	

*Chi-square test

cessation.[20] Solberg *et al.* observed that 37.3% of current cigarette smokers were satisfied with physician counseling and smokers who had been asked about tobacco use or advised to quit it during the latest visit were more likely to

Table 7: Association between information related to smoking cessation clinics visits and satisfaction with smoking cessation services among the participants

Association between information related to smoking cessation clinics visits and satisfaction with smoking cessation services	Satisfaction with smoking cessation services		*P*-value*
	Unsatisfied *n*=79 *n* (%)	Satisfied *n*=92 *n* (%)	
Number of clinic visits in the last 12 months			
First (*n*=85)	37 (43.5)	48 (56.5)	0.914
Second (*n*=39)	19 (48.7)	20 (51.3)	
Third (*n*=17)	8 (47.1)	9 (52.9)	
>Third (*n*=30)	15 (50.0)	15 (50.0)	
Provided services at the clinics			
Nicotine replacement therapy (gum-patch) (*n*=22)	14 (63.6)	8 (36.4)	0.306
Champix treatment (*n*=87)	40 (46.0)	47 (54.0)	
Counseling cessions (*n*=59)	24 (40.7)	35 (59.3)	
Traditional herbal medicine (*n*=3)	1 (33.3)	2 (66.7)	

*Chi-square test

Table 8: Association between history of quitting attempts and satisfaction with smoking cessation services among the participants

Association between history of quitting attempts and satisfaction with smoking cessation services	Satisfaction with smoking cessation services		*P*-value*
	Unsatisfied *n*=79 *n* (%)	Satisfied *n*=92 *n* (%)	
History of previous quitting among the participants			
None (*n*=23)	13 (56.5)	10 (43.5)	0.667
Once (*n*=79)	35 (44.3)	44 (55.7)	
Twice (*n*=34)	14 (41.2)	20 (58.8)	
3 times (*n*=13)	5 (38.5)	8 (61.5)	
>3 times (*n*=22)	12 (54.5)	10 (45.5)	
Longest duration of quitting			
None (*n*=23)	14 (60.9)	9 (39.1)	0.304
≤1 month (*n*=80)	36 (45.0)	44 (55.0)	
>1 month (*n*=68)	29 (42.6)	39 (57.4)	

*Chi-square test

be satisfied with services compared to their counterparts.[23] However, it has been documented that physicians in our region have low perception of their role in helping smokers to quit.[15,16] It seems from the aforementioned studies that better knowledge, attitude, and practice of physicians regarding smoking cessation is an essential element for customer`s satisfaction.

Furthermore, most of the participants in the present study will recommend smoking cessation service to other smokers who want to stop smoking, will be back to the clinic, if start smoking again to help stop smoking, will be welcomed back if go back to the clinic for help stopping smoking in the future, and contact the smoking clinic easily when decided to stop smoking. Conroy *et al.* reported that smokers' reports of smoking cessation interventions delivered during primary care practice was associated with

Table 9: Association between history of smoking relapse and satisfaction with smoking cessation services among the participants

Association between history of smoking relapse and satisfaction with smoking cessation services	Satisfaction with smoking cessation services		*P*-value*
	Unsatisfied *n*=79 *n* (%)	Satisfied *n*=92 *n* (%)	
Yes (*n*=57)	26 (45.6)	31 (54.4)	0.914
No (*n*=114)	53 (46.5)	61 (53.5)	

*Chi-square test

greater patient satisfaction with their healthcare, even among those not ready to quit.[24]

In the present survey, most of smoking cessation clinics attendees were satisfied with the amount of time they had to wait for first appointment, the place for appointments and the appointment times. However, only one-third of them reported a call from the smoking cessation clinic before appointment to encourage them to attend treatment. Halladay *et al.* through a focus group with current smokers or those having quit within 6 months concluded that smoking cessation counseling requires seeking the patient voice early in the process and participants preferred honest, consistent, and pro-active discussions and actions.[26] In Bahrain, lower satisfaction rates were observed concerning clinic days and opening hours.[21]

In the current study, more than half of the smoking cessation clinic attendees have smoked since their last appointment with the service; mainly just a few puffs. Similarly, Conroy *et al.* reported that bout two-thirds of the participants (65.9%) smoked at the time of the visit to anti-smoking clinic.[24] This indicates that smoking is not easy to stop and great efforts are needed to achieve this goal.

Overall, more than half of the participants (53.8%) were satisfied with services offered by the smoking cessation clinic in the current study. In another study carried out in Bahrain, most participants were satisfied with the services provided by the clinics; however, the majority wanted an increase in the working days of the clinic.[21] In USA, high levels of satisfaction with their tobacco-related care were observed.[24]

In the current study, none of the investigated factors; demographic, smoking-related, and smoking-cessation clinic related was associated with the level of satisfaction. In a study carried out in USA, smokers who received treatment were more satisfied with health-care services.[22] In another USA study, smokers reported smoking cessation interventions delivered during primary care practice were associated with greater satisfaction with their healthcare, even among those not ready to quit.[24]

Strengths and Limitations

Among strengths of the present study are that it is, up to the best of our knowledge, unique of its kind in evaluating the satisfaction of smokers with services offered by the smoking cessation clinics in the KSA. Furthermore, this study could have an important role for health-care policy makers for empowering these clinics and increasing their efficiency. On the other hand, the main limitation was its conduction in one health-care facility which could impacts the generalizability of the results. Furthermore, its cross-sectional nature proves only association and not causality between independent and dependent variables.

CONCLUSION

A considerable proportion of smoking cessation clinic attendees in Armed Forces hospital, Al-Jubail is satisfied with offered services, exceeding half of them. However, lower satisfaction was reported regarding the written information provided by the medical staff and having calls from the smoking cessation clinic before appointment to encourage them to attend treatment. None of the demographic, smoking-related, and smoking-cessation clinic related factors was associated with the level of satisfaction with the offered services.

Recommendations

Based on the findings of the present study, the following are recommended:

1. Increasing awareness of the general population regarding the existence and importance of smoking cessation clinics, through educational announcements at schools, universities, and public places
2. Improving efficiency of smoking cessation clinics by making them easily accessible with sufficient working hours
3. Healthcare professionals should inquire about smoking among their patients and advise them to quit smoking and encourage them to seek help in smoking cessation clinics
4. Written information provided by the medical staff in smoking cessation clinics should be reconsidered
5. There should be calls from the smoking cessation clinic before appointment of smokers to encourage them to attend treatment
6. Further study including attendees to other smoking cessation clinics in needed to have more information about the whole situation in Al-Jubail.

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Original Article

Study of Influence of Hemoglobin Levels during Healing of Soft-tissue Wounds of High Energy Trauma to the Extremities

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Abstract

Background: Wound healing requires a higher concentration of oxygen at the local site, which acts against pathogens and helps in wound granulation. The study aimed to observe the relation between hemoglobin levels and its effect on wound healing in orthopedic wound management and also to assess wound-related morbidity associated with it.

Materials and Methods: This is a prospective observational study, conducted at tertiary care hospital from January 2016 to February 2019, for a period of 3 years. 200 patients of orthopedic wounds were included in the study. The sample was divided into two Groups A and B. Group A had patients with hemoglobin more than 12 g%, while Group B had patients with hemoglobin <12 g%. Both the group patients were evaluated and compared for the time taken for wound healing, duration of hospital stay, number of secondary procedures required, and incidence of infection.

Results: Number of wound debridements required in Group A (range 0–2, mean 1) was less compared to Group B (range 2–5, mean 3). Group A patients required less duration of hospital stay (mean −9 days), less secondary procedures, less time for wound healing (mean −12 days), and wound contraction as compared to Group B (mean hospital stay −22 days, mean wound healing time −28 days) and which was statistically significant and the Correlation coefficient was r=0.751.

Conclusion: We recommend to maintain the blood hemoglobin level above 12 g% in the management of orthopedic wounds which helps in early wound healing, less hospital stay, fewer chances of infection, and secondary procedures.

Key words: Hemoglobin, Orthopedic practice, Wound healing

INTRODUCTION

At the emergency room, the common challenge faced by orthopedics surgeons is still managing the larger and deeper wounds of extremities resulting from road accidents. Conditions which require proper wound management include compound fractures, crush injuries, postoperative wounds, and amputation stumps. The proper management of the above conditions is essential to prevent long duration of hospital stay, infections, multiple surgeries and to prevent associated morbidity and mortality in these patients. Hence, proper wound care and early wound healing help in preventing the above complications.

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The primary goal of treating compound injuries is the healing of soft tissues first and obtaining wound cover. Before plastic surgeon intervenes, the orthopedic surgeon may have to overcome challenges of preserving soft tissue, avoid soft-tissue sacrifices during repeated debridements, multiple surgical procedures, avoid a prolonged hospital stay, undue expenditure, and financial burden on caregivers, psychological problems such as anxiety, depression amongst patients, and caregivers to delayed results. The burden on the family is the highest due to constant engagement in patients treatment and inability to engage in activities of earnings. The most influential factors delaying or complicating wound healing

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are poor nutrition, unhealthy lifestyle, cardiorespiratory compromise due to bedridden state, lack of aerobic exercises, and breathing exercises. Resultantly decrease local blood flow due to arteriolar/small vessel blockage due to septic thrombi thereby decrease in oxygen to the dying tissues.

Wound healing requires a higher concentration of oxygen at the local site, which acts against pathogens and helps in wound granulation, cell proliferation, vascularization, and synthesis of collagen.[1] Hemoglobin is a very good transporter of oxygen molecules to the tissue.[2] Low hemoglobin before surgery or a decrease in hemoglobin levels while surgery is a potentially modifiable factor. Identification of the above factor in patients who undergoes orthopedic surgery, which helps to create treating protocols to correct the hemoglobin level and assessment of this impact on outcome.[3] Blood and oxygen supply to the traumatic tissue lower than normal levels is associated with wound complications.[2,4,5] According to the current knowledge, tissue hypoxia is the common etiology of wound healing disorders[6] and pathogenesis of chronic wounds.

There are various treatment options available for healing of orthopedic wounds such as repeated debridement, Eusol dressing, hyperbaric oxygen therapy, improving the nutritional status by protein supplementation, vacuum-assisted closure (VAC) application, topical hemoglobin applications,[7] and use of oxygen carrier substitute.[8]

The various treatment options mentioned above do not merely help in wound healing but just support the wound healing if normal blood hemoglobin concentration is maintained. Most of the orthopedic patients are anemic because of blood loss due to compound fractures, crush injuries or during surgery, which hinders the wound healing capacity leads to wound-related morbidity and mortality. Literature suggests adequate hemoglobin levels in blood helps in early wound healing but there is no clarity regarding how much percentage of hemoglobin should be maintained. The objective of this article was to observe the influence of hemoglobin levels during wound healing in orthopedic practice. The hypothesis is that decreased hemoglobin levels are responsible for more tissue death due to low oxygen-carrying capacity and resultant loss of ongoing tissue death increases its dimensions, death cells invite infection, more damage, and constituting further delay. On the contrary, the normal oxygen-carrying capacity is responsible for timely repair of wound thereby reducing complications and delay.

MATERIALS AND METHODS

This was a prospective observational study of 200 patients of orthopedic wounds, conducted at tertiary care hospital from January 2016 to February 2019, over a period of 3 years. The sample was divided into two groups, each group had 100 patients each. Group A had patients with a blood hemoglobin level of more than 12 g% and Group B had patients with a blood hemoglobin level of <12 g%.

Patients who sustained compound fractures (Gustilo Anderson Grade 2 and Grade 3A), amputation wounds and post-operative wounds between 20 and 75 years were included in the study. However, patients having closed fractures, compound fractures with Gustilo Anderson Grade 1 and Grades 3B and C, hematological disorders (hemoglobinopathies and coagulation disorder), cardiovascular problems, patients have comorbidities such as diabetes mellitus, protein-energy malnutrition (criteria as per Constans *et al.*),[9] immunodeficiency (HIV), patients having suspected clostridium welchii (gas gangrene organism), and patients with neurological disease and impaired sensation were excluded from the study.

Patient Evaluation

After the initial evaluation and hemodynamic stabilization of the patients, X-rays of the involved limb AP and Lateral views were taken in cases of fracture by emergency ward orthopedic consultant. Pre-operative investigations such as hemoglobin, complete blood counts, blood sugars, serum proteins, and HIV tests were done.

The baseline wound assessment was done after thorough wound wash using chlorhexidine and copious amount (9L of saline), The parameters included are dimensions of the wound, severity of damage from the skin, subcutaneous tissue, facia, muscles, and loss of periosteum. Wound swab was sent for culture to rule out infection. Gas gangrene clostridium welchii organisms' infection was ruled out in suspected cases. The above-mentioned parameters were assessed by two separate orthopedic consultants at two separate times without knowing the patient details and hemoglobin levels to eliminate the bias.

Secondary wound assessment was done after primary debridement after removal of contaminated dead soft tissues till visibility of punctate bleeding. The parameters included are dimensions of the wound, severity of damage from the skin, subcutaneous tissue, facia muscles, and loss of periosteum. The VAC dressings were applied once wound shows no further necrotic and dead tissues or infection and no further debridements were necessary. The patients were given a high protein diet, and micronutrients to avoid delayed wound healing due to deficiency and avoiding bias in the study. Periodic assessment of wound status was done every 7th day or at the time of removal of dressing in the case where VAC dressing was used as an adjunctive. Periodic every weekly hemoglobin levels

were monitored in both groups. Packed cell volume transfusions were given to maintain hemoglobin in Group B. Perioperative antibiotics cefixime 1 g, gentamicin, and metronidazole were given till 48 h or as per culture sensitivity report in doubtful infected cases. Oral iron supplements were given in both groups.

The parameters include size and dimensions of the wound, color of the granulation tissue, signs of infections, time taken for the shrinkage of the wound, and number of debridement required. The above parameters were used for both Group A and Group B patients and wound assessment was done every alternate day. Hemoglobin percentage in Group B patients was repeated once in every 3 days, we used to transfuse blood for Group B patients to maintain the hemoglobin level above 12.

Every alternate day, we used to assess the wound condition in both Groups A and B by checking the parameters such as the color of the granulation tissue, wound infection, rate of change in wound dimensions, and the number of secondary procedures involved and duration of hospital stay. The above parameters were compared with both the groups.

Statistical Analysis

All statistical analysis was performed using the Statistical Package for the Social Sciences for Windows, version 20.0 (IBM Corp.; Armonk, NY, USA). For categorical variables, the Chi-square test was used to detect differences. Pearson's correlation test was used to determine correlations between Groups A and B patients. Data are presented as mean ± standard deviation. $P < 0.05$ was considered statistically significant.

RESULTS

Group A had 72 male patients and 28 female patients, Group B had 76 males and 24 female patients [Graph 1]. 62 patients were between 20 and 40 years, 36 patients between 41 and 60 years, and 2 patients between 61 and 75 years in Group A as compared to Group B which had 60 patients between 20 and 40 years, 29 patients between 41 and 60 years, and 11 patients between 61 and 75 years and there was no statistical difference between sex and age of Group A and Group B patients [Table 1].

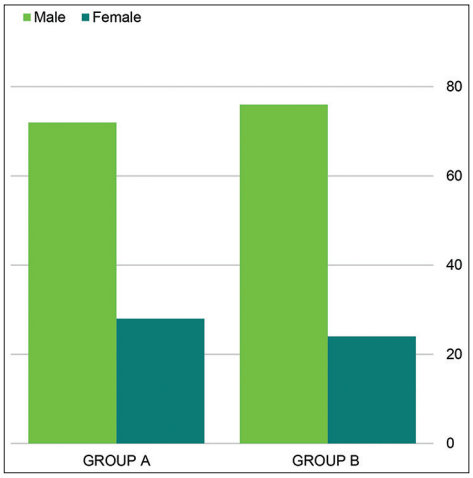
In Group A, 72 patients had road traffic accidents, 23 had railway accidents, and five had fall and in Group B, 68 patients had road traffic accidents, 30 had railway accidents, and two had a fall.

Group A had 18 patients of upper limb trauma and 82 patients of lower limb injuries, in comparison to Group B which had 15 patients with upper limb trauma and 85 patients of lower limb trauma.

About 40% of patients in Group B had associated infections as compared to Group A, which had only 7% of infection which was statistically significant ($P < 0.05$) [Graph 2]. The number of wound debridements required in Group A (range 0–2, mean 1) was less compared to Group B (range 2–5, mean 3) [Table 2] and which was statistically significant ($P < 0.05$).

Group A patients required less duration of hospital stay, less secondary procedures, less time for wound healing, and wound contraction as compared to Group B patients, which was statistically significant ($P < 0.05$). Mean days of hospital stay in Group A patients were, 7 days for compound Grade 2 wounds, 12 days for compound Grade 3B wounds, 8 days for amputation wounds, and 8 days for post-operative wounds. Mean days of hospital stay in Group B patients were, 20 days for compound Grade 2 wounds, 26 days for compound Grade 3B wounds, 21 days for amputation wounds, and 24 days for post-operative wounds [Tables 3 and 4].

Mean days of wound healing in Group A patients were, 9 days for compound Grade 2 wounds, 14 days for compound Grade 3B wounds, 12 days for amputation wounds and 12 days for post-operative wounds. Mean days of wound healing in Group B patients were, 24 days



Graph 1: Bar chart showing the Sex distribution of male and female patients in Groups A and B

Table 1: The age distribution of patients in Groups A and B with range from 20 to 75 years

Groups	20–40 years	41–60 years	61–75 years	Total
A	62	36	2	100
B	60	29	11	100
Total	122	65	13	200

*More patients were between 20 and 40 years age group

for compound Grade 2 wounds, 33 days for compound Grade 3B wounds, 27 days for amputation wounds, and 28 days for post-operative wounds [Graph 3 and Figures 1-3].

Correlation analysis showed a significant positive correlation between the duration of hospital stay, the number of secondary procedures, wound healing time with blood hemoglobin levels (r = 0.751).

DISCUSSION

Default blood supply to the extremities is poorer as compared to face and trunk. Furthermore, there is a watershed area of hypovascularity with proceeding distally.

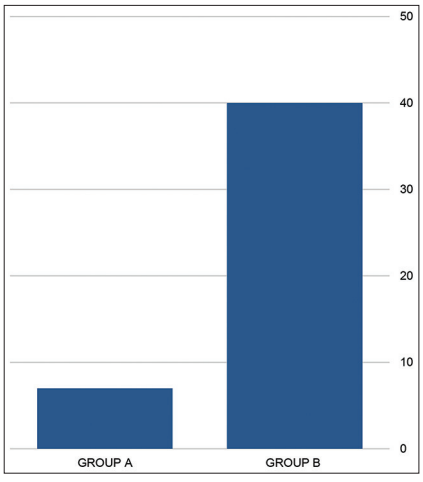
Table 2: The number (mean and range) of debridements required before the wound healing in Groups A and B patients

Groups	Range	Mean
A	0–2	1
B	2–5	3

*More number of debridements were required in Group B patients

Table 3: Comparison of parameters such as wound color, healing time, infection rate, number of debridements required, hospital stay, and secondary procedures between Group A and Group B patients

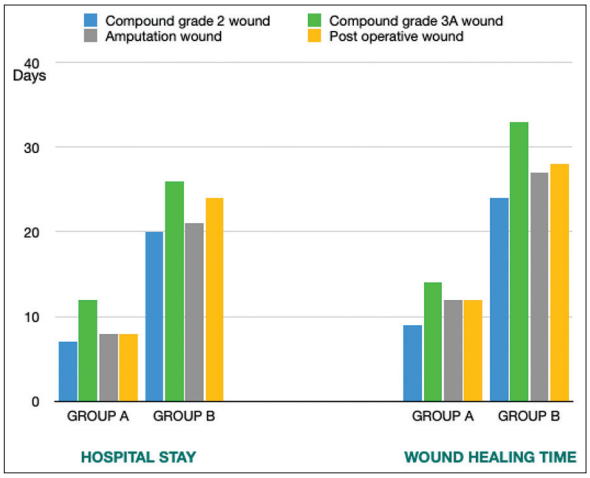
Parameters	Group A (Hb>12g%)	Group B (Hb<12g%)
1. Colour of granulation tissue	Red	Pale
2. Healing time	More	Less
3. Infection rate	More	Less
4. Debridement requirement	More	Less
5. Rate of change in wound dimension	FAST AND EARLY	Slow and late
6. Duration of hospital stay	More	LESS
7. Number of secondary procedures required	More	Less
8. Mental stress to patient and relatives	More	Less



Graph 2: Bar chart showing associated infections in Group A and B

Due to such natural variation and peculiarity of blood supply, wound healing is a naturally complex phenomenon to get a full understanding of the subject. However, concepts and theories postulated have made an understanding of secondary wound healing better. The researcher has taken may efforts to improve wound healing like chemical agents like silver nitrate, dressing materials, hyperbaric oxygen therapy, VAC dressings, local oxygen chambers, Enzymes, and free radicals (nascent oxygen, chloride, hydrogen, etc.) to initiate and progress of granulation tissue which ultimately allow epithelization and complete coverage.

Wound healing is a normal biological process in the human body, which goes through four stages: Hemostasis, inflammation, proliferation, and remodeling. Most of the orthopedics wounds due to substantial soft tissue, that is, skin, subcutaneous tissue, and muscular loss heal with secondary intensions. Potential barriers to the healing are the presence of dead and necrotic tissue, debris, and slough collection. For healing to progress normally, the surgeon has to take the challenge of removing the dead and necrotic materials which is done by debridement of wounds. Chemical debridements achieved using hydrogen peroxide, EUSOL solution helps in removing the little amount of the smaller tissue. They are not effective for the larger one. Hence, surgical debridement of wounds is still the gold standard for removing dead tissues from larger traumatic compound wounds for achieving better secondary healing. However, the procedure itself creates larger soft-tissue defects. Repeated debridements may increase the dimensions of wounds which may further delay healing and granulation tissue, may take longer time to fill the soft-tissue defects, further soft-tissue procedures may get delayed and this hugely contributes to a prolonged hospital stay, and financial burden thereby.



Graph 3: Comparison between Groups A and B in relation to hospital stay and wound healing time in patients with compound Grade 2, 3A wounds, amputation wounds, and post-operative wounds

One of the major steps to reduce healing time and hospital stay is to avoid repeated debridements and the further increase of dimensions of wounds by repeated surgical debridement procedures. A single complete primary debridement, maintaining microscopic debris to be removed by macrophages and achieving healthy progress of granulation tissue till it fills the crater up to the skin so that skin coverage can be easily done.

Oxygen is very essential for cell metabolism, mainly for energy production using ATP, and is very important in wound-healing processes. It prevents wound infection, induces angiogenesis, increases keratinocyte differentiation, migration, and re-epithelialization, enhances fibroblast proliferation and collagen synthesis, and promotes wound contraction.[10]

Low rate of infections observed in patients with hemoglobin more than 12 g% is because of a high level of superoxide production (a key factor for the oxidative killing of microorganisms) by polymorphonuclear leukocytes and is critically dependent on oxygen levels. Faster wound healing and less duration of hospital stay observed in our study with Group A patients, which is because of More hemoglobin in the blood helps in more tissue oxygenation at the local site, which helps in early wound contraction by fibroblast proliferation and collagen synthesis.

During the early stages of wound healing, due to the high oxygen utilization by the metabolically active cells and also due to vascular disruption, the microenvironment becomes hypoxic. Tissue oxygen tension of chronic wounds

Table 4: Comparison of quantitative parameters such as hospital stay, secondary procedures required, and wound healing time between Group A and Group B patients

Parameters	Group A		Group B	
	Range	Mean	Range	Mean
Hospital stay in days				
Compound Grade 2 wound	3–16	7	15–35	20
Compound Grade 3A wound	7–21	12	21–43	26
Amputation wounds	3–20	8	15–30	21
Post-operative wounds	3–15	8	16–36	24
Number of Secondary procedures (Debridements)				
Compound Grade 2 wound	0–1	1	2–3	3
Compound Grade 3A wound	0–2	1	2–5	4
Amputation wounds	0–1	1	2–4	3
Post-operative wounds	0–2	1	2–4	3
Wound healing time in days				
Compound Grade 2 wound	7–18	9	18–40	24
Compound Grade 3A wound	8–26	14	25–51	33
Amputation wounds	7–24	12	20–36	27
Post-operative wounds	8–20	12	17–38	28

*more hospital stay, secondary procedures, and wound healing time were observed in Group B patient

Figure 2: (a) (case 2) Lower limb crush injury when hemoglobin <12 g% (b) (case 2) same patient showing wound healing and contraction after improving the hemoglobin of more than 12 g%

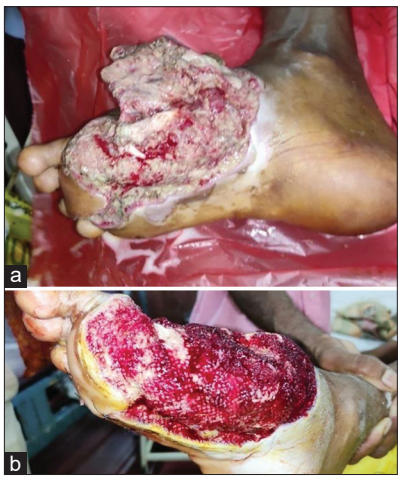


Figure 1: (a) (case 1) - Crush foot wound when hemoglobin was <12 g% (b) (case 1)-same wound after improving of hemoglobin of more than 12 g%

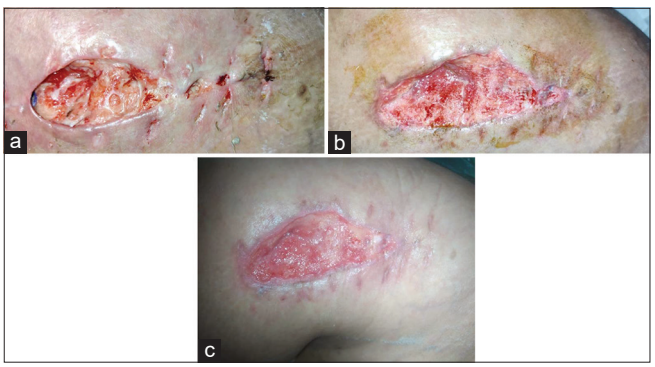


Figure 3: (a) (case 3) Operated wound with necrosis (b) (case 3) same wound after debridement showing pale granulation tissue with hemoglobin level <12 g% (c) (case 3) same wound showing pale granulation tissue, minimal wound healing, and wound contraction with hemoglobin level <12 g%

measured transcutaneously is between 5 and 20 mm Hg as compared to control tissues of 30 and 50 mm Hg and chronic wounds are hypoxic.[11]

In wounds where oxygenation is not maintained adequately, healing is impaired. Temporary hypoxia after injury triggers wound healing, but prolonged or chronic hypoxia delays wound healing.[12] In normally healing wounds, reactive oxygen species such as hydrogen peroxide (H_2O_2) and superoxide (O2) are acts as cellular messengers to stimulate main processes of wound healing, including cell motility, cytokine action, and angiogenesis.

As healing progress from the walls of the debrided subcutaneous tissue walls, the migrating granulation tissue and the cells derive the nutrition from the adjoining capillaries by diffusion. The cell deaths are expected to happen when oxygen is less subtle supply. Hence, the oxygen-carrying capacity of the blood has to be maintained to normal levels and delivery of oxygen's to inured and inflamed tissues are adequate to avoid cell death and subsequently, the progress of granulation tissue goes unhampered. The supply of micronutrients such as zinc, molybdenum which is required for proliferation and phagocytosis function of macrophages needs to be maintained. Essential nutrients for tissue repair such as amino acids, Vitamins c and E are also supplied through the blood only, they are essential to complete wound healing. Their deficiency may delay the healing. Therefore, the supplements of above nutrients are crucial for early and normal progress in the healing of orthopedic wounds.

The cause of most of the orthopedics wounds is higher energy trauma during road traffic accidents causing severe devastating internal injuries to the soft tissues and their internal blood supply. Most micro thrombi cause local hypoxia, low oxygen-carrying capacity due to anemia and low hemoglobin will not stop the further tissue deaths.

In our study, it was noted that the wound healing among female was slightly delayed as compared to the males, this is due to the fact these females have long-standing anemia as nutritional problems. Nutritional deficiency of proteins and micronutrients has been coexisted simultaneously; hence, initial time is taken for the correction of nutritional deficiencies and once hemoglobin levels and nutritional deficiencies have overcome, the wound started healing with a faster rate. Even the initial number of debridements was more. This explained by faster tissue deaths due to preexisting anemic state further increased by blood loss in accidents. However, this problem was very well tackled by faster correction of hemoglobin levels in Group B during the early weeks of post-injury which has reduced delay in the formation of granulation tissue among the female population.

Open wounds have been constantly losing blood products through serous, serosanguinous discharge, blood loss during dressings, and procedures. Even granulation tissue bleeds significantly during dressings. RBCs are often sucked during vacuum-assisted dressings. Damaged RBCs undergo hemolysis. Even transfused red packed cell have a smaller half-life and they undergo early hemolysis. All these factors account for the fall in hemoglobin levels. It often reflected by the quality of wound especially paleness, accumulation of debris and dead tissues and slower granulation tissue formations. Hence, maintaining normal hemoglobin levels throughout the healing phase reduces complications and delay in wound healing.

Delay in wound healing causes a delay in the discharge of the patients from the hospitals, long duration of hospital stay causes psychosocial issues in patients. The long duration of hospital stay make the patients to unnecessary exposure to hospital-acquired infection and also financial issues. The family and caregivers are constantly under stress and burden. The patients themselves may experience psychological problems if things are not moving to heal. Repeated surgical procedures make patients prone to develop anxiety and depressions. The patients may become non-compliant to treatment. There may be a chance of losing faith and trust in treating orthopedicians. Delay in wound healing makes the operating surgeon wait for the definitive management of compound fractures; otherwise, it can lead to infections and if the wound is not healing properly and associated with infections, it gives problem to the plastic surgeons for wound coverage. Overall delay in wound healing complicates the whole scenario of treatment.

Hence, the maintenance of proper oxygen level is crucial for optimum wound healing, which can be done by maintaining adequate hemoglobin level in the blood (more than 12 g%) so that we can prevent wound-related morbidity.

CONCLUSION

Normal hemoglobin levels have a major role in supplying oxygen and nutrients to the healing tissues. Hence, we recommend to maintain the blood hemoglobin level above 12 g% in the management of orthopedic wounds which helps in early wound healing, less hospital stay, and fewer chances of infection. It also decreases the secondary procedures required for the wound management and morbidity associated with it.

HIGHLIGHTS

- Maintaining of blood hemoglobin level of more than 12 g% is essential for early wound healing
- Early wound healing reduces wound-related morbidity
- Blood hemoglobin level of more than 12 g% reduces the chances of infections.

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Original Article

Prevalence of Thyroid Dysfunction in Type 2 Diabetes Mellitus Patients

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Abstract

Background: Diabetes mellitus (DM) and thyroid dysfunction (TD) are the two most common endocrine disorders in clinical practice. The unrecognized TD may adversely affect the metabolic control and add more risk to an already predisposing scenario for cardiovascular diseases. The objective of this study was to investigate the prevalence of TD in patients with type 2 DM (T2DM).

Materials and Methods: This is an observational study. Hundred patients with T2DM visiting medicine outpatient department of RIMS Raichur included in the study. All patients underwent a clinical and laboratory evaluation. All patients were investigated for TD (thyroid-stimulating hormone, T3, T4).

Results: Out of the 100 patients studied 85 of them were euthyroid, ten patients found to have subclinical hypothyroidism and five patients had overt hypothyroidism. Female patients had higher prevalence of hypothyroidism.

Conclusions: TD is frequently observed in T2DM. Subclinical hypothyroidism is the most common thyroid abnormality detected, followed by overt hypothyroidism. TD was commonly seen in female patients.

Key words: Prevalence, subclinical and overt hypothyroidism, Thyroid dysfunction, Type 2 diabetes mellitus

INTRODUCTION

Diabetes mellitus (DM) is a common metabolic disease characterized by hyperglycemia and metabolic disturbances of carbohydrates, proteins, and lipids principally caused by pancreatic β-cell dysfunction, hyperglucagonemia, and increased renal glucose reabsorption.[1] DM is rapidly becoming one of the major health problems worldwide. About 422 million people worldwide have diabetes, particularly low- and middle-income countries. Diabetes is one of the leading causes of death worldwide.[2] There were over 72.946.400 cases of diabetes in India in 2017, 8.8% of the adult population.[3]

Thyroid hormones are essential for metabolism and energy homeostasis and participate in insulin action and glucose regulation. The previous studies reported higher prevalence rates of thyroid disorders in diabetic patients compared with non-diabetic individuals, and overt hypothyroidism was frequently observed in type 2 DM (T2DM).[1] Subclinical hypothyroidism (SCH), a pathological status defined as an elevated serum thyroid stimulating hormone (TSH) value with normal concentrations of free thyroid hormones,[4] is receiving increasing concerns in recent years. A meta-analysis reported that the pooled prevalence of SCH in T2DM patients was 10.2%. Meanwhile, high levels of TSH and low levels of free triiodothyronine (FT3) within the normal range were related to a higher risk of chronic kidney disease.[5] Furthermore, low level of serum FT3 was found to be independently associated with urinary protein in T2DM patients.[6]

Hence, the present study is done to find the prevalence of thyroid dysfunction (TD) in diabetic patients in our institute so that it can be included as a must screening investigation in patients with T2DM.

Aims and Objectives

The aim of the study was to find the prevalence of TD in T2DM in RIMS, Raichur, Karnataka, India.

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MATERIALS AND METHODS

Source of Data

Patients diagnosed with T2DM attending medicine Outpatient Department (OPD), RIMS, Raichur.

Method of Collection of Data

Information will be collected through a pretested and structured pro forma for each patient. The study will be

Table 1: Age distribution of patients studied

Age in years	Number of patients	%
<30	2	2.0
30–40	35	35.0
41–50	26	26.0
51–60	26	26.0
>60	11	11.0
Total	100	100.0

Mean±SD=46.95±10.97

Table 2: Gender distribution of patients studied

Gender	Number of patients	%
Female	83	83.0
Male	17	17.0
Total	100	100.0

Table 3: Duration of DM distribution of patients studied

Duration of DM in years	Number of patients	%
1–2	15	15.0
3–5	42	42.0
6–10	36	36.0
11–15	2	2.0
16–20	5	5.0
Total	100	100.0

Mean±SD: 6.47±4.09; DM: Diabetes mellitus

Table 4: RBS (mg/dl) distribution of patients studied

RBS (mg/dl)	Number of patients	%
<200	75	75.0
>200	25	25.0
Total	100	100.0

RBS: Random blood sugar

Table 5: Thyroid status distribution of patients studied

Thyroid status	Number of patients	%
Euthyroid	85	85.0
SCH	10	10.0
Overt Hypothyroidism	5	5.0
Total	100	100.0

SCH: Subclinical hypothyroidism

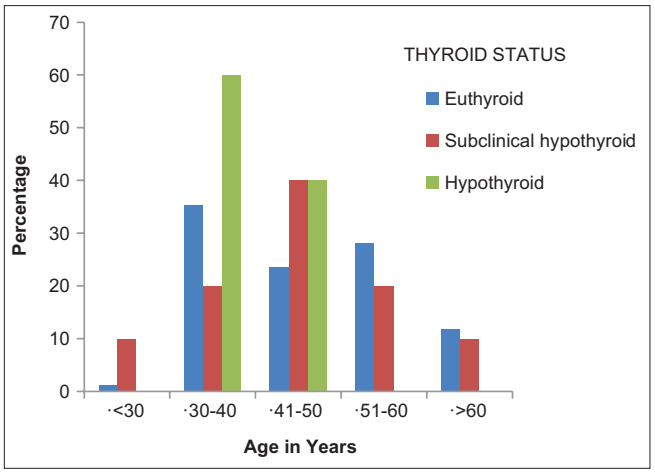

Figure 1: Distribution of study participants depending upon thyroid status and age

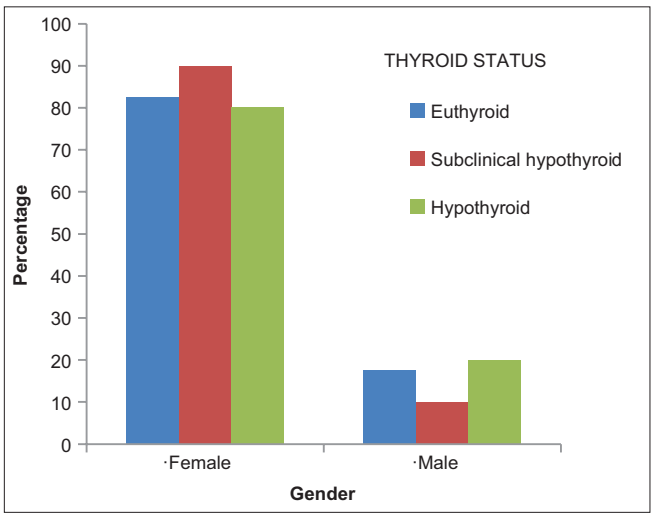

Figure 2: Distribution of study participants depending upon thyroid status and gender

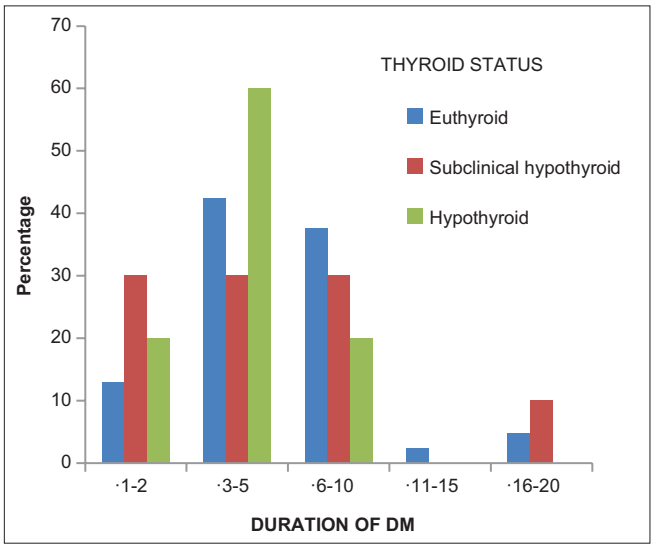

Figure 3: Distribution of study participants depending upon thyroid status and duration of Diabetes

Table 6: Association of frequency distribution of clinical variables in relation to thyroid status of patients studied

Variables	Thyroid status (%)			Total (%)	*P*-value
	Euthyroid	Subclinical hypothyroid	Hypothyroid		
Age in years					
<30	1 (1.2)	1 (10)	0 (0)	2 (2)	0.351
30–40	30 (35.3)	2 (20)	3 (60)	35 (35)	
41–50	20 (23.5)	4 (40)	2 (40)	26 (26)	
51–60	24 (28.2)	2 (20)	0 (0)	26 (26)	
>60	10 (11.8)	1 (10)	0 (0)	11 (11)	
Gender					
Female	70 (82.4)	9 (90)	4 (80)	83 (83)	1.000
Male	15 (17.6)	1 (10)	1 (20)	17 (17)	
Duration of DM					
1–2	11 (12.9)	3 (30)	1 (20)	15 (15)	0.699
3–5	36 (42.4)	3 (30)	3 (60)	42 (42)	
6–10	32 (37.6)	3 (30)	1 (20)	36 (36)	
11–15	2 (2.4)	0 (0)	0 (0)	2 (2)	
16–20	4 (4.7)	1 (10)	0 (0)	5 (5)	
Total	85 (100)	10 (100)	5 (100)	100 (100)	

Chi-square Test/Fisher exact test; DM: Diabetes mellitus

Table 7: Association of frequency distribution of clinical variables in relation to thyroid status of patients studied

Variables	Thyroid status (%)			Total (%)	*P*-value
	Euthyroid	Subclinical hypothyroid	Hypothyroid		
RBS (mg/dl)					
<200	62 (72.9)	9 (90)	4 (80)	75 (75)	0.695
>200	23 (27.1)	1 (10)	1 (20)	25 (25)	
HBA1C					
<6.0	5 (5.9)	3 (30)	0 (0)	8 (8)	0.095
6.0–6.4	15 (17.6)	0 (0)	1 (20)	16 (16)	
>6.5	65 (76.5)	7 (70)	4 (80)	76 (76)	
Total	85 (100)	10 (100)	5 (100)	100 (100)	

RBS: Random blood sugar

Table 8: Comparison of clinical variables according to thyroid status of patients studied

Variables	Thyroid status			Total	*P*-value
	Euthyroid	Subclinical hypothyroid	Hypothyroid		
Age	47.45±10.96	46.50±11.87	39.20±6.76	46.95±10.97	0.263
Duration of DM	6.63±4.10	6.10±4.72	4.40±1.94	6.47±4.09	0.477
RBS (mg/dl)	162.90±102.19	135.60±71.36	131.60±87.54	158.61±98.69	0.588
HBA1C (%)	7.65±1.59	7.34±1.72	6.98±0.72	7.59±1.57	0.566

Table 9: Comparison of thyroid variables according to thyroid status of patients studied

Variables	Thyroid status			Total	*P*-value
	Euthyroid	Subclinical hypothyroid	Hypothyroid		
T3 (nmol/L)	1.79±0.34	1.67±0.35	0.91±0.70	1.74±0.41	<0.001**
T4 (nmol/L)	102.55±23.64	91.73±15.33	55.92±6.08	99.13±24.63	<0.001**
TSH (mIU/L)	2.49±1.21	7.44±1.17	26.15±24.07	4.18±7.31	<0.001**

TSH: Thyroid-stimulating hormone

carried out on T2DM patients fulfilling the inclusion and exclusion criteria.

Sample Size

100 patients attending the medicine OPD, RIMS, Raichur.

Table 10: Pearson correlations

Pair	r value	*P*-value
T3 (nmol/L) versus age in years	0.063	0.531
T3 (nmol/L) versus duration of DM	0.051	0.612
T3 (nmol/L) versus RBS (mg/dl)	–0.136	0.178
T3 (nmol/L) versus HBA1C (%)	–0.076	0.452
T4 (nmol/L) versus age in years	0.226	0.024*
T4 (nmol/L) versus duration of DM	0.217	0.030*
T4 (nmol/L) versus RBS (mg/dl)	0.104	0.304
T4 (nmol/L) versus HBA1C (%)	–0.014	0.891
TSH (mIU/L) versus age in years	–0.148	0.140
TSH (mIU/L) versus duration of DM	–0.065	0.518
TSH (mIU/L) versus RBS (mg/dl)	–0.075	0.457
TSH (mIU/L) versus HBA1C (%)	–0.069	0.496

RBS: Random blood sugar; DM: Diabetes mellitus

Table 11: Comparison of age group

Study	Pramanik *et al.*[7]	Nair *et al.*[8]	Palma *et al.*[9]	Present study
Mean age group	45.4±11.2 years	53±11.15 years	60.7±10.6 years	46.95±10.97 years

Table 12: Gender distribution

Study	Pramanik *et al.*[7]	Nair *et al.*[8]	Demitrost and Ranabir[10]	Present study
Male (%)	51	64.4	30.19	17
Female (%)	49	35.6	69.80	83

Table 13: Average duration of DM

Study	Pramanik *et al.*[7]	Nair *et al.*[8]	Demitrost and Ranabir[10]	Present study
Average duration of DM	7.76±5.57 years	9.6±7.8 years	5 years	6.47±4.09 years

DM: Diabetes mellitus

Type of Study

This was a cross-sectional study.

Inclusion Criteria

The following criteria were included in the study:

1. Patients diagnosed with DM
2. Adults aged more than 18 years
3. Both male and female patients included.

Exclusion Criteria

The following criteria were excluded from the study:

1. Known cases of thyroid disorder
2. Patients on drugs altering thyroid hormone metabolism
3. Abnormal liver function test's with SGOT/SGPT levels >3 times normal range
4. Abnormal renal function test's with serum creatinine >1.6 mg%
5. Pregnant women.

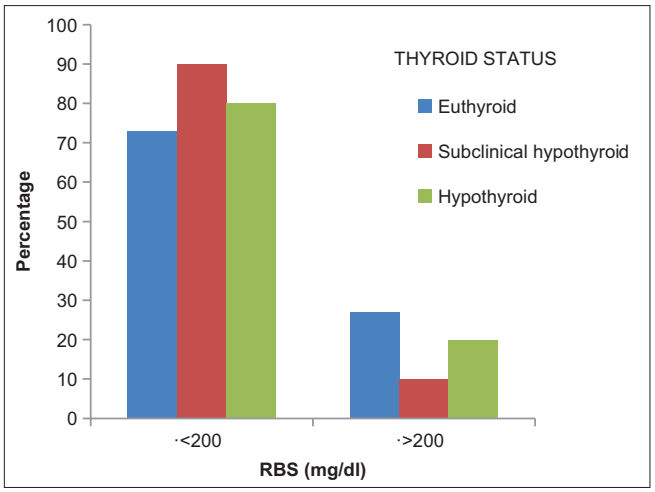

Figure 4: Distribution of study participants depending upon thyroid status and blood sugar levels

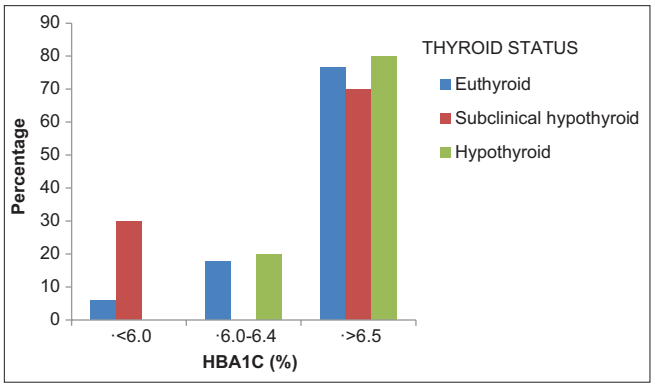

Figure 5: Distribution of study participants depending upon thyroid status and HbA1c levels

Investigations

1. Thyroid profile
2. HbA1C
3. RFT
4. Liver function test.

RESULTS

Percentages, proportions, and Chi-square chart correlation are used, with respect to age and sex.

Most of the patients in the study group belonged to the age group of 30–40 years (35%), with the mean age 46.95 ± 10.97 years [Table 1].

Majority of the study participants were females [Table 2].

Forty-two patients in the study had DM of 3–5 years duration. Mean duration of DM in the study population was 6.47 ± 4.09 years [Table 3].

Seventy-five patients in the study had random blood sugar (RBS) <200 mg/dl and 25 patients had >200mg/dl [Table 4].

Eighty-five patients in the study were euthyroid, ten patients had SCH and five patients had overt hypothyroidism [Table 5].

In the study out of ten patients who are found to have SCH, four belonged to the age group of 41–50 years, two patients in each 30–40 years and 51–60 years group, and one patient each in <30 years and >60 years group [Table 6].

Among the five patients who are found to have hypothyroidism three belonged to 30–40 years group and two patients in 41–50 years group [Figure 1].

Out of the ten SCH patients, nine were females. Out of the five overt hypothyroid patients, four were females [Figure 2].

Of the ten SCH patients, nine had diabetes for a duration of <10 years and all patients with overt hypothyroidism had diabetes for <10 years duration [Figure 3].

Nine and four patients in the subclinical hypothyroid and overt hypothyroid patients had RBS of <200 mg/dl [Figure 4].

Seven and four patients in the subclinical and overt hypothyroidism, respectively, had HbA1C value of >6.5% [Figure 5].

When the association of thyroid status and blood glucose levels were seen, there was no difference in the prevalence of hypothyroidism in both the groups. Similarly, the association between HbA1c and thyroid status was calculated and it was not statistically significant [Table 7].

No statistical significance was found between TD and age of the patient, duration of DM, RBS value, or HBA1C levels [Table 8].

The association between thyroid hormone levels and thyroid status was found to be statistically significant [Table 9].

Moderately significant correlation noted between T4 with age in years and duration of DM [Table 10].

Different similar studies were compared with the present study and the findings were similar [Table 11].

DISCUSSION

Nair *et al*.[8] study found that 8.33% patients had known history of hypothyroidism; 17 (1.5%) persons were diagnosed to have newly detected hypothyroidism (TSH >10 μ IU/ml) during the study period. Hence, the prevalence of clinical hypothyroidism was 9.83. 68 (5.9%) patients were found to have SCH. When comparison was done between the clinical hypothyroid and euthyroid persons, the presence of hypothyroidism was found to be associated with female sex, hypertension, dyslipidemia, obesity, a duration of diabetes more than 2 years, anemia, and an elevated ESR.[7]

Demitrost and Ranabir study, data of 202 T2DM patients studied. Out the 202 T2DM patients, 139 (68.8%) were euthyroid, 33 (16.3%) had SCH (10 males and 23 females), 23 (11.4%) had hypothyroidism (6 males and 17 females), 4 (2%) SCH, and 3 (1.5%) hyperthyroidism cases. Maximum TD noted in the age group of 45–64 years. Patients with BMI >25 were at increased risk of having hypothyroidism ($P < 0.016$) [Tables 11-13].[9]

In the present study, there were no patients with the previous history of thyroid abnormalities. Out of the 100 patients studied 85 of them were euthyroid, ten patients found to have SCH and five patients had overt hypothyroidism. Female patients had higher prevalence of both subclinical (nine out of ten) and overt (four out of five) hypothyroidism. <10 years was the duration of DM in SCH (90%) and overt hypothyroidism (100%). Mean duration of DM, RBS, and HBA1C values was 6.10 ± 4.72 years, 135.60 ± 71.36 mg/dl, 7.34 ± 1.72 and 4.40 ± 1.94 years, 131.60 ± 87.54 mg/dl and 6.98 ± 0.72, respectively, in subclinical and overt hypothyroidism.

CONCLUSION

TD is frequently observed in T2DM. SCH is the most common thyroid abnormality detected, followed by overt hypothyroidism. TD was commonly seen in female patients. No statistical significance was found between TD and age of the patient, duration of DM, RBS, and HBA1C values.

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Original Article

Iodine Deficiency Disorder Survey among 6 to 12 Years Children in Rural Areas of Raichur District

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Abstract

Introduction: The survey was to carry out as per the "Revised Policy Guidelines of the National Iodine Deficiency Disorders Control Program." The present survey was done in rural areas of Raichur during the period of February 2020 and March 2020.

Objectives: The objectives of the survey were: (1) To know the prevalence of goiter among children between 6 and 12 years. (2) To assess the level of iodization in salt sample collected from houses of children. (3) To determine urinary iodine excretion level in school children.

Materials and Methods: A total of 30 villages and 2700 children, 90 children in each village were selected using the method of population proportionate to size sampling. Only rural areas were included. Goiter was graded clinically. Salt sample from home was collected from every 5th child. Urine for iodine estimation was collected from every 10th child.

Results: Goiter prevalence was 18.6%. About 12.9% were of Grade 1 and 5.7% were of Grade 2 goiter. There was no difference in prevalence with respect to age groups. Prevalence of goiter was more in boys than girls. Iodine level was adequate in 47% of the samples and <15 ppm in 63% of the samples. Urine Iodine level was adequate among 45.5% of the children

Conclusion: The present survey showed mild–to-moderate Goiter severity among 6–12 years children in rural areas of Raichur district. Goiter is endemic and is considered as public health problem in rural areas of Raichur district based on clinical and laboratory indicators.

Key words: Goiter, Iodine deficiency, Salt iodine levels, Urine iodine estimation

INTRODUCTION

Iodine (atomic weight 126.9 g/atom) is an essential component of the hormones produced by the thyroid gland. Thyroid hormones, and therefore iodine, are essential for mammalian life. Iodine (as iodide) is widely but unevenly distributed in the earth's environment. Most iodide is found in the oceans (≈50 μg/L), and iodide ions in seawater are oxidized to elemental iodine, which volatilizes into the atmosphere and is returned to the soil by rain, completing the cycle. However, iodine cycling in many regions is slow and incomplete and soils and ground water become deficient in iodine. Crops grown in these soils will be low in iodine, and humans and animals consuming food grown in these soils become iodine deficient.[1]

In plant foods grown in deficient soils, iodine concentration may be as low as 10 μg/kg dry weight, compared to ≈1 mg/kg in plants from iodine-sufficient soils. Iodine deficient soils are most common in inland regions, mountainous areas and areas of frequent flooding, but can also occur in coastal regions.[2]

Iodine is an essential micronutrient required for normal body growth and mental development. Nutritional iodine deficiency reckons its impact right from development of

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the fetus to all ages of human beings. It could result in many disorders such as abortion, still birth, mental retardation, deaf mutism, squint, dwarfism, goiter, and neuromotor defects. Iodine deficiency during pregnancy leads to decreased availability of thyroxine to the fetus which leads to the decreased synthesis of thyroxine which is an essential hormone manufactured by thyroid gland of the fetus. The decreased availability of thyroxine prevents the normal development of the fetal brain and body, condition which at birth can be diagnosed with the help of sophisticated investigations. Most of these disorders are permanent and incurable. Iodated salt consumed daily offers complete protection against all iodine deficiency disorders (IDD) our country is self-sufficient in production of iodinated salt.

The most serious adverse effect of iodine deficiency is damage to the fetus. Iodine treatment of pregnant women in areas of severe deficiency reduces fetal and perinatal mortality and improves motor and cognitive performance of the offspring. Severe iodine deficiency *in utero* causes a condition characterized by gross mental retardation along with varying degrees of short stature, deaf mutism, and spasticity that is termed as cretinism.

There is cross-sectional evidence that impairment of thyroid function evidenced in mothers and neonates in conditions of mild-to-moderate iodine deficiency affects the intellectual development of their offspring. Aghini-Lombardi *et al.* reported that in children aged 6–10 years in an area in Tuscany who had mild iodine deficiency (64 μg iodine/day), the reaction time was delayed compared with matched controls from an iodine sufficient area (142 μg iodine/day).[3]

Iodine deficiency is found everywhere including plains, riverine areas, and even the coastal regions. Studies conducted all over India have shown prevalence of Goiter. Out of 587 districts in India, 282 have been surveyed for IDD and 241 were found goiter endemic. After Implementation of National IDD Control Programme (NIDDCP) in the year 1992, India, has made considerable progress towards IDD elimination. Recently, <5% total goiter rate (TGR) was found in nine out of 15 districts studied in 11 states by Indian Council of Medical Research.

The present IDD survey was done in rural areas of Raichur district according to the guidelines of Nutrition department, Directorate Health and Family Welfare services, Bengaluru. The objectives of survey were to know prevalence of goiter among 6–12 years of school children; to determine urinary iodine excretion (UIE) level in urinary samples of school children; and to study the iodization status of salt samples collected from households of school children.

Four methods are generally recommended for assessment of iodine nutrition in populations: Urinary iodine concentration (UI), the goiter rate, serum thyroid-stimulating hormone, and serum thyroglobulin.[4]

MATERIALS AND METHODS

The IDD survey was conducted in rural areas of Raichur district in Karnataka state. The survey was done according to state nutrition cell guidelines. The staff who was involved in the survey were given basic training in examination and collection of samples, according to the guidelines provided. The 30 villages were selected using the method of population proportionate to size sampling and the survey was done in the government primary schools of these villages among the children in the age group of 6 to 12 years.

Selection of Villages using Proportionate Population Sampling Method

Zila panchayat office, Raichur was approached to obtain the list of all the villages of Raichur district to select 30 villages according to the guidelines. These villages were selected after calculating cluster interval and the first village was selected randomly. The present survey was carried out only in rural areas of Raichur district. The government primary schools of these villages were visited for the IDD survey.

Selection of Students from Each Village

On visiting the school, the list of all children aged 6 to 12 years was collected and a sample of 90 children in the age group of 6 to 12 years from the school was selected systematically. Out of these 90 children, 45 were boys and 45 were girls. If the attendance rate of the children in the school was 90% or more, all the 90 children were selected from the school itself. If the attendance rate was less or the total number of children in 6- to 12-year age group was not sufficient, the remaining sample was collected from out of school children in the households till the desired sample size was achieved. After allocation of total sample to schools and out of school, the next step was selection of sample of children from the school. The children were selected from each age group in the school using systematic sampling.

Even after this if the desired sample size of 90 children from each village was not achieved then the school of nearest village was approached and samples were collected.

Examination for Classification of Goiter

According to the WHO grading system, the goiter grades have been classified into three grades as Grade 0, Grade 1 and Grade 2:

- Grade 0: No palpable or visible goiter or no goiter
- Grade 1: A mass in the neck that is consistent with an enlarged thyroid that is palpable but not visible, when the neck is in normal position. It moves upward in the neck as the subject swallows. Nodular alteration can occur even when the thyroid is not enlarged or goiter palpable but not visible
- Grade 2: A swelling in the neck that is visible when the neck is in a normal position and is consistent with an enlarged thyroid when the neck is palpated or goiter visible and palpable [Photo 1].

Selecting Children for Collection of Salt and Urine Samples

Out of 90 children selected, every fifth child was selected to collect salt sample from the households. Thus, 18 samples in each village were collected for the estimation of Iodine in the salt. Hence, a total of 540 samples of salt were collected for Iodine estimation from 30 villages.

Among the children who were asked to collect the salt sample from the households, every alternate child was asked to collect the urine sample in the school. Preservative was added to urine sample immediately after collecting the sample. Thus, nine urine samples in each village were collected for the estimation of Iodine in urine. Hence, a total of 270 samples of urine were collected for Iodine estimation from 30 villages.

Photo 1: Goiter swellings found during survey

Laboratory Tests for Salt Sample and Urine Sample

After the survey was done in each village, the salt and urine samples collected were transported to Laboratory of MRHRU at PHC, Sirwar, an affiliated center to RIMS, Raichur and NITM, ICMR Unit, Belagavi. The Iodine content of salt was estimated by iodometric titration method and UIE levels in urine samples were estimated by Wet digestion method (Sandell -Kolthoff).

Guidelines of the NIDDCP for Analysis of Results

1. Endemic District: The district is declared as endemic district if the TGR is above 5% in the children of the age group 6–12 year surveyed
2. Severity of Public Health is graded as: Mild (TGR 5–19.9%); moderate (TGR 20–29.9%) and severe (TGR >30%).
3. Severity of public health is graded as mild (median UIE 50–99); moderate (median UIE 20–49) and severe (median UIE <20).
4. Proportion of urine samples with low median UIE <100 should be <20%
5. Iodine level of salt samples should be >15 ppm at the consumer/household level
6. Proportion of households consuming adequately iodized salt(>15ppm) should be >90%.

RESULTS

The study participants are evenly distributed according to age and gender and the difference was not statistically significant [Table 3].

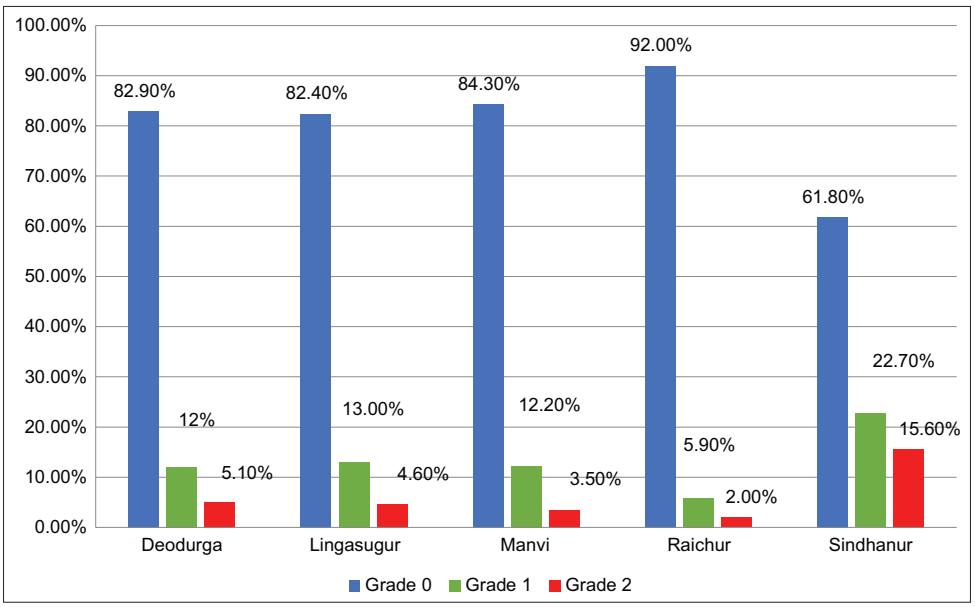

Figure 1: Distribution of the prevalence of goiter among children according to talikas. *P* < 0.001.

When children wear grouped in a particular age group, increasing trend in the prevalence of goiter was seen. Prevalence was maximum in the age group of 12 years both in case of goiter Grades 1 and 2 [Table 4].

The prevalence of goiter was more among girls than boys and the difference was significant at $P < 0.1$ [Table 5].

Table 1: The spectrum of IDD

Fetus	Miscarriage, stillbirths congenital anomalies increased perinatal morbidity and mortality endemic cretinism
Neonate	Neonatal goiter, neonatal hypothyroidism endemic neurocognitive impairment increased susceptibility of the thyroid gland to nuclear radiation
Child and adolescent	Goiter, (Subclinical) hypothyroidism impaired mental function retarded physical development increased susceptibility of the thyroid gland to nuclear radiation
Adult	Goiter with its complications hypothyroidism impaired mental function spontaneous hyperthyroidism in the elderly iodine-induced hyperthyroidism increased susceptibility of the thyroid gland to nuclear radiation

IDD: Iodine deficiency disorders

Distribution of the Prevalence of Goiter among Children According to Talukas

The prevalence of goiter TGR was found to be maximum in Sindhanur taluk (38.3%) and minimum in Raichur taluk (7.9%) [Figure 1].

The prevalence of goiter among children when plotted against the occupations of fathers, maximum prevalence was seen among the children whose fathers were agriculturists (Goiter prevalence in children – 23.9%) and self-employed (Goiter prevalence in children – 23.9%). The difference in prevalence of goiter in this distribution was found to be significant [Table 6].

The prevalence of goiter among children when plotted against the occupations of fathers, maximum prevalence was seen among the children whose mothers were agriculturists (Goiter prevalence in children – 22.9%) and laborers (Goiter prevalence in children – 19.3%). The difference in prevalence of goiter in this distribution was found to be significant [Table 7].

The overall prevalence of goiter was more in mixed diet individuals than among having vegetarian diet. The difference was not found to be significant [Table 8].

Table 2: Methods for assessment of iodine nutrition in populations

Indicator	Age group	Advantages	Disadvantages
Median UI (μg/L)	School-age children, adults and pregnant women	1. Spot urine samples are easy to obtain 2. Relatively low cost external quality control program in place	1. Not useful for individual assessment 2. Assesses iodine intake only over the past few days Meticulous laboratory practice needed to avoid contamination 3. Sufficiently large number of samples needed to allow for varying degrees of subject hydration
Goiter rate by palpation (%)	School-age children	1. Simple and rapid screening test: Requires no specialized equipment	1. Specificity and sensitivity are low due to a high inter-observer variation 2. Responds only slowly to changes in iodine intake
Goiter rate by ultrasound (%)	School-age children	1. More precise than palpation reference values established as a function of age, sex, and body surface area	1. Requires expensive equipment and electricity 2. Operator needs special training 3. Responds only slowly to changes in iodine intake
TSH (mIU/L)	Newborns	1. Measures thyroid function at a particularly vulnerable age 2. Minimal costs if a congenital hypothyroidism screening program is already in place 3. Collection by heel stick and storage on filter paper is simple	1. Not useful if iodine antiseptics used during delivery 2. Requires a standardized, sensitive assay 3. Should be taken by heel-prick at least 48 hours after birth to avoid physiological newborn surge
Serum or whole blood Tg (μg/L)	School-age children and adults	1. Collection by finger stick and storage on filter paper is simple 2. International reference range available 3. Measures improving thyroid function within several months after iodine repletion	1. Expensive immunoassay 2. Standard reference material is available, but needs validation

TSH: Thyroid stimulating hormone; Tg: Thyroglobulin; UI: Urinary iodine concentration

Majority of the salt samples (62.96%) were having Iodine level <15 ppm which included four samples with zero Iodine level. The Iodine level was between 15 and <30 ppm in 25.92% of the samples. Only 11.11% of samples were having Iodine level more than 30 ppm [Table 9].

The difference in levels of Iodine in salt samples according to gender was not significant at $P < 0.05$ [Table 10].

More than half of the children (54.5%) had UIE <100 μg/L [Table 11].

Table 3: Socio-demographic profile of study population

Variables	Frequency	Percentage
Age (years)		
6	373	13.8
7	381	14.1
8	398	14.7
9	392	14.5
10	386	14.3
11	379	14.0
12	391	14.5
Gender		
Female	1350	50.0
Male	1350	50.0
Father occupation		
Father occupation	15	0.6
Father occupation	39	1.4
Father occupation	1015	37.6
Father occupation	423	15.7
Father occupation	1142	42.3
Father occupation	66	2.4
Mother occupation		
Died	4	0.1
Professional	9	0.3
Agriculture	659	24.4
Self-employed/business	142	5.3
Labor	1103	40.9
Housewife	768	28.4
Unemployed	15	0.6
Diet		
Vegetarian	375	13.9
Mixed	2325	86.1
Age group		
6–7	754	27.9
8–9	790	29.3
10–11	765	28.3
12	391	14.5

The difference in levels of UIE according to gender was significant at $P < 0.05$ [Table 12].

DISCUSSION

In India, the previous studies had shown that no states or union territories were free from IDD although being preventable disorders.[5,6] For assessment of the severity of the iodine deficiency of any geographical area, WHO/UNICEF/ICCIDD had established the criteria on the basis of total goiter prevalence (palpable and visible goiter).[7] Any geographical area is classified as endemic for iodine deficiency when a total goiter prevalence rate in that area is more than 5% among school children aged 6–12 years.[8] With an objective to find the prevalence of IDD in district Raichur, we conducted goiter survey in 2700 school children aged 6–12 years and found that the total goiter prevalence was 18.6% [95% CI 17.14%–20.11%] which means goiter is a mild public health problem in Raichur district.

Based on UIE levels, IDD is mild-to-moderate public health problem. The reasons for this might be availability of non-iodized salt for human consumption. There is a complete ban on sale of non-iodized salt. However, the study shows that there is still availability of non-iodized salt in the rural areas. Non-iodized salt is cheaper and sold in loose compared to packed iodized salt.

One more finding found during the survey that few of the schools were using non-iodized salt in cooking mid-day meals for school children. Those schools were informed not to use non-iodized salt.

The presence of goiter among boys and girls was almost equal with fewer gender differences. This finding proved that individual sex has no role in IDD and it is the consumption of iodine as salt with foods that makes the difference.

We found a unique pattern in the prevalence of goiter with age. The prevalence of goiter was found to be rising from 6 years and maximum in 12 years age group. The increased

Table 4: Distribution of children according to goiter grade in particular age group

Father occupation	Father occupation (%)			Father occupation (%)	Father occupation (%)
	0	1	2		
6–7	632 (83.8)	86 (11.4)	36 (4.8)	122 (16.2)	754 (100.0)
8–9	635 (80.4)	114 (14.4)	41 (5.2)	155 (19.6)	790 (100.0)
10–11	623 (81.4)	93 (12.2)	49 (6.4)	142 (16.6)	765 (100.0)
12	308 (78.8)	54 (13.8)	29 (7.4)	83 (21.2)	391 (100.0)
Total	2198 (81.4)	347 (12.9)	155 (5.7)	502 (18.6)	2700 (100)

P-value=0.207

Table 5: Distribution of the prevalence of goiter among children according to the gender

Gender	Goiter grade (%)			Total (%)
	0	1	2	
Female	1077 (79.8)	184 (13.6)	89 (6.6)	1350 (100)
Male	1121 (83.0)	163 (12.1)	66 (4.9)	1350 (100)
Total	2198 (81.4)	347 (12.9)	155 (5.7)	2700 (100)

P-value=0.062

Table 6: Distribution of the prevalence of goiter among children according to father's occupations

Father's occupation	Goiter grade (%)			Total (%)
	0	1	2	
Died	14 (93.3)	0 (0.0)	1 (6.7)	15 (100.0)
Professional	33 (84.6)	4 (10.3)	2 (5.1)	39 (100.0)
Agriculture	773 (76.2)	164 (16.2)	78 (7.7)	1015 (100.0)
Self-employed/ business	322 (76.1)	72 (17.0)	29 (6.9)	423 (100.0)
Labor	1001 (87.7)	97 (8.5)	44 (3.9)	1142 (100.0)
Unemployed	55 (83.3)	10 (15.2)	1 (1.5)	66 (100.0)
Total	2198 (81.4)	347 (12.9)	155 (5.7)	2700 (100.0)

P<0.001

Table 7: Distribution of the prevalence of goiter among children according to mother's occupations

Mother occupation	Goiter grade (%)			Total (%)
	0	1	2	
Died	4 (100.0)	0 (0.0)	0 (0.0)	4 (100.0)
Professional	7 (77.8)	2 (22.2)	0 (0.0)	9 (100.0)
Agriculture	508 (77.1)	100 (15.2)	51 (7.7)	659 (100.0)
Self-employed/ business	122 (85.9)	12 (8.5)	8 (5.6)	142 (100.0)
Labor	891 (80.8)	148 (13.4)	64 (5.8)	1103 (100.0)
Housewife	655 (85.3)	81 (10.5)	32 (4.2)	768 (100.0)
Unemployed	11 (73.3)	4 (26.7)	0 (0.0)	15 (100.0)
Total	2198 (81.4)	347 (12.9)	155 (5.7)	2700 (100.0)

P=0.015

Table 8: Distribution of the prevalence of goiter among children according to the type of diet consumed

Type of diet	Goiter grade (%)			Total (%)
	0	1	2	
Vegetarian	310 (82.7)	52 (13.9)	13 (3.5)	375 (100.0)
Mixed	1888 (81.2)	295 (12.7)	142 (6.1)	2325 (100.0)
Total	2198 (81.4)	347 (12.9)	155 (5.7)	2700 (100.0)

P=0.113

Table 9: Distribution of salt samples according to the Iodine level estimation

Salt iodine level	Frequency	Percentage
0 ppm	04	0.74
0.1–14.999 ppm	336	62.22
15–29.999 ppm	140	25.92
≥30 ppm	60	11.11
Total	540	100.0

Table 10: Association of gender and salt iodine level

Salt iodine level	Female (%)	Male (%)	Total (%)
0 ppm	0 (0.0)	4 (1.4)	4 (0.7)
0.1–14.999 ppm	170 (64.6)	166 (59.9)	336 (62.2)
15– 29.999 ppm	60 (22.8)	80 (28.9)	140 (25.9)
≥30 ppm	33 (12.5)	27 (9.7)	60 (11.1)
Total	263 (100.0)	277 (100.0)	540 (100.0)

P=0.067

Table 11: Distribution of salt samples according to the urine iodine level

Urine iodine level	Frequency	Percentage
<20 μg/L	34	11.7
20–49.99 μg/L	36	12.4
50–99.99 μg/L	88	30.3
≥100 μg/L	132	45.5
Total	290	100

Table 12: Association between gender and urine iodine level

Urine iodine level	Female (%)	Male (%)	Total (%)
<20 μg/L	24 (16.9)	10 (6.8)	34 (11.7)
20–49.99 μg/L	15 (10.6)	21 (14.2)	36 (12.4)
50–99.99 μg/L	38 (26.8)	50 (33.8)	88 (30.3)
≥100 μg/L	65 (45.8)	67 (45.3)	132 (45.5)
Total	142 (100.0)	148 (100.0)	290 (100.0)

P=0.040

demand of thyroid hormone with advancing age may be attributed to this relation of age and prevalence. The World Health Organization urged to implement universal salt iodization and iodine supplementation strategies for preventing and controlling IDD. National goiter control program was launched in 1962 by Government of India and renamed NIDDCP in 1992 with the aim to reduce the prevalence of IDD to below 10% by 2010.[9] After 28 years of implementation of NIDDCP, the present study shows that the national program has had much impact in lowering down the prevalence of goiter.

CONCLUSION

The present study shows total goiter prevalence of 18.6% in the rural areas of Raichur district indicating that it is still an endemic area, where goiter remains a significant public health problem. Although the prevalence of goiter has been reduced

over years, it is still endemic. The proportion of households consuming adequately iodized salt (median UIE ≥100 μg/l) is far below the recommended level. Effect of geographical locations, dietary factors, storing salt techniques, cooking techniques, and interaction of iodine with other nutrients is some areas where further research can be done in future.

LIMITATIONS OF THE STUDY

1. All students were examined for the presence of goiter, but salt iodine testing and urine iodine testing was done for every fifth and tenth child. Testing for salt iodine and urine iodine in children with Grade 1 or 2 goiter may indicate the causal factors for goitre in that child
2. A subset of the selected students was asked to bring salt samples from their homes for testing for iodine levels. Many households have reported consumption of both common salt and crystal salt; but the salt sample testing was done only for one sample that was brought by the students. This may not give the accurate picture of the pattern of consumption of iodized salt in the community.

RECOMMENDATIONS

1. Efforts must be made to ensure that the quality of iodized salt meets the required standards at the consumer level
2. Strict implementation of legislative measures to check the sale of non-iodated salt starting from manufacture level to retail store
3. Educating the retailers about importance of iodated salt and counseling them not to sell non-iodated salt by making them aware of punishments for selling non-iodated salt
4. Educating public about benefits of consumption of iodated salt. Awareness programs to educate the community about the hazards of consumption of un-iodized salt should be undertaken
5. Health personnel in the respective health centers to have strict vigilance on implementation of regulations
6. Periodic surveys to find out the prevalence of IDD to find out the burden of disease.

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Original Article

Role of Ultrasonography in Evaluation of Focal Hepatic Lesions

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Abstract

Introduction: Liver is the site of maximum no. of biochemical reactions of the body. Focal liver lesions are common on pathologic or imaging evaluation of the liver. Ultrasonography is economic, widely available, noninvasive, and nonionizing investigation that allows imaging of liver in multiple planes with high sensitivity and specificity for correct diagnosis and characterization of focal liver lesions.

Aims and Objectives: The aim of the study was to evaluate the role of ultrasonography in different types of focal hepatic lesions and characterization of the lesions.

Materials and Methods: This was hospital-based prospective study done on May 2019 to April 2020 at the Department of Radiodiagnosis of Nil Ratan Sircar Medical College and Hospital, Kolkata. Patients referred for ultrasonography with clinically suspected of having focal hepatic lesions with complaints and incidentally found focal hepatic lesions on patient's ultrasonography done for other reasons from both inpatient and outpatient departments.

Results: Hence, most common lesion was liver abscess and least common lesion was hemangioma in my study. I found single lesion in 32 cases (64%) and multiple lesions in 18 cases (36%).

Conclusion: With ultrasonography as an initial imaging modality, time and cost to arrive at an diagnosis were significantly reduced.

Key words: Echogenicity, Focal hepatic lesion, Ultrasonography

INTRODUCTION

Liver is the largest and one of the most important organs of the body, often called as chemical laboratory of the body as it is the site of maximum no. of biochemical reactions of the body required for tissue respiration, metabolism, detoxification, storage, etc. Focal liver lesions are common on pathologic or imaging evaluation of the liver and include a variety of malignant and benign neoplasms, as well as congenital and acquired masses of inflammatory and traumatic nature. Evaluation of focal liver lesions is a complex tissue which is often the major focus of a cross sectional imaging study.[1] Next only to lymph nodes, liver is the most common site for metastases. At death, 40–50% of all primary carcinomas will have metastases within the liver.[2] Ultrasonography is economic, widely available, noninvasive, no ionizing investigation that allows imaging of liver in multiple planes with high sensitivity and specificity for correct diagnosis and characterization of focal liver lesions. According to ALARA protocol (as low as reasonably achievable) in the low- and middle-economic background like West Bengal, it is needed to re-emphasize the role of the cheap and harmless investigation ultrasonography as the primary diagnostic tool for the various focal hepatic lesions. Sonography is widely accessible, relatively inexpensive, portable, noninvasive, nonionizing, allows imaging in multiple planes, and can be repeated frequently. It assists in real-time evaluation of organ under examination, especially the liver which is situated just below the ribcage without intervening gas, has a high sensitivity and reasonable specificity.[3] Sonography has excellent spatial and contrast resolution, hence gray-

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scale morphology of a mass allows for differentiation of cystic and solid masses and in many instances, characteristic recognized appearances may suggest the correct diagnosis without further evaluation.[1] Characterization of a liver mass on conventional sonography is based on the appearance of the mass on gray scale imaging.[1] Sonography is widely available and inexpensive. Based on the patient's complaints such as vague upper abdominal pain, jaundice, fever, or unexpected abnormal liver function tests many clinicians request sonography as the initial imaging modality for clinically suspected liver pathology.[4,5]

The presence of diffuse liver disease such as cirrhosis or steatosis may largely vary the gray-scale sonographic appearance of the hepatic tumors because the echogenecity of the background liver may be altered and make the characterization of the tumors difficult.[6]

Aims and Objectives

General objective

The general objective of the study is as follows:

- To evaluate role of ultrasonography in different types of focal hepatic lesions and characterization of the lesions.

Specific objective

The specific objective of the study is as follows:

- To study ultrasonography as a prime diagnostic modality for patients with clinical features of focal liver diseases
- To evaluate the ultrasound imaging spectrum of focal hepatic lesions
- To study the relative prevalence of different focal hepatic lesions detected by ultrasound during the study period
- To make early diagnosis so that treatment can be started as early as possible.

MATERIALS AND METHODS

Study Design/Experimental Design

This was a hospital-based prospective study.

Study Period

The study period was from May 2019 to April 2020.

Place of study

This study was conducted at Nil Ratan Sircar Medical College and Hospital, Kolkata.

- Department of radiodiagnosis
- Department of pathology

Study population

Patients referred for ultrasonography at department of Radiodiagnosis Nil Ratan Sircar Medical College, Kolkata, with clinically suspected of having focal hepatic lesions with complaints and incidentally found focal hepatic lesions on patient's ultrasonography done for other reasons from both inpatient and outpatient departments during May 2019–April 2020

Inclusion Criteria

- Patients with complaints such as vague upper abdominal pain, jaundice, fever, abdominal mass, or unexpected abnormal liver function tests with suspicion of focal liver disease
- Only adult patients (more than 18 years of age) will be included
- Focal liver lesions of diameter more than 10 mm.

Exclusion Criteria

Patients with diffuse liver disease such as steatosis, cirrhosis, hepatitis, storage diseases, diffuse malignancies, and also post-traumatic and post-operative cases.

Sample size

The sample size was 50 patients.

Sample design

The sample design was randomized.

1. Clinical history
   - Patient demographics
   - Main presenting complaint
2. General examination
3. Systemic examination: Local abdominal examination and palpation of liver.
4. Investigations:
   - Blood – Hb%, total count, differential count, erythrocyte sedimentation rate, Fasting blood sugar. Liver function test
   - Ultasonography: Discussed in details below
   - Pathological investigation:
     o FNAC from the lesion
     o Biopsy (if needed).
   - Other relevant investigation(s):
     o Computed tomography (CT) scan of Abdomen (non-contrast and contrast)
5. Study tools
   - Ultrasonography machine: Philips HD7 and Samsung SonoAce R7 machine with 3.5–5 MHz curvilinear probe and 3–12 MHz linear probe and sector probe whenever needed
   - A pro forma designed for recording age of presentation, sex, clinical, radiological, and other investigations findings.
6. Radiological procedure
   - Consent forms duly signed
   - Grey scale real-time ultrasonography to be performed using 3.5–5 MHz curvilinear probe and

3–12 MHz linear probe and sector probe whenever needed

Patient preparation and scanning technique

- Once the patient agrees to participate in the study, informed consent was taken before ultrasound examination, followed by detailed history and brief clinical examination
- Patients were kept nil by mouth ideally for 6 h so that bowel gas is limited before ultrasound examination
- Patients were examined in the supine position to begin with and then in decubitus (right or left) and sitting position if needed
- Suspended inspiration enables examination of the dome of the liver, frequently an ultrasound blind spot
- Liver was scanned in various planes such as sagittal, parasagittal, transverse, oblique, subcostal, intercostal, and coronal planes. Comprehensive scanning of other upper abdominal organs was done
- In some cases clinical condition of patient demanded an ultrasound examination without prior preparation
- The real time scan has many advantages and is easier to perform and it can be easily maneuvered and most of the liver can be evaluated. It provides easy visualization of vascular landmarks. The liver is best examined with real-time sonography, The normal liver is homogeneous, contains fine-level echoes, and is either minimally hyperechoic or isoechoic compared to the normal renal cortex. The liver is hypoechoic compared to the spleen. The portal vein is encased in collagenous sheaths running in common with the hepatic artery and bile duct and their margins tend to be echodense. The apex of the angle of the portal vein has a horizontal orientation. The caliber increases toward the porta hepatis. Hepatic veins can be traced to inferior vena cava and since the collagen content in their walls is less the walls are imperceptible. The apex of the hepatic vein bifurcation is longitudinal toward inferior vena cava and their caliber increases as they course toward the inferior vena cava
- The liver is examined using 3–3.5 MHz. In children and superficial lesions 5 MHz transducers is necessary.

RESULTS

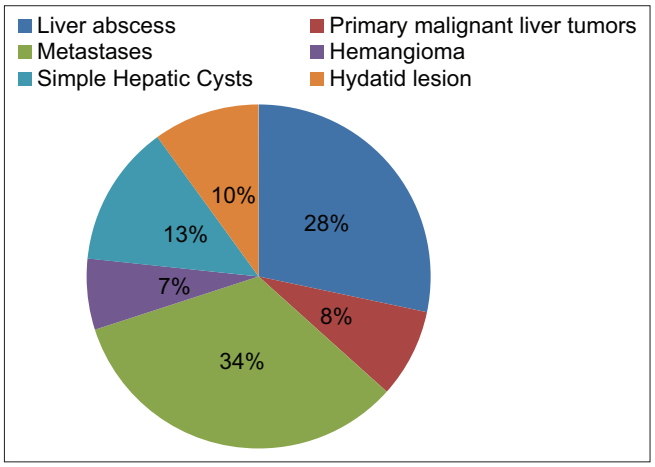
We found that the most common presenting age group in the study was 51–60 year (24%). Among all cases 58% were males and 42% were females. Most common complain of patients were abdominal pain and least common complain were itching (urticaria) [Table 1]. The lesions were distributed as liver abscess (34%), primary malignant liver tumors (10%), metastases (20%), hemangioma (8%), simple hepatic cysts (16%), and hydatid lesion (12%) [Graph 1]. Hence, most common lesion was liver abscess and least common lesion was hemangioma in my study. I found single lesion in 32 cases (64%) and multiple lesions in 18 cases (36%). Our study showed that most of the lesions were distributed in right lobe (64%). Rest 3% in left lobe and 15% cases involved both lobes. Most of the lesions had round and regular margin (76%) and few had irregular margin (24%). Considering echogenicity of the lesions they are mostly mixed echogenic (36%), hypoechoic (28%), hyperechoic (10%), and anechoic (26%). Hepatomegaly was present in 52% cases and absent in 48% cases. We found complications (Necrosis, Calcification) in 48% cases [Table 2].

DISCUSSION

- In our study 50 patients, who were clinically suspected of having focal hepatic lesions and incidentally detected focal hepatic lesions were included in the study. The age group of the subjects ranged from 18 years to 75 years. Study group contained 58% males and 42% females with the male to female ratio being 1.4:1. Most lesions were found in the age group of 51–60 with 12 patients, followed by 41–50 years age group compromising ten patients

Table 1: Distribution of symptoms in focal liver lesions

Clinical features	Number of cases	% Total (Out of 50 cases)
Abdominal pain	30	60
Loss of weight	12	24
Loss of appetite	12	24
Abdominal distension	8	16
Fever	24	48
Mass Per abdomen	5	10
Jaundice	11	22
Urticaria	2	4



Graph 1: Ultrasound diagnosis

Table 2: Sonographic features of the focal liver lesions

Sonographic	Hepatic	PMLT	Metastasis	Hemangioma	Simple hepatic	Hydatid
Features	Abscess				Cyst	Lesion
Hepatomegaly	13	4	7	0	1	1
Number - Single	13	4	0	4	6	5
Number - Multiple	4	1	10	0	2	1
Lobar involvement : Right lobe	13	4	0	4	7	4
Lobar involvement: Left lobe	2	0	0	0	0	1
Lobar involvement: Both lobes	2	1	10	0	1	1
Shape round and borders regular	15	0	5	4	8	6
Irregular shape borders	2	5	5	0	0	0
Lesion hyperechoic –	0	1	0	4	0	0
Lesion–hypoechoic	13	0	2	0	0	0
Lesion - Mixed	4	4	8	0	0	1
Lesion - Anechoic	0	0	0	0	8	5
Necrosis	16	3	4	0	0	1
Calcification	0	2	0	0	0	1

7. Hepatic abscess was the most common focal hepatic lesion in the study with an incidence of 34% (17 patients) which is in close correlation to the study of Hapani *et al.*[7] and study of Vishwanath.[8] It was most commonly seen in the age group of 21–30 years. Majority of the patients presented with non-specific abdominal pain and fever. Ultrasonography is unable to differentiate pyogenic from amebic abscess.

- Hepatic metastases compromised the second most common focal hepatic liver lesion in the study group with an incidence of 20% (ten patients) .It was most commonly seen in the age group of 51–60 years. Females constituted majority (60%) and males the remainder. Most (80%) of them presented with loss of weight and loss of appetite. Constitutional symptoms such as abdominal pain, abdominal distension, mass per abdomen, and jaundice were noted in rest of the patients. On examination majority, seven patients (70%) had hepatomegaly. About 50% of the lesions were round and irregular margins. All lesions involved both lobes. Mixed echogenic pattern was noted in eight patients (80%). All the patients had multiple lesions (100%) [Figure 1]. The sonographic features were in close correlation with study conducted by Yoshida *et al.*[9]
- There were 8 (16%) cases of simple primary liver cysts in the age group of 51–60 years. Cases were distributed more in males with male female ratio 1.3:1. Right lobe preference was noted in 7 (83.3%) and 1 (16.7%) in the left lobe. The most common complaint was non-specific abdominal pain seen in two cases. Sonographically the lesions were anechoic with absence of internal structure, sharp smooth borders, and strong posterior sonic transmission, which was consistent with Spiegel *et al.*[10] study [Figure 2]
- Five cases (10%) cases of primary malignant liver tumor with age range of 41–50 years. Majority of the patients were males 3 (60%) and 2 (40%) females. It was more common in the right lobe 4 (80%) and 1 (20%) in both lobes with most of them being solitary

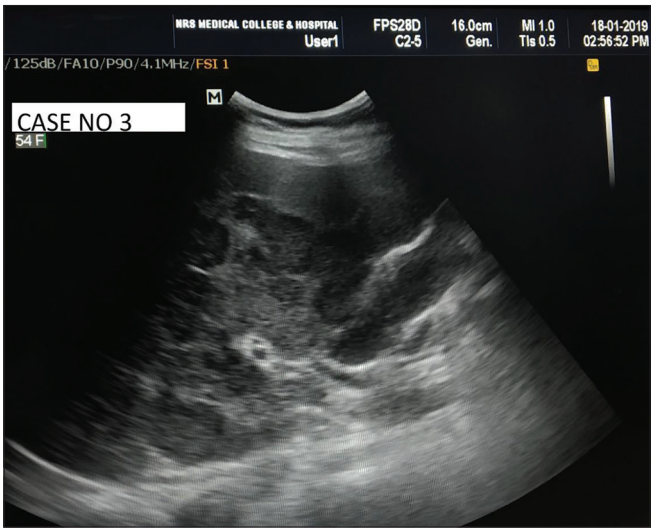


Figure 1: Ultrasonography: Multiple echogenic metastatic deposits in both lobes of liver

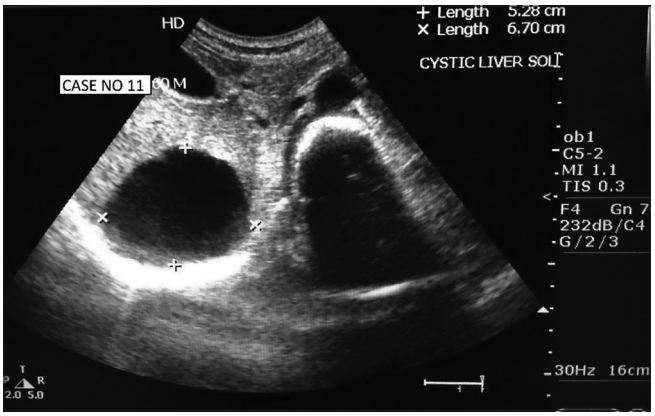


Figure 2: Ultrasonography: Simple hepatic cyst in the right lobe

4 (80%) and 1 with multiple lesions. Majority 4 (80%) of them presented with pain abdomen, loss of weight and appetite, followed by abdominal distension in two and jaundice in three patients. Sonograhically they were mixed echogenic with irregular border [Figure 3]. The findings were in close correlation with the previous studies.[11]

- Six cases (12%) of hydatid cystic lesion were noted in the study, in the age group of 18–30 years of age. Females were the predominant group compromising 5 (82%) and 1 (18%) male patient. Right lobe was affected in four patients, left in one patient and both lobes affected in one patient. Majority of patients presented with pain abdomen, fever, and mass per abdomen. Five patients had solitary lesion and one patient had multiple lesions. On ultrasound they were complex cystic lesion with well-defined walls with multiple septa daughter cysts and internal echogenic matrix [Figure 4].

Four cases were diagnosed as hemangioma of liver occurring in mid age to old age, male, and females had equal sharing of two cases each. They were single lesion occurring in right lobe having round and regular border and hyperechoic echotexture. All patients complained of vague pain abdomen.

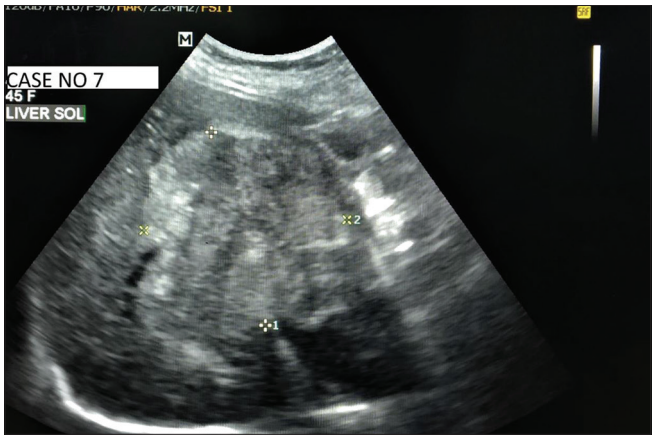


Figure 3: Ultrasonography: Mixed echogenic lesion with irregular border in the right lobe of liver : Primary malignant liver tumor

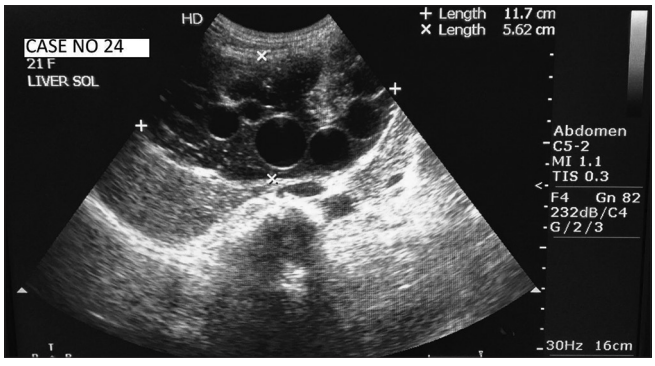


Figure 4: Ultrasonography: Hepatic hydatid lesion with daughter cyst

SUMMARY AND CONCLUSION

A total of 50 patients, clinically suspected of having focal space occupying lesions in the liver who underwent sonography were chosen for the study during a period of 18 month.

- The mean age of the patients in the sample study was 55 years with an age range of 18–75 years
- Majority of the patients were males
- The most common complaints were abdominal pain and fever
- The most common lesions were hepatic abscess followed by hepatic metastases
- In this study, out of 50 cases, hepatic abscess was present in 17 patients, metastases in ten patients, simple hepatic cyst in eight patients, primary malignant liver tumor in five patients and hemangioma in four patients, hydatid lesion six patients
- Ultrasonography serves as an important diagnostic tool in imaging and characterization of focal liver lesions
- Ultrasonography is a safe and effective method of detecting focal liver lesions. It is easy availability, portability, flexibility, lack of dependence on organ function, and lack of ionizing radiation makes it ideal for imaging the liver
- Ultrasonography also serves a key role in guided FNAC, which avoid unnecessary repeated trauma to the patient and also help to yield productive specimen for histopathological evaluation. It also helps the operating surgeon in planning a in the pre-operative approach to the lesions
- Its multiplanar imaging ability and portability has a significant advantage in sick patients to detect lesions, to locate lesion, and to identify solid from the cystic nature of lesion, thereby aid in characterization of lesions
- Information regarding the secondary features of liver disease such as ascites, primary source of malignancy, secondaries in the abdomen, splenomegaly, and pleural effusion can be evaluated
- As ultrasonography is safe, repeatable, and low cost as compared to newer modalities CT and MRI, it is still one of the most effective imaging modality for characterization and for overall assessment of abdomen

Limitation

In my study, 50 patients were studied for the period of 12 months. The study would be more productive and efficacious if we could run the study for longer period. The samples were taken randomly. Hence, we did not include

all patients. The study would be better if we were able to include all patients in our study.

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Original Article

Role of Transfontanelle Neurosonography in the Imaging Evaluation of Meningitis in Neonates and Infants

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Abstract

Introduction: Acute bacterial meningitis still remains as one of the major causes of infant morbidity and mortality even with the recent advances of antibiotics and supportive treatment. The early diagnosis and appropriate medical and surgical interventions of the complication can reduce the morbidity and mortality to a considerable extent. The use of transfontanelle ultrasound to examine these infants has been rapidly increased being relatively simple, easy to perform, and safer, makes it an ideal method for the early detection of signs of meningitis, its complication, and follow-up of the patients. Study aimed to establish role of ultrasonography in evaluation of meningitis and its complication in neonates and infants.

Materials and Methods: A total of 40 patients who were suspected clinically or pathologically for meningitis were evaluated by transfontanelle ultrasound on Mindray DC 30 machine with linear probe (7 MHz–12 MHz) and curvilinear probe (3 MHz–5 MHz).

Results: A study was performed on 40 patients (newborn to 1 year old) of suspected meningitis. Transfontanelle ultrasonography was obtained out of which 12 patients were normal. The spectrum of sonographic abnormalities includes echogenic sulci (52.5%) and cerebritis (32.5%), ventriculomegaly (55%), ventriculitis (27.5%), subdural effusion (7.5%), epidural effusion (2.5%), encephalomalacia (5%), and cerebral abscess (7.5%) in patients.

Conclusion: Transfontanelle ultrasound in neonates/infants is a rapid, real-time, safe, and effective method for initial diagnosis, to identify complications, planning the treatment of meningitis and its follow-up even when the signs and symptoms are non-specific. It gives us information not only in early as well as late changes seen in meningitis.

Key words: Brain, Meningitis, Neonates, Transfontanelle, Ultrasonography

INTRODUCTION

Acute bacterial meningitis still remains as one of the major causes of infant morbidity and mortality even with the recent advances of antibiotics and supportive treatment. The early diagnosis and appropriate medical and surgical interventions of the complication can reduce the morbidity and mortality to a considerable extent.[1]

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The use of transfontanelle ultrasound to examine these infants has been rapidly increased. Transfontanelle scan being relatively simple, easy to perform, and safer, makes it an ideal method for the early detection of signs of meningitis, its complication, and follow-up of the patients.

Using the color Doppler ultrasound, one can also differentiate benign enlargement of subarachnoid space from subdural effusion.[2] Transfontanelle ultrasound is also extremely beneficial in evaluating interventricular contents, and debris and septations.[3]

The objectives of the study were early diagnosis of meningitis by transfontanelle ultrasound, early detection of its complications, and early therapeutic interventions and to establish the relationship between imaging findings and underlying pathological changes.

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MATERIALS AND METHODS

The study was performed in the Department of Radiodiagnosis, NSCB Medical College, Jabalpur, Madhya Pradesh. It is a hospital-based descriptive and observational study. Only the patients who were willing to take part in the study were included, the patients who were suspected clinically or pathologically for meningitis.

A total of 40 patients were included in the study from the age group ranging from day 0 to 180. Transfontanelle ultrasound was performed on Mindray DC 30 machine. Patients were examined on both high-frequency 7 MHz–12 MHz and low-frequency probe 3 MHz–5 MHz; coronal, axial, and sagittal images were taken, under aseptic precautions to reduce any chances of infection to the neonates/infants.

Brain parenchyma, ventricular system, brainstem, cerebellar hemisphere, outline/content of ventricle, cerebrospinal fluid (CSF), and extra-axial spaces were examined carefully. The patients were evaluated for the presence of echogenic/widening of sulci, signs of ventriculitis, parenchymal echogenicity, any extra-axial fluid collection, and for any evidences of abscess, infarcts, and encephalomalacia.[4,5]

RESULTS

Amongst 28 cases which had spectrum of findings on transfontanelle scan; sulcal widening and echogenicity was seen in 21 of the cases, ventriculomegaly in 22, signs of ventriculitis in 11, focal cerebritis in 13, subdural/epidural effusion in 4, abscess was found in 3 cases and encephalomalacia in 2 of the cases [Table 1].

Out of these 28 patients, 15 cases underwent sequential follow-up scans few had contrast-enhanced computed tomography/magnetic resonance imaging to rule out further complications. Fifteen cases which underwent transfontanelle scan were performed on the seventh and the 14th or on discharge day whichever was earlier and the findings were then compared.

Out of these, there was a significant decrease in the findings with sulcal echogenicity with prompt use of antibiotics and supportive therapy, however, the case with the abscess showed deterioration.

DISCUSSION

Meningitis is a common cause of morbidity and mortality in the pediatrics age group. An early identification of macroscopic pathological changes is important for timely diagnosis and treatment.

Our study consisted of 40 infants of age group ranging from 0 to 180 days with mean age of 24 days. Maximum cases were seen of age group of 0–1 month which is 37.5%, male preponderance was seen in our study and these were also found in the studies done by Soni *et al.*[6]

We did evaluate 40 patients with suspected/clinical CSF positively diagnosed cases out of which normal sonogram was seen in 12 of the cases, which is 30% of total. Similar pattern was seen under the study [Table 2].[6-9]

In early stages, first, there are widening and increased echogenicity of sulci due to intense inflammatory exudates accumulating in the fissures and sulci. In our study, it was observed in 52.5% of the patients, whereas Hans *et al.*[8] reported 82% of cases, Soni *et al.*[6] in 63% of the cases, Baruah *et al.*[7] in 60%, and Mahajan *et al.*[10] in 62% of the total cases. All the mentioned studies found that echogenic sulci as the earliest findings in case of meningitis [comparison Table 3 and Figure 1].

An abnormal parenchymal echogenicity; focal or diffuse represents cerebritis or infarction, which is common in complicated meningitis and carry poor prognosis. In our study, focal cerebritis was found in 32.5% of the cases our study is consistent with Soni *et al.*[6] which reported it in 29.5%, Chaudhary *et al.*[11] in 65%, and Patel *et al.*[9] in 30.7% of patients.

Ventriculomegaly can be an early or late finding on transfontanelle scan. An early ventriculomegaly represents

Table 1: Sonographic spectrum in cases of meningitis (*n*=40)

Findings	Number (*n*)	Percentage
Echogenic sulci	21	52.5
Focal cerebritis	13	32.5
Ventriculomegaly	22	55
Ventriculitis	11	27.5
Subdural effusion	3	7.5
Epidural effusion	1	2.5
Abscess	3	7.5
Hemorrhagic inflammation	2	5
Encephalomalacia	2	5

Table 2: Radiological findings according to gender distribution

Diagnosis	Male	Female	Total
Normal study	7	5	12
Abnormal findings	15	13	28
Total	22	18	40

Table 3: Comparison with various previous studies

Findings	Our study (%)	Soni *et al.* (%)	Baruah *et al.* (%)	Han *et al.* (%)	Patel *et al.* (%)
Normal findings	30	35.4	40	38.4	19.2
Echogenic sulci	52.5	63	60	39.7	53.8
Focal cerebritis	32.5	29.5	–	11.5	30.7
Ventriculomegaly	55	59	28.6	14	46
Ventriculitis	27.5	35	1.4	6	23
Subdural effusion	7.5	2.2	–	33.3	7.6
Epidural effusion	2.5	2.2	–	33.3	3.8
Abscess	7.5	2.2	–	1.2	7.6
Hemorrhagic infarcts	5	–	–	–	3.8
Encephalomalacia	5	2.2	–	–	3.8

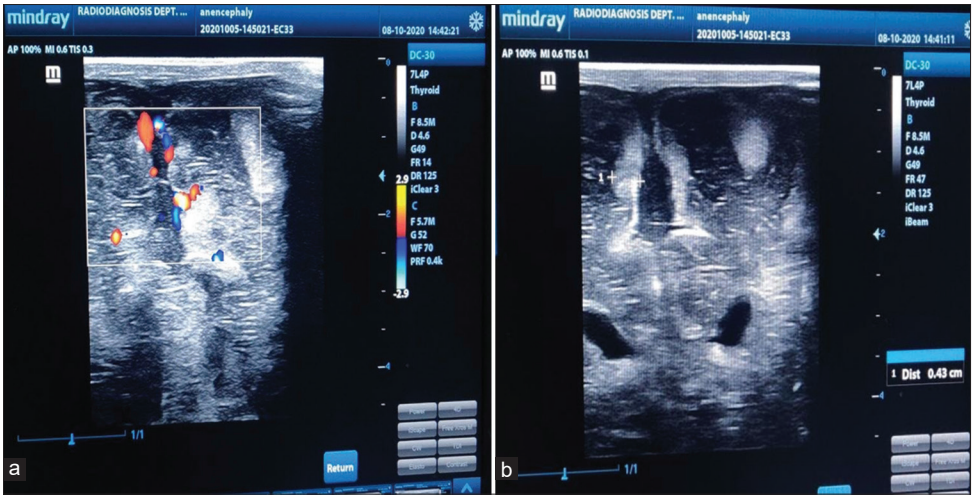

Figure 1: Transfontanelle ultrasound in an infant shows (a, b) thickened and echogenic bilateral frontal sulci with increased vascularity on color Doppler

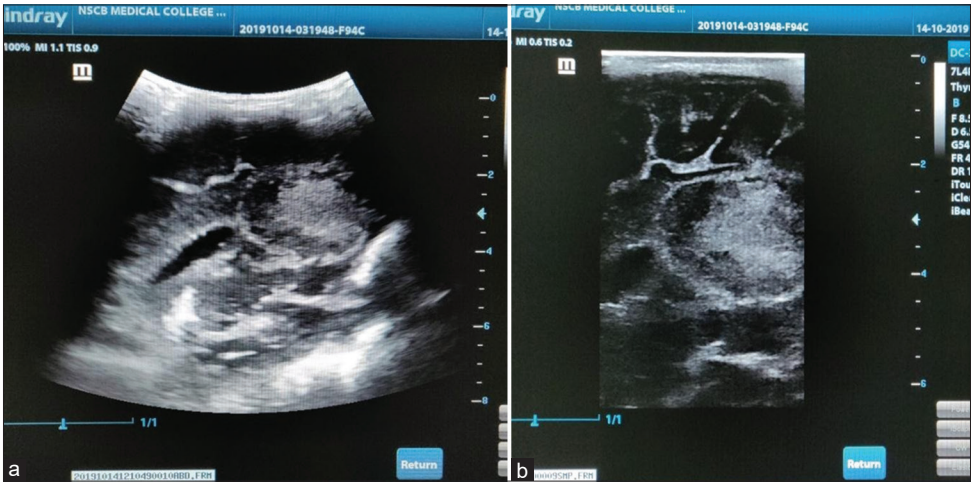

Figure 2: Transfontanelle ultrasound in an infant shows (a, b) a well-defined round to oval lesion with smooth margin and heterogeneously hypo-hyperechoic content within suggestive of cerebral abscess

non-obstructive normal pressure hydrocephalus and is usually reversible.[12] However, late is generally due to obstruction secondary to accumulation of purulent exudates or secondary to chronic inflammatory changes. In our study, it was found in 55% of the cases. Baruah *et al.*[7] found the same in 28.6% of patients, Soni *et al.*[6] in 59% of the cases, and Patel *et al.*[9] in 46% of patients.

Ventriculitis arises from the ependymal linings or from the choroid plexus. On ultrasound, there is echogenic

ependyma with irregular hyperechoic choroid plexus, exudates, and septations.[13-15] In the present study, it was seen in 27.5% of the patients which was consistent with the studies such as Soni *et al*.[6] 33%, Mahajan *et al*.[10] 21%, and Patel *et al*.[9] in 23% of the cases.

Abscess is identified as well-defined, thick hyper echoic rim with hyperechoic content and may be seen as the complications of meningitis.[16,17] In our study, it was reported in 3 cases (7.5%) which was consistent with other studies done by Soni *et al*. 2.2% and Patel *et al*. 7.6%.[6,9]

Subdural and extradural effusion and subdural empyema were reported as complications of meningitis [Figure 2].[18-20]

CONCLUSION

Transfontanelle ultrasound in neonates/infants is a rapid, real-time, safe and effective method for initial diagnosis, to identify complications, planning the treatment of meningitis and its follow-up even when the signs and symptoms are non-specific. It gives us information not only in early as well as late changes seen in meningitis.

Therefore, the role of transfontanelle Neurosonography in providing accurate imaging and pathological information can help in planning its timely medical or surgical interventions and prognosis of the patients.

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Original Article

Effects of the Celiac Plexus Block versus Splanchnic Nerve Block for Upper Abdominal Tumors on Pain Relief and Quality of Life–randomized Comparative Study

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Abstract

Introduction: The diagnosis of early cancer and therapeutic options in advanced management has improved of patient's expectancy of life. However, pain management for these patients is important concerns since pain is the most common symptom in 88% of these patients with an advanced stage of the disease.

Aim: This study aimed to assess the effectiveness of a neurolytic celiac plexus block versus a splanchnic nerve block for control of pain and the effects of these methods on the quality of life.

Materials and Methods: This is a randomized comparative study from September 2018 to August 2019 in Tamil Nadu Government Multi Super Speciality Hospital, Omandurar Estate. A total of 30 patients, 15 in each group, were allocated randomly into celiac plexus block and splanchnic nerve block, and the results were analyzed statistically and discussed below.

Results: Out of 30 patients, 22 were males, and eight were females. The mean age was 53.07 years in group splanchnic nerve block (SNB) and 56.6 years in group celiac plexus block (CPB), respectively. There was a significant decrease in visual analog scale score in group SNB versus group CPB on the 1st week and 2nd week of post-procedure and last week. Strong opioid consumption significantly decreased in group SNB versus group CPB at following times of post-procedure visit during days 7, 14, 28, 42, 56, 70, and 84. In the SNB group, nine patients had a backache, four had diarrhea, and two patients had hypotension. In the CPB group, three patients had a backache, seven had diarrhea, and eight patients had hypotension.

Conclusion: The statistical data and results of this study illustrate that a SNB appears to be clinically comparable to the CPB. However, all statistically significant differences are of little clinical value.

Key words: Celiac, Plexus, Splanchnic, Tumors

INTRODUCTION

Early cancer and therapeutic options in advanced management have improved the patient's expectancy of life. However, pain management for these patients is important concerns since pain is the most common symptom in 88% of these patients with an advanced stage of the disease. It was found that many of the cancer patients have inadequate pain control, and many of them end in mortality with pain. A combination of an interventional treatment with neurolysis (alcohol chemical neurolysis) and pharmacotherapy (oral opioids) is recommended as a collective approach as a palliative treatment. Neurolysis reduces pain by disrupting pain signals along the neural pathway.[1] Interventional therapy is needed for patients whose pain has not been controlled by drugs (pharmacotherapy) or patients who have suffering drug-related side effects.[2]

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The celiac plexus is a complex network of nerves located in the abdomen. The celiac trunk can give rise to the superior mesenteric artery or one or both of the inferior phrenic arteries. Celiac plexus block (CPB) is recommended in the upper abdomen cancer cases, chronic pancreatitis, abdominal metastases, retroperitoneal tumors, and chronic abdominal pain in patients who are on high-dose narcotic analgesia or those who not respond topharmacotherapy.[3]

Thoracic splanchnic nerves are splanchnic nerves that arise from the sympathetic trunk in the thorax and travel inferiorly to provide sympathetic innervation to the abdomen. The nerves contain preganglionic sympathetic fibers and general visceral afferent fibers. Interruption of the splanchnic nerve at the level of T11 can provide relief from intolerable pain associated with intra-abdominal tumors.[4] This study aims to compare the effectiveness of a splanchnic nerve block (SNB) versus CPB for effective control of pain and the effects of these interventions on the quality of life upon a 3 months follow-up post-intervention for patients with upper abdominal tumors.[5]

Quality of life on follow-up has been assessed using the QLQ-C30 questionnaire. The European Organization for Research and Treatment of Cancer (QLQ-C30) developed a quality of life questionnaire version 3.0 to assess cancer patients' quality of life. It is composed of both multi-item scales and single-item scales. It is classified into

1. Five functional scales (role, physical, cognitive, emotional, and social)
2. Three symptom scales (fatigue, pain, nausea, and vomiting)
3. Two questions are assessing the overall quality of life.

Both multi-item scales and single-item measures range in score from 0 to100. A high scale score shows a higher response level. Thereby high score for the functional scale, the global health scale represents a high quality of life. However, a high score for a symptom scale represents a low quality of life.[6]

Aim

This study aimed to assess the effectiveness of a neurolytic CPB versus a SNB for control of pain and the effects of these methods on the quality of life.

MATERIALS AND METHODS

This randomized comparative study was done from September 2018 to August 2019 in Tamil Nadu Government Multi Super Speciality Hospital, Omandurar Estate, to assess the effectiveness of a CPB versus a SNB for control of intolerable pain and the effects of these neurolytic blocks on the quality of life on a 3 months follow-up period from post-intervention for patients with upper gastrointestinal tract (GIT) tumors. A total of 30 patients, 15 in each group, were allocated randomly to CPB and SNB. Informed patient consent from patients who were involved in this study was obtained. Inclusion criteria include patients on palliative care who had inoperable upper GIT tumors, including cancer of the lower one-third of the Esophagus, Stomach, and cancer of the Biliary tract, Chronic abdominal pain due to cancer, ASA I, II, III, no comorbid cardiovascular illness/psychiatric illness, Coagulation disorders/Technical difficulties (e.g., Huge tumors with altered anatomy), Refractory to analgesics, opioids, and patients who had given valid informed consent. Exclusion criteria include patient refusal, patients with cardiac disorders, comorbid illness/psychiatric illness, coagulation disorders/technical difficulties (e.g., huge tumors with altered anatomy), patients who had coagulation defects, local infections, hypotension, any metastatic lesions, uncooperative mental illness, and failed previous neurolytic block.

The patients were kept nil per oral for 6 h before the procedure. All patients were preloaded with 500 ml of normal saline. The patient was asked to stop any form of pain relief tablets on the day of the procedure. The oral immediate-release morphine tablet (oxycodone) was stopped for 4 h, and the morphine sustained/extended-release tablet morphine slow release tablet (MST) was stopped 12 h before the procedure. The analgesics such as tablet paracetamol were stopped 6 h, and the other nonsteroidal anti-inflammatory drugs were stopped either 12–24 h preoperatively before the injection.

For the SNB, the T12 vertebrae were visualized under a posteroanterior view of the C arm with fluoroscopy. The C-arm was rotated to the ipsilateral side by 20°–30° until the T12 transverse processes are merged with the anterolateral border of the T12 vertebrae (Scottie dog sign). The skin and subcutaneous tissue was infiltrated with 1% lignocaine. After local infiltration, a 22-long spinal needle was advanced toward the anterolateral border of T12 vertebrae under fluoroscopy guidance (3 ml of contrast material was injected) in lateral view, and the final position was confirmed by the spread of contrast (omnipaque) adhering to the T11 and T12 vertebral body with no posterior leaking of contrast.

The neurolytic SNB was given using 3 ml of 1% xylocard through the long spinal needle; after 5 min of local anesthetic action, 10 ml of 99.9% alcohol followed by 1 ml of 1% xylocard to prevent tract formation was given on both sides after a negative aspiration of blood or fluid (contrast).

For the CPB, the L1 vertebrae were visualized under an oblique view of the C-arm with fluoroscopy. After subcutaneous infiltration of local anesthetic, a 22G 15 cm long spinal needle is inserted on the left side along the body of L1 vertebrae and advanced following the twelfth rib direction medially until contact is made with the anterior border of the L1 vertebral body. The needle is then withdrawn a bit and redirected to graze by the vertebral body to 1–2 cm beyond the vertebral body's anterior margin. The procedure is repeated on the right side, and a contrast medium is injected after negative aspiration under fluoroscopic guidance. Neurolysis is carried out with 5 ml of 1% xylocard through the long spinal needle, after 5 min of LA action, 10 ml of 99.9% alcohol, followed by 1 ml of 1% xylocard to prevent tract formation through each needle.

The neurolytic block was considered positive if there was a significant reduction in pain intensity (measured in NRS) for at least 60 min after the injection. Further patients were observed for any immediate hemodynamic events and the delayed side effects. The regular analgesics were started once the patient experience pain after 6 h of procedure as per the WHO guidelines.

RESULTS

Out of 30 patients, 22 were males, and eight were females. Mean age and body weights were 53.07 years and 53.93 in group SNB and 56.6 years and 57.8 in group CPB. Based on the tumor site, four patients had in the gall bladder, three in the pancreas, six patients in the pancreas' tail and body, three in the colon, one in the liver, one in the secondary's liver, and 12 in the stomach Table 1.

There was a statistically significant difference in heart rate and mean arterial pressure during and after the procedure [Figures 1 and 2]. There was a significant decrease in visual analog scale (VAS) score in group SNB versus group CPB on the 1st week and 2nd week of post-procedure (P = 0.0001). Meantime there were no statistical differences between both groups after the 2nd week onwards (with P values of 0.054, 0.266, 0.559, 0.793, and 0.432 in each visit time, respectively). Later, the VAS decreased significantly in both groups SNB and CPB, compared to its VAS before the procedure. Strong opioid consumption significantly decreased in group SNB versus group CPB at following times of post-procedure visit during days 7, 14, 28, 42, 56, 70, and 84 with P values of 0.001, 0.0001, 0.0001, 0.0001, 0.005, 0.0001, and 0.0001, respectively. However, opioid consumption during follow-up was significantly increased in group CPB than group SNB [Figures 3 and 4].

In the SNB group, nine patients had a backache, four had diarrhea, and two patients had hypotension. In the CPB group, three patients had a backache, seven had diarrhea, and eight patients had hypotension [Table 2].

There was a significant improvement on the global functioning scale in group SNB versus group CPB at 2nd, 4th, 6th, 8th, and 12th weeks with P = 0.0001, and there was a significant improvement on the symptom scale in group SNB versus group CPB at the 4th, 6th, and 12th weeks with

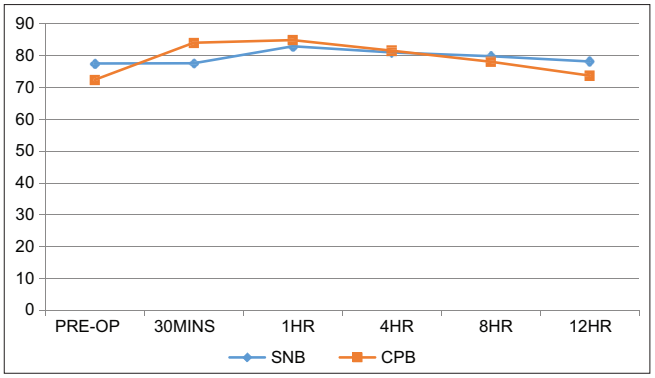

Figure 1: Comparison of splanchnic nerve block and celiac plexus block heart rate during and after the procedure splanchnic nerve block

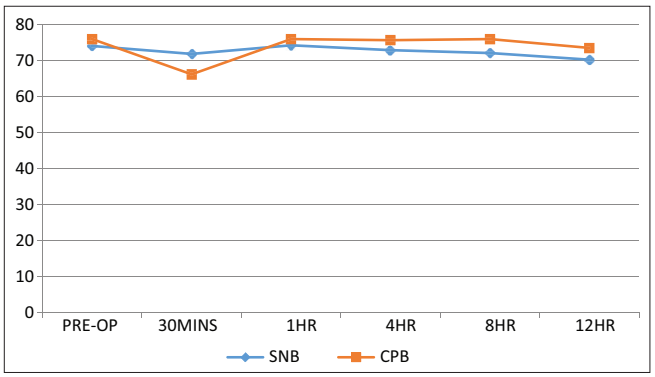

Figure 2: Comparison of splanchnic nerve block and celiac plexus block mean arterial pressure during and after the procedure

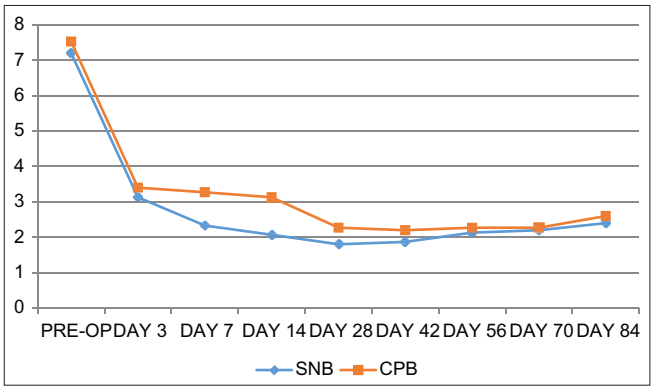

Figure 3: Comparison of splanchnic nerve block and celiac plexus block visual analog scale and opioid consumption

values 0.0001. Meanwhile, the physical scale improved significantly in group SNB versus group CPB at 10th and 12th weeks with $P = 0.0001$; there was a significant improvement on the emotional scale in group SNB versus group CPB 2nd, 4th, 8th, and 12th weeks with $P = 0.0001$. There was a significant improvement on the role functioning scale in group CPB versus group SNB at 2nd, 4th, 6th, 8th, 10th, and 12th weeks with $P = 0.0001$. However, the social scale improved significantly in group SNB versus group CPB at 4th weeks with $P = 0.0001$; the cognitive scales improved significantly in group SNB versus group CPB at 2nd, 4th, 6th, 10th, and 12th weeks with $P = 0.003$ [Table 3].

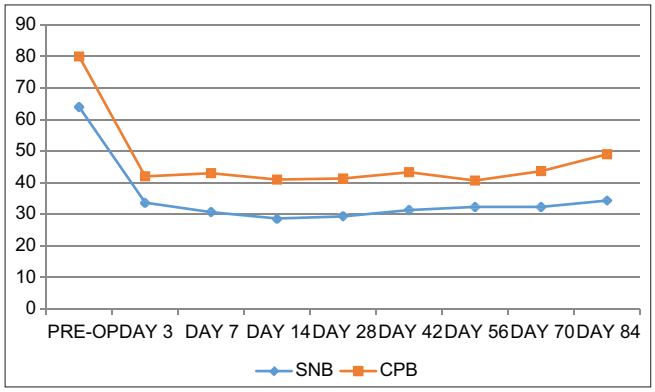

Figure 4: Comparison of splanchnic nerve block and celiac plexus block opioid consumption

Table 1: Patients characteristics

Parameters	SNB	CPB
Age	53.07	56.6
Male/Female	10/5	12/3
Body weight	53.93	57.8
Site of the tumor		
Gall bladder	3	1
Head of pancreas	0	3
Pancreas body and tail	4	2
Colon	1	2
Liver	0	1
Secondary's liver	1	0
Stomach	6	6

SNB: Splanchnic nerve block CPB: Celiac plexus block

Table 2: Side effects

S. No	Side effects	SNB	CPB
1	Backache	9	3
2	Diarrhea	4	7
3	Hypotension	2	8

SNB: Splanchnic nerve block; CPB: Celiac plexus block

DISCUSSION

The nociceptive impulses from the upper abdominal viscera pass through the splanchnic nerve and celiac plexus. They are the perfect target for a block for cancer pain management, and the CPB is the most widely used interventional procedure for therapeutic pain relief. Nowadays, the thoracic SNB has been widely used because the thoracic splanchnic nerve lies in a small triangular space with well-defined landmarks and boundaries. Hence, thoracic SNB enables good blockade with neurolytic solutions compared to conventional CPB.

This study shows that a SNB for inoperable upper GIT cancers has better results than a CPB. Many patients retained a good analgesic response from the 2nd week onward with improved global health status, functional scales, and symptom scales on quality of life assessments.

This study indicated that both groups have reduced opioid consumption and improved VAS scores from the 2nd week. Still, SNB has superior results compared to CPB. Reduced opioid consumption may improve the quality of life by enhancing the immune system since opioid harms cellular levels. Furthermore, there were decreased sedative effects of opioids. Stefaniak *et al.*,[7] in their study, compared the effectiveness of neurolytic CPB, thoracic splanchnicectomy, and a control group as conservative treatment published that neurolytic block resulted in a significant reduction in cancer pain along with significant improvement in physical, global functioning scale, and social well-being.

Tewari *et al.*[8] compared trans aortic versus retrocrural CPB for pain relief in the upper abdominal cancer patients and found that the retrocrural approach group had provided superior pain relief and there was a reduction opioid

Table 3: Quality of life

QOL	SNB							CPB						
	PRE-OP	14	28	42	56	70	84	PRE-OP	14	28	42	56	70	84
GHS	27.78	38.89	45	51.11	54.44	66.67	67.22	32.22	41.11	46.67	52.22	57.22	65.56	68.33
SS	62	36	34	34	22	22	21	66	36	32	30	22	22	19
PFS	16	40	46	54	60	64	68	21	48	52	60	62	63	66
EFS	40	60	68	74	80	83	84	34	58	66	76	78	84	83
SFS	19	32	39	50	54	61	62	25	38	39	56	60	63	79
RFS	19	36	54	64	70	74	78	21	37	59	67	76	79	82
CFS	42	70	76	82	84	89	91	36	63	71	81	84	87	88

SNB: Splanchnic nerve block; CPB: Celiac plexus block

requirement as compared to the trans aortic neurolytic celiac plexus group. One of the earliest studies performed to evaluate a SNBs effectiveness, by Raj *et al*.[9] involving 107 patients with abdominal pain of malignant and non-malignant origins, revealed good to excellent results in 55–70% of patients for pain scores. Still, no information was given regarding the quality of life.

Ozyalçin *et al*.[10] evaluated the efficacy of celiac plexus versus splanchnic nerve neurolysis in patients with pancreatic cancer pain. It revealed that splanchnic nerve neurolysis led to significantly better pain relief, quality of life, and analgesic consumption until the end of the patients' lives. Marra *et al*.[11] compared both neurolytic methods and found that applying a SNB under computed tomography guidance produced more effective pain relief than a CPB. Meanwhile, Gangi *et al*.[12] noted that a SNB requires a smaller volume of alcohol and has indications similar to those for a CPB.

In this study, the mortality for both groups SNB and CPB was nil and minor complications such as transient backache, hypotension, and self-limiting diarrhea noted. They were treated symptomatically. In the present study, hypotension incidence was 13% in group SNB and 53% in the group CPB. Diarrhea was reported at 26% in the SNB group and 46% in the CPB group. These lesser incidences than other studies done earlier were that the performance of a block with image guidance and an after injection of a local anesthetic before the injection of neurolytic agents significantly reduces the risks of such complications.

CONCLUSION

The statistical data and results of this study illustrate that a SNB appears to be clinically comparable to the CPB. However, all statistically significant differences are of little clinical value.

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Original Article

Pre-operative Clinical Profile of Lens-Induced Glaucoma in a Tertiary Care Hospital in Karnataka – A Descriptive Study

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Abstract

Introduction: Lens-induced glaucoma (LIG) can be defined as a secondary glaucoma characterized by raised intraocular pressure (IOP) due to lens related problem, secondary angle closure associated with pupillary block, and secondary to open angle associated with lens mater and products of inflammation. It includes phacomorphic, phacolytic, phacotoxic, and phacotopic glaucomas.

Methods: This is hospital-based prospective study of 1 year with sample size of 50. The material for study was drawn from patients attending the outpatient department of ophthalmology. Patients satisfying the inclusion criteria were selected among the patients presenting with LIG. Patients were subjected to detailed ophthalmic history and examination.

Results: A total of 50 patients were included in this study, 18 (36%) were male and 32 (64%) were female. Phacomorphic cases were more than noted in phacolytic cases. Maximum cases were found in 60–70 years of age group 26 (52%). Patients presented with reduced vision in 48 (96%) cases, eye pain in 43 (86%) cases, redness of eye in 38 (76%) cases, corneal edema noted in 14 (28%) cases, anterior chamber inflammation in 15 (30%) cases, vomiting as presenting complaints in 9 (18%) cases, and headache in 17 (34%) patients. Average IOP measured was 41.5 mmHg. Maximum patients in this underwent small incision cataract surgery with posterior chamber intraocular lens implantation of about 43(86%), PI done in 5 (10%) cases, and trabeculectomy in 2 (4%) cases.

Conclusions: Early presentation and prompt treatment have a better visual outcome. The treatment for LIG is the lens extraction followed by an intraocular lens implantation.

Key words: Intraocular pressure, Lens-induced glaucoma, Phacolytic glaucoma, Phacomorphic glaucoma

INTRODUCTION

Lens-induced glaucoma (LIG) was first described in the year 1900 by Gifford[1] and Von Reuss[2] independent of each other. While the former described it as a glaucoma associated with hyper mature cataract, the latter described it as a glaucoma associated with spontaneous absorption of lens substance through intact lens capsule. Subsequently, various workers described such types of cases under different names such as LIG, lens-induced uveitis and glaucoma, phacotoxic glaucoma, phacogenic glaucoma, and finally phacolytic glaucoma.[2-5] These terms including the more popular term phacolytic glaucoma have been discarded for various reasons and convenience in favor of the term "LIG." At present, LIG is a clinical condition characterized by (1) a violent secondary glaucoma (resembling acute angle closure glaucoma) in one eye with senile mature cataract, hyper mature senile cataract (rarely immature senile cataract) yet with an open angle, (2) normal intraocular pressure (IOP) and open angle in other eye, and (3) a prompt relief of symptoms and restoration of vision after cataract extraction in the effected eye.

Late reporting for the treatment of cataract leading to serious complications like LIG remains one of the

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most important cause of irreversible loss of vision, especially so in the rural population. This preventable and curable condition, though rare in developed countries, is unfortunately still prevalent in India. In the developing world, like India, financial, cultural, and psycho-social barriers to accessing excellent surgical services still exist. There is an ever-increasing backlog of cataract due to the population explosion, increased life expectancy and low productivity in terms of utilization of the available surgical services. The uptake of eye care services by the rural community has also been sub optimal in countries like India, where LIGs are a common cause of ocular morbidity.[6]

It has long been recognized clinically that several forms of glaucoma may occur in association with the formation of cataracts, which are an important cause of secondary glaucoma in the developing world. These LIGs are a common occurrence in India, hardly surprising in a situation where the incident of cataract cases far exceeds the total number of surgeries performed currently.[7]

The outstanding features of this group of patient's are
1. Sudden onset of glaucoma in an eye with mature or hyper mature cataract
2. Advanced age of the patient, generally above fifties
3. Almost constant observation of fairly good vision and normal tension in the opposite eye which may be aphakic or otherwise.[7]

Objectives

The objectives are as follows:
1. To study clinical profile of LIG
2. To find out age- and sex-wise distribution of LIG (socio-demographic profile)
3. To evaluate the visual prognostic factors before surgery
4. To educate the patients for prevention of the same for the other eye.

METHODS

This hospital-based prospective study was conducted at Raichur Institute of Medical sciences in accordance with tenets of the Declaration of Helsinki. Ethical clearance was obtained from Institutional Ethical Committee. Study duration was 1 year with sample size of 50 was taken using purposive sampling method. The material for study was drawn from patients attending the outpatient department of ophthalmology. Patients were subjected to detailed ophthalmic evaluation and data were recorded in a specially designed pro forma which was transferred to master sheet. The data were subjected to statistical analysis by the biostatistician of our institution. During the above said period, patients satisfying the inclusion criteria were selected among the patients presenting with LIG.

Inclusion Criteria

All cases of LIG with senile immature cataract, senile mature cataract, and senile hyper mature cataract, who attended the outpatient department of RIMS Raichur were included in the study.
1. Associated with acute rise in IOP above a level known to cause clinical signs and symptoms
2. Slit lamp examination to diagnose phacomorphic, lens particle, and phacolytic glaucoma.

Exclusion Criteria

The following criteria were excluded from the study:
1. Primary open and closed angle glaucoma
2. Other secondary glaucoma's (such as due to trauma, intraocular inflammation, and neovascular glaucoma)
3. Abnormal material deposition in anterior chamber (mainly pigment dispersion syndrome, and pseudo exfoliation syndrome)
4. Complicated cataract
5. Lens displacement
6. Corneal dystrophies and degenerations with cataract
7. Patient unfit for surgery due to extremely poor general condition scuh as uncontrolled diabetes mellitus (DM), hypertension (HTN), and ischemic heart disease (IHD)
8. Non-compliant patients.

Assessment of Patients Consists of

Pre-operative
1. External examination and assessment of ocular motility
2. Visual acuity recording
3. Detailed systemic clinical examination of patients will be done
4. Slit-lamp bio microscopy
5. Examination of the pupil with special attention to the presence of relative afferent
6. Pupillary defect
7. IOP measurement
8. Gonioscopy
9. A scan.

Post-operative
1. Visual acuity on 1st, 7th post-operative day and finally at 6th week
2. Refraction at 6th week
3. IOP measurement at 6th week
4. Slit-lamp bio microscopy
5. Detailed examination of the optic disc and retina
6. Visual fields: If glaucoma is suspected, and automated perimetry is performed.

Surgical procedure

Informed written consent was taken from all patients. After controlling IOP with appropriate treatment, all patients will underwent manual small incision cataract surgery (SICS) with intraocular lens implantation with iridectomy and or trabeculectomy when necessary had been the established treatment.

Technique of surgery

1. Peribulbar injection of lignocaine+ bupivacaine is given using 24 gauge needle under aseptic precautions
2. Eye ball and periorbital region is painted and draped
3. Universal wire speculum is used to keep the lids apart during surgery
4. Superior rectus bridle suture is placed, then fornix based conjunctival flap is made
5. Incision is made around 2 mm away from the superior limbus using 15 no. surgical blade, length of incision being 6–6.5 mm
6. Using a 2.6 mm crescent blade, sclera-corneal tunnel is made up to 1.5 mm into the clear cornea
7. Side port is made using keratome at 9 or 3 o'clock limbus depending on RE/LE respectively
8. AC formed using air and anterior chamber stained with Trypan blue
9. AC formed using viscoelastic
10. Capsulotomy was done either by continuous curvilinear capsulorhexis/can-opener technique using cystitome
11. AC formed with visco-elastic and entry into the AC through the main tunnel done using 2.8 mm keratome
12. Hydro dissection was done using 27 gauze hydro dissection needle
13. Nucleus prolapsed into AC and delivered out by viscoexpression
14. Remaining cortical matter removed by continuous irrigation and aspiration
15. AC formed using viscoelastic and capsular bag distended
16. IOL is implanted into capsular bag/sulcus
17. AC wash was done to remove the visco-elastic
18. wound closed by hydrating the side port
19. Subconjunctival injection of gentamycin+ dexamethasone was given
20. Eye padding and bandage was done.

Statistical Analysis

Descriptive statistics were done for all data. Based on normality, parametric, and non-parametric tests were done and were declared statistically significant for $P < 0.05$.

RESULTS

A total of 50 patients were included in this study, out of which 50 patients 18 (36%) were male and 32 (64%) were female with ratio of 1:2 [Table 1]. In this study, we noted that phacomorphic noted in 37 (74%) and phacolytic in 13 (26%) patients. Maximum cases were found between 60 and 70 years age group of about 26 (52%) cases. After that, 10 (20%) cases found in between 70 and 80 years age group, 8 (16%) cases in above 80 years age group, and 6 (12%) cases between 50 and 60 years age group. In almost, all age group females had maximum presentation in comparison to males. Patients presented to the hospital with reduced vision in 48 (96%) cases, eye pain in 43 (86%) cases, redness of eye in 38 (76%) cases, corneal edema noted in 14 (28%) cases, anterior chamber inflammation in 15 (30%) cases, vomiting as presenting complaints in 9 (18%) cases, and headache in 17 (34%) patients. Average IOP measured was 41.5 mmHg and in the range of 28–55 mm Hg. Maximum patients in this underwent SICS with posterior chamber intraocular lens (PCIOL) implantation of about 43 (86%), PI done in 5 (10%) cases, trabeculectomy in 2 (4%) cases. In maximum post-operative cases, IOP was average of about 14.6 mmHg and visual acuity was above 6/24 in 27 (54) patients [Table 2].

DISCUSSION

In 2014, Yaakub *et al.* reported that out of 38 patients of LIG, phacomorphic (28) was the main cause of LIG, followed by phacolytic[8] and in our study we noted 37 cases of phacomorphic and 13 cases of phacolytic. The main clinical symptoms were reduced vision (94.7%), eye pain (84.2%), and eye redness (81.6%). In our study, it was 96%, 86%, and 76%, respectively. Most patients presented with visual acuity of hand movements (84.2%) or worse and in our study we have in 86% of cases. Ocular pressure more than 40 mmHg (53.3%) and in this study

Table 1: Age-and group-wise distribution of patients

Age group	No of cases *n* (%)	No of male *n* (%)	No of females *n* (%)
50–60	6 (12)	2 (4)	4 (8)
61–70	26 (52)	8 (16)	18 (36)
71–80	10 (20)	4 (8)	6 (12)
>80	8 (16)	4 (10)	4 (6)
Total	50	18 (36)	32 (64)

Table 2: Presentation of patients

Symptoms/sign	No of cases *n* (%)
Reduced vision	48 (96)
Eye pain	43 (86)
Eye redness	38 (76)
Vomiting	9 (18)
Headache	17 (34)
Corneal edema	14 (28)
Anterior chamber inflammation	15 (30)

average IOP noted was 41.5 mmHg. Nineteen patients underwent extracapsular cataract extraction (ECCE) with primary PCIOL implantation; in our study, 43 (86%) cases under went SICS with PCIOL implantation. Twenty-eight patients were able to stay free from pressure lowering drugs after operation. In the study done by Yakub, IOP reduced tremendously on discharge with a mean of 15.2 mmHg and vision had improved exceptionally (>6/36) and in our study it was 14.6mmHg and in 27 (54%) cases respectively.

In 2014, Dakshayini reported that among 50 cases of LIG, the maximum prevalence of LIG occurred in age group of 50–65 years. Females are more affected than male. Majority were affected by phacomorphic and phacolytic glaucoma's, ECCE or SICS with PCIOL implantation was alone is curative in LIG of duration <7 days. In case of duration more than 7 days, trabeculectomy has to be combined. The need for trabeculectomy in LIG needs further comparative study.[9]

In 2010, Ramakrishnan *et al.* published their results on visual prognosis following manual SICS. A total of 74 eyes with phacomorphic glaucoma were included in this study. The pre-operative mean IOP was 38.4 and mean IOP at last follow-up was 12.7 mmHg. The final post-operative best corrected visual acuity was 20/40 or better in 51 patients. Eighteen eyes had corneal edema and 36 eyes had anterior chamber inflammation. Both conditions resolved following standard medical therapy.[10] In 2007, Venkatesh *et al.* conducted a study on safety and efficacy of manual SICS for phacolytic glaucoma. Post-operative IOP was 22 mmHg or less in all cases and 87.9% achieved a post-operative visual acuity of 20/60 or better. They had no major complications.[11]

In 2001, Pradhan *et al.* reported a study on 413 patients with LIG who were followed over a 12 month period. Visual acuity was hand movements or less before surgery. 311 of these patients underwent cataract surgery. 120 of 311 operated eyes (38.6%) achieved 6/60 or better, 94 (30.2%) <3/60. The main causes of poor outcome in 94 patients were optic atrophy in 32 (34%), uveitis in 25 (26.6%) eyes, and corneal edema in 24 (25.5%) eyes. The results highlight the importance of early diagnosis and treatment of visually disabling cataract.[12]

In 1996, Prajna *et al.* reported a study review on 93 patients with LIG, 49 phacomorphic, and 44 phacolytic. About 57% with phacomorphic and 61% with phacolytic glaucoma recovered visual acuity of 6/12 or better. They concluded that patients more than 60 years and in patients whom glaucoma was present for more than 5 days had a significantly higher risk of poor visual outcome.[13]

In 1994, Singh *et al.* published their results on phacolytic glaucoma its treatment by planned ECCE done on five patients, with a mean follow-up of 2 years, all patients (100%) maintained a normal postoperative IOP of <20 mmHg. The final best corrected visual acuity in four cases (80%) was 6/12 or better, while in one case it was 6/24 due to a senile maculopathy.[14]

CONCLUSIONS

Late reporting for treatment of cataract leading to serious complications like LIG. It remains one of the most important causes of irreversible loss of vision, especially in the rural population of India. Early recognition and treatment are necessary for all mature and hypermature cataract cases.

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Original Article

Clinical Profile and Risk Factors of Acute ST-elevation Myocardial Infarction in Elderly Population

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Abstract

Background: Cardiovascular disorders are the leading cause of death worldwide, and they are prevalent in both developed and developing countries. This study aims to determine the clinical profile of 60 cases of ST-elevation myocardial infarction (STEMI) in elderly aged 65 and above and analyze the risk factors of STEMI.

Materials and Methods: This study was conducted from June 2009 to November 2009 period in Government Stanley Medical College and Hospital. Sixty consecutive patients of age 65 and above admitted to the coronary care unit with a diagnosis of acute STEMI were included in the study. Special emphasis was made on presenting complaints, risk factors, comorbidities, vital signs, and arrhythmias. The patients' clinical profile, including age, sex, presenting symptoms and their duration, clinical signs, and risk factors associated with STEMI, was documented and analyzed.

Results: Maximum number of cases (25/60) was in the age group of 65–69 years. Females 53% were predominant as compared to males 47%. The most common clinical symptom was chest pain (92%), followed by dyspnea 48% and sweating 43%. The most common risk factor found in this study was smoking, which was seen in 33% of the cases, followed by diabetes mellitus in25%.

Conclusion: The incidence of STEMI in elderly 65 years and above is more common in females, the difference being high as the age advances. Even though chest pain is the most common presentation, atypical presentation without chest pain is also high. Tachypnea and tachycardia are the most commonly observed signs and smoking is the most common risk factor, followed by diabetes mellitus.

Key words: Arrhythmia, Cardiac ischemia, Dyspnea, Elderly, Myocardial infarction

INTRODUCTION

The diagnosis and management of ischemic heart disease in the elderly are an increasingly frequent challenge. The elderly constitute the most rapidly growing segment of our society. They represent a much larger proportion of cardiac disease patients treated in a hospital or a physician's office.[1] In the elderly, ischemic disease itself is responsible for over one-half of the deaths and the vast majority of congestive heart failure and cardiac disability patients.

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Age-related cardiac function and structure changes are well described in normal man and the mechanisms responsible for these are explored in animal models of aging. The most important of these are prolonged contraction and relaxation and a diminished response to ß-adrenergic sympathetic stimulation.[2]

Prolonged relaxation as evidenced by a decrease in the slope of early mitral valve closure on M-mode echocardiography, a decrease in peak filling rate and an increase in the time to peak filling rate on radionuclide angiography studies, and an increase in Doppler indices of atrial contribution to the left ventricular (LV) filling.[3] Prolonged contraction and delayed relaxation properties may also be related to physical conditioning status and endocrine function, as exercise protocols and thyroid hormone administration reverse some of these age-related changes. These changes may alter presenting symptoms in patients with

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ischemic disease. Ischemia, similar to aging, alters diastolic properties to increase end-diastolic pressure for any given volume.[4] Therefore, older individuals may be more likely than younger patients to experience dyspnoeic symptoms for any given ischemic or tachycardic insult. Decreased dependence on sympathetic-induced cardiovascular changes to mediate an exercise response suggests that ß-adrenergic blockers may be less effective anti-ischemic agents during exercise in older population.[5]

Although the significance of risk factors for the development of the coronary disease is well recognized in the younger and middle-aged groups, the importance of risk factor management in the elderly is sometimes debated. This study aims to study the clinical profile of 60 cases of ST-elevation myocardial infarction (STEMI) in elderly aged 65 and above and analyze the risk factors of STEMI.

Aim

The aim of the study was to study the clinical profile of 60 cases of STEMI in elderly aged 65 and above and analyze the risk factors of STEMI.

MATERIALS AND METHODS

This study was conducted from June 2009 to November 2009 period in Government Stanley Medical College and Hospital. Sixty consecutive patients of age 65 and above admitted to the coronary care unit with a diagnosis of acute STEMI were included in the study. All patients included in the study were subjected to electrocardiogram (ECG) examination with conventional 12 leads and V3R, V4R, V7 to V9. Rhythm strips were taken in patients with arrhythmia. All the patients were assessed clinically and electrocardiographically to make a diagnosis of STEMI. Special emphasis was made on presenting complaints, risk factors, comorbidities, vital signs, and arrhythmias. All patients were followed up till death or discharge. Pre-discharge ECHO was done to assess the LV function. Patients with age <65 and patients with Non-STEMI, unstable angina, and Recurrent myocardial infarction (MI) were excluded from the study. The patients' clinical profile, including age, sex, presenting symptoms and their duration, clinical signs, and risk factors associated with STEMI, was documented and analyzed.

RESULTS

The study comprised 60 cases of acute STEMI aged 65 years and above. Cases were divided into groups of 5 years difference for comparing age and sex incidence. Incidence in male and female was almost equal in the age group 65–74 Table 1. The incidence is increased in females in the age group 75 and above. The highest age was a female with 85 years old.32 patients (53%) were females and 28 (47%) were males, Figure 1.

Chest pain, dyspnea, sweating, palpitation, vomiting, and syncope were the common symptoms experienced by patients in our study. About 92% of the patients had chest pain, followed by dyspnea seen in 48% of the patients. About 10% of the patients who did not have chest pain had dyspnea as their presenting complaint Figure 2. Sweating and palpitations were present in 43% and 30% of the patients, respectively.

Radiation of chest pain was noticed in 36 patients (60%). Radiation to the left upper limb was seen in 24 patients (40%), six patients had radiation to the epigastrium (10%), and another three patients (5%) had radiation to right upper limb. Other sites of radiation in three patients (5%) Figure 3.

The time duration from the onset of symptoms and patient reaching the hospital was noted. Sixteen patients (26%) presented after 24 h. Forty-four patients presented within 24 h. Among them, only 17 patients (29%) reached the hospital within 6 h Table 2.

Table 1: Age distribution

Age	No. of patients *n*=60	Percent	Male	Female
65–69	25	42	14	11
70–74	17	28	8	9
75–79	8	13	3	5
80–84	9	15	3	6
85 and above	1	2	0	1

Table 2: Duration of symptoms

Time	No. of patients	%
0–6 h	17	29
6–12 h	27	45
>12 h	16	26

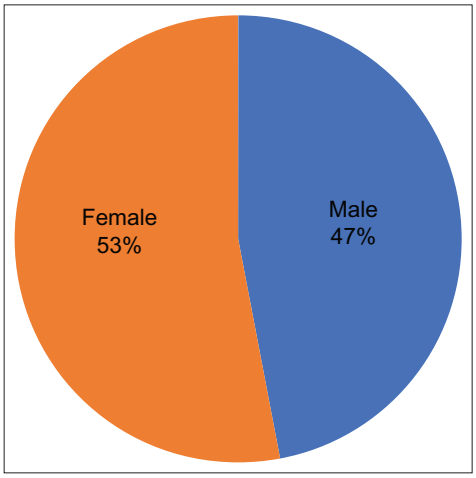

Figure 1: Sex distribution

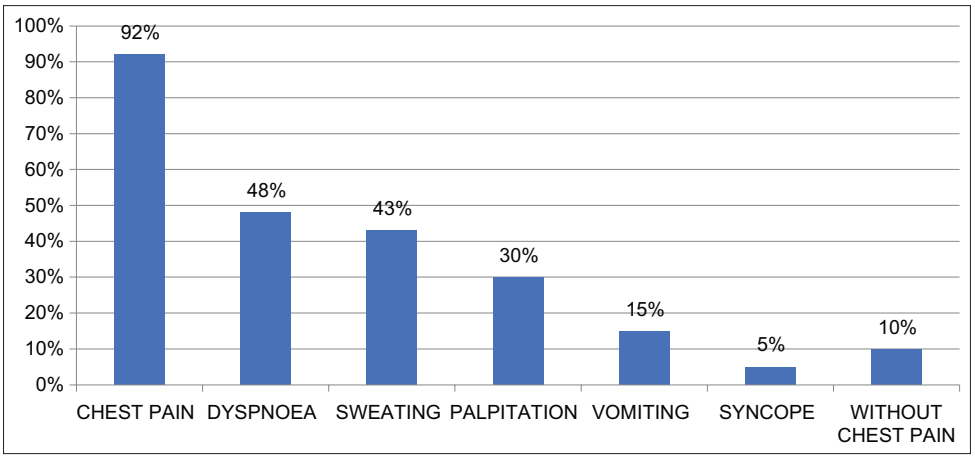

Figure 2: Presenting symptoms

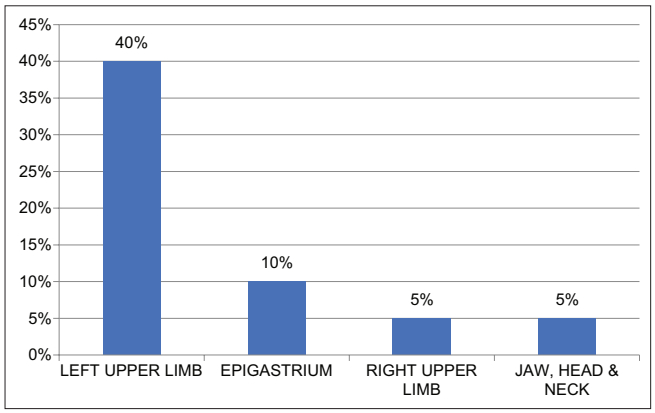

Figure 3: Radiation of chest pain

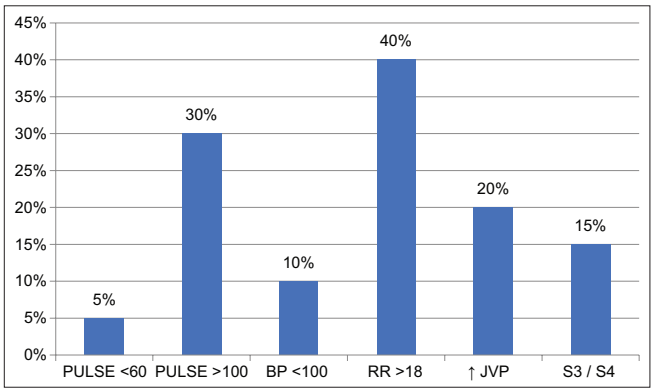

Figure 4: Clinical signs

Tachypnea was the most common clinical sign observed in 24 patients (40%). Three patients (5%) had bradycardia and tachycardia was seen in 18 patients (30%). Hypotension was noticed in six patients (10%). Twelve patients (20%) had raised jugular vein pressure. Third or fourth heart sound was detected in ten patients (15%) Figure 4.

Risk factor assessment showed that 33% of the patients had smoking habit and it is the main risk factor leading up to MI, according to our study. Out of 28 males, 20 were smokers. None of the female patients was smokers. All the smokers were smoking 10–20 beedies/cigarettes per day for at least 10 years. About 60% of them were current smokers.

This was followed by diabetes mellitus (25%) and all of them were on oral hypoglycemic agents. An attempt was made to go through the earlier medical records wherever available. Patients were considered to be hypertensive if they had been told to have hypertension earlier by a doctor and put on antihypertensive drugs or serial BP recordings in the hospital were consistently high. Thirteen patients had hypertension (22%).

Out of 28 males, 12 were in the habit of consuming alcohol. None of the female patients was in the habit of consuming alcohol. Dyslipidemia and obesity were present in 5% of each of the patients Figure 5.

DISCUSSION

Sixty proven cases of acute STEMI of age 65 and above were selected for analyzing the various risk factors, clinical features, and complications. All patients were subjected to ECG examination of conventional 12 leads, V3R V4 R and V7V8V9 and rhythm strip wherever needed. On analyzing the incidence, it was found that STEMI in the elderly is slightly more in our study (53% – females and 47% – males). It is a contrast with middle age, where MI is more common in males. Hence, with aging, the incidence of MI is likely to have an equal gender distribution.

About 92% of the patients presented with chest pain as their chief symptom in our study. All of them had typical retrosternal chest pain lasting for more than 30 min. Most of the patients developed chest pain while at rest. Mahajan *et al.*, in their study among 160 ischemic patients, also

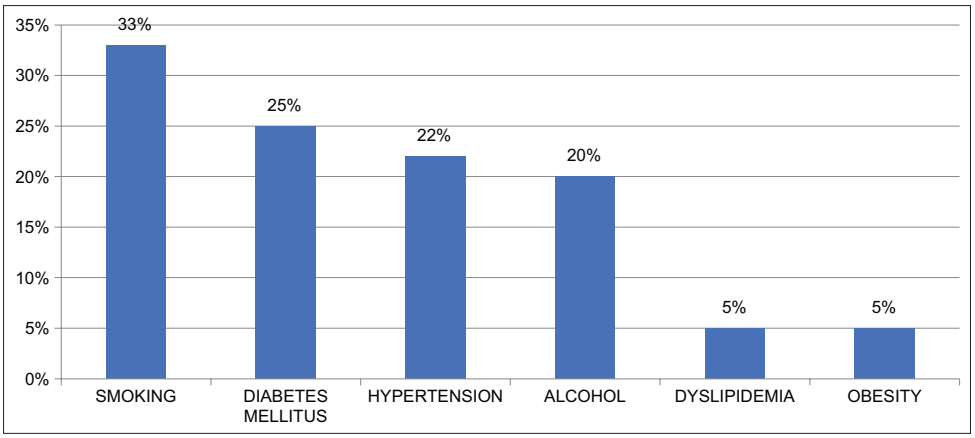

Figure 5: Risk factors of myocardial infarction

showed that chest pain was the most common presenting symptom present in 100% of the patients.[6] When analyzing symptoms other than chest pain, Dyspnea was observed in 48% of patients. This points out that the elderly tend to have more dyspnea than the younger for compromised cardiovascular status. Bhatia *et al.* encountered in their study that dyspnea was more common in the elderly.[7]

Patients who presented without chest pain were around 10%. These patients had either dyspnea or syncope, as reported by our study findings. These kinds of observations were well recognized. Atypical presentation in the Framingham study is around 30% in males aged 75–84 years compared with only 5% in men aged 45–54.[8] On analyzing the duration of symptoms, that is, the time taken from the start of symptoms and to reach the hospital, only 74% reached the hospital within 12 h. This is the window period where thrombolysis is effective and myocardium could be salvaged. About 26% of patients presented late and not eligible for thrombolytic therapy. Rajagopalan *et al.* in their study, found that age >65 years independently predicted late presentation.[9]

On analyzing MI's risk factors, smoking (33%) was the most common and exclusively seen in males. None of the females was smokers. In common to both males and females, diabetes is the leading risk factor observed in 25%. Hypertension and dyslipidemia were observed in 13% and 5%, respectively. All dyslipidemics were found to be coexisting with diabetes. Obesity was not observed significantly (around 5%). On analyzing the clinical presentation, the most observed signs were tachypnea and tachycardia, 40% and 30%, respectively. Bueno *et al.*, in their studies, had analyzed the incidence of risk factors. He had found hypertension in 45%, diabetes mellitus in 23%, smoking in 63%, obesity in 22%, and dyslipidemia in 25%.[10]

CONCLUSION

The incidence of STEMI in elderly 65 years and above is more common in females, the difference being high as the age advances. Even though chest pain is the most common presentation, atypical presentation without chest pain is also high. Delayed presentation is common among the elderly. Tachypnea and tachycardia are the most commonly observed signs and smoking is the most common risk factor, followed by diabetes mellitus. Patients without any conventional risk factors were 30%.

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Original Article

Safety and Efficacy of Iron Sucrose Compared to Blood Transfusion in Iron Deficiency Anemia in Pregnancy

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Abstract

Introduction: Iron deficiency anemia is one of the worst public health issues globally, affecting 52% of pregnant women in developing countries and 23% in developed countries. The iron shortage is the world's most common food shortage disease. Roughly 600–700 million people around the world have severe anemia of iron deficiency.

Aim: The aim of the study was to study the safety and effectiveness of iron sucrose and blood transfusion in iron deficiency anemia in pregnancy.

Methods: From November 2009 to October 2010, this prospectively randomized control analysis was carried out in the Obstetrics and Gynecology Department of Kilpauk Medical College. There were two groups of 100 patient's treated, intravenous (IV) iron sucrose in Group 1 and blood transfusion in Group 2. Data were collected and analyzed.

Results: The mean age was 23.48 and 25.08 in Group A and Group B, respectively. About 47% belonged to Class V socioeconomic status and 46% belonged to Class IV socioeconomic class. Hemoglobin's average rise was 3.44 g/dl and 3.51 g/dl, respectively in Group I and Group II. In Group II, more adverse effects such as headache 2/50 (4%) chills and rigor 12/50 (24%), itching 8/50 (16%) were found. About 10% (5 patients) in iron sucrose group (Group I), and 26% (13 Patients) in the blood transfusion group (Group II) delivered preterm.

Conclusion: IV iron sucrose is as effective as a blood transfusion in treating iron-deficient anemia in pregnancy and healthy compared to blood transfusion without any adverse effects.

Key words: Anemia, Blood transfusion, Iron, Pregnancy

INTRODUCTION

Anemia is identified as a hemoglobin (Hb) concentration <11 g/dL by the World Health Organization during pregnancy. Anemia is a significant contributory cause to motherhood morbidity, motherhood mortality, and higher perinatal mortality rates in under-developed nations, affecting a 52% of pregnant women in developing and a 23% of the pre-determined women in the developed world.[1] Anemia is most commonly (about 80%) caused during pregnancy by iron deficiency and often complex disorders with defects in erythrocyte production or rapid destruction.

Iron, as the oxygen-carrying pigment in the blood, is an essential element of Hb. Pregnant women are required to maintain iron balance by 1000 mg iron all through the pregnancy, that is, 3.5 mg/day. Demand grows to about 6.7 mg a day during the last half of pregnancy and several weeks after birth. In India, the severity of nutritional anemia remains a significant public health issue, despite steps taken in the past two decades to regulate anemia during pregnancy and lactation.[2] Iron is an essential ingredient for Hb, myoglobin, and certain enzymes. It functions as

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an oxygen and electron carrier and acts as an oxygen and hydroxylation catalyst. It can also trap an electron (Fe++/Fe++ cycling) and release it. Iron deficiency anemia during breastfeeding is treated in many ways. These are different forms of iron (oral tablets and parenteral iron), transfusion of blood, and erythropoietin.

Long-lasting oral therapy, in particular digestive effects, can induce non-conformity. Intramuscular (IM) injection parenteral administration is a debilitating option with different degrees of success. The preparation of iron sucrose IV improves hematological hints with fewer side effects and allergic reaction dramatically across the formulations of iron. Most anecdotally, the administration of intravenous (IV) and IM iron indicates an allergy. In comparison to IM iron, IV.[3] The study concluded that blood transfusion, pending preventive blood screening, carries the risk of transmitting parasite or viral infections including HIV, hepatitis, and chagas (trypanosomiasis) diseases. Bovine spongiform encephalitis and viral infections are also likely. Risk of acute lung damage due to transfusion (Transfusion-related acute lung injury) is also present.[4]

Aim

The aim of the study was to study the safety and effectiveness of iron sucrose and blood transfusion in iron deficiency anemia in pregnancy.

MATERIALS AND METHODS

From November 2009 to October 2010, this prospectively randomized control analysis was carried out in the Obstetrics and Gynecology Department of Kilpauk Medical College. A thorough general examination and extensive obstetrical examination were conducted after receiving informed consent. Criteria for participation include ages from 18 to 45 years, singleton pregnancy weeks from 28 to 34 and Hb- 7–8 g/dl. The exclusion criterion is patients with hypertension, gestational diabetes, respiratory failure, peptic ulcers and thalassemia, iron-containing H/o allergy, H/o allergy, asthma, and H/o bleeding.

The two classes had been randomly distributed to patients with iron deficiency anemia that met both conditions Section I and Section II, respectively. There are 50 patients in each group. The iron demand is based on the following formula 2.4 × (target Hb–patient Hb) × Weight of Pre-pregnancy (kg) + 500 (iron storage) = mg of elementary iron. Group I patients had an IV iron sucrose complex that had been injected with 100 mg of elementary iron diluted with 0.9 ml of regular saline for an alternating duration of 15 min before the required dosage was injected. One unit of bundled cell transfusion was given to patients from Group II, and after 48 h, the Hb had reassessed additional transfusions before the requisite Hb had been met.

The following parameters have been observed during the treatment: Critical (pulse, temperature, and blood pressure), adverse effects such as nausea/abdominal pain, and chills. Two weeks after the procedure, we recommended that patients to attend our outpatient department and measured the criteria below, which include symptomatic progress, Hb, hematocrit, and mean corpuscle volume (MCV).

RESULTS

Out of 100 patients, 50 patients included in Group 1 and 50 patients included in Group 2. The mean age of Group 1 is 23.48, and Group 2 is 25.08.

Among the 50 patients in Group I, 36% were booked and 64% were unbooked. In Group II, 52% were booked and 48% were unbooked. There was no significant change in both groups. About 48% of patients in Group I and 48% of patients in Group II, were primigravida, while only 4% in group and 7% Group II were gravid 4. Both primi and multipara were equally distributed in both the groups

Out of 100 patients, in Group 1, based on socioeconomic status, two patients are in Class 3, 23 patients are in Grade 4, and 25 patients are in Level 5. In Group 2, five patients are in Class 3, 23 patients are in Grade 4, and 22 patients are in Class 5 [Table 1].

Table 1: Socioeconomic status

Socioeconomic status	Group 1	Group 2
Class 1	0	0
Class 2	0	0
Class 3	2	5
Class 4	23	23
Class 5	25	22

Table 2: Blood parameters

Variables	Group 1			Group 2		
Blood parameters	Hb	Hematocrit	MCV	Hb	Hematocrit	MCV
Pretreatment	7.4±0.3	28.4±1.39	69.19±3.70	7.5±0.3	30±1.5	69.03±2.58
Post treatment	10.9±0.3	33.9±1.56	86.69±1.86	11.09±0.5	38±1.25	86.01±1.90

Hb: Hemoglobin, MCV: Mean corpuscle volume

The average rise of Hb was 3.44 g/dl and 3.51 g/dl, respectively, in Group I and Group II ($P = 0.417$), which was statistically not significant. The average rise of Hb was 3.44 g/dl and 3.51 g/dl, respectively, in Group I and Group II ($P = 0.417$), which was statistically not significant. The average gain in MCV was 17.49 fl and 17.09 fl in Group I and Group II, respectively [Table 2].

Out of 100 patients, in Group 1 based on symptoms 27 patients had easy fatigability and pallor, five patients had breathlessness and pallor, 13 patient's pallor of skin and mucus membrane, five patients had easy fatigability pallor and breathlessness. In Group 2 based on symptoms 22 patients had easy fatigability and pallor, four patients had breathlessness and pallor, 19 patient's pallor of skin and mucus membrane, and five patients had easy fatigability pallor and breathlessness [Table 3].

Out of 100 patients, in Group 1, no patient had an adverse effect. In Group 2, 12 patients had chills and rigor, eight patients had itching, and two patients had a headache [Table 4].

Out of 100 patients, in Group 1, based on gestational age at delivery, five patients had a preterm delivery, and 45 patients had correct term delivery. In Group 2, 13 patients had a preterm delivery and 37 patients had accurate term delivery [Table 5].

Table 3: Comparison of symptoms

Symptoms	Group 1	Group 2	*P*-value
Easy fatigability and pallor	27	22	0.0627
Breathlessness and pallor	5	4	
The pallor of skin and mucous membrane	13	19	
Easy fatigability pallor and breathlessness	5	5	

Table 4: Adverse effect

Adverse effect	Group 1	Group 2	*P*-value
Chills and rigor	0	12	<0.0001
Nausea and vomiting	0	0	
Itching	0	8	
Joint pain	0	0	
Headache	0	2	
Anaphylactic reaction	0	0	
Thrombophlebitis	0	0	

Table 5: Gestational age at delivery

Gestational age at delivery	Group 1	Group 2	*P*-value
Preterm	5	13	0.018
Term	45	37	

DISCUSSION

In our sample, the highest proportion was for the 20–25-year age team. In our sample, 47% of women were socioeconomic in Class V and 46% were socioeconomic in Class IV. Many women in a low socioeconomic community had iron deficiency anemia.

In the study, both the iron sucrose group and blood transfusion groups were improving symptomatically in all patients (100%). For the two groups tested, there was no statistical difference.

Our survey indicates an average improvement of 3.44 g/dl–3.51 g/dl ($P = 0.417$) in Hb, which was not statistically relevant for pre-treatment and post-treatment comparisons. Close to Bayoumeu *et al.* (2005),[5] our analysis of iron sucrose achieves the target levels within a brief period apart from being more compelling. Related experiments have demonstrated a Hb improvement between 3.8 g/dl and 3.2 g/dl by Wali *et al.*[6] and European Journal of Obstetrics and Gynaecology.

The time needed to achieve maximal Hb level was significantly shorter in the iron sucrose complex group as compared with the control group (6.9 ±1.8 weeks vs. 14.9 ±3.1 weeks).[7]

The average increase in hematocrit in pre- and post-treatment comparisons was 5.51% and 8.0%, which was also not statistically significant for the iron sucrose and blood-transfusion groups. His study showed an increase in hematocrit as well, by Breymann *et al.*[8] and Dede *et al.*[9]

In our analysis, the average improvement in MCVs for the pre-treatment/post-treatment contrast was 15,886 fL and 17,09 fL, which was similarly not important for Group I and Group II. A thesis by Raja *et al.*, Pakistan Medical Association newspaper, Vol. 28 demonstrated a mean MCV pre-treatment of 65 fL, a mean MCV 3 weeks after treatment of 75 fL, and a mean improvement in MCV of 10 fL with statistically meaningful $P < 0.10$.[10]

There were no adverse reactions to the treatment of iron deficiency anemia in women treated with iron sucrose in our research. In Group II; however, other side effects were found for patients infected with blood transfusion. Iron sucrose is costlier than OI and requires a hospital setting for administration.[11] Other related studies reported by Hoigne *et al.*,[12] Al,[13] and Al Momen *et al.*[7] and also found no adverse reactions.

In our study, the frequency of preterm delivery was high in patients treated with blood transfusion relative to the iron sucrose group.

CONCLUSION

IV iron sucrose is as effective as a blood transfusion in the treatment of iron-deficient anemia in pregnancy and healthy compared to blood transfusion without any adverse effects.

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Original Article

Classification and Treatment Outcomes of Acute ST-elevation Myocardial Infarction in Elderly Population

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Abstract

Background: Acute myocardial infarction is classified according to the finding of ST-segment elevation on the presenting electrocardiogram (ECG), with different treatment strategies and practice guidelines for the elderly.

Materials and Methods: The study included 60 patients with ST-elevation myocardial infarction (STEMI) aged 65 years and above admitted to the Cardiology Department of June 2009 to November 2009 period in Government Stanley Medical College and Hospital. A thorough clinical and ECG evaluation were done to diagnose STEMI. Patients were assigned to Killips class depending on the signs of heart failure at the time of presentation. ECG pattern was analyzed, and the mortality rates were studied.

Results: Out of the 60 study patients, a female predominance was noticed. About 58% of the patients belonged to Killips Class I and 10% belonged to Class IV. ECG evidence of Inferior Wall myocardial infarction was observed in 24 patients (40%). A 44% mortality rate was observed in patients aged 75 and above and with Killips Class IV, the mortality rate was 100%.

Conclusion: Mortality associated with STEMI is high in elderly patients. Increasing age and higher class of Killips are associated with an increased mortality rate. Post-infarction morbidity in the left ventricular dysfunction is also high among patients >65 years of age.

Key words: Coronary artery disease, Geriatrics, Ischemia, Myocardial infarction

INTRODUCTION

Cardiovascular diseases are responsible for most of the deaths worldwide, mostly due to coronary heart disease.[1,2] In developing countries, acute myocardial infarction (AMI) is a leading cause of death and cardiovascular diseases have become a major public health concern despite advances in diagnosis and treatment over the last three decades.[3] The WHO has stated emphatically that AMI has evolved into a new epidemic. Numerous research on the prevalence of AMI in hospital patients has been published in the literature.[4] AMI is a disorder that mostly affects people in their 40s and 50s. Since this disease is so prevalent and has such broad consequences, it has paved the way for cardiology to become a specialty field. Most of the patients present with the usual chest pain symptoms, sweating and dyspnea, but the elderly atypical presentation is more common.[5]

The mortality rates associated with AMI is higher in the elderly age group when compared to the other age groups. Although thrombolytic therapy shows greater effects in the elderly, they are treated less aggressively than the younger age group. Mortality due to AMI has decreased in the last few decades among the elderly age group due to improved prevention and advanced treatment strategies.[6] Nonetheless, elderly patients with acute coronary syndrome still have a greater risk of death and functional decline than younger patients. Many studies have shown that although adherent guideline-recommended treatment strategies are followed, the outcomes are worse in the elderly. The question arises as to whether the observed decline

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in guideline-recommended therapies with rising age is explained by comorbidities and decreased life expectancy. Therefore, we analyzed the classification and treatment outcomes of 60 cases of ST-elevation myocardial infarction (STEMI) in elderly aged 65 years and above to see if the mortality rates improved in the short term on treatment effectiveness.

Aim

The aim of the study was to analyze and study the classification and treatment outcomes of 60 cases of STEMI in elderly aged 65 years and above.

MATERIALS AND METHODS

The study included 60 patients with STEMI aged 65 years and above admitted to the Cardiology Department of June 2009 to November 2009 period in govt. Stanley Medical College and Hospital. All the patients underwent electrocardiogram (ECG) examination with 12 conventional leads and V3R, V4R, V7 to V9. A thorough clinical and ECG evaluation were done to diagnose STEMI. The patient's presenting complaints, vital signs, comorbid conditions, and associated risk factors were documented clearly. Patients <65 years of age, those with Non-STEMI, recurrent myocardial infarction (MI) and those unwilling to participate in the study were excluded from the study. Patients were followed up until death or discharge. The informed consent form was taken from all the patients before the study's start and Institutional Ethical Committee approval was obtained. Patients were assigned to Killips class depending on the signs of heart failure at the time of presentation:

1. Class I – No heart failure
2. Class II – Mild-to-moderate heart failure. (Presence of S3, Rales at the base or rales not exceeding half of the chest)
3. Class III – Severe heart failure (pulmonary edema)
4. Class IV – cardiogenic shock.

ECG pattern was analyzed, and the mortality rates were studied.

RESULTS

Sixty patients aged >65 years were included in the study, of which 53% were females and 43% were males. Thirty-five patients (58%) presented in Killips Class I. Thirteen patients (22%) were in Killip Class II, Class III, and Class IV, each consisting of six patients (10%) Table 1.

ECG evidence of inferior wall MI (IWMI) was observed in 24 patients (40%). Anteroseptal MI was noted in 18 patients (30%). Extensive anterior wall MI was observed in 16 patients (27%). Other patterns were observed in 2 patients (3%) Figure 1.

Right bundle branch block (RBBB) was observed in 12 patients (20%). Left bundle branch block (LBBB) was noted in one patient. Bifascicular block (RBBB + LAFB) was seen in three patients (5%). First degree AV block is seen in three patients (5%). Complete heart block (CHB) developed in three patients (5%). Ventricular premature beats were observed in three patients (5%). Ventricular Tachycardia or Ventricular fibrillation occurred in nine patients (15%). Atrial fibrillation was present in two patients (3%) Figure 2.

Out of the total 60 patients, 15 patients (25%) expired in the hospital. Eight patients were female and seven were male. Seven patients were of the age group of 65–74. Eight patients were of age 75 and above Table 2. The comparison of age and mortality and Killips class and mortality is shown in Figures 3 and 4.

45 out of 60 patients were discharged. Pre-discharge ECHO was done to assess the left ventricular (LV) systolic function. Thirty-two patients (71%) showed mild-to-moderate LV dysfunction. Two patients (5%) showed

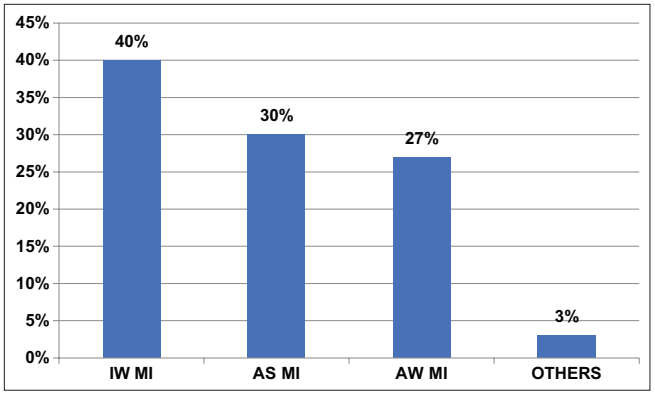

Figure 1: Electrocardiogram pattern

Table 1: Killips class

Class	No. of patients	Percent
I	35	58
II	13	22
III	6	10
IV	6	10

Table 2: Age and sex distribution of deaths

Age	Male	Female	Total
65–74	4	3	7
75 above	3	5	8
Total	7	8	15

severe LV dysfunction. Eleven patients (24%) showed near-normal LV function Figure 5.

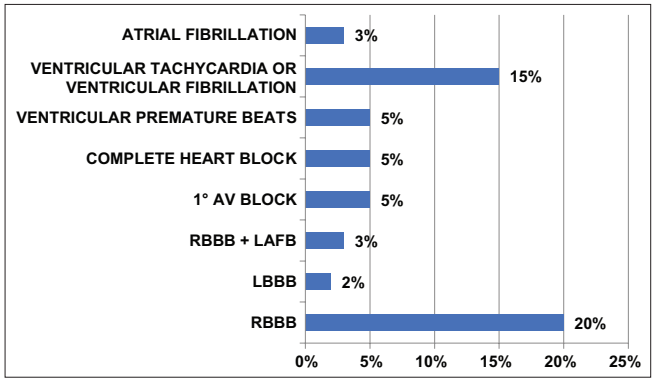

Figure 2: Arrhythmias

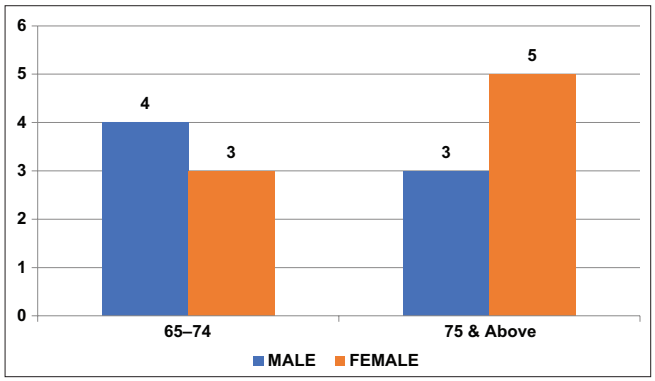

Figure 3: Age and mortality

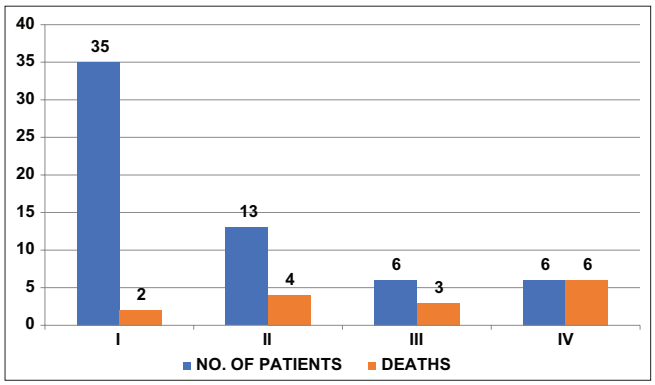

Figure 4: Killips class and mortality

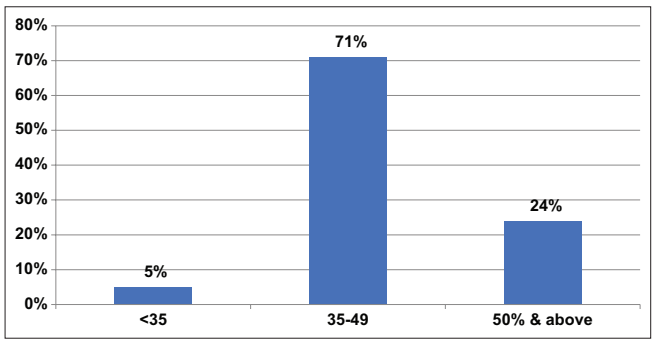

Figure 5: Left ventricular ejection fraction at discharge

DISCUSSION

The present study confirms that STEMI is associated with poor outcome in the elderly. STEMI is characterized by an abrupt closing of a main coronary section in the absence of collateral circulation and myocardial preconditioning, all of which are more common in patients with a history of coronary artery disease (CAD) and revascularization procedures.[7] Most of the study patients were in Killips Class I (58%) and 10% were in Class IV. About 22% of patients had creps not exceeding half of the chest, that is, Killips Class II. About 10% were having extensive rales and elevated jugular vein pressure, that is, Killips Class III. Another 10% of patients were in cardiogenic shock, that is, Killips Class IV. This indicates that the risk of cardiogenic shock and output failure is more in elderly patients. The elderly tend to present higher Killips class (20%) which significantly predicts the higher morbidity and mortality they tend to develop. Widimsky also showed in his study that higher Killips class is associated with poor outcomes in elderly.[8]

On analyzing MI's pattern, the IWMI was the most common (40%), followed by anteroseptal MI and Anterior Wall MI 18% and 16%, respectively. Other patterns were observed in 3% of the patients. Regarding IWMI, 25% associated with posterior wall involvement and 33% associated with right ventricular involvement. Chockalingam *et al.*, in their study, revealed that right ventricular MI was seen in one-third of acute IWMI.[9]

The significant percentage of AWMI, that is, 27%, reveals a higher degree of CAD. In a contemporary clinical trial database, patients above 80 years who underwent angiography had a 72% prevalence of multi vessel disease against 33% in patients <65 years of age. On looking into the treatment, 64% received thrombolytic therapy, 36% had not received it. Analyzing the reasons for not thrombolysis, most of them, that is, 16 out of 22 patients, presented late. Another six patients were in hypotension. On follow-up, arrhythmic complications were observed in 45%. The most commonly observed arrhythmia was RBBB (20%), followed by VT/VF (15%).

Bifascicular block was observed in 5% and CHB was around 5%. All patients who developed CHB were treated with temporary pacing. The reported incidence for CHB by Podrid *et al.* is around 8%.[10] Atrial fibrillation was observed in only two patients. Among the two, one had to coexist with rheumatic heart disease (3%). Berger *et al.*, in their studies of complication of AMI, found atrial fibrillation in 10% of patients with IWMI.[11]

On analyzing the deaths, the mortality is high around 25%. Most of the deaths happened in Killips Class III, Class IV,

and age >75. GUSTO I Trial established that old age is the independent risk factor for high mortality (31.2%). 45 out of 60 patients were discharged from the hospital. Among them 11 patients (24%) showed near-normal LV function (ejection fraction [EF] >50%). Thirty-two patients (71%) showed mild-to-moderate LV dysfunction (EF 35–49%) and two patients (5%) showed severe LV dysfunction (EF <35%). Among the discharged, 34 patients (76%) left with underlying morbidity in the form of LV dysfunction. They have to be evaluated for further risks of coronary events and to be followed up with medical management and revascularization if indicated.

CONCLUSION

Our study results state that the Higher Killips class is common among the elderly age group and the most common pattern is IWMI. Significant number of patients were not thrombolysed.

Mortality is high in females and age >75 years and higher Killips class are associated with even higher mortality rates. Post-infarction morbidity in the form of LV dysfunction is also high among the elderly age group. Overall, STEMI is associated with a poor outcome in patients aged >65 years.

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Original Article

Awareness of Anemia and its Association with the Severity of the Disease in Pregnant Women

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Abstract

Introduction: Pregnant women are at high risk of developing anemia. Women, overall, are at increased risk of anemia due to various reasons. Anemia during pregnancy increases the risk of mortality and low birth weight. Awareness of anemia and its consequences in pregnancy is essential for managing the condition.

Aim: The aim of the study was to study the level of awareness of anemia in pregnant women suffering from this condition.

Methods: Fifty women suffering from anemia who visited the outpatient department for antenatal check-up were enrolled in the study. The data were collected with the help of a questionnaire.

Results: Severe anemia occurs in only 9.4% of the patients having awareness of this condition compared to severe anemia in 44% of the patient with no awareness of the disease. About 52% (26) of the women with anemia fall within the age range of 21–25 years, followed by 36% (18) in 26–30 years.

Conclusion: There was a statistical difference between awareness and severity of anemia. Awareness reduces the risk of severe anemia in pregnant women.

Key words: Awareness, Anemic, Antenatal women, Pregnancy, Severe anemia

INTRODUCTION

Anemia is one of the most common nutritional deficiency disorders affecting pregnant women; the prevalence in developed countries is 14%, in developing countries 51%, and in India, it varies from 65% to 75%.[1] Anemia is the second most common cause of maternal death in India and contributing to about 80% of the maternal deaths caused by anemia in South East Asia.[2] Anemia is also an established risk factor for intrauterine growth retardation, leading to poor neonatal health and prenatal death.[3]

Anemia occurs at all stages of the lifecycle but is more prevalent among pregnant women due to their physiological state of health.[4] The World Health Organization (WHO) recommends that hemoglobin ideally be maintained at or above 11.0 g/dl and should not fall below 10.5 g/dl in the second trimester.[5]

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Anemia in pregnancy decreases the oxygen-carrying capacity of the blood to the body tissues. The importance of adequate Hb concentration during pregnancy for both the woman and the growing fetus cannot be overemphasized. Being a driving force for tissue oxygenation, a reduction below acceptable levels can be detrimental to both the fetus and the mother.

Iron-deficiency Anemia (IDA)

This type of anemia is most common and is occurs when the body does not have enough iron to produce adequate amounts of hemoglobin. In iron-deficiency anemia, the blood cannot carry enough oxygen to tissues throughout the body.[6,7]

Folate-deficiency Anemia

Folate is the vitamin found naturally in certain foods like green leafy vegetables. The body needs folate to produce new cells, including healthy red blood cells. During

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pregnancy, women need extra folate. However, sometimes they do not get enough from their diet. When that happens, the body cannot make enough normal red blood cells to transport oxygen to tissues throughout the body.[6,8]

Vitamin B12 Deficiency

The body needs vitamin B12 to form healthy red blood cells. When a pregnant woman does not get enough vitamin B12 from their diet, their body cannot produce enough healthy red blood cells. Women who do not eat meat, poultry, dairy products, and eggs have a greater risk of developing vitamin B12 deficiency.[6,9]

The reduction and control of anemia among women are prioritized worldwide as public health interventions, especially in childbearing age. The figure of moderate and mild forms of anemia during pregnancy in India is not declining. The sociodemographic factors, such as literacy rate, socioeconomic status, and iron consumption, are highly significant factors that affect the study group's hemoglobin (Hb) status.[10]

This study aimed to assess the correlation between awareness of anemia and the prevalence of anemia among women.

Aim

This study was to study the level of awareness of anemia in pregnant women suffering from this condition.

MATERIALS AND METHODS

The observational study was conducted on pregnant women attending the outpatient antenatal check-up. Fifty with anemic were included in the study. The women with other co-morbid conditions were excluded from the study.

A total of 50 women were enrolled in the study. A random sampling technique was used. The samples were collected with the pregnant anemic patients irrespective of parity and gestational age.

Data were collected from the respondents through a structured questionnaire. The patients who scored average were deemed to have an awareness of anemia. The questionnaire was prepared in English and was comprehensively explained to the respondents.

The questionnaires were checked for completion. The data were entered into the SPSS statistical software. To determine a significant difference between the expected frequencies and the observed frequencies, we used the Chi-squared test. $P < 0.05$ was considered statistically significant.

RESULTS

Fifty pregnant women with anemia visiting the antenatal clinic were included in the study. The women with co-morbid conditions were excluded from the study. Table 1 shows the frequency distribution of demographic data. The maximum number of patients lies between the age of 21 and 25 years.

Table 2 shows the frequency of awareness of anemia among women. Almost 64% of women were aware. The maximum awareness was found in women with moderate anemia. Most women with severe anemia were unaware.

Table 3 indicates the frequency distribution of parity among 50 women. The highest percentage was of the primigravida women, followed by gravid 2 women.

Table 4 mentions the frequency distribution regarding the severity of anemia. About 56% of the women were suffering from moderate anemia.

Table 1: Frequency distribution of demographic data of 50 patients

Age group	Frequency	Percentage
<20	2	4.0
21–25	26	52.0
26–30	18	36.0
>31	4	8.0

Table 2: Frequency distribution of awareness in 50 pregnant women

	Anemia			Total	*P*-value
	Mild	Moderate	Severe		
Awareness					
Yes					
Count	7	22	3	32	0.011
% within row	21.9%	68.8%	9.4%	100.0%	
No					
Count	4	6	8	18	
% within row	22.2%	33.3%	44.4%	100.0%	
Total					
Count	11	28	11	50	
% within row	22.0%	56.0%	22.0%	100.0%	

Table 3: Frequency distribution of parity in 50 pregnant women

Parity	Frequency	Percentage
Primigravida	23	46.0
Gravid 2	19	38.0
More than 2	8	16.0

Table 5 indicates the frequency distribution of morphological type of anemia in 50 women. About 72% of the women suffered from microcytic hypochromic anemia and 10% suffered from dimorphic anemia.

DISCUSSION

In this study, we determine the degree of awareness among pregnant women suffering from anemia. Another purpose for performing, this study was to find the relationship between the patient's age and the severity of anemia. Through this study, we also concluded the most common type of anemia present in pregnant women. Patients having a hemoglobin level <11 g/dl were considered anemic while those having a level <7 g/dl were considered severe anemic.

About 52% (26) of the women with anemia fall within the age range of 21–25 years followed by 36% (18) in 26–30 years. The results were almost like Kawak *et al*., where 62.3% of the pregnant women with anemia were in the age range of 20–35.[11]

In our study, 46% of the women were primigravida, while 38% and 16% were Gravid 2 and more than 2, respectively. Our results contrast with Kawak *et al*., wherein only 18.7% of the nulliparous women have anemia.[1] Our results are also non-consistent with Barroso *et al*., which, in a study done on 2103 women, concluded that predictors of having anemia during the gestation period include increased parity.[12]

Of 50 women included in our study, 56% have moderate anemia and 22% have mild anemia. Severe anemia was present in 22% of the patients. Our study results were inconsistent with Wemoker, which concluded that 25% each was mildly and moderately anemic and one woman was severely anemic with respect to the severity of anemia.[13]

Table 4: Frequency distribution of severity of anemia in 50 pregnant women

Anemia	Frequency	Percentage
Mild	11	22.0
Moderate	28	56.0
Severe	11	22.0

Table 5: Frequency distribution of morphological type in 50 pregnant women

Morphological type of anemia	Frequency	Percentage
Microcytic hypochromic	36	72.0
Macrocytic	4	8.0
Dimorphic	5	10.0
Normocytic normochromic	2	4.0

Our study concludes that 72% of pregnant women's anemia was microcytic hypochromic anemia followed by dimorphic anemia in 10% of the cases. Contradictory results were found in Abusharib who concluded that a total of 116 participants (58%) had a dimorphic pattern, followed by 50 participants (25%) with a microcytic hypochromic pattern, 20 participants (10%) with a macrocytic pattern, and 14 participants (7%) with a normochromic normocytic pattern.[14]

Severe anemia occurs in only 9.4% of the patients having awareness of this condition compared to severe anemia in 44% of the patient with no awareness of the disease. Further, 64% of the patients have knowledge and awareness of anemia, while 36% of the women do not have awareness. Appiah *et al*., in a study done on 598 pregnant women, concluded similar results where 13.5% of the pregnant women had high knowledge while 58.4% of the women had a fair knowledge of anemia and 28.1% of them had low knowledge.[15]

CONCLUSION

The awareness of anemia in severe anemic pregnant women is low. It is important to create awareness among pregnant women regarding the consequences of anemia during pregnancy. This will help in reducing mortality and low birth weight.

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Original Article

Comparative Study on Homocysteine Levels between Preeclampsia Patients and Healthy Pregnant Volunteers

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Abstract

Background: Preeclampsia is a pregnancy-specific disorder which complicates about 3–10% of all nulliparous gestation. Hyperhomocysteinemia has been associated with pregnancy-induced hypertension, abruption, vasculopathy, recurrent pregnancy loss, still birth, deep vein thrombosis, and neural tube defects of the newborn.

Materials and Methods: This was a case–control study. After obtaining proper informed consent, patients diagnosed with preeclampsia and healthy pregnant volunteers were enrolled for the study. Homocysteine levels were estimated in both healthy volunteers and preeclampsia patients and comparative assessment was carried out.

Results: Mean serum homocysteine in preeclamptic women is 16.9, and in normotensive women, it is 9.6, *t*-test for equality of mean is 14, *P* = 0.000, which is statistically very significant. Hence, serum homocysteine is a significant predictor of preeclampsia.

Conclusion: From the observations in our study, we can conclude that preeclampsia is associated with hyperhomocysteinemia. In preeclampsia, homocysteine levels are directly related to the severity of preeclampsia. A study involving a larger population is necessary to validate our findings.

Key words: Healthy pregnant volunteers, Hyperhomocysteinemia, Preeclampsia

INTRODUCTION

Preeclampsia is a pregnancy-specific disorder which complicates about 3–10% of all nulliparous gestation.[1]

Homocysteine is a non-protein sulfur containing amino acid. It is similar to cysteine and is derived as a result of conversion of methionine. Increased homocysteine levels in the blood causes endothelial cell dysfunction, activation of hemostasis, and oxidative stress. Hyperhomocysteinemia has been associated with pregnancy-induced hypertension, abruption, vasculopathy, recurrent pregnancy loss, still birth, deep vein thrombosis, and neural tube defects of the newborn.

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Hyperhomocysteinemia leads to endothelial dysfunction through various mechanisms. In addition to that, homocysteine also affects the fibrinolytic pathway which is contributing to the pathophysiology of preeclampsia. In normal pregnancy, homocysteine levels are decreased compared to the non-pregnant level,[2] either due to hemodilution of pregnancy or the relative deficiency due to increase in requirement by the mother and the fetus. It has been proposed that preeclampsia is associated with vascular damages similar to those associated with the hyperhomocysteinemia.

The normal serum homocysteine level in non-pregnant adult female ranges between 5 and 15 μmol/L. Homocysteine exists in two forms. About 75–80% exists as protein bound form and 15–25% exists as acid-soluble free form.[3] Numerous studies have found an association between homocysteine and various pregnancy-related disorders. Klai *et al*.[4] assessed the genetic makeup of patients with proven placental vasculopathies and found an association with MTHFRA1298C polymorphism which leads to hyperhomocysteinemia. Elevated homocysteine levels are

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associated with the development of vasculopathy of the placenta. Many hypotheses have been proposed for the pathogenesis of homocysteine-induced vasculopathy and endothelial dysfunction.

Aims and Objectives

The aim of the study was to estimate the homocysteine levels in normal pregnant women and preeclamptic women and to compare the values, and to find the association of the homocysteine levels in preeclampsia and normal pregnancy.

MATERIALS AND METHODS

This was a case–control study carried out in the Department of Obstetrics and Gynaecology, Government Kilpauk Medical College and Hospital, Chennai, Tamil Nadu, India. A total of 60 age-matched pregnant women were enrolled for the study. Out of the 60 women, 30 normal healthy pregnant women formed the control group while another 30 preeclamptic patients formed the case group. All the patients underwent detailed history taking and clinical examination. Blood pressure was recorded (two measurements 6 h apart in the semi-recumbent position). For the measurement of serum homocysteine, 5 mL of blood was drawn from the antecubital vein after overnight fasting and the specimen was transported immediately to laboratory and centrifugation was done at 3000 rpm for 5–7 min and the clear serum is transferred to a plastic vial and stored in refrigerator until analysis. Serum homocysteine was measured by fluorescence polarization immunoassay run on Abbott AxSYM machine using Abbott's kit.

Inclusion Criteria

Cases

Cases include

1. Pregnant women with BP≥ 140/90 mmHg (previously normotensive women) on at least two occasions 6 h apart
2. Gestational age 28–40 weeks (sure of gestational age by last menstrual period or ultrasonography in the 1st or early 2nd trimester).

Controls

Healthy pregnant normotensive women of gestational age of 28–40 weeks formed the control group.

Exclusion Criteria

Subjects with the following diseases or disorders were excluded from the study: Chronic hypertension, gestational diabetes mellitus type 1 and 2 diabetes mellitus, connective tissue disorders, multiple pregnancy, liver diseases, severe anemia, smoking, obesity, and pregnancy with antiphospholipid syndrome.

OBSERVATION AND RESULTS

As shown in Table 1, mean gestational age for preeclamptic women is 36.03 years and that of normotensive women is 35.70 years, *t*-test for equality of mean is $P = 0.372$. Gestational age difference between cases and controls is not statistically significant. Hence, they are matched by age [Figure 1].

As shown in Table 2, mean serum homocysteine in preeclamptic women is 16.9, and in normotensive women, it is 9.6, *t*-test for equality of mean 14, $P = 0.000$, which is statistically very significant. Hence, serum homocysteine is a significant predictor of preeclampsia [Figure 2].

As shown in Table 3, the area under the ROC is 0.998333 $P < 0.0001$. Hence, serum homocysteine is a statistically significant variable to predict preeclampsia.

Statistical Significance

$P < 0.0001$ was considered statistically significant. Hence, serum homocysteine is a statistically significant variable to predict preeclampsia with $P < 0.0001$ [Figure 3].

As shown in Table 4, the Youden index J is 1.000 which suggests that homocysteine is a perfect test to predict preeclampsia in pregnant women.

DISCUSSION

In our study, 60 pregnant women were included after fulfilling the inclusion and exclusion criteria. Thirty of the women had preeclampsia and 30 of them had normal pregnancy. The average gestational age of preeclamptic women was 36.03 weeks and normal pregnant was 35.70 weeks. There was no statistical difference in the gestational age in both the groups.

In our study, the mean homocysteine level among normal pregnant mothers was 9.624 μmol/L. This is similar to the study conducted by Hoque *et al.*[5] which had homocysteine levels of 8.46 μmol/L in. In the study conducted by Stolkova *et al.*,[6] the mean homocysteine level was 9.24 μmol/L almost similar to our study.

In our study, the homocysteine level among the preeclamptic women was 16.92 μmol/l. This is close to the study of Hasanzadeh *et al.*[7] where the homocysteine level was 13.8 ± 7. In another study by Ingec *et al.*,[8] the homocysteine level among preeclamptic women was 16.7 ± 10.1 μmol/L which is almost similar to our study. In our study, there was a statistically significant difference between the homocysteine level among normal pregnant women and women with preeclampsia ($P < 0.001$). Hence, our study proves that serum homocysteine

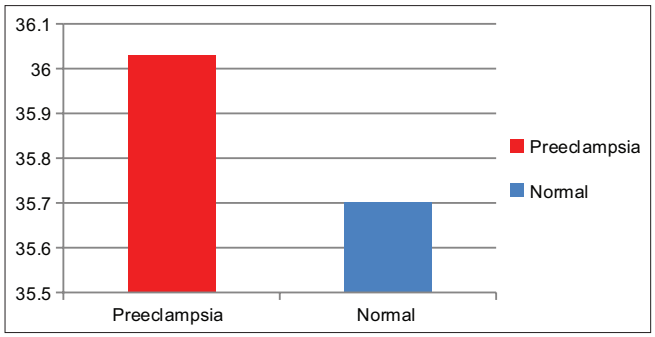

Figure 1: Age matching

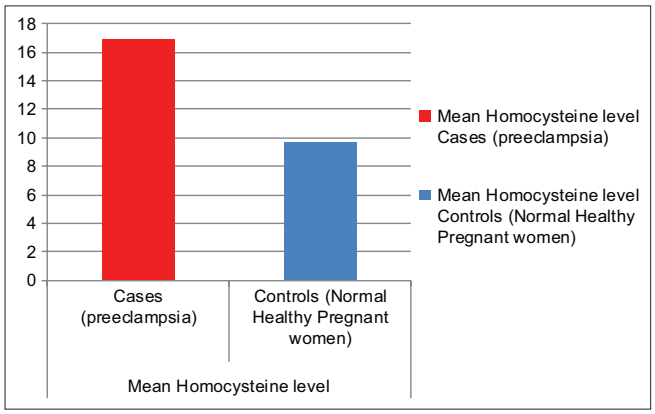

Figure 2: Mean homocysteine level

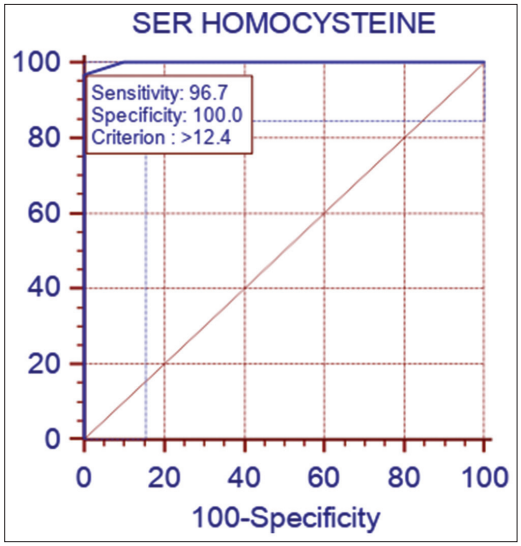

Figure 3: Receiver operating characteristic curve for serum homocysteine in relation to preeclampsia

is raised in preeclampsia and there is an association between preeclampsia and hyperhomocysteinemia. Several studies have proven this concept that preeclampsia is associated with hyperhomocysteinemia.[5-13] The large Hordaland Homocysteine Study – a population-based study[14] done over a period of 7 years in a population of about 7053, concluded that hyperhomocysteinemia is a risk factor for preeclampsia.

Table 1: Age matching

Study group	n	Age	Standard deviation	Std. error mean	*P*-value
Cases (preeclampsia)	30	36.03	1.326	0.242	0.372
Controls (normal pregnant women)	30	35.70	1.535	0.280	

Table 2: Comparison of mean homocysteine levels (μmol/L)

Study group	*n*	Mean homocysteine level	Standard deviation	Std. error mean	*P*-value
Cases (preeclampsia)	30	16.923	2.3218	0.4239	0.000
Controls (normal pregnant women)	30	9.647	1.4088	0.2572	

Table 3: Area under the receiver operating characteristic (ROC) curve

Statistical Parameter	Value
Area under the ROC curve (AUC)	0.998333
Standard error[a]	0.00254
95% confidence interval[b]	0.937079–1.000000
Z statistic	196.319
Significance level *P* (area=0.5)	<0.0001

Table 4: Youden index

Statistical Parameter	Value
Youden index J	1.0000
Associated criterion	>12.2

In the study conducted by Stolkova *et al.*,[6] maternal homocysteine level correlated with the severity of preeclampsia. Our study shows that maternal homocysteine level is directly associated with the severity of preeclampsia.

Baksu *et al.*[12] in his study showed that levels differed significantly among the severe and non-severe group. However, another study by Hasanzadeh *et al.*[9] failed to show an association between the severity of preeclampsia maternal homocysteine level although this study confirmed hyperhomocysteinemia in preeclampsia.[9] These findings reveal that hyperhomocysteinemia has a potential role in the pathogenesis of preeclampsia.

CONCLUSION

Hyperhomocysteinemia is seen in preeclampsia and it plays a major role in the pathogenesis of preeclampsia. In preeclampsia, homocysteine levels are directly related to the severity of preeclampsia.

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Original Article

A Study on Correlation of Spot Urine Protein-Creatinine Ratio with 24 h Urinary Protein in Type 2 Diabetes Mellitus Patients

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Abstract

Introduction: Proteinuria is an independent risk factor for renal diseases and a predictor of end-stage renal disease (ESRD). Accurate identification and quantification of proteinuria are of prime importance in the diagnosis and management of chronic renal disease.

Aims and Objectives of the Study: This study aims to evaluate and standardize the method of spot urine protein-creatinine ratio for estimation of proteinuria.

Materials and Methods: The present study is conducted in Mahatma Gandhi Memorial Hospital, Kakatiya Medical College, Warangal. The study period was June 2019-May 2020.

Results: This study included 73 patients with type 2 diabetes mellitus who got admitted to the Department of Internal Medicine, Mahatma Gandhi Memorial Hospital, Warangal. Findings in the patients studied were evaluated and tabulated using Microsoft Excel.

Discussion: Diabetes-specific renal disease (diabetic nephropathy) develops in about one-third of all people with Type 1 or Type 2 diabetes and it contributes to about 30% of end-stage renal disease (ESRD). Early identification of patients at high risk for diabetic nephropathy (DN) is important to intensify the treatment and modify associated risk factors.

Key words: Diabetic retinopathy, Type 2 diabetes mellitus, Urine protein creatinine ratio

INTRODUCTION

Proteinuria is an independent risk factor for renal diseases and a predictor of end-stage renal disease (ESRD).[1] Accurate identification and quantification of proteinuria are of prime importance in the diagnosis and management of chronic renal disease. An increased proteinuria is associated with an increased risk of progressive renal failure and is used as both diagnostic and prognostic values in detection and confirmation of renal diseases or response to therapy.[2]

Diabetic nephropathy accounts for about 20% of cases of chronic renal failure and is the single most common cause of ESRD in many countries.[3] Diabetic kidney disease (DKD) is a life-threatening and irreversible microvascular complication characterized by the presence of persistent proteinuria, hypertension, and progressive decline in renal function. It predisposes to excess morbidity and mortality resulting from renal failure and cardiovascular disease.

Early identification of patients at high risk for diabetic nephropathy (DN) is important to intensify the treatment and modify associated risk factors. Measurement of protein excretion in a 24 h urine collection is the gold standard for the quantitative evaluation of proteinuria. However, this method is inconvenient, since it is difficult to collect a complete 24 h urine sample accurately, especially in an outpatient setting. An alternative method for quantitative evaluation of proteinuria is a measurement of protein-to-creatinine ratio in a spot urine sample which provides a convenient method to assess protein excretion.[4] The spot urine protein-creatinine ratio can be used as a surrogate and faster diagnostic substitute for 24 h urine protein estimation in the screening and evaluation of diabetic nephropathy.

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Aims and Objectives of the Study

This study aims to evaluate and standardize the method of spot urine protein-creatinine ratio for the estimation of proteinuria.

MATERIALS AND METHODS

Source of Data

Place of study

The present study is conducted in Mahatma Gandhi Memorial Hospital, Kakatiya Medical College, Warangal.

Study period

The study period was June 2019-May 2020.

Inclusion Criteria

Type 2 diabetes mellitus patients were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

Patients with:

- Acute febrile illness
- Urinary tract infections and excretion of abnormal amount of leukocytes in urine >5 leucocytes/high-power field
- Chronic renal failure
- Hypertensives
- Glomerulonephritis due to other systemic conditions
- Hematuria
- Pregnant women.

Method of Data Collection

A random sample of male and female patients with type 2 diabetes mellitus, satisfying the inclusion and exclusion criteria was selected. Data were collected with the aid of a pro forma, which included patient history, clinical parameters such as duration of diabetes, the prevalence of diabetic retinopathy, and biochemical parameters such as serum creatinine, eGFR, glycated hemoglobin, urine protein-creatinine ratio, and 24 h urine protein. On the test day, in the morning at the start of the collection period (6.00 a.m.), patients were asked to void urine and discard this sample (as it contains the overnight urine present in the bladder). Subsequently, urine was collected for the next 24 h. The last sample was to be collected on the next day at 6.00 a.m. A random sample was also collected on the day of the deposition of 24 h sample (the test day). Urine protein was estimated using the pyrogallol red-molybdate method and urine creatinine by modified Jaffe's method. Creatinine clearance was calculated using the modified diet in renal disease (MDRD) equation: GFR (mL/min/1.73 m^2) = 175 × (Scr)-1.154 × (Age)-0.203 ×(0.742 if female) × (1.212 if African American).

RESULTS

This study included 73 patients with type 2 diabetes mellitus who got admitted to the Department of Internal Medicine, Mahatma Gandhi Memorial Hospital, Warangal. Findings in the patients studied were evaluated and tabulated using Microsoft Excel.

Patient Characteristics

Age-wise distribution

The age of the patients studied ranged from 30 years to 80 years. The mean age of the patients was 51.9 ± 10.4 years. The mean age of female and male patients was 51.2 ± 10.4 years and 52.37 ± 10.5, respectively. The maximum number of patients was noted in the age group 41–50 years, that is, 26 (35.1%) and least in the age group of 20–30 years, that is, 1 (1.35%).

Gender-Wise Distribution

Of the 73 patients studied, 49 (67.1%) patients were male and 24 (32.9%) patients were female.

Creatinine Clearance

In our study, the majority of patients had creatinine clearance (calculated by MDRD equation) between 30 and 60 ml/min^1/1.73 m^{-2} – 25 patients (34.24%) creatinine clearance (ml/min^1/1.73m^{-2}) [Table 1].

Correlation between Urine PCR and 24 h Urine Protein

There was a significant positive correlation between urine PCR and 24 h urine protein in our study ($r = 0.87$ $P < 0.001$) [Chart 1].

Correlation between Urine PCR and 24 H Urine Protein at Different Levels of GFR

Correlation coefficient (r): 0.784. P value: <0.001 [Chart 2].

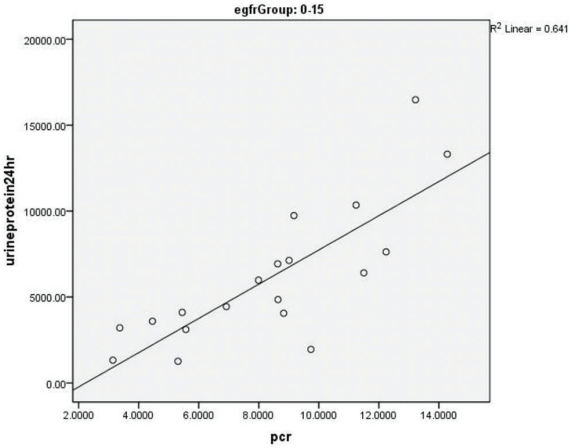

Table 1: Distribution of cases (percentage) at different levels of proteinuria

Degree of proteinuria (mg/24 h)	Percentage	No. of patients
<300	4.11	3
300–3500	61.64	45
>3500	34.25	25

Correlation between Urine PCR and 24 H Urine Protein at Different Levels of Proteinuria

Different levels of proteinuria was (<300 mg/24 h). Correlation coefficient (*r*): 0.93. *P* value: <0.001 [Chart 3].

Proteinuria Group (300–3500 mg/24 h)

Correlation coefficient (*r*): 0.632. $P < 0.001$.

Proteinuria (mg/24 h)	Correlation coefficient (r)	*P* value
<300	0.93	<0.001
300–3500	0.632	<0.001
>3500	0.783	<0.001

There was a significant positive correlation between urine PCR and 24 h urine protein at different levels of proteinuria. The maximum correlation was seen in the proteinuria group <300.

Correlation between Urine PCR and Serum Creatinine

Correlation coefficient (*r*): 0.774. *P* value: <0.001 [Chart 4].

Correlation between 24 H Urine Protein and Serum Creatinine

There was a significant positive correlation between serum creatinine and 24 h urine protein in our study population ($r = 0.656$, $P < 0.001$) [Chart 5].

DISCUSSION

Diabetes-specific renal disease (diabetic nephropathy) develops in about one-third of all people with Type 1 or Type 2 diabetes and it contributes to about 30% of end-stage renal disease (ESRD). Early identification of patients at high risk for diabetic nephropathy (DN) is important to intensify the treatment and modify associated risk factors. Proteinuria is an independent risk factor for renal diseases and a predictor of end-stage renal disease (ESRD). Measurement of protein excretion in a 24 h urine collection is the gold standard for the quantitative evaluation of proteinuria in diabetes. An alternative method for quantitative evaluation of proteinuria is a measurement of protein-to-creatinine ratio in a spot urine sample which provides a convenient method to assess protein excretion. Seventy-three patients with type 2 diabetes mellitus and proteinuria were studied.

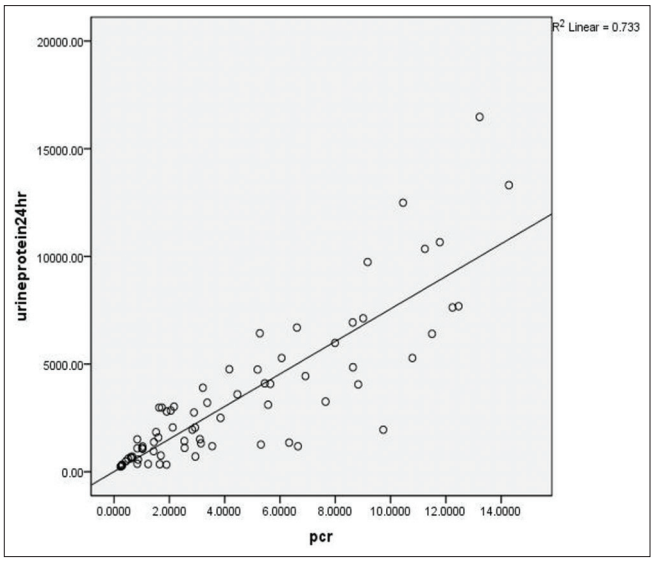

Chart 1: Correlation coefficient (*r*): 0.87. *P* < 0.001

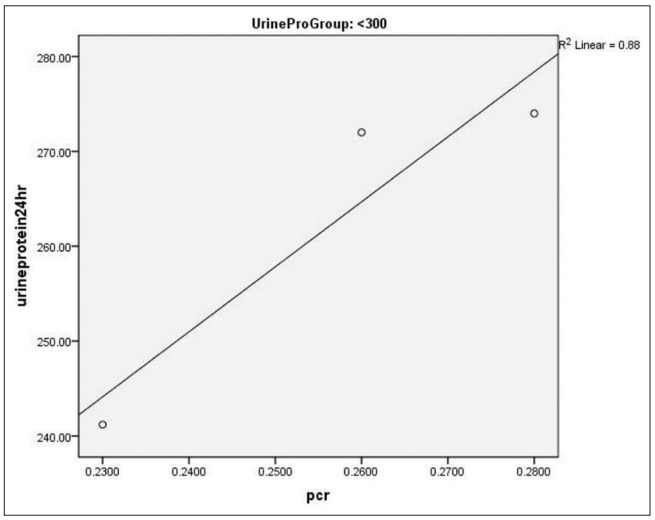

Chart 2: Correlation between urine PCR and 24 h urine protein (<300 mg/24 h)

Age-Wise Distribution of Cases

The age of the patients studied ranged from 30 years to 80 years. The mean age of the patients was 51.9 ± 10.4 years. The mean age of female and male patients was 51.2 ± 10.4 years and 52.37 ± 10.5, respectively. The maximum number of patients was noted in the age group of 41–50 years, that is, 26 (35.1%) and least in the age group of 20–30 years, that is, 1 (1.35%).

Gender-Wise Distribution of Cases

Of the 73 patients studied, 49 (67.1%) patients were male and 24 (32.9%) patients were female. Male-to-female ratio is 2.04:1.

Degree of Proteinuria

In our study, out of the 73 patients with proteinuria, 25 patients (34.25%) had nephrotic range proteinuria

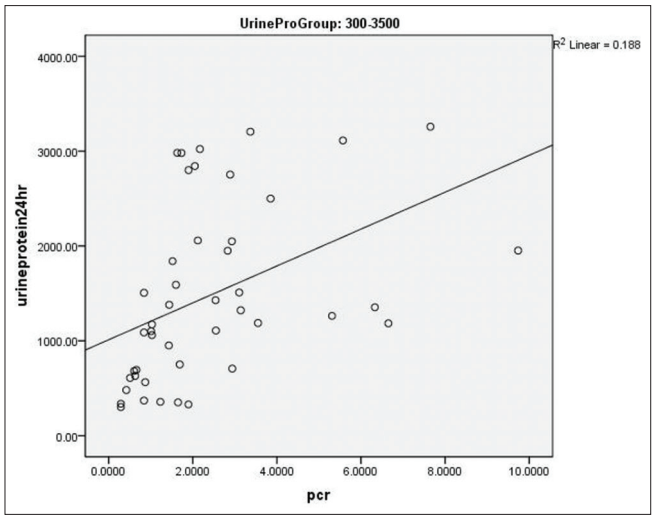

Chart 3: Correlation between urine PCR and 24 h urine protein (300–3500 mg/24 h)

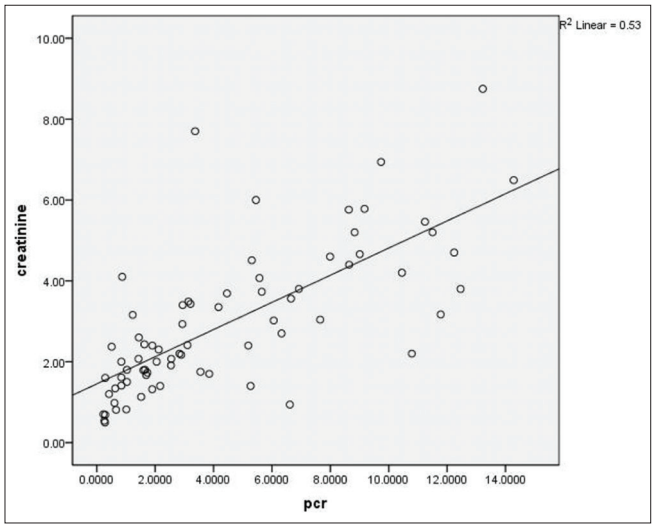

Chart 4: Correlation between urine PCR and serum creatinine (mg/dL)

(>3.5 g/24 h) and 48 patients (65.75%) had proteinuria of <3.5 g/24 h.

Stoycheff *et al.*, in their study of 1467 participants with diabetic kidney disease, 641 (44%) had urine total protein level of 3.5 g/d or greater.[5]

Duration of Diabetes

Nelson *et al.*[6] selected 364 Pima Indians aged 35 years older with type 2 diabetes and proteinuria. They found out that the incidence of ESRD attributed to diabetic nephropathy increased from 0 cases/1000 person-years at 0–5 years to 40.8 cases/1000 person-years at greater than or equal to 20 years duration of diabetes. Longer the duration of diabetes, the higher the frequency of diabetic nephropathy. The mean duration of diabetes in our study was 9.24 ± 6.1

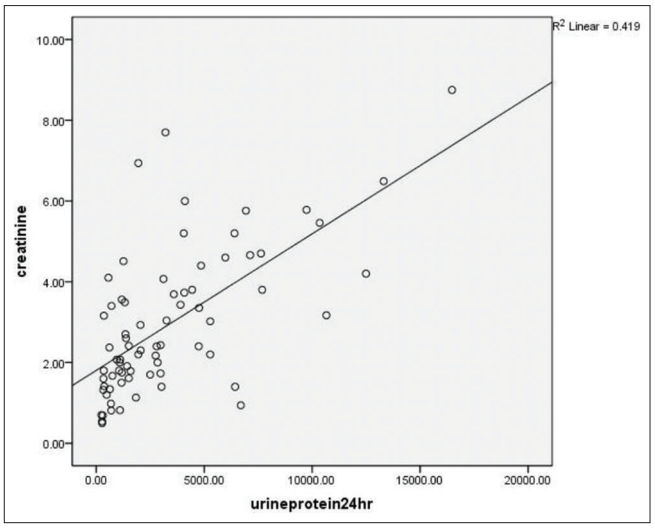

Chart 5: Correlation between 24 h urine protein and serum creatinine

years. The majority of patients had a duration of diabetes between 5 and 10 years – 38 patients (52.05%).

Correlation between Urine PCR and 24 h Urine Protein

Several studies have compared urine PCR to 24 h urine estimation in the screening and evaluation of diabetic nephropathy. A good correlation between urine PCR and 24 h urine protein has been demonstrated in patients with diabetic nephropathy.

Biradar *et al.*,[7] in a study of 42 diabetic patients, have found a positive correlation between 24 h of urinary protein and spot urine PCR ($r = 0.925$). Yadav *et al.*[8] have also shown similar results ($r = 0.892$).

Ruggenenti *et al.* in his studies concluded that the 24 h urine protein can be directly predicted from a random urine specimen by estimating the protein-creatinine ratio. There was a significant positive correlation between urine PCR and 24 h urine protein in our study ($r = 0.87$, $P < 0.001$).

In a study on 46 patients by Ginsberg *et al.*,[9] an excellent correlation between 24 h urine protein and the protein/creatinine ratio in a single urine sample was found.

Correlation between Urine PCR and 24 H Urine Protein at Different Range of GFR

There was good correlation between urine PCR and 24 h urine protein at all levels of GFR in our study. The correlation in different levels of GFR was: 0–15 group: $r = 0.784$, $P \leq 0.001$, 15–30 group: $r = 0.756$, $P \leq 0.001$, 30–60 group: $r = 0.725$, $P \leq 0.001$, and >60 group: $r = 0.99$, $P \leq 0.001$. Maximum correlation was seen in the GFR >60 group. High correlation coefficients ($r = 0.91$, 0.95, and 0.98) were observed in patients with normal, reduced,

and severely reduced renal function in a study done by Antunes *et al*.[10] A study done by Absar *et al*.[11] showed that correlation between 24 h urine protein and urine PCR was significant at different levels of GFR, confirming that the ratio can be used instead of 24 h urine protein. However, the result in GFR < 15 ml/min was not very convincing.

Morales *et al*.[12] in his study showed that morning urine PCR had good sensitivity and specificity even in patients with reduced renal function.

Correlation between Urine PCR and 24 h Urine Protein at Different Range of Proteinuria

A good correlation was observed between spot urine protein/creatinine ratio and 24 h urine total protein excretion in different proteinuria ranges. The correlation in different levels of proteinuria was: <300 mg ($r = 0.93$, $P < 0.001$), 300–3500 mg ($r = 0.632$, $P < 0.001$), and 3500 mg ($r = 0.783$, $P < 0.001$). Maximum correlation was seen in the proteinuria group <300. A study done by Agarwal[13] showed highly statistically correlation between 24 h urine protein and urine PCR at all levels of proteinuria. According to a study by Montero *et al*., a strong correlation was observed between spot urine protein/creatinine ratio and 24 h urine total protein excretion in proteinuria levels from 300 mg/day to 3499 mg/day. A lower correlation was maintained in 24 h urine total protein <300 mg and nephrotic range proteinuria.

Mohan *et al*. studied the correlation between spot urine protein-creatinine ratio and 24 h urine protein in type 2 diabetes. The positive correlation was good but was less with an increasing degree of proteinuria.

Correlation between Urine PCR and Creatinine

A significant positive correlation was found between urine PCR and serum creatinine in our study ($r = 0.774$, $P < 0.001$). Similar good correlation was found between 24 h urine protein and creatinine ($r = 0.656$, $P < 0.001$) also. Studies have shown that proteinuria (assessed by urine PCR and 24 h urine protein) correlated well with creatinine levels. In the Ramipril Efficacy in Nephropathy (REIN) trial, urinary protein excretion was found to be correlated significantly with GFR decline.

Correlation between Urine PCR and Duration of Diabetes

In our study, no significant correlation was found between urine PCR and the duration of diabetes. Since the onset of type 1 diabetes is readily identifiable and the onset of type 2 diabetes is not, patients newly diagnosed with type 2 diabetes may present with advanced diabetic nephropathy. Hence, the duration of diabetes may not correlate with the degree of proteinuria in type 2 diabetes mellitus.

Correlation between Glycated Hemoglobin and Proteinuria

No statistically significant correlation was found between HBA1C levels and degree of proteinuria in our study.

Correlation between Degree of Diabetic Retinopathy and Proteinuria

There was a good correlation between the degree of diabetic retinopathy and proteinuria – assessed by urine PCR in our study. Several studies have shown a close relationship between the presence of diabetic retinopathy and abnormal increase in urinary albumin excretion. The patients with retinopathy had a significant increase in proteinuria, whereas the patients without had a stable protein excretion. Study by Trevisan *et al*.[1] demonstrated that protein and albumin excretion rate increased significantly in patients with retinopathy.

CONCLUSION

In our study of 73 patients with type 2 diabetes mellitus and proteinuria, it was found that:

- A maximum number of patients were noted in the age group of 41–50 years.
- Males were more than females in the ratio of 2.04:1.
- The majority of patients had a duration of diabetes between 5 and 10 years (52.05%).
- The mean duration of diabetes was 9.24 ± 6.1 years.
- Twenty-five patients (34.25%) had nephrotic range proteinuria.
- There was a good correlation between urine PCR and 24 h urine protein at different levels of GFR.
- Maximum correlation between urine PCR and 24 h urine protein was seen in the GFR >60 group.
- There was a good correlation between urine PCR and 24 h urine protein at different ranges of proteinuria.
- A maximum correlation between urine PCR and 24 h urine was seen in the proteinuria group <300.
- There was a good correlation between urine PCR and serum creatinine.
- No statistically significant correlation was found between HBA1C levels and degree of proteinuria.

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Original Article

Single Dose of Cefotaxime in Preventing Surgical Site Infections in Abdominal Surgery: A Prospective Study

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Abstract

Background: In both developed and developing countries, surgical site infections (SSI) are the most commonly identified healthcare-acquired infection and surgical complication, which have an adverse impact on patients. It leads to an increased rate of morbidity, which is an important factor for increased healthcare costs.

Aim: The aim of the study was to the single-dose use of cefotaxime antibiotic in SSI in elective abdominal surgery.

Materials and Methods: The study was conducted on over 50 patients admitted for elected surgery in the hospital. The patients were taken care of as per NICE guidelines to prevent SSI. Cefotaxime 1 g antibiotic injection was administered intravenously 30 min before the incision site before surgery.

Results: In 50 patients included in the study, 56% were males and 44% were females. The 32% who have undergone surgery were from age groups 41-50 and 28% from age group 31–40. Most patients underwent hernioplasty (38%), followed by excisions, hernia mesh repair, cholecystectomy 22%, 14%, and 12%. The post-operative wound complications were also reduced in the patients.

Conclusions: To conclude, single-dose antibiotics Cefotaxime before 30 min of surgery may help prevent SSI in uncomplicated surgeries.

Key words: Antibiotic, Cefotaxime, Elective surgery, Surgical site infection

INTRODUCTION

Every year, hundreds of millions of people around the world undergo surgery. Surgical infections are infections that occur due to a surgical procedure or need surgical intervention as part of their treatment. They are caused due to failure in mechanical/anatomic defense mechanisms and are associated with increased morbidity, significant mortality, and increased healthcare costs.

Surgical site infections (SSIs) continue to be a significant cause of morbidity and mortality among surgical patients, accounting for approximately one-fifth of all healthcare-associated infections.[1] They are also sometimes responsible for increased treatment costs, re-admission of the patients, prolonged length of hospital stay, and a significant increase in patient's morbidity and mortality, causing increased economic burden.

Despite advancements in operating room practices, modern instrument sterilization methods, improved surgical techniques, preventive strategies, and SSI remain a concerning cause of hospital-acquired infection.[2]

Considering the developed countries with the most modern facilities and best standard protocols, SSI has been reported to affect 5% to 15% of hospitalized patients in regular wards and up to 50% or more of patients in intensive care units (ICUs), while the magnitude of the problem remains primarily underestimated in developing countries.[3]

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Endogenous contamination, such as skin flora, and exogenous contamination, such as healthcare personnel or contaminated surgical instruments, have been highly correlated to the pathogenesis of SSI. Other factors, such as organism burden and pathogen virulence factors, also play a significant role in SSI occurrence.[4]

People who develop SSI need advanced medical care. An unwanted medical stay also increases by 60% of the patients with SSI than an uninfected surgical patient. It was well observed that the most commonly found organisms associated with SSI are Gram-positive bacteria such as *Staphylococcus aureus*, coagulase-negative *Staphylococcus, Enterococcus* species.[5]

It has also been observed that patients who develop SSIs have a 2–11 times higher mortality rate than patients who do not develop SSIs.

Due to the high incidence of SSI, antibiotics play a particularly important role in the post-operative care of patients undergoing elective surgery (SSI). It has been reported that when an antibiotic is not used, 30–40% of patients develop post-operative SSI.[6] Considering the importance of antibiotic administered along with anesthesia, induction is recommended during any surgery.

Antibiotics should be specific and targeted to the likely causative organisms and appropriate for the patient, taking allergies, and co-morbidities into account. The dose should be not being administered sooner than 120 min before the incision is made (WHO).

Aim

The aim of the study was to the single-dose cefotaxime antibiotic before the surgery in preventing SSI in elective surgery.

MATERIALS AND METHODS

The study is a type of prospective study conducted in the department of general surgery in which the patients who were admitted and underwent abdominal surgeries were involved. The study included 50 patients who underwent elective surgery in a tertiary care hospital's general surgery department.

Patients who were admitted and met the inclusion criteria were recruited for the study. Following that, written consent to participate in the study was obtained, and a full history and physical examination were performed. A pretested interviewer-administered semi-structured questionnaire was used to collect patient data.

Inclusion Criteria

Patients who underwent elective surgery, more than 18 years had no sign of infection before the surgery.

Exclusion Criteria

The study excluded surgeries on severely immunocompromised patients, patients with incomplete primary wound closure, and re-look surgeries or with any other co-morbidities.

An in-depth examination of these cases in terms of admission date, history, clinical features, type of surgery (emergency or elective), preoperative preparation, type of incision, contamination, a procedure performed, preoperative findings, drain used, and its type and duration of operation and post-operative management were recorded and tabulated.

The Swabs were collected from infected post-operative wounds of the patients using standard microbiological methods. Sterile swabs of collected samples were transported to the laboratory at room temperature within 15 min of the collection; swabs were inoculated on different culture media types. The chocolate, blood, and MacConkey agar as a culture media were used. The inoculated plates were incubated for 24–48 h at 35–37°C. A Gram stain procedure was performed on culture growths to report the organisms.

RESULTS

In this study, 50 people were recruited from the hospital who had elective surgery. Patients over the age of 18 who did not have diabetes, high blood pressure, antibiotic allergies, or immunosuppressive diseases were eligible. Patients were treated following NICE guidelines. The patients were examined preoperatively, intra-operatively, and postoperatively. The patients included 28 males 22 females, as depicted in Figure 1. The age of the patients was in the range of 18 years to 70 years. Twelve patients, that is, 24% of the sample studied, were in the age group of > 30. Fourteen patients, that is, 28%, were in the age group of 31–40. Sixteen patients, that is, 32%, were in the age group of 41–50 and 8 patients, that is, 16% of the total population studied were > age of 50, as shown in Graph 1.

Among various abdominal elective surgery opted by the patients, the hernioplasty was the most commonly performed procedure (38%), followed by excisions (22%), hernia mesh repair (14%), and cystolithotomy (12%) followed by 3 procedures of appendicectomy 1 patient of cholecystectomy was observed as shown in Figure 2.

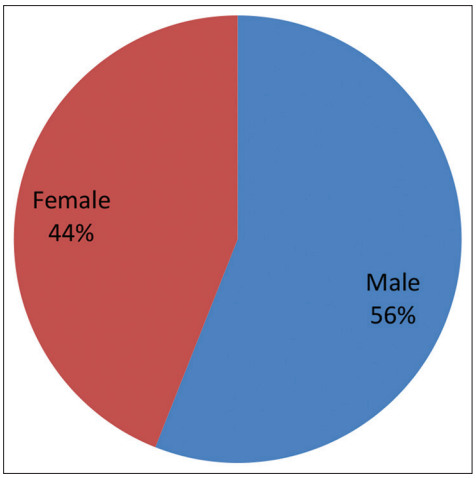


Figure 1: The total number of patients involved in the study

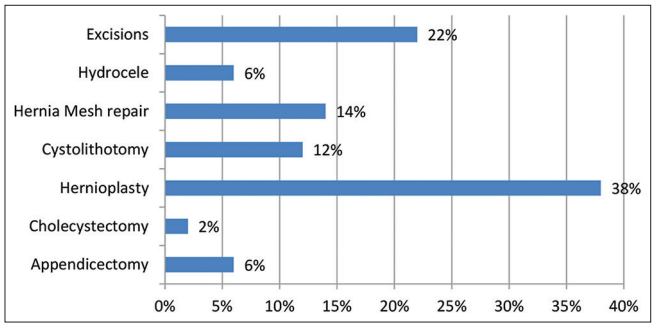


Figure 2: Distribution of surgery

The study witnessed and reported a significantly lower SSI incidence after being injected with a single dose of a cefotaxime antibiotic before elected surgery. The study shows a reduced incidence of <10% of post-wound complications such as fever, pain swelling, or any wound discharge from the surgery site, as depicted in Figure 3.

It was also very clearly reported that after the single-dose administration of cefotaxime antibiotic 14 days before the elected surgery, there was a significant reduction in SSI development cases. There were 94% cases in which there was no SSI development, whereas 6% of the cases experience moderate SSI development after the medical procedure, as shown in Graph 2.

The most commonly identified bacteria from the SSI were *E. coli* followed by the Staphylococcal was isolated from a case of hernioplasty, appendicectomy, and ventral hernia mesh repair. Patients who had SSI were evaluated. Antibiotics were administered and the patients were monitored regularly.

DISCUSSION

SSIs are widely recognized as one of the leading causes of nosocomial infections worldwide. They continue to be a

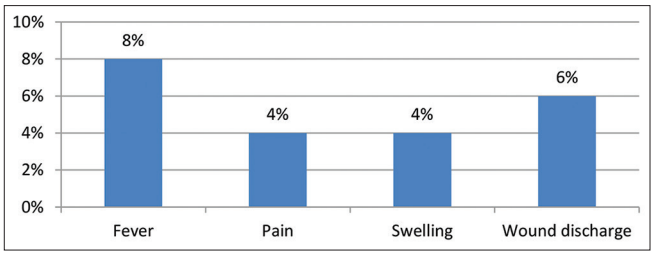
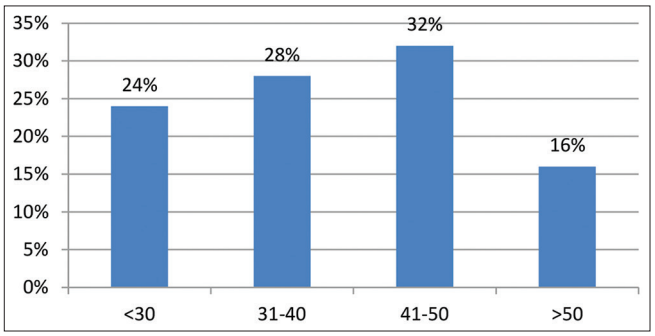
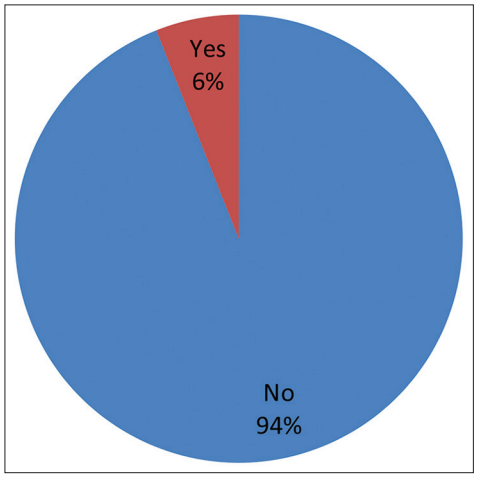


Figure 3: Distribution of post wound complication



Graph 1: Age group of the sample studied



Graph 2: Distribution of SSI cases post-surgery

major public health issue, resulting in increased antibiotic use, increased associated costs, prolonged hospitalization, and increased patient morbidity and mortality.[7] According to various studies, the SSI rate ranges from 2.5% to 41.9% worldwide and from hospital to hospital.[8]

From a historical perspective, there has been a significant improvement in postsurgical outcomes. However, these incremental gains have slowed in recent decades. The benefit of antibiotics was reported as far back as the 1960s from randomized trials, and this practice has had a marked impact on surgical practice. Antibiotics are typically given intravenously at the time of anesthesia induction.

This systematic study aimed to identify implementation interventions used in the field of abdominal surgery to

implement SSI prevention measures. The study conducted by Borade *et al.* reported 3% of superficial SSI.[9] In another study conducted by Shah *et al.*, it was compared that single-dose antibiotics before surgery were compared with multiple-dose antibiotics treatment and found that 11% of patients undergoing laparoscopic surgery had SSI both the single-dose and multiple-dose antibiotic regimens. It was concluded that a single dose of antibiotics is more patient-friendly, cost-effective, has fewer side effects, and prevents the emergence of antibiotic resistance.[10] The results regarding the administration of antibiotics are mostly consistent with findings from other reviews. The present study's overall infection rate was < 1%, a very less occurrence of SSI compared to the other studies that reported rates ranging from 2.5% to 41.9%.[11]

CONCLUSION

This study concluded with a reduced rate of SSI. SSI when single dose prophylactic Cefotaxime is used. A multidisciplinary and multifaceted approach to SSI is necessary to continue to improve these critical outcomes of surgery.

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Original Article

Comparison of Bupivacaine with Fentanyl and Bupivacaine with Dexmedetomidine Intrathecally in Lower Abdominal Surgical Procedures

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Abstract

Introduction: Spinal block is still the first choice because of its rapid onset, superior blockade, low risk of infection from the catheter *in situ*, fewer failure rates, and cost-effectiveness. Various intrathecal adjuvants, such as morphine, fentanyl, ketamine, midazolam, and clonidine, improve analgesia quality and duration.

Aim: This study aimed to analyze bupivacaine's effectiveness with fentanyl and dexmedetomidine intrathecally in a lower abdominal surgical procedure.

Materials and Methods: Forty patients included in this study were randomly allocated to two groups (20 patients each): Group BF and Group BD. Group BF patients received 2.5 ml of 0.5% hyperbaric bupivacaine with 25 μg (0.5 cc) of fentanyl to a total volume of 3.0 ml intrathecally. Group BD 2.5 ml of 0.5% hyperbaric bupivacaine with 5 μg (0.5 cc) of preservative-free Dexmedetomidine to a total volume of 3.0 ml intrathecally. Results were analyzed statistically and discussed below.

Results: Patients in the dexmedetomidine group had a faster onset of sensory block and motor block, one patient had hypotension, three patients had pruritis, and one patient had vomiting. The mean rescue of analgesia and duration of surgery were higher in the dexmedetomidine group. In the fentanyl group, six patients had hypotension, two patients had bradycardia, and one patient had vomiting.

Conclusion: Intrathecal dexmedetomidine supplementation to spinal bupivacaine seems to be a good alternative to intrathecal fentanyl since it produces prolonged postoperative analgesia with minimal side effects, excellent quality of spinal analgesia, prolonged motor and sensory block, hemodynamic stability, and reduced demand for rescue analgesics in 24 h.

Key words: Dexmedetomidine, Fentanyl, Intrathecal, Spinal anesthesia

INTRODUCTION

Lower abdominal and lower limb surgeries may be performed under local, regional (spinal or epidural), or general anesthesia (GA), but neuraxial blockade is the preferred mode of anesthesia. A spinal block is still the first choice because of its rapid onset, superior blockade, low risk of infection from the catheter *in situ*, fewer failure rates, and cost-effectiveness, but it has the drawbacks of shorter duration of block and lack of post-operative analgesia. Spinal anesthesia is widely used in various operations because it provides adequate analgesia, muscular relaxation with simple operation, and rapid onset of action.[1] However, local anesthetics alone has a short duration and is inadequate for visceral pain.[2,3] Various intrathecal adjuvants, such as morphine, fentanyl, ketamine, midazolam, and clonidine, improve analgesia quality and duration.[4]

In recent years, intrathecal adjuvants have gained popularity to prolong the block's duration, better success rate, patient satisfaction, decreased resource utilization compared with GA, and faster recovery. Adequate pain management is essential to facilitate rehabilitation and accelerate functional

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recovery, thus enabling patients to return to their normal activity more quickly. The quality of spinal anesthesia has been reported to improve with the addition of opioids (e.g., morphine, fentanyl, and sufentanil) and other drugs (e.g., dexmedetomidine, clonidine, magnesium sulfate, neostigmine, ketamine, and midazolam), but no drug to inhibit nociception is without associated adverse effects.[5]

Dexmedetomidine is a highly selective α2 adrenergic agonist, which has been used for premedication and as an adjunct to GA. It reduces opioids and inhalational anesthetic requirements. Intrathecal α2 receptor agonists are found to have antinociceptive action for both somatic and visceral pain.[6] Intrathecal α2 adrenoceptor agonist act by depressing C-fiber transmitters' release and hyperpolarization of post-synaptic dorsal horn neurons.[7] Reports from earlier human studies suggest that intrathecal 10 μg dexmedetomidine would produce more postoperative analgesic effect along with bupivacaine in spinal anesthesia with very few side effects.

Fentanyl is one of the short-acting narcotic analgesics with potent morphine-like action. It produces many of its clinical effects rapidly after intrathecal administration.[8] Neuroaxial administration of lipophilic opioids such as fentanyl and sufentanil tends to provide a rapid onset of analgesia. Their rapid clearance from cerebrospinal fluid may limit the cephalic spread and develop certain side effects such as delayed respiratory depression.[9]

Aim

This study aimed to analyze bupivacaine's effectiveness with fentanyl and dexmedetomidine intrathecally in a lower abdominal surgical procedure.

MATERIALS AND METHODS

This study was done in prospective double-blinded randomized manner. It was conducted at our institute between March 2017 and August 2017 after approval from the institution's ethical committee and written informed consent. 90 American Society of Anaesthesiology I (ASA-I) patients undergoing elective lower abdominal surgeries under spinal anesthesia were recruited.

Inclusion Criteria

Patients in the age group of 30 and above, both sexes, ASA–I were included in the study.

Exclusion Criteria

Hypersensitivity to the study drug, renal or hepatic dysfunction, uncontrolled labile hypertension, and diabetes mellitus were excluded from the study. Patients were randomly allocated to two groups (20 patients each): Group BF and Group BD. Group BF patients received 2.5 ml of 0.5% hyperbaric bupivacaine with 25 μg (0.5 cc) of fentanyl to a total volume of 3.0 ml intrathecally. Group BD 2.5 ml of 0.5% hyperbaric bupivacaine with 5 μg (0.5 cc) of preservative-free Dexmedetomidine to a total volume of 3.0 ml intrathecally.

Intrathecal drugs were prepared by an anesthesiologist not involved in the study and were administered by another anesthesiologist who was blinded and performed spinal anesthesia. The volume of the drug, size of the syringe, and color of the drug of interest were similar in the three groups. The final volume of injected solutions was 3.0 ml in three groups. Surgical anesthesia was graded as excellent if there was no complaint of pain at any time during surgery. Good, if there was minimal pain or discomfort, which was relieved by a small dose of iv pentazocine 0.5 mg/kg and poor if GA has to be administered.

In PACU, the pain was assessed every 15 min. When the patient reaches the pain score 2 Inj. Diclofenac 75 mg Injection was given. Duration of effective analgesia was defined as the time interval between onset of subarachnoid block and the time to reach pain score-2. Patients were shifted to the post-operative ward after complete resolution of motor blockade.

RESULTS

Patients in the dexmedetomidine group had a faster onset of sensory block and motor block. The mean rescue of analgesia, meantime for regression of motor and sensory block, and surgery duration was higher in the dexmedetomidine group [Table 1].

Sixteen patients had B3, and four patients had B2 grade of motor block in group BF. In Group BD, 17 patients had B3, two patients had B2 grade, and one patient had B1 grade [Table 2].

In Group BF, ten patients had a maximum sensory block level at level T6, even patients at T8, two patients at T10, and one patient at T12. In a group, BD, 17 patients had a maximum level of sensory block at level T6 and three patients at T8 [Table 3].

In Group BD, one patient had hypotension, three patients had pruritis, and one patient had vomiting. In Group BF, six patients had hypotension, two patients had bradycardia, and one patient had vomiting [Table 4].

DISCUSSION

The mechanism by which intrathecal α2 adrenoceptor agonists prolong the motor and sensory block of

Table 1: Characteristics of motor and sensory block

Parameters	Group BF	Group BD	*P*-value
Mean duration of surgery	74.28	78.24	0.542
Mean onset of sensory block T10	2.81	2.72	0.556
Mean onset of sensory block T6	5.11	4.81	0.172
Meantime to reach motor block	6.92	6.66	0.134
Meantime for regression of sensory block	382.82	467.23	<0.0001
Meantime for regression of motor block	241.28	286.52	0.002
Mean time for rescue analgesia	224.52	286.74	0.002

Table 2: Maximum grade of motor block

Group	B1	B2	B3	*P*-value
Group BF	0	4	16	0.428
Group BD	1	2	17	

Table 3: Maximum level of sensory block

Group	T6	T8	T10	T12	*P*-value
Group BF	10	7	2	1	0.093
Group BD	17	3	0	0	

Table 4: Side effects

Side effects	Group BF	Group BD
Hypotension	6	1
Bradycardia	2	0
Pruritis	0	3
Vomiting	1	1

local anesthetics is unknown. They act by binding to the presynaptic C-fibers and post-synaptic dorsal horn neurons. Their analgesic action results from depression of the release of C-fiber transmitters and hyperpolarization of post-synaptic dorsal horn neurons.[7] Fentanyl is an opioid analgesic generally used for pain relief together with other medications for anesthesia. It is 100 times more potent than morphine. Intrathecally, fentanyl exerts its Effect by combining with opioid μ receptors in the spinal cord's dorsal horn and may have a supraspinal spread and action.[10] Pain is frequently encountered during surgery on the female genital organs under spinal local anesthetics. Intrathecal fentanyl, when added to spinal local anesthetics, reduces significantly visceral and somatic pain, and many studies have proved this analgesic effect.[11] Intrathecal fentanyl prolongs the duration of spinal anesthesia produced by bupivacaine and lignocaine, and this effect has been shown in obstetric and non-obstetric patients undergoing various surgeries.[9] The prolongation of the duration of spinal analgesia produced by intrathecal fentanyl is not dose-related.[12]

Dexmedetomidine is a highly selective α2-adrenoreceptors agonist approved as an intravenous sedative and adjuvant to anesthesia. Dexmedetomidine, when used intravenously during anesthesia, reduces opioid and inhalational anesthetics requirements.[13]

Fukushima *et al.* administered 2 μg/kg epidural dexmedetomidine for post-operative analgesia in humans but did not report neurologic deficits.[14] Our study has shown that the addition of dexmedetomidine with hyperbaric bupivacaine significantly prolongs both sensory and motor block.

Al-Mustafa *et al.* studied the Effect of dexmedetomidine 5 and 10 μg with bupivacaine in urological procedures. They found that dexmedetomidine prolongs the duration of spinal anesthesia in a dose-dependent manner.[15]

Al-Ghanem *et al.* had studied the effect of the addition of 5 μg dexmedetomidine or 25 μg fentanyl intrathecal to 10 mg isobaric bupivacaine in vaginal hysterectomy and concluded that 5 μg dexmedetomidine produces more prolonged motor and sensory block as compared with 25 μg Fentanyl.[16]

Al-Ghanem *et al.*[16] demonstrated a significant decrease in the heart rate and mean arterial blood pressure by comparing the addition of 5 μg dexmedetomidine with intrathecal bupivacaine with 25 μg Fentanyl in the gynecological procedure. Abdelhamid also supported this, and El-Lakany[17] reported a significant decrease in the heart rate in the dexmedetomidine group on comparing the use of 5 μg dexmedetomidine with hyperbaric bupivacaine only. In our study, the fentanyl group had more side effects compared to the dexmedetomidine group.

CONCLUSION

Intrathecal dexmedetomidine supplementation to spinal bupivacaine seems to be a good alternative to intrathecal fentanyl since it produces prolonged postoperative analgesia with minimal side effects and excellent quality of spinal analgesia, prolonged motor and sensory block, hemodynamic stability, and reduced demand for rescue analgesics in 24 h.

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Original Article

Study of Patients Presenting with Complaints of Headache in Ear, Nose, and Throat Outpatient Department – A Prospective Study

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Abstract

Introduction: Headache is one of the most commonly experienced physical discomforts. About half of the adults have a headache in a given year. In most cases, headaches are not harmful, but in some cases, they can show symptoms of severe or/and life-threatening disorders such as meningitis, subarachnoid hemorrhage, stroke, or brain tumor.

Aim: This study aims to study the patients presenting with complaints of headache in the ear, nose, and throat (ENT) department.

Materials and Methods: A total of 100 patients were selected randomly, attending the ENT outpatient department at our site hospital from June 2019 to May 2020. A ready questionnaire was used to record the data of patients. A patient approaching with the first and foremost complaint of headache with a history of the recurrent episode was included in the study. Patients coming with different forms of neuralgic pain were excluded from the study.

Results: The patients of the age group of more than 50 years were more experiencing headaches. Women suffer more than men do from headaches. The presence of eye pain symptoms and comorbid condition of diabetes mellitus are associated more with the patient in the ENT department. The maximum patients complaining of headaches in the study were diagnosed with an ophthalmic-related problem.

Conclusion: The study showed challenges of patients experiencing headaches and approaching the ENT department to determine the exact cause of the headache and get satisfactory treatment. A group of doctors consisting of ENT specialists, neurologists, ophthalmologists, psychiatrists, and psychologists can bring many benefits to remove or cut short the victims' sufferings.

Key words: Headache, Migraine, Primary headache, Sinus headache

INTRODUCTION

Headaches are a common complaint among the public; the World Health Organization (WHO) estimates the prevalence of headaches among adults at 47%, with half to three-quarters of adults aged 18–65 years experiencing headaches in the past year.[1] Headache is defined as pain or any unpleasant sensation in the cranial vault region above the orbitomeatal line.

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The International Classification of Headache Disorders (ICHD) defines more than 200 different types of headaches.[2] ICHD classified headaches into two principal types – primary headache and secondary headache. A primary headache is the one where research scientists have failed to reach any specific cause. Secondary headache is attributed to innumerable reasons and can be caused by any physical disorder or discomfort.[3] Primary headaches are migraine, tension-type headache (TTH), cluster headache, and other trigeminal autonomic cephalalgias.

It is hard to find out a human being who had never experienced a headache in a lifetime. However, consultation with the physician is done very seldom. Therefore, the true incidence of headache remains unknown. In general, primary headache disorders constitute nearly 98% of all headaches; TTH and migraine are the most prevalent. TTH

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affects 60–80% of the population, while migraine has a prevalence of 11–15%.[4,5]

Although many patients come to the ear, nose, and throat (ENT) specialists with a headache claiming to have "sinus trouble," in reality, a minority of these individuals found solely nasal headaches or sinus in origin,[6] it is also rarely caused by other secondary reasons though important to be recognized for timely intervention.

Sinonasal etiology of headache and facial pain is often suspected in otorhinolaryngologic, neurologic, or general practice. However, establishing a diagnosis is sometimes challenging, even for experienced physicians. Misunderstandings usually start with patients receiving an incorrect diagnosis or trying to diagnose themselves. In these instances, "sinus headache" (SH) and "sinus facial pain" are suspected. The rationale behind this assumption lies in clinical similarities between rhinogenic and neurogenic headaches: Both may cause pain located directly over paranasal sinuses and both can be accompanied by nasal discharge and congestion.[7] That is why in many cases, SH eventually turns out to be a neurologic disorder misattributed to rhinology diseases, and patients often wait decades for adequate treatment.[8] These observations are supported by the results of a population-based study, where 36.5% of patients fulfilling criteria of migraine had been previously diagnosed with SH. That proportion was even higher (42%) in a similar study conducted almost two decades earlier.[9] Clinical observations confirmed those results: In a retrospective analysis of 130 migraine patients, 81.5% had been previously diagnosed with SH. Consequently, according to some authors, SH is the most common misdiagnosis in migraines.[10]

The prevalence of headaches in ENT patients and its subsequent chances of misdiagnosis are high. Hence, this study was aimed to analyze the incidence of headaches in ENT department patients and various triggering factors for headaches.

Aim of Study

This study aims to study the patients presenting with complaints of headache in the ENT department.

MATERIALS AND METHODS

A total of 100 patients were selected randomly, attending the ENT outpatient department at our site hospital from June 2019 to May 2020. Patients approaching with the first and foremost complaint of headache with a history of recurrent episodes were included within the study. Patients coming with different forms of neuralgic pain in the head-neck region diagnostic of temporomandibular joint, neuralgia, trigeminal neuralgia, glossopharyngeal neuralgia, or atypical facial pain were excluded from the study.

For every case, the characteristics of headache, symptoms, comorbidity associated with it, and complaints related to ENT head-neck region or eye or central nervous system were noted very carefully. Any previous head injury history, past or present medical disorder was also documented in the ready sheet. An inquiry was made about the regular use of drugs, particularly OTC analgesics, oral contraceptives, and herbal medicines. Every patient went through complete ENT head-neck and neurological examinations.

RESULTS

In this study, a total of 100 patients were enrolled randomly from the ENT department. The maximum patients were found in the age group of more than 50 years and least found in the age group of <13 years [Figure 1].

In all patients under study, 28 (28%) were men and 72 (72%) were women. Whereas 10 children's (both genders) were also reported in all patients enrolled for the study [Figure 2].

Analyzing the symptoms of patients under study, it was found that all patients showed the symptoms of headaches.

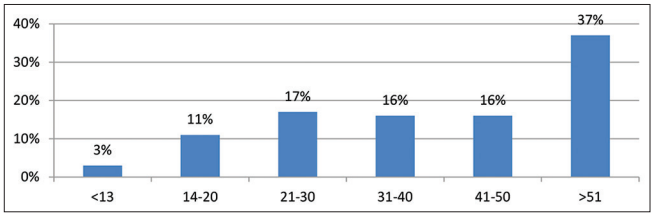

Figure 1: Age distribution of patient (100 patients)

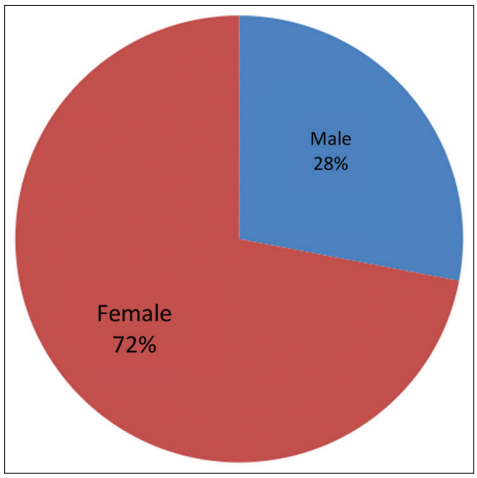

Figure 2: Gender distribution of patients

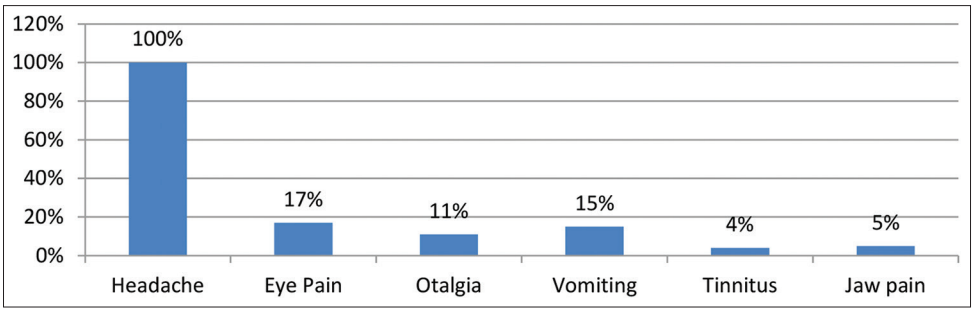

Figure 3: Symptoms of patients

Eye pain symptom was observed in 17% of patients, which is highest after headaches. Tinnitus symptom was observed in the least number of patients (4%) [Figure 3]. About 72% of patients reported headaches for more than 15 days of duration, 11% reported for 8–14 days, whereas 17% reported for <7 days [Figure 4].

In all the study patients, 35% of patients were reported diabetes mellitus (DM), 17% reported hypertension (HTN), whereas only 3% reported cardiac ailments comorbidity with headaches [Figure 5].

When evaluated the various headaches cases reported to the ENT department, it was found that the maximum cases were ophthalmic related (17%), followed by septal spar. Whereas least cases were reported of temporal arteritis headaches (2%) [Figure 6].

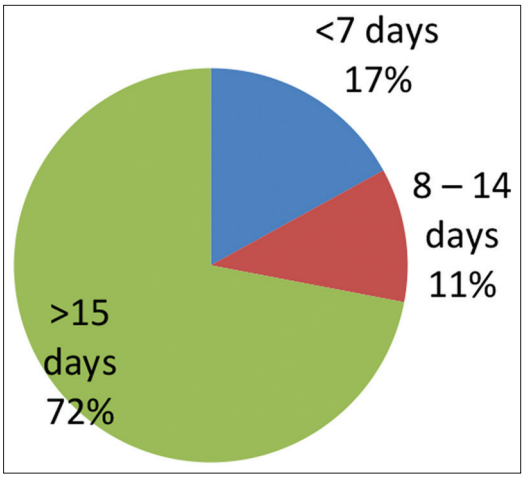

Figure 4: Duration of headaches in patients

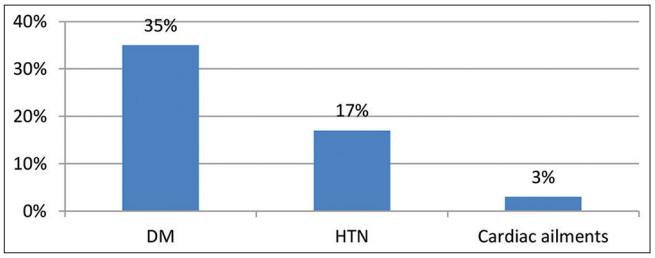

Figure 5: Comorbidity in patients

DISCUSSION

Headaches are a common complaint among the public; the WHO estimates the prevalence of headaches among adults at 47%, with half to three-quarters of adults aged 18–65 years experiencing headaches in the year 2020.[1]

The prevalence of headaches increased with an increase in age, reaching a maximum in the age group of more than 50 years (37%). Our study's findings are contrary to Ahmed *et al.*, where there was an increase in the prevalence of headaches from the age group of 11–20 years (31.67%) to 31–40 years (37.16%). A significant decrease in headaches incidence was observed in the higher age group, 6.66 % in 41–50 years and 0.84% in 51–60 years.[11]

Females are seen as sufferers of headaches more than males, as evidenced by various literature studies with headaches' epidemiology. In this 72%, women were observed with headaches in comparison to 28% in men.[12]

Eye pain (17%) and vomiting (15%) were the most common symptom found in patients in our study. Whereas tinnitus (4%) and jaw pain (5%) were reported least. These findings are in accordance with various clinical studies done for the evaluation of symptoms of headaches.[13,14]

A significantly high percentage of patients (72%) experienced headaches for more than 15 days; it might be due to comorbidity associated with patients. As in our study, 35% of patients suffered from DM, 17% HTN, and 3% cardiac ailments and these in these condition headaches are very common. These comorbidities in patients could have increased the duration of headaches in patients.[15]

In this study, the headache patients approaching the ENT department diagnosed as having ophthalmic-related problems highest (17%) followed by septal spur (16%) and allergic headaches along with vestibular migraine (both 15%). This might be due to an ophthalmic patient

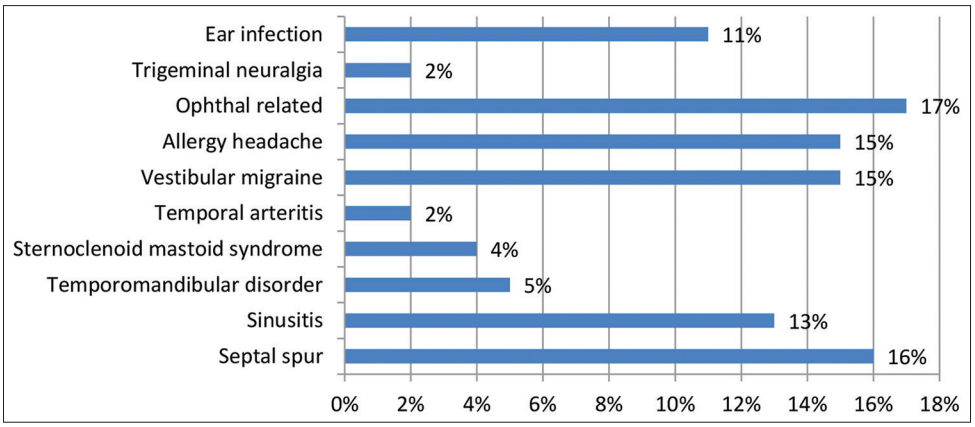

Figure 6: Various headaches cases reported in ear, nose, and throat department

experiencing pressure on the eyes increasing tendency to headaches.[16]

CONCLUSION

Headaches are one of the common complaints in ENT department patients. The presence of comorbidity could increase the duration of headaches. Most patients are suffering from either vascular or muscular headaches, though diagnosed by a medical person or self as having SH. A group of doctors consisting of ENT specialists, neurologists, ophthalmologists, psychiatrists, and psychologists can bring many benefits to remove or cut short the sufferings of headaches patients.

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Original Article

To Study the Incidence of Serious Otitis Media in Allergic Rhinitis Patients

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Abstract

Introduction: The prevalence of serious otitis media (SOM) in children with persistent allergic rhinitis (AR) in different countries varies between 82% and 93%. Many risk factors of otitis media with SOM have been studied and proven. However, its association with AR remains controversial.

Aim: The aim of the study was to determine the incidence of SOM in patients with AR.

Methods: It was a cross-sectional study performed in our site hospital from the period of August 2019 to July 2020. A total of 100 patients meeting inclusion criteria were randomly selected from the ENT department of our site hospital for the study. Patients with acute upper respiratory tract infection within a couple of weeks and those with craniofacial malformations or with significant ear wax were excluded from the study.

Results: In our study, women showed a higher incidence of SOM in comparison to men. Patients in the age group of 11–30 years were observed with the highest SOM incidence. SOM with perforation incidence was observed maximum in patients especially in women.

Conclusion: A higher frequency of SOM was found in patients with AR. Therefore, patients having AR should also be screened for coexisting conditions like SOM and should be treated along with AR.

Key words: Allergic rhinitis, Incidence, Otitid media, Otitis media with effusion, Serious ototis media

INTRODUCTION

Allergic rhinitis (AR) affects a large number of children and adults in our community and other parts of the world especially developed countries.[1] It affects millions of people in the world, especially the Caucasian races. Asthma and rhinitis are often coexistent in a majority of patients.[2] Some allergens in the air may produce symptoms throughout the year and these affect children's quality of life.

The nasopharyngo-tubal unit or the "unified airspace" consists of the nose nasopharynx and middle ear.[3] The Eustachian tube (ET) plays a pivotal role in the pathophysiology of diseases related to this region. It is responsible for aeration, clearance, and defense of the middle ear. It stops the traveling of infectious secretions from the naso-opharynx to the middle ear.[4]

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The drainage of secretions from the middle ear is carried out by the mucociliary transport (MCT) system, which is localized in the cartilaginous portion of the ET. The functioning of the MCT system of the ET is enhanced by the surface tension lowering substance, which allows the rolling of the mucus. The periodical opening of the ET fibro-cartilaginous portion prevents the aspiration of inflammatory or infectious secretions from the rhinopharynx. Furthermore, the ET is provided with specific defense mechanisms by antimicrobial substances such as lysozymes and by resident microbial flora which competes with pathogens. The local lymphoid tissue is scattered in the superficial layer of the chorion of the cartilaginous portion and is particularly plentiful around the pharyngeal ostium.[5]

AR causes congestion of mucosa of ET resulting in ET dysfunction which is pivotal to the development of otitis media with effusion (OME) called serious otitis media

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(SOM). SOM is the most frequent cause of hearing loss and delayed speech development in children and adults.[6] SOM may result from multiple factors such as a bacterial infection, poor clearance, local inflammation, or atopy.[7] Many animal studies have proposed a relation between AR inflammation and ET dysfunction. A nasal allergy-induced in rats caused ET congestion and negative pressure resulting in the stoppage of mucociliary clearance.[8] Hence, a link between AR and SOM has been proposed. SOM has a close association with allergic diseases.[9] This warrants an increased awareness of SOM in children with AR. In a study done on children aged 4–14, it was reported that 7.5% of children with AR had OME.[10] In another study, secretions of the middle ear showed a higher number of eosinophils and T-lymphocytes in atopic patients with SOM in comparison with non-atopic individuals.[11] For the management of SOM, intranasal corticosteroids having limited systemic absorption are safer than oral corticosteroids and their use results in quicker resolution of SOM.[12]

The rationale of this research is to determine the frequency of SOM in patients with AR. If we find a high incidence, then in the future children with AR can be screened for OME, and hence they can be treated along with AR.

METHODS

This cross-sectional study was performed in our site hospital from the period of August 2019 to July 2020 after taking prior permission from the ethical committee. A total of 100 patients meeting inclusion criteria were randomly selected from the ENT department of our site hospital for the study. All patients enrolled in the study consisted of 12 children (below age 15 years) of which nine were male and three were female. Patients of either gender having AR, diagnosed at least 1 year ago, were included in the study. The study was explained to patients and guardians of children's then informed consent was obtained.

Patients with acute upper respiratory tract infection within a couple of weeks and those with craniofacial malformations or with significant ear wax were excluded from the study. All cases having AR underwent clinical examination using tympanometry to diagnose SOM as per operational definition.

RESULTS

A total of 100 patients from period of August 2019 to July 2020 were enrolled for study. The age of patients in our study was divided in to 4 age group categories, that is, <10 years, 11–30, 31–40, and 41–50 years. The data showed that maximum incidence of SOM was observed in age group of 11–30 years (37%). AR incidence observed least in <10 years and 41–50 years group (both 12%) [Table 1].

In our study, female patients showed higher incidence of SOM (61%) in comparison to men (39%) [Table 2].

Table 3 depicts the incidences of type of SOM in AR patients. From the data, it can be inferred that female patients showed more incidence of SOM of both type, that is, with perforation and without perforation in comparison to men, whereas incidence of Bulging tympanic membrane (TM) with ear pain type SOM was observed in men more than in women. While evaluating incidence in children's, it was found that SOM with perforation was observed in eight children's whereas SOM without perforation and Bulging TM with ear pain was observed in two children's in both cases.

DISCUSSION

AR is a long-standing disease in which there is an allergic hypersensitivity response of the upper airways to allergens in the air. Coexistent morbidities in patients with AR include asthma, rhinosinusitis, SOM, and sleep disturbance.[13] Studies on the pathogenesis of SOM have pointed to an interplay between infection, allergy, and ET dysfunction.[14] A study was done by Martines *et al.* in two groups of children (atopic and non-atopic) revealed that atopic children are more likely to develop OME and to have worse hearing loss than non-atopic children's.[15]

Table 1: Age distribution with frequency of SOM

Age group	Frequency
<10	12
11–30	37
31–40	29
41–50	12

SOM: Serious otitis media

Table 2: Gender distribution and frequency of SOM

Gender	Frequency
Male	39 (9 children's)
Female	61 (3 children's)

SOM: Serious otitis media

Table 3: Incidence of SOM in AR patients

Incidence	Males	Females	Children
SOM with perforation COM	14	25	8
Bulging TM with ear pain	6	3	2
SOM without perforation	10	30	2

SOM: Serious otitis media, TM: tympanic membrane, COM: Chronic otitis media, AR: Allergic rhinitis

In our study, patients from age ranging from 10 to 50 years were analyzed and patients in the age group of 11–30 years showed the maximum incidence of SOM (37%) whereas patients with age of 10 years showed the least incidence of SOM (12%). The findings in our study are in contradiction to the study done by Norhafizah *et al.* where the maximum incidence of SOM was observed in the age group of 4–8 years of age (53.8%) and least in the age group of 14–18 years (12.3%).[16]

Female patients in our study showed more incidence of SOM (61%) than men (39%) which is in accordance with the study done by Riaz *et al.*, in which female patients observed 54.8% SOM incidence and men observed 45.2%.[17]

Analyzing the incidences of types of SOM in all patients, it was found that SOM with perforation chronic otitis media was observed maximum (47%), followed by SOM without perforation (42%). The women showed maximum incidences of both SOM with or without perforation in comparison to men. These findings are in accordance with various clinical studies done for SOM.[18]

CONCLUSION

As per the findings of this study, there is a high prevalence of SOM in AR patients. Hence, the cases of AR should also be screened for co-existing conditions like SOM and should be treated along with AR.

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Original Article

A Study of Clinicopathological Patterns of Anemia in Different Groups of Schoolchildren

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Abstract

Introduction: Anemia is a global public health problem affecting both developing and developed countries with major consequences for human health as well as social and economic development.

Aims and Objectives: This study is intended to be carried out with an aim to determine prevalence pattern and various hematological as well as morphological types of anemia in children.

Materials and Methods: Prospective observational study including children from the age 5 to 15 years from selected day schools and residential schools in Warangal. Period of study was from December 2018 to November 2020.

Discussion: Anemia makes individual susceptible to various health-related risks including infection anemia in childhood and infancy has long-lasting neural and behavioral effects too apart from delaying and impairing the growth.

Aims of Study: The number of subjects was less as compared to other studies as consent to draw blood was given in limited number of children and study was conducted in only few schools.

Results: This study has pointed out that the problem of anemia is widespread especially among residential schoolchildren, especially among boys rather than commonly considered groups of lactating and pregnant women.

Conclusion: In the present study, prevalence of anemia is higher in 5–10 years age group, with a mean age group of 8.6 ± 2.4 years. Male preponderance is observed in our study.

Key words: Anemia, Nutritional status, Prevalence, Risk factors

INTRODUCTION

Anemia is a global public health problem affecting both developing and developed countries with major consequences for human health as well as social and economic development. Anemia is a condition in which the hemoglobin in the blood is below the normal range appropriate for age and sex.[1] Anemia is the most widespread global issue prevalent in the developing nations like India, particularly in children and females.[2,3]

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According to estimate carried out between 1993 and 2005 by the WHO, prevalence of anemia in preschool children was 47.4% and school-aged children was 25.4%, while that of preschool children from Southeast Asia as per the WHO region was 65.5%. As per data in 2013, anemia has caused over 183,000 deaths.[4] Etiology of anemia is multifactorial. Although the extent of the developmental difficulty varies with individual child, studies have shown that marked iron deficiency can cause CNS damage.[5] If anemia is left un treated, it will lead to reduced body functions, decreased performance, slow down normal physiology, increased comorbidities, and mortality.[6] As anemia accounts for significant morbidity and mortality and in view of not enough studies done comparing prevalence of anemia among residential schoolchildren and day schoolchildren, there is a need for study to know the prevalence of nutritional anemia.

The present study was undertaken to evaluate the hematological and biochemical parameters to aid in

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understanding clinicopathological patterns of anemia and their causes in schoolchildren and to determine the prevalence of various morphological types of anemia in two different groups of schoolchildren.

Aims and Objectives

Aims

This study is intended to be carried out with an aim to determine prevalence pattern and various hematological as well as morphological types of anemia in children.

Objectives

The objectives of the study were as follows:

1. To assess case burden and various etiologies of anemia
2. To detect morphological types of anemia prevalent among schoolchildren.

MATERIALS AND METHODS

Study Design

Prospective observational study including children from the age 5 to 15 years from selected day schools and residential schools in Warangal.

Study Period

The study period was from December 2018 to November 2020.

Source of Data

Children of age group from 5 to 15 years who are clinically diagnosed as anemic are studied from December 2018 to November 2020 at hostels in Warangal shall be selected for the present study.

Inclusion Criteria

Children of age 5–15 years among day and residential schools were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

1. Age below 5 years and above 15 years
2. Children with primary hematological disorders involving diseases of WBCs, platelets, and hereditary anemia
3. No consent.

Sample Size

A total of 210 children from the age 5 to 15 years from selected day schools and residential schools were included in the study.

Method of Data Collection

Informed consent was obtained from the parents, and the Institutional Ethical Committee approved the study protocol. The data regarding socioeconomic status, nutritional status, and dietary habit were collected with the help of junior residents and school teachers. The pro forma also included information on the known medical problems of child if any. All children were weighed and taken as under nourished according to Indian Academy of Pediatrics criteria.

During physical examination, the following signs and symptoms were noted: Pallor, edema, clubbing, skin (dryness, rashes, and irritation), abnormal pigmentation, coarse hair, puffiness of face, thinning of eyebrows, nail defects, eyes, and face.

Venous blood was drawn from all the patients with clinical pallor and every sample was analyzed for hemoglobin (Hb) concentration, hematocrit, erythrocyte indices (mean corpuscular volume, mean corpuscular hemoglobin, and mean corpuscular Hb concentration), differential count, erythrocyte sedimentation rate, and red cell distribution width. Serum iron levels, total iron binding capacity, serum ferritin, and serum Vitamin B12 levels were done wherever necessary. Peripheral blood film was prepared using Leishman's stain. The red blood cell morphology was studied. Grading of anemia among different age groups was done using the WHO Hb concentrations for the diagnosis of anemia and assessment of severity criteria. Microscopic evaluation of blood was also done to obtain the microscopic picture. Stool samples were obtained and were evaluated under microscope to rule out intestinal parasitic infections.

OBSERVATIONS AND RESULTS

The present study is carried out in 210 children in the age group of 5–15 years. 5–10 years children were found to be most affected, constituting 72.40% followed by 27.60% of 10–15 years children. The average age effected was 8 years and 6 months with a standard deviation of 2.471.

Out of the 210 children studied, 117 (55.70%) were male and 93 (44.30%) were female. Distribution of male and female children is almost equal in day scholar and residential schools with no statistical significance ($P = 0.0507$).

Economic status is evaluated using modified Kuppuswamy scale. Out of 210 children studied, 109 (51.90%) children have low socioeconomic background and 101 (48.10%) are in middle class. There is no significant difference in socioeconomic status in two groups of schoolchildren ($P = 0.129$).

Out of 95 (45.20%) children of lower upper class, 52 (24.80%) are male, 43 (20.50%) are female. Out of 94

(44.80%) children of lower middle class, 50 (23.80%) are male, 44 (21%) are female. Overall in lower socioeconomic classes, male children were higher in number but statistically *P*-value is not significant (0.388).

In our study, anemia was found to be higher in non-vegetarians constituting 148 (70.50%) than vegetarians 62 (29.50%), in both day and residential schoolchildren. However, this finding is not significant statistically ($P = 0.901$).

Out of 148 (70.50%) children who consume non-vegetarian diet, 85 (40.50%) are male and rest are female constituting 63 (30%). Out of 62 (29.50%) children who are vegetarians, 32 (15.20%) are male, and rest are female constituting 30 (14.30%).

Out of 210 children, 126 (60%) have BMI between 10 and 50th centile, 27 (12.90%) children have BMI between 5 and 10th centile followed by 22 (10.50%) children have BMI of 3rd centile, with no significant difference in BMI among children with anemia in day and residential schoolchildren.

In the present study, the common presenting symptoms were easy fatiguability 174 (82.9%) and pica 20 (9.5%) which is more in females (5.20%) when compared to males (4.30%). Other symptoms such as hair loss, rapid heartbeat, decreased concentration, and headache were found only in few children with moderate and severe grades of anemia.

In the present study, most common sign was pallor constituting 47.6%. Other signs include bald tongue (6.1%), hypopigmented hair (3.33%), and nail changes, that is, koilonychia and platynychia constituting (2.8%).

In the present study, majority of them 82 (39%) had moderate anemia followed by 44 (21%) children had mild anemia and 18 (8.6%) had severe anemia. Incidence of moderate and severe anemia in residential schoolchildren is higher than day schoolchildren, which was found to be statistically significant with $P = 0.043$.

Among 210 children, 144 children had anemia, therefore, in the present study, total prevalence of anemia is 68.57%. Among 102 (48.57%) children of 5–10 years, 31 were found to have mild anemia, 57 had moderate anemia, and 14 had severe anemia. Out of 42 (20%) children among 11–15 years, 13 had mild anemia, 25 had moderate anemia, and 4 had severe anemia. In the present study among all age groups, moderate anemia is more common. Statistically, this association between age and severity of anemia was not found significant ($P = 0.879$) [Tables 1-6].

DISCUSSION

Anemia makes individual susceptible to various health-related risks including infection. Anemia in childhood and infancy has long-lasting neural and behavioral effects too apart from delaying and impairing the growth. A number of studies on anemia in children have been performed; however, they focus on the prevalence and severity of anemia. Moreover, there are limited or almost no studies available comparing this problem in children aged 5–15 years in day and residential schools. Hence, the present study was planned, evaluating the clinic pathological profile of anemia in two groups of schoolchildren and also to know the influence of factors such as age, sex, socioeconomic status, and diet in day schools and residential schoolchildren.

This is a prospective observational study conducted from December 2018 to November 2020 among 5–15 years anemic children from randomly selected schools in Warangal.

A total of 210 children free of any hematological disorder affecting white blood cell and platelet counts were enrolled in the study. In the present study, we used the WHO criteria for the assessment of severity of anemia.

Data analysis done, results depicted in tables and figures. At the completion of the study, results were tabulated and analyzed. The results are compared with other studies on anemia in schoolchildren and discussed as below.

The age group included in our study was similar to the study done by Kumar *et al.* Male:female distribution is similar to studies done by Muthuraman *et al.* and Jain *et al.*

In the present study, maximum number of cases were aged 5–10 years followed by those aged 11–15 years. Mean age of children affected with anemia was 8.6 ± 2.4 years.

Comparison of Prevalence of Anemia

Studies	Muthuraman *et al.*	Jain *et al.*	Present study
Prevalence	20%	56.5%	68.57%

In our study, the prevalence of anemia was 68.57% which was similar to the prevalence of Jain *et al.* study. In Muthuraman *et al.* study, the prevalence was 20%, including wide age group and more number of subjects.

Comparison of Gender Distribution in Anemic Children

Studies	Muthuraman *et al.* (%)	Ramanastry *et al.* (%)	Kumar *et al.* (%)	Present study (%)
Male	61.2	36.37	53.36	55.7
Female	38.8	63.63	46.64	44.3

In the presents study, majority of anemic children were male (55.7%), similar findings are seen in Sumanth Kumar and Muthuraman study. However, no significant association between anemia severity and gender could be seen. Saba *et al.* in their study have shown 58.4% of males being affected. Muthusamy *et al.* in their study had 55.6% affected males. Chhabra *et al.* in their hospital-based study reported the dominance of males (64.4%). However, Sharma *et al.* found majority of anemic children to be girls (51.4%).

Comparison of Socioeconomic Status in Anemic Children

Study	Kumar *et al.* (%)	Present study (%)
Upper class	3.37 (class 1)	-
Middle class	33.17 (class 2+3)	44.8 (class 3)
Lower class	63.46 (class 4+5)	45.20 (class 4)

In this study, the prevalence of anemia was more in lower socioeconomic class, as a total number of children in Class 3 and Class 4 socioeconomic classes are more in our study. These findings are comparable with Sumanth Kumar study.

The lower socioeconomic status of the parents also has been reported as a major risk factor for the development of anemia. Rani and Bandrapalli (2017) have also reported that with the improvement of socioeconomic status, the prevalence of anemia decreases, the high prevalence of anemia was reported in children belonging to class 4th contrast, Chopra *et al.* (2011) have observed a high prevalence of anemia among children belonging to the upper and upper middle socioeconomic class.

Dietary factors play an important role in the development of iron deficiency anemia. A significant correlation has been reported between severe malnutrition and less protein consumption with iron deficiency anemia.

In our study, it was noted that among anemic children, 22.8% take vegetarian diet while majority of them 45.7% take non-vegetarian diet. Reason for this could be less frequent intake of non-veg food or habit of drinking tea or coffee along with major meals. Studies have shown that patients who take less than 2 servings of the red meat per week are more prone to develop IDA. The inhibitory effect of tea and coffee on absorption of iron is well proven. Desalegn *et al.* (2014) have reported that children who do not consume protein rich food are more likely to develop iron deficiency anemia than those who consume protein-rich foods. In a study of Chaturbedi *et al.* (2017), have observed that in vegetarians, anemia was higher than non-vegetarians. In addition, they have also pointed out that post-meal consumption of tea and coffee had increased association with anemia.

In the present study, major presenting complaints included easy fatiguability (82.9%), pallor (47.6%), and pica (9.5%). Similar to our study, weakness and pallor have been reported to be the common findings in different studies similar to our study, Nalli *et al.* also reported pallor and fatigue as the presenting symptoms in a large majority (87.5% and 72.5%) of their cases. Pica is found in 50% of children in a study conducted by Crosby *et al.* However, according to the WHO, clinically visible pallor appears in children when the Hb level falls below 7–8 g.

The common sign of anemia is characterized by pallor because of reduced oxyhemoglobin concentration in the skin and in the mucous membrane. In severely anemic individual troubled breathing, lightheadedness and hair loss have also been reported. Unnikrishnan *et al.* (2017) classified the study subjects primarily based on the physical examination. In their study, they have shown that depending on the presence of mucosal and conjunctival pallor, nail changes, and associated symptoms, 30% of girls and 20% of boys were successfully identified clinically as having anemia.

In our study, we found that mild, moderate, and severe anemia were 21%, 39%, and 8.60%, respectively. Studies conducted by Sumanth Kumar and Abhay Prakash also had predominant distribution of moderate anemia.

Compared to the findings of the present study, Saba *et al.* in their study also showed mild, moderate, and severe grades of anemia in 12.7%, 75.82%, and 11.43% of patients, respectively, thus showing a dominance of children with moderate anemia as observed in the present study. While, studies conducted by Muthuraman and Ramanasastry had predominant distribution of severe anemia.

The role of socioeconomic factors, regional differences, and other demographic factors could also affect the profile of severity of anemia in different studies.

Table 1: Age-wise distribution in study population

Age group (years)	Frequency	Percentage
5–10	152	72.40
10–15	58	27.60
Total	210	100

Table 2: Gender-wise distribution in study population

School	Gender (%)		Total (%)	Chi-square	*P*-value
	Male	Female			
Residential school	55 (26.20)	48 (22.90)	103 (49)	0.44	0.507
Day scholar	62 (29.50)	45 (21.40)	107 (51)		
Total	117 (55.70)	93 (44.30)	210 (100)		

Table 3: Socioeconomic status distribution in study population

Socioeconomic status	School (%)		Total (%)	Chi- square	*P*-value
	Residential	Day scholar			
Middle upper (class 2)	4 (1.90)	3 (1.40)	7 (3.30)	5.663	0.129
Middle lower (class 3)	45 (21.40)	49 (23.30)	94 (44.80)		
Lower upper (class 4)	43 (20.50)	52 (24.80)	95 (45.20)		
Lower lower (class 5)	11 (5.20)	3 (1.40)	14 (6.70)		
Total	103 (49)	107 (51)	210 (100)		

Table 4: Association between socioeconomic status and gender

Socioeconomic status	Gender (%)		Total (%)	Chi-square	*P*-value
	Male	Female			
Upper middle	6 (2.90)	0.50 (14.30)	7 (3.30)	3.064	0.388
Lower middle	50 (23.80)	44 (21)	94 (44.80)		
Lower upper	52 (24.80)	43 (20.50)	95 (45.20)		
Lower lower	9 (4.30)	5 (2.40)	14 (6.70)		
Total	117 (55.70)	93 (44.30)	210 (100)		

Table 5: Distribution of dietary habits in schoolchildren

Food	School (%)		Total number and %	Chi- square	*P*-value
	Residential	Day school			
Veg	30 (14.30)	32 (15.20)	62 (29.5)	0.015	0.901
Non-veg	73 (34.80)	75 (35.70)	148 (70.50)		
Total	103 (49)	107 (51)	210 (100)		

Table 6: Association between gender and dietary habits

Food	Gender		Total	Chi- square	*P*-value
	Male	Female			
Veg	32 (15.20)	30 (14.30)	62 (29.50)	0.6	0.439
Non-veg	85 (40.50)	63 (30)	148 (70.50)		
Total	117 (55.70)	93 (44.30)	210 (100)		

The majority of children in this study is found to have iron deficiency anemia constituting for 137 (65.23%) out of 210 and 7.6% megaloblastic anemia**.** The prevalence of iron deficiency anemia in the present study is similar to prevalence in studies conducted by Gomber *et al.*, Kuamr *et al.*, and Muthuram *et al.* and Sastry *et al.* studies have slight higher prevalence than the present study.

Serum ferritin levels are low in iron deficiency anemia children, this finding correlates with the studies done by Shine *et al.* who concluded that low serum ferritin is the best single laboratory parameter to diagnose iron deficiency.

Limitations of the Study

1. The number of subjects was less as compared to other studies as consent to draw blood was given in limited number of children and study was conducted in only few schools
2. The descriptive diet assessment was not possible in this study. A detailed analysis of the dietary assessment was needed to point out the exact association between the diet and the anemia
3. Only few stool samples were evaluated as the parents and children were reluctant to provide the stool sample for the study
4. The small study sample had made the scope of his study limited. A prospective longitudinal study multicenter study is needed to validate the findings observed in this study.

CONCLUSION AND SUMMARY

- In the present study, the prevalence of anemia is higher in 5–10 years age group, with a mean age group of 8.6 ± 2.4 years
- Overall prevalence of anemia was 68.57%
- Male preponderance is observed in our study
- Non-vegetarian children are more affected compared to their vegetarian counterparts
- Children belonging to middle and lower socioeconomic class (Class 3 and 4) have higher prevalence of anemic
- Easy fatiguability is most common symptom which is more observed in female children than males and pallor is the most common sign
- Among anemic children in all age groups, moderate anemia is more common. Proportion of mild-moderate and severe anemia was 39%, 21%, and 8.6%, respectively
- Among day school and residential schoolchildren, who are anemic, majority are non-vegetarians with moderate grade anemia

- Residential schoolchildren are more anemic than day schoolchildren
- Among residential schoolchildren, males are more affected than females
- Mean Hb among day schoolchildren is 10.7 ± 1.6 and residential schoolchildren is 9.9 ± 1.6
- Mean MCV among day schoolchildren is 75.8 ± 6.9 and residential schoolchildren is 73.7 ± 6.8
- Mean MCH among day schoolchildren is 24.9 ± 3.6 and residential schoolchildren is 24.3 ± 3.3
- Microcytic hypochromic anemia is most common morphological form followed by normocytic normochromic anemia
- Iron deficiency anemia is most common cause of anemia among schoolchildren.

SUMMARY

1. This study has pointed out that the problem of anemia is widespread especially among residential schoolchildren, especially among boys rather than commonly considered groups of lactating and pregnant women
2. Awareness of anemia is very poor in school-going children. Nutrition and health education session should be conducted in school with teachers and parents' involvement to raise awareness regarding anemia and WIFS program
3. Awareness creation on water and sanitation and nutritional counseling to parents on consumption of iron-rich foods and iron supplementation to prevent anemia among young children with special emphasis on those from low-income group and socioeconomic deprived communities.

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Original Article

Study of Intrauterine Contraceptive Device Acceptance in Postpartum Period – A Retrospective Study

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Abstract

Introduction: Postpartum period is defined to be an ideal time for family planning counseling. Being the second-largest populated country, India has a high rate of unintended pregnancy, especially in postpartum women. There is a need for accessible, reliable contraception like postpartum intrauterine contraceptive device (PPIUCD) in our country. The present study attempts to determine the safety and complication of intrauterine devices in postpartum women.

Materials and Methods: This retrospective study was done in the department of obstetrics and gynecology in January 2021. After delivery, women who had accepted PPIUCD (vaginally or by lower segment cesarean section) were included in this study. With the help of data collected, relevant parameters were critically analyzed in our study.

Results: A total of 438 deliveries took place, out of which only 412 were inserted PPIUCD. Hence, the total acceptance rate was 94%. The majority of cases were below the age of 25 (60%) and most of them were primipara (65%). In our study, menorrhagia (4%) was the most common complication.

Conclusion: The IUCD insertion has been proven to be a safe and effective contraceptive method with very few side effects and no major complications.

Key words: Contraceptive, Lower segment cesarean section, Postpartum intrauterine contraceptive device, Postpartum

INTRODUCTION

Women in India have used intrauterine contraceptive devices (IUCDs) for decades for spacing pregnancies. It is the most commonly used reversible method of contraception worldwide, with about 127 million current users.[1,2] According to the National Family Health Survey (NFHS) 4 data, the contraceptive prevalence rate in India is 56.3% and more than 40% of the couples are not using any contraception method.[3,4] Approximately 27% of births in India occur <24 months after a previous birth. Another 34% of births occur between 24 and 35 months; 61% of births in India occur at intervals shorter than the recommended birth-to-birth interval of approximately 36 months.[5] Short intervals between births are linked with higher maternal and child mortality and morbidity.[6] The postpartum period is a highly vulnerable period for unintended pregnancy as there are limited contraceptive options for breastfeeding mothers. Immediate postpartum is the ideal time to begin contraception as women in this period are more receptive to family planning advice. Postpartum family planning (PPFP) prevents unintended and closely spaced pregnancies through the first 12 months following childbirth.[3] Studies show that pregnancies taking place within 24 months of previous birth have a higher risk of adverse outcomes such as abortions, preterm labor, postpartum hemorrhage, low birth weight babies, fetal loss, and maternal death.[7]

According to NHF-4, In India, 78.9% of deliveries are institutional delivery. With increasing numbers of women electing to give birth in health institutions, India's

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government decided to strengthen PPFP and introduced postpartum IUCD (PPIUCD) services in a phased manner. The provision of PPIUCDs is rapidly scaled up in India. The Government of India is promoting institutional deliveries through programs like Janani Suraksha Yojana. This program scheme has increased the institutional deliveries rate and postpartum care in government hospitals. Hence, it allows the health-care providers to counsel women regarding PPIUCD insertion.[8]

The present study was planned to describe the experience of immediate postpartum IUCD in women delivering vaginally and lower segment cesarean section (LSCS).

Aim

The aim of the study was as follows:

- To determine the proportion of women who had accepted the PPIUCD insertion related to age, parity, and mode of delivery.
- To determine the complications/complaints of immediate PPIUCD insertion among patients who had accepted the device.

MATERIALS AND METHODS

This retrospective study was done in the department of obstetrics and gynecology in January 2021.

Inclusion Criteria

Woman who had accepted immediate postpartum (after removal of the placenta) IUD insertion following delivery (vaginally or by LSCS) was included in the study.

Exclusion Criteria

Women were excluded from having anemia (hemoglobin <10 g/dl), PPH, premature rupture of membranes >18 h, obstructed labor, fibroid, congenital malformation of uterus, active sexually transmitted disease, lower genital tract infection, and allergy to copper.

Skilled obstetricians did the insertion of PPIUCD under asepsis after informed consent. The standard infection prevention protocols were followed. Insertion of IUCD was done postplacental, intracesarean, and immediate postpartum. Patients were followed for 2 months. The quality of PPIUCD services provided at the center was assessed and monitored as per the performance standards for immediate PPIUCD counseling and assistance.

RESULTS

During the study period, January 1, 2021–January 31, 2021, the total number of PPIUCD acceptance was 412 out of 438 counseled patients. Of these 412 accepted patients, 60% of patients were from the age group <25 years followed by 32% from 26 to 30 years. Out of 412 patients (total accepted), the majority of acceptance (81%) was observed from the rural location as compared to urban location (19%) [Table 1].

Maximum 65% acceptance was observed among primipara compared to 35% in multipara [Table 2]. Out of total acceptance, 70% of patients accepted PPIUCD following vaginal delivery while 30% accepted PPIUCD LSCS [Table 3].

Among the total accepted patients, 40% and 30% had inserted PPIUCD within 10 min and 48 h after vaginal delivery, respectively, while 30% had inserted after LSCS [Table 4].

Of the 412 patients, 44 had complications/complaints. It was observed that 3% had expulsion, 1 showed infection, 3% had complaint of abdominal pain, and 4% showed menorrhagia [Table 5].

DISCUSSION

According to a WHO report in 2006, better family planning and birth spacing services resulted in better maternal and neonatal outcome. When promoted in countries with high birth rates, 32% of all maternal deaths and over 1 million deaths of children under five could be prevented. Healthy timing and spacing of pregnancies have a positive effect on maternal health and newborn outcomes.[2,9]

The IUD is more effective than oral contraceptives at preventing pregnancy and it is reversible. Once it is

Table 1: Acceptance of postpartum intrauterine contraceptive device in relation to age group

Total deliveries	Accepted postpartum intrauterine contraceptive device	Location	Age group	Count	Percent accepted	Total accepted before counseling	Total accepted after counseling
438	412 (94%)	Rural 332 (81%)	<25	248	60%	244 (59%)	168 (41%)
		Urban 80 (19%)	26–30	130	32%		
			31–35	28	7%		
			>36	6	1%		
			Total			412	

Table 2: Acceptance of postpartum intrauterine contraceptive device in relation to parity

Parity	Count	Percentage
Primi	267	65%
Multi	145	35%

Table 3: Acceptance of postpartum intrauterine contraceptive device in relation to mode of delivery

Mode of delivery	Count	Percentage
Vaginal delivery	290	70
Lower segment cesarean section	122	30
Total	412	

Table 4: Acceptance of postpartum intrauterine contraceptive device in relation to insertion time

Insertion time	Count	Percentage
Within 10 min	168	40
Within 48 h	122	30
After lower segment cesarean section	122	30

Table 5: Post-insertion complications

Post-insertion complications	Count	Percentage
Expulsion	12	3
Infection	4	1
Abdominal pain	12	3
Menorrhagia	16	4

removed, fertility returns. (Studies have found no adverse effects on fertility with the current IUDs).[10]

- Unlike the pill, there is no daily routine to follow
- Unlike the barrier methods (spermicides, diaphragm, cervical cap, and the male or female condom), there is no insertion procedure to cope with before or during sex
- Intercourse can resume at any time and as long as the IUD is properly positioned, neither the user nor her partner typically feels the IUD or its strings during sexual activity
- It is the least expensive form of contraception over the long term.

Out of all women who are present in the study, the total acceptance of 412 women was observed most of them were coming from a rural background (81%) and remaining from urban area (19%). The highest rate of acceptance was observed among the age group of below 25 years (60%), which is comparable with studies done by Doley and Pegu,[2] whereas in a study by Maluchuru *et al.*[11] from Guntur, the highest rate of acceptance was among the age group of 30–39 years (27.67%). In this study, the acceptance was higher in primipara (65%) contrary observation was found in a study in North India, by Shukla *et al.*[7] where the acceptance was higher in multipara (68.33%).

Studies by Grimes *et al.*[12] and Borthakur *et al.*[13] GMCH Assam also found higher acceptance among multipara. Goswami *et al.*[14] also found higher acceptance (48%) among multipara, whereas Maluchuru *et al.* found a higher acceptance in primipara, which were 15.42, 71.91, and 15.47%, respectively.[11,15,16]

In our study, the acceptance among LSCS patients and vaginally delivered patients was 30% and 70%, respectively. Whereas Gautam *et al.*[15] observed LSCS – 36.09% and NVD – 11.33% and Jairaj and Dayyala,[3] Telangana, showed LSCS – 43.9%, NVD – 6.3%. Borthakur *et al.*[13] found more than 50% of acceptors among patients undergoing LSCS. In our study, menorrhagia was the most common complication (4%). It is similar to Mishra[17] (23.5%) and Gautam *et al.*[15] (19%). Whereas Maluchuru *et al.*[11] found a missing thread (16%) as the most common complication in their study. In a study in Central India by Kanhere *et al.*,[18] the expulsion was the most common complication (22%). Hence, PPIUCD was reported to be one of the safe and effective methods.

CONCLUSION

This study found a good acceptance of PPIUCD among women participants. Thus, immediate postpartum IUCD insertion appears to be a safe and effective contraceptive method with very few side effects and no major complications.

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Original Article

Evaluation of Modified Alvarado Scoring System in Pre-operative Diagnosis of Acute Appendicitis

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Abstract

Background: Acute appendicitis is the most common surgical cause of emergency laparotomy. Despite more than 100 years of experience, accurate diagnosis still evades the surgeon. The rate of negative appendicectomy has been reported to be between 20 and 30%. Surgeons have been resorting to various scoring systems to aid in diagnosis and operative decision-making.

Aims and Objectives: The aim of this study is to review the usefulness of modified Alvarado scoring system and to evaluate its feasibility and value as an aid to surgical diagnosis and in reducing the number of negative laparotomies.

Methodology: A study of 50 patients presenting with pain abdomen and diagnosed provisionally as acute appendicitis was undertaken. Depending on individual presentation, a score was calculated for each case, from nine values (based on modified Alvarado system). Operative and conservative intervention was undertaken in patients with scores between 5–9 and <5, respectively. When surgery was done, the appendix specimen was sent for holoprosencephaly. An attempt was made to correlate the clinical presentation with pathological findings.

Results and Observations: In our study, males were predominant in number, in the ratio of 1.7:1 with females. Out of 44 who were operated, 36 had appendicitis and 8 had normal appendix with other diseases. The overall sensitivity of the MASS was 87.87%. Males had a sensitivity of 90.62% and females had sensitivity of 72.22%. After application of the scoring system, the overall negative appendicectomy rate was 16%.

Conclusion: Modified Alvarado scoring system significantly reduced the rate of negative appendicectomy. It can be applied in routine practice, even in district general hospitals with minimal laboratory facilities. It has greater sensitivity in adult males than in females.

Key words: Acute appendicitis, Modified Alvarado score, Sensitivity

INTRODUCTION

Acute appendicitis is the most common surgical cause of emergency laparotomy. Simple appendicitis can progress to perforation, which is associated with a much higher morbidity and mortality, and surgeons have, therefore, been inclined to operate when the diagnosis is probable rather than wait until it is certain.[1] The surgical principle about acute appendicitis *"when in doubt, take it out"* is not correct in view of the number of major and minor complications following appendicectomy. Despite more than 100 years experience, accurate diagnosis still evades the surgeon. Due to its myriad presentations, acute appendicitis is a common but difficult diagnostic problem. The accuracy of the clinical examination has been reported to range from 71% to 97% and varies greatly depending on the experience of the examiner.[2] However, because missed ruptured appendixes have dire consequences, surgeons have traditionally accepted 20% rate of negative findings at appendectomy and the removal of a normal appendix.[3] The rate of negative appendectomy (removal of a normal appendix in patients with other causes of abdominal pain) is reported to be between 20% and 30%.[3,4]

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The classical signs and symptoms of acute appendicitis were first reported by Fitz[5] in 1886. Since then, it has remained the most common diagnosis for hospital admission requiring laparotomy.[6,7] Approximately 6% of the population will suffer from acute appendicitis during their lifetime, therefore, much effort has been directed toward early diagnosis

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and intervention.[8] This effort has successfully lowered the mortality rate to less than 0.1% for non-complicated appendicitis, 0.6% where there is gangrene, and 5% for perforated cases.[8] The diagnosis of appendicitis can be difficult, occasionally taxing the diagnostic skills of even the most experienced surgeon. Equivocal cases usually require inpatient observation. This delay in diagnosis may increase the morbidity and costs. Attempts to increase the diagnostic accuracy in acute appendicitis have included computer-aided diagnosis, imaging by ultrasonography, laparoscopy, and even radioactive isotope imaging.[9-12] Various scoring systems have been devised to aid diagnosis.[13,14]

The Alvarado score was described in 1986[15] and has been validated in adult surgical practice. The use of an objective scoring system such as the Alvarado system can reduce the negative appendicectomy rate to 0–5%.[15-17]

A scoring system described by Alvarado was designed to reduce the negative appendicectomy rate without increasing morbidity and mortality which was modified by Kalan *et al*.[18]

However, this system is not a substitute for clinical judgment and just an aid in diagnosing acute appendicitis and assists in arriving at a conclusion whether a particular case should be operated or not so that the number of negative laparotomies will be reduced.

AIM AND OBJECTIVE OF THE STUDY

Aim

The aim of this study was to evaluate the sensitivity of modified Alvarado scoring system in the diagnosis of acute appendicitis in adults.

Objective

The objective of the study was to evaluate its feasibility and value as an aid in surgical decision-making in cases of possible appendicitis and in reducing the number of negative laparotomies.

METHODOLOGY

A prospective study of 50 patients who were ill enough to warrant surgery for suspected appendicitis admitted in Government Medical College, Siddipet, under various surgical units was conducted during a period from January 2019 to January 2020.

Inclusion Criteria

Patient coming to hospital with pain abdomen and diagnosed provisionally as acute appendicitis and are willing for surgery are included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

- Patient coming to hospital with pain abdomen along with distention of abdomen
- Pregnant females
- Any mass per abdomen
- Patient with previous history of any abdominal surgeries
- Patient not willing for surgery.

Depending on individual presentation of signs and symptoms, a score was calculated for each case of suspected appendicitis from nine values (based on modified Alvarado system).

OBSERVATIONS AND RESULTS

Study Design

A prospective clinical study consisting of 50 acute abdomen cases that were ill enough to warrant surgery for suspected appendicitis is undertaken to evaluate the sensitivity of modified Alvarado scoring system with respect to its diagnostic accuracy.

Statistical Methods

Fisher's exact test has been used to find the significance of scoring system of appendicitis in male and female in conformation with holoprosencephaly (HPE). The odds ratio has been used to find the strength of relationship between scoring system with HPE. Diagnostic statistics has been used to find the diagnostic value of scoring system in diagnosing for appendicitis [Tables 1-8].

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. Although there are lots of advances in the diagnostic field with the invention of sophisticated investigations, diagnosis of acute appendicitis remains an enigma for the attendant surgeon. None of the investigations such as ultrasound, computed tomography, and nuclear magnetic resonance can conclusively diagnose appendicitis.

Time and again, it has proved that some of the investigations already discussed are costly, time consuming, require more sophisticated equipment, and expertise, while some are not feasible and not readily available.

Hence, even today, a thorough clinical examination with basic investigations like white blood cell (WBC) count

remains cornerstone in the diagnosis of acute appendicitis. With this background, many eminent surgeons and physicians have been adopting different scoring systems to decrease negative appendicectomy.

Although there has been some improvement in the diagnosis of acute appendicitis over the past several decades, the percentage of normal appendices reported in various series varies from 8 to 33%.[14,16] Clinical scoring systems have proved useful in the management of number of surgical conditions. In the past few years, various scores have been developed to aid the diagnosis of acute appendicitis. Although many diagnostic scores have been advocated, most are complex and difficult to implement in the clinical situation. The Alvarado score is a simple scoring system that can be instituted easily. To be useful, a scoring system must be both sensitive and specific.

The modified Alvarado score proved to be effective in one study in adult patients with acute appendicitis. The modified Alvarado scoring system is simple to use and easy to apply, since it relies on history, clinical examination, and basic laboratory investigations.

The present study was undertaken to evaluate the usefulness of modified Alvarado scoring system in reducing the number of negative appendicectomy and to evaluate the sensitivity of MASS in the diagnosis of acute appendicitis.

Our results and observations were discussed and compared with various other studies. The age group in which acute appendicitis occurred commonly was between 11 and 30 years. It is clear that incidence is less in younger and older age groups with peak incidence in the 2nd and 3rd decades.

In the present series, the males outnumbered females in the ratio of 1.7:1.

Pain was the most common presenting symptom and has been observed in all the cases (100%) in the present series. The classical shifting of pain from umbilical region to the right iliac fossa (RIF) was seen in all cases.

Next common symptoms observed were nausea/vomiting in 86% of cases and anorexia in 74% of cases.

Burning micturition was seen in 6% and bowel disturbance was seen in the form of constipation (8%) and diarrhea (10%).

Majority of the patients had aching type of pain and some (8%) had colicky pain.

Fever was of low grade with corresponding rise in pulse rate and was present in 74% of cases.

Majority of the patients presented within 24 h after the onset of pain, with most of them presenting between 12 and 24 h of onset of pain.

On clinical examination, tenderness at McBurney's point was the most common sign (92%). Guarding was present in 20% of patients. It was present when the inflammation was severe. Rebound tenderness was present in 68%. In these cases, there was the presence of local peritonitis or when inflamed appendix was more anteriorly placed. Abdominal rigidity in 8% was due to perforated appendix or gangrenous appendix.

Rovsing's sign was positive in 14%. This sign is seen whenever there is inflammation in the RIF. Psoas test was positive in 12% of cases, whereas obturator test was positive in 24% due to retrocecal appendix.

Hyperesthesia was present in 8%, rectal tenderness in 6%. About 4% had appendicular mass.

In the present study, the thin-layer chromatography was increased in 76%, and it was within normal range in 24%.

Plain X-ray abdomen taken in erect posture showed ground-glass appearance in 2 patients, suggestive of diffuse peritonitis. Two patients had fluid levels localized to the cecum. Free gas under the diaphragm was not present in the cases with perforated acute appendicitis. In none of the patients, fecolith casting a radio-opaque shadow could be demonstrated.

For assessment, the patients were categorized into three groups, namely, male, female, and children. Out of 50 cases studied, 32 were male, 18 were female, and 2 were children (<12 years).

Out of 32 males, scores of >7–9 were 23; scores of 5–7 were 6, and 3 had score <5 and 2 patients had mass in RIF.

These five patients did not undergo surgery. The patients with mass in RIF were advised for interval appendicectomy.

Out of 18 female patients, 12 had score >7–9, 5 had score 5–6, and 1 had score <5, none had mass in RIF. Management was on same lines as for males. One patient did not undergo operation.

All the two children had score >7–9 and were operated on.

A total of 44 patients were operated, of which 27 were male, 17 females, and 2 children. Twenty-one males having score of 7–9 were had acute appendicitis, 1 patient had normal appendix with Meckel's diverticulitis.

Male patients having score of 5–6 were 6, out of which 4 patients had acute appendicitis, 2 patients had normal appendix, and 2 patients had mesenteric lymphadenitis.

In 12 female patients having a score 7–9, 9 had acute appendicitis, 3 patients had normal appendix with other diseases, out of which 2 had pelvic inflammatory disease (PID) and 1 patient had mesenteric lymphadenitis. In 5 females with score 5–6, 3 had acute appendicitis, 2 had normal appendix with other diseases -1 PID, and 1 mesenteric lymphadenitis.

All the children subjected to appendicectomy had acute appendicitis.

In our series, a score of 7–9 using modified Alvarado system had a total sensitivity of 87.87%.

Increased proportion (36.36%) of negative appendicectomy is noticed (4.14 times more) for the Alvarado score 5–6 and significantly decreased proportion (12.12%) negative appendicectomy is noticed (0.24 times less) for the Alvarado score 7–9.

In our series, negative appendicectomy rate in females with score 5–6 was 40% and with score 7–9 was 25%. Men with score 5–6 had negative appendicectomy rate of 33.34% and with score 7–9 had negative appendicectomy rate of 4.76%. Hence, in the overall, females (27.78%) had more negative appendicectomy rate compared to males (9.38%), as the other diseases like PIDs were more common in the reproductive age group. Since intra-abdominal infection in females, particularly lower abdomen, can be quite confusing, it is difficult to differentiate acute appendicitis from gynecological conditions like twisted ovarian cyst and PID.

The overall Alvarado score >5 has got more sensitivity (87.87%) and diagnostic accuracy (76%) of diagnosing patients for appendicitis. This indicates that by particularly adopting this system, negative laparotomies can be reduced by a figure of 16%. Those patients who scored <5 did not require subsequent laparotomy, indicating the usefulness of the system in ruling out acute appendicitis.

In our series, when the score was more than 7, suggesting an inflammation localized to the RIF, surgery was done within 6 h of the patient getting admitted to hospital and it was observed that these patients had badly inflamed appendices, again indicating the sensitivity of the system. Laparoscopy can be advised as a diagnostic tool to minimize negative appendicectomy rates.

In patients whom score was 5–6, were observed and reassessed after a period of 12–24 h. Where there was persistence of abdominal tenderness with increased WBC count, appendicectomy was done. These patients were also found to have congested and inflamed appendix.

In our series, we had two patients in pediatric age group. All of them had a score of >7 and were operated within

Table 1: Age distribution with sex

Age in years	Male	Female	Total
10	2 (6.3)	-	2 (4.0)
11–20	17 (53.1)	8 (44.4)	25 (50.0)
21–30	10 (31.3)	6 (33.3)	16 (32.0)
31–40	2 (6.3)	2 (11.1)	4 (8.0)
41–50	1 (3.1)	2 (11.1)	3 (6.0)
>50	-	-	-
Total	32	18	50
Inference	82% of the cases are in the age group of 11–30 years		

Table 2: Presentation of clinical features

Clinical features	Number	%
Symptoms		
Abdominal pain	50	100.0
Anorexia	37	74.0
Nausea/vomiting	43	86.0
Constipation	4	8
Diarrhea	5	10
Burning micturition	3	6

Table 3: Presentation of clinical features

Clinical features	Number	%
Signs		
Right iliac fossa – tenderness	46	92.0
Rebound – tenderness	34	68.0
Fever	37	74.0
Muscle guarding	5	10
Abdominal rigidity	3	6
Mass in right iliac fossa	2	4
Psoas sign	3	6
Obturator sign	6	6
Rovsing's sign	2	4
Hyperesthesia at Sherren's triangle	2	4
Rectal tenderness	3	6

Table 4: Presentation of clinical features

Clinical features	Number	%
Symptoms		
Migratory right iliac fossa pain	50	100.0
Anorexia	37	74.0
Nausea/vomiting	43	86.0
Signs		
Right iliac fossa –tenderness	46	92.0
Rebound –tenderness	34	68.0
Fever	37	74.0
Laboratory findings		
Leukocytosis	38	76.0

Table 5: Results of modified Alvarado score

Alvarado score	Total (*n*=50)	Male	Female	Children
<5	4 (8.0)	3 (6.0)	1 (2.0)	-
5–6	11 (22.0)	6 (12.0)	5 (10.0)	-
7–9	35 (70.0)	23 (46.0)	12 (24.0)	2* (4.0)
Mass in right iliac fossa	2 (4.0)	2 (4.0)	-	-

* Male children

Table 6: Pathological diagnosis of the specimen of appendix sent for histopathological study

Histopathology (*n*=44)	Number	%
Normal	8	
AC. Catarrhal	10	22.73
AC. Suppurative	19	43.18
AC. Gangrenous	4	9.09
AC. Perforative	3	6.82

Table 7: Negative appendicectomy

Negative appendicectomy (*n*=50)	Number	%
Male	3	9.38
Female	5	27.78
Children	-	-
Overall	8	16.00

Table 8: Post-operative complications

Post-operative complications (*n*=50)	Number	%
Wound infection	2	4
Respiratory tract infection	1	2
Paralytic illness	1	2

6 h of admission. Operative finding was invariably, an inflamed appendix, indication 100% sensitivity in children.

In our present study, the usefulness of the system was demonstrated beyond doubt by reducing the number of negative laparotomies, especially in men and children. In women, negative laparotomies were still high and this can be reduced by laparoscopy.

CONCLUSION

- Alvarado scoring system significantly reduces the number of negative laparotomies without increasing overall rate of appendicular perforation
- It can work effectively in routine practice as an adjunct to surgical decision- making in questionable acute appendicitis
- It is effective in children and men but diagnostic laparoscopy is advised to minimize the unacceptably high false-positive rate in women
- It is simple to use and easy to apply since it relies only on history, clinical examination, and basic laboratory investigations
- It is cost effective and can be used in all district general hospitals with basic laboratory facilities.

SUMMARY

- A study to evaluate the usefulness of modified Alvarado system as an aid to diagnosis in suspected case of appendicitis and help in surgical decision-making
- Fifty individuals admitted with provisional diagnosis of acute appendicitis, scored according to presentation, on a total of 9
- Patients treated conservatively or surgically based on score
- Results of conservative, surgical intervention, and HPE reviewed
- It was found that modified Alvarado score correlated very well with diagnosis of acute appendicitis, especially in children and adult males and to a lesser degree in females
- It was concluded that modified Alvarado scoring system significantly reduces the rate of negative laparotomies without increasing overall rate of appendicular perforation.

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Original Article

Clinical Categorization of Under Five Wheezers

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Abstract

Introduction: The incidence of wheeze is very high in children, approximately 25–30% of infants will have had at least one wheezing, by 3 years of age, an episode of wheeze will have occurred in 40% of children and 50% will have at least one episode of wheezing by 6 years.

Aim of the Study: The aim of the study was to categorize different types of wheeze among children aged 6 months–5 years based on history, clinical profile, etiology, and risk factors.

Materials and Methods: All children aged 6 months–5 years admitted in department with definite history of wheezing and respiratory distress with typical clinical features.

Observations and Results: One hundred five children with recurrent wheeze were studied in the age group of 6 months–5 years.

Discussion: There are many children getting admitted with recurrent wheezing in <5 years age group. This study could help in identifying the etiology, categorization of wheezers, and risk factors predisposing these children to wheeze compared to other children.

Conclusion: In our study, various categories for recurrent wheezing based on clinical phenotypes are: Episodic wheeze 40%, multitrigger wheeze 42.8%, asthma 12.3%, and gastroesophageal reflux disease 4.7%.

Key words: Asthma, Child, Wheeze

INTRODUCTION

The incidence of wheeze is very high in children, approximately 25–30% of infants will have had at least one wheezing, by 3 years of age, an episode of wheeze will have occurred in 40% of children, and 50% will have at least one episode of wheezing by 6 years.[1]

In India, the incidence of wheeze is high in children. It has been found that one in three children has their first episode of wheeze in infancy, and the prevalence of wheeze is nearly 50% by 6 years of age. About 25% of children who develop persistent asthma started to wheeze by age of 6 months and 75% by 3 years of age.[2]

A recurrent wheeze is estimated to occur in one-third of children of preschool age and can cause significant morbidity, decrease quality of life, and increase the frequency of the use of health care services and economic costs.[3]

Data have confirmed that wheezing is clinically heterogeneous in early life in terms of its temporal pattern (i.e., age of onset and duration until symptoms disappear) and its risk factors, which include atopy and genetic or environmental factors, and the outcomes are different for such phenotypes.[4,5]

Different wheezing phenotypes have been reported in the literature, with the first such report being the Tucson childhood respiratory study of Martinez *et al.*,[6] in which children were classified into four main subtypes, including never wheezing, early transient wheezing, persistent wheezing, and late-onset wheezing; later reports further categorized patients with persistent wheeze as having nonatopic persistent wheezing or atopic/IgE-associated wheezing.[7,8]

Regardless of whether five or six different types are included in an assay, it remains difficult to differentiate these phenotypes clinically because the expression of symptoms

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and risk factors can change over time. In addition, different factors, including genetic, environmental, and host factors (and interactions among these factors), can impact a child's condition and contribute to the development of wheezing and the progression of a patient's symptoms.[9]

Our proposed operational criteria are aimed at simplifying the types of wheezing used to categorize children of preschool age and identifying risk factors for the persistent wheezing subtypes that can impact lung function[10] or lead to the subsequent development of asthma as these conditions should be treated by appropriate medical interventions.[11]

Wheeze can be Divided According to its Pattern and Duration

Wheeze subtypes according to pattern (symptomatic classification)

a. Episodic wheeze: Wheezing within a discrete period that is often associated with clinical evidence of a viral cold. There is no wheezing between episodes[12]
b. Multitrigger wheeze: Wheezing presenting with and apart from an acute viral episode.[12,13]

Wheeze according to duration

a. Transient early wheeze: This is a type of wheeze that starts early in the 1st year of life and then continues through the 2nd year before beginning to subside after the 3rd year. Most of these patients are not atopic and exhibit no evidence of eosinophilia or other markers of inflammation, which are observed in approximately 16% of affected patients.[14] The main risk factors in this group are maternal exposure to smoke, prematurity, low maternal age, low socioeconomic status, low birth weight, attending day-care center at an early age, and more than two siblings at home. In addition, in these patients, pulmonary function test scores are low even before the onset of the wheeze, suggesting that affected individuals may have had smaller airways than were observed in the control group and remain slightly lower than those reported in their peers in adolescence[6]
b. Late-onset wheeze: This presents as infrequent wheezing from 6 to 42 months old age that becomes more frequent at 42 months of age and then persists to an age of 6 years (approximately 1.7e6%).[14,15] A skin allergy test usually produces strong results in this group, and this is known to be a major prognostic factor. Allergies in the nose are also commonly associated with late-onset wheezing, similar to smoke exposure, is known to be a risk factor in males[6,14]
c. Persistent wheeze: This is wheeze with onset at 6 months of age or later that occurred in approximately 3.1% of patients in the PIAMA study, 4.1% of patients in SIDRIA, and 8.9% of patients in the ALSPAC study.

Aims and Objectives

Aim of the study

The aim of the study was to categorize different types of wheeze among children aged 6 months–5 years based on history, clinical profile, etiology, and risk factors.

Objectives of the Study

The objectives of the study were as follows:

1. To assess case burden of wheeze presenting with recurrent wheezing in children from age group of 6 months–5 years
2. Evaluate various etiologies and prognosis.

MATERIALS AND METHODS

Type of Study

Descriptive study

Period of study: December 2018 to November 2020

Inclusion Criteria

All the patients between 6 months and 5 years of age who presented with wheeze (recurrent wheeze or persistent wheeze) were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

- Children above 5 years of age group and <6 months
- Known or suspected immunodeficiency
- Other chronic diseases (TB, bronchiectasis, cystic fibrosis, and CHD).
- Foreign body aspiration.

Sample Size

All children aged 6 months–5 years admitted in department with definite history of wheezing and respiratory distress with typical clinical features.

MATERIALS AND METHODS

- All children aged 6 months–5 years admitted in the department with a definite history of wheezing and respiratory distress with typical clinical features
- Routine and specific diagnostic tests.
- Detailed history, clinical examinations, and required baseline investigations such as hemogram, total leukocyte count, and absolute eosinophil count, chest radiography, Mantoux test would be done.

Source of Data

Cases were admitted in Mahatma Gandhi Memorial Hospital, Warangal, during the study period.

Statistical Data Analysis and Interpretation

Data were entered into Microsoft Excel (Windows 10; Version 2019) and analyses were done using the Statistical Package for the Social Sciences (SPSS) for Windows software (version 22.0; SPSS Inc, Chicago). Descriptive statistics such as mean and standard deviation for continuous variables, frequencies, and percentages were calculated for categorical Variables were determined. Bar charts and pie charts were used for visual representation of the analyzed data.

OBSERVATIONS AND RESULTS

One hundred five children with recurrent wheeze were studied in the age group of 6 months–5 years.

Demographic Characteristics

Total no. of males = 55 (52.38%).

Total no. of females = 50 (47.61%).

No predilection to sex was observed.

The study population comprises 55% male and 50% female, there is no significant difference (P = 0.6255) in male-female distribution when we consider the study population in total [Table 1]. Of these in infancy, there is male predominance, 7 out of 11 were male, constituting 63.6% of the total population in infancy.

Out of 105 children, 11 (10.4%) were <1 year of age; 18 (17.1%) belonged to the age group 1–2 years ;23 (21.9%) to the age group 2–3 years; 27 (25.7%) to the age group 3–4 years; and 26 (24.7 %) children to the age group 4–5 years.

In the study population, 41 (39.04 %) had onset of symptoms <1 year of age and 64 (60.95 %) had symptoms onset after 1 year of age [Table 2].

Table 3 shows that 10 (9.5%) of the study population had eczema, 18 (17.1%) had rhinitis, and 43 (40.9%) had a family history of atopy.

One hundred (95.2%) children with recurrent wheeze had a good response to short-acting beta analog (SABA) and 5 (4.7%) had poor response to SABA [Table 4].

Episodic wheezers had 100% association with viral-induced wheeze and fever, multitrigger wheezers have 100% association with other triggers such as exposure to cold, sweet, chocolate, and cool drinks, asthma group has in addition to triggers personal atopy in the form of eczema 8 (61.5%), rhinitis 11 (84.6%), and family history of atopy 100%.

Clinical features in various etiology of recurrent wheeze.

Table 1: Age and sex distribution in the study population

Age (years)	Male *n* (%)	Female *n* (%)	Total *n* (%)
6 months–1 year	7 (63.6)	4 (36.3)	11 (10.4)
1–2 years	8 (44.4)	10 (55.5)	18 (17.1)
2–3 years	13 (56.5)	10 (43.4)	23 (21.9)
3–4 years	14 (51.8)	13 (48.1)	27 (25.7)
4–5 years	13 (50)	13 (50)	26 (24.7)
Total	55 (52.3)	50 (47.6)	105 (100)

Table 2: Age of onset of symptoms in the study population

Age of onset	Cases (*n*=105)	Percentage
<1 year	41	39.04
>1 year	64	60.95

Out of the 42 children with episodic wheeze, 23 (54.7%) were male and 19 (45.2%) were female, showing no sex predilection. Seventeen (40.4%) had onset before 1 year and 25 (59.5%) had onset after 1 year. All 42 children had fever, cough, 10 (23.8%) had noisy breathing, none had personal atopy, and 8 (19.04%) had family H/O atopy. All of them had wheeze in response to viral infection and all of them responded well to SABA.

Out of 45 children with multi-trigger wheeze, 23 (51.1%) were male, 22 (48.8%) were female, showing no sex difference. Fourteen (31.1%) had onset of symptoms before 1 year of age and 31 (68.8%) had onset of symptoms after 1 year of age. Forty-two (93.3%) had cough, 10 (22.2%) had fever, 5 (11.1%) had noisy breathing, 2 (4.4%) had eczema, 7 (15.5%) had rhinitis, 22 (48.8%) had family H/O atopy, 7 (15.5%) had wheeze associated with a viral infection, all of them had triggers other than viral infection, and all of them responded well to SABA.

Out of 13 children with asthma, 7 (53.8%) were male, 6 (46.1%) were female showing no sex difference. Six (46.2%) had onset of symptoms before 1 year of age and 7 (53.8%) had onset of symptoms after 1 year of age. All of them had cough, none had fever noisy breathing, 8 (61.5%) had eczema, 11 (84.6%) had rhinitis, all had family H/O atopy, all of them had triggers other than viral infection, and all of them responded well to SABA.

Out of 5 children with gastroesophageal reflux disease (GERD), 2 (40%) were male and 3 (60%) were female. Four (80%) had onset of symptoms before 1 year of age, 1 (20%) had onset of symptoms after 1 year of age, 4 (80%) had cough, none had fever, 1 (20%) had noisy breathing, and 5 (100%) had either poor or partial response to SABA.

Of the 105 cases under our study, 59 (56.1%) were of rural location and 46 (43.8%) were of urban location.

Table 3: Personal and family H/O atopy in the study population

H/O	6 months– 1 year *n*=11 (%)	1–2 years *n*=18 (%)	2–3 years *n*=23 (%)	3–4 years *n*=27 (%)	4–5 years *n*=26 (%)	Total *n*=105(%)
Eczema	0	0	4 (17.3)	5 (18.5)	1 (3.8)	10 (9.5)
Rhinitis	0	1 (5.5)	6 (26.0)	7 (25.9)	4 (15.3)	18 (17.1)
Family H/O atopy	2 (18.1)	6 (33.3)	11 (47.8)	14 (51.8)	10 (38.4)	43 (40.9)

Table 4: Response to short-acting beta analog in the study population

Response to short acting beta analogue	6 months to 1 year *n*=11 (%)	1–2 years *n*=18 (%)	2–3 years *n*=23 (%)	3–4 years *n*=27 (%)	4–5 years *n*=26 (%)	Total *n*=105(%)
Good	8 (72.7)	16 (88.8)	23 (100)	27 (100)	26 (100)	100 (95.2)
Poor	3 (27.2)	2 (11.1)	0	0	0	5 (4.7)

In our study, 90 (85.7%) were born at term, while 15 (14.2%) were born preterm.

In our study, the majority were of normal weight at birth while 18 (17.1%) were low birth weight.

In our study, 47 (44.7%) were exclusively breastfed, 17 (16.1%) were partially (mixed) breastfed, and 41 (39.0%) were formula-fed children.

Of the 105 cases of our study population, 89 (84.7%) were nutritionally healthy, while 16 (15.2%) were underweight [Tables 5-9].

DISCUSSION

There are many children getting admitted with recurrent wheezing in <5 years age group. This study could help in identifying the etiology, categorization of wheezers, and risk factors predisposing these children to wheeze compared to other children.

The exact proportion of various causes of wheeze is not yet published in the Indian population. Causes of recurrent wheeze in infants, toddlers, and preschool children may vary that need to be emphasized.

A descriptive study was conducted at MGM Hospital, Warangal, to find out the demographic characteristics, clinical profile, etiology, and risk factors of recurrent wheeze based on which categorization is done in children <5 years of age.

One hundred five children of age group between 6 months and 5 years admitted at our institution who met the inclusion and exclusion criteria were recruited. We had 42 (40%) episodic wheezers, 45 (42.8%) multitrigger wheezers, 13 (12.3%) asthma, and 5 (4.7%) GERD.

In our study, 55 were male and 50 were female, showing no difference sex-wise, but in age <1 year, there was male predominance. Out of 105 children, 11 (10.4%) were <1 year of age; 18 (17.1%) belonged to the age group 1–2 years; 23 (21.9%) to the age group 2–3 years; 27 (25.7%) to the age group 3 to 4 years; and 26 (24.7%) children to the age group 4 to 5 years.

LY *et al.* found no significant difference in gender in early-onset wheeze (<3 years) which is consistent with our study. Patra *et al.* report in children <2 years, there was male predominance.

In the study population, 41 (39.04%) had onset of symptoms <1 year of age and 64 (60.95%) had symptoms onset after 1 year of age.

In addition to wheeze and breathlessness, 101 (96.1%) presented with cough, 52 (49.5%) had associated fever, 16 (15.2%) had noisy breathing, 58 (55.2%) had triggers in the form of exposure to cold, consumption of ice cream, cool drinks, chocolate, etc. Forty-nine (46.6%) of the children wheeze during viral illness.

Saglani *et al.* in his study on recurrent wheeze in children between 3 months and 5 years.

The previous study is based on investigations which may not be possible in a resource-poor setting like ours whereas our study is mainly based on clinical features. Viral-associated wheeze is less than in our study. This could be explained by the fact that the previous study was conducted at London, where infection rate is less than our population. Incidence of asthma is very high in the previous study, but they have not attempted to separate multitrigger wheezers.

Mathieu *et al.* found a high prevalence of atopy in children with recurrent wheeze who are at risk of developing asthma. Our study also shows a high association between atopy and wheeze, 19.04% of episodic wheezers had a

Table 5: Location-wise distribution of cases

Location	Case	Percentage
Rural	59	56.1
Urban	46	43.8
Total	105	100

Table 6: Gestation age-wise distribution

Gestational age	Case	Percentage
Term	90	85.7
Preterm	15	14.2
Total	105	100

Table 7: Distribution with relation to birth weight

Birth weight	Case	Percentage
<2500 g	18	17.1
>2500 g	87	82.8
Total	105	100

Table 8: Distribution with relation to different feeding practice

Feeding practice	Case	Percentage
Exclusive breastfeeding	47	44.7
Partially breastfed	17	16.1
Artificial feeding	41	39.0
Total	105	100

Table 9: Distribution with relation to nutritional status

Nutritional status	Case	Percentage
Healthy	89	84.7
Underweight	16	15.2
Total	105	100

family history of atopy, 48.8% of multitrigger wheezers had family H/O atopy, 100% of asthmatics had family H/O atopy, of which 61.5% had personal H/O eczema, and 84.6% had H/O allergic rhinitis.

Litonjua *et al.* showed that odds of having a child with asthma are high with parental history of asthma. This is consistent with our study which shows 100% association of family H/O atopy in asthmatics.

Patra *et al.* found that GER is an important cause for recurrent wheezing among children <2 years of age. This is consistent with our study.

Breastfeeding

It is shown that the duration of breastfeeding should be at least 6 months to be protective against respiratory tract infections. Recurrent episodes of wheezing decreases were with increasing duration of breastfeeding which is consistent with our study. In our study, children who were partially breastfed (16.1%) and formula-fed (39.0%) for 1st 6 months were found to be recurrent wheezers.

Maternal Smoking in Pregnancy

Maternal smoking in pregnancy is a risk factor for all types of wheezing but not for asthma itself. It increases the risk of transient early wheezing and impaired lung function in infancy but not in later childhood. It appears to affect lung development, resulting in reduced lung capacity and smaller airways, as well as prematurity and low birth weight. In a study by Dezateux *et al.* in 101 infants, the odds of wheezing were significantly increased in those with a family history of asthma and those exposed to maternal smoking during pregnancy. However, in our study, we found maternal smoking is not a risk factor for recurrent wheezing.

Low maternal age: Rusconi, Galassi, Corbo, *et al.* showed that young motherhood (<20 years) has not been found to be a risk factor for wheezing respiratory illness in the 1st years of life because of the low number of mothers younger than 20 years (2.1%). However, in our study, young motherhood found to be a risk factor for recurrent wheezing.

Birth History

In a study done by Sherriffa *et al.*, prematurity was a significant risk factor recurrent wheezing, while our study showed that children who presented with recurrent wheeze predominantly were term according to their gestational age (85.7%).

CONCLUSION AND SUMMARY

There are a very few Indian studies on the study of wheezing <5 years and their follow-up.

1. In our study, various categories for recurrent wheezing based on clinical phenotypes are: Episodic wheeze 40%, multitrigger wheeze 42.8%, asthma 12.3%, and GERD 4.7%
2. Episodic wheezers were usually associated with wheeze during viral illness (100% viral associated) and they were asymptomatic in between
3. In our study, multitrigger wheezers and asthma have wheeze due to various other triggers and some of them had family history of atopy multitrigger (48.8%) and asthma (100%)
4. In our hospital, it is being observed that an increasing number of children with symptom of wheezing are frequently attended by pediatrics in ED, OPD, and ward, thereby proving an added burden to the younger age group

5. In our study, the risk factors identified for recurrent wheezers are male child in infants (63.6%), passive smoking (58%), rural areas (56.1%), and children who were not exclusively breastfed for 6 months (55.1%). However, we could not find maternal smoking as a risk factor in our study due to the sociocultural lifestyle in the study population.

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Original Article

A Clinical Study of Duodenal Ulcer Perforation

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Abstract

Background and Objective: Duodenal perforation is one of the most important complications of peptic ulcer. It is still a life-threatening catastrophe. This study deals with age and sex incidence and incidence of acute and chronic duodenal ulcer going for perforation, mode of presentation, and role of operative treatment versus conservative management. The post-operative complications, mortality of duodenal ulcer perforation, and prevention and role of early intervention are studied.

Materials and Methods: A 30 patients were selected who were diagnosed as duodenal ulcer perforation admitted in Government Medical College, Siddipet, during September 2018–December 2019. The patient underwent definitive treatment. Data related to the objectives of the study were collected.

Results: Majority of patients belong to the age group of 30–39 years and common in males. Most of the perforation are in the I part of duodenum anteriorly. Common in low socioeconomic group and maximum seasonal incidence in July to September (40%). The open surgery (97%), that is, simple closure with Graham's patch in 70% of cases is the commonly done procedure with minimum complications. Only one case managed conservatively.

Conclusion: I conclude that the duodenal ulcer perforation is common in the 4th decade, in males and related to heavy smoking, anxiety, chronic alcoholism, intake of nonsteroidal anti-inflammatory drugs (NSAIDs), and also long-standing untreated duodenal ulcer. Even with the advent of laparoscopic surgery, open surgery like simple closure with Graham's patch is the most common procedure done and is the most effective treatment. The post-operative complications are usually very less.

Key words: Chronic duodenal perforation, Duodenal ulcer, Graham's patch, Omentum

INTRODUCTION

Perforation is one of the most important complications of a peptic ulcer. In spite of modern management, it is still a life-threatening catastrophe. The sudden release of gastric or duodenal contents into the peritoneal cavity through a perforation leads to a devastating sequence of events which if not properly managed, is likely to cause death. Perforation may occur in a patient with a known chronic peptic ulcer or it may happen without any preliminary symptoms at all (20%).

Recent statistics indicates that roughly 10% of the population develop a gastric or duodenal ulcer in lifetime. Roughly 1–3% of population above the age of 20 years have some degree of peptic ulcer activity during any annual period.

Acute perforation is one of the complications of chronic duodenal ulcer (DC) and occurs in about 10–15% of all recognized chronic peptic ulcers.

Lort Moynihan has stated that perforation of duodenal or gastric ulcer is one of the most serious and most overwhelming catastrophes that can befall a human being.

A detailed history with regard to the symptomatology of the patient, a meticulous examination of the patient, radiological and biochemical investigations help to arrive at a correct preoperative diagnosis.

Operative method is still the treatment of choice and simple closure of perforation is the method followed in most of the surgical centers.

Conservative treatment is definitely unsuitable for routine use. However, few of the patients who are brought to

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the hospital at a late stage, have major concurrent illness and pre-operative shock, may improve with conservative treatment with Herman Taylor's regimen.

Immediate treatment for perforated peptic ulcer has been an established procedure for sometimes now. It can be stated that immediate definitive surgery like truncal vagotomy with a drainage procedure or proximal gastric vagotomy (PGV) after simple closure for perforated duodenal ulcer offers the prospects of a permanent cure with a mortality and morbidity comparable to that of patients with elective surgery.

The recent studies show that whenever a definitive surgery is deemed an appropriate addition to a simple closure of perforated DU, PGV is the procedure of choice.

If the condition is not diagnosed properly and not adequately treated, is progressed in a definite manner with a typical course, and may lead to the death of the patient due to bacterial peritonitis in about 7–8 days.

Objectives

1. The present study has been undertaken to evaluate the age and sex incidence, the incidence of acute and chronic duodenal ulcer going in for perforation
2. The importance of various clinical signs and mode of presentation, the role of operative treatment compared to conservative treatment, definitive surgery versus simple closure of perforation
3. The post-operative complications and mortality of duodenal ulcer are also studied.[1-5]

MATERIALS AND METHODS

This study has been based on the analysis of 30 cases of duodenal ulcer perforation, admitted Government Medical College, Siddipet, during September 2018–December 2019. The cases were admitted as emergencies. After admission, a detailed history was taken and clinical examination was done and possible immediate investigations were done.

Out of 30 cases admitted, 29 cases were subjected to emergency laparotomy and one case was treated conservatively. At laparotomy, the site of perforation, size of perforation, and amount of peritoneal contamination were determined. The following procedures were adopted in the management, namely, conservative, simple closure and definitive procedure, peritoneal toilet, and flank drainage.

The decision regarding the line of treatment and type of surgery to be undertaken for each case was arrived after consideration of the following factors:

1. Age of the patient
2. General condition of the patient
3. Evidence of shock
4. Duration of perforation
5. Associated medical illness – for example, cardiac and respiratory
6. Amount of peritoneal contamination of laparotomy.

Patients who were fit to undergo operative line of management were subjected to surgery and if the peritoneal contamination was less and the gap between onset of pain and admission to hospital was within 24 h and the patient was young, they were subjected to definitive surgery. If the patient was old, duration of perforation was long and peritoneal contamination was gross, they were treated with simple closure with omental patch.

That patient who came 48 h after developing perforation with associated shock and associated medical illness was declared not fit for surgery and treated conservatively.

Patients were followed up everyday with continuous bedside monitoring of vital data in the immediate post-operative period. Due attention was paid to note the development of any complication. Suitable and appropriate treatment was instituted from time to time according to the needs of the patients.

After satisfactory improvement, patients were discharged from the hospital with advice regarding the diet, rest, drugs to be taken, and need for periodic checkup and need to undergo esophagogastroduodenoscopy (EGD) after 6 months.

Patients who came for regular checkup were examined in detail. A general physical examination and examination of the abdomen were carried out to note the condition of the operative scar and for evidence of tenderness over the various regions of the abdomen. Patients were advised necessary treatment and the need to undergo EGD after 6 months to know the presence or absence of ulcer. If present, the patients were impressed on the necessity of undergoing definitive surgical line of treatment for the chronic duodenal ulcer.

After studying 30 cases, an extensive review of the available literature has been made. All the cases were analyzed and the results were tabled.

RESULTS AND DISCUSSION

Summary of 20 Cases of DU Perforation

The discussion is based on the analysis of data pertaining to 30 cases.

This is summarized as follows:

Age Incidence

In the present series of 30 cases of DU perforation, the age of the patient varied from 20 years to 75 years. The peak age incidence was between 30 and 39 years, which is quite in conformity with the opinion expressed by leading authorities who have made observation regarding age incidence of perforation.

The present series shows that incidence of DU perforation is uncommon in adolescence as shown by the incidence of only one case, who was 16 years old. Study conducted by Mohammed and Mackey in 1982, had only three patients out of 22 cases during adolescence. Illingworth *et al.* noted (1944) that perforated DU was relatively rare in early adolescence.

Sex Incidence

In this present series of 30 cases, all were male. The majority of authors have reported that incidence is high in males when compared to females.

The present series is not a large series to give a definite opinion regarding the study of sex incidence but it definitely brings to light the preponderance of male incidence over the female sex. The high incidence of male can be explained on the basis of greater hardship, strains, anxiety and indulgence in smoking, alcoholism, and intake of NSAIDs. They have to endure in earning the livelihood for their family.

Occupational Incidence

The maximum number of cases in the present series occurred in lower socioeconomic group. In the present study, 21 were farmers and 9 were unskilled laborers. Longman noted in 1979 that perforation is more common in lower socioeconomic group of people,

Seasonal Incidence

The analysis of 30 cases of perforation in the present series in relation to various months showed that maximum incidence of perforation was during July and September (45%) followed by October–December (30%). It was lowest during January–March (10%).

Examination of Abdomen

The findings noted in the present series of 30 cases and results obtained after local examination of the abdomen have been discussed as follows:

Movement with respiration: In all the 30 cases, the movement of the entire abdomen with respiration was restricted.

Tenderness: In all 30 cases, tenderness was elicited. Only in two cases, the tenderness was limited to the upper abdomen and rest of 28 cases had diffuse tenderness. Generalized tenderness all over the abdomen is due to widespread peritonitis.

Guarding and rigidity: Guarding and rigidity were present to a variable extent over the upper abdomen and mainly generalized guarding and rigidity was present in majority of the cases due to protective spasms of the abdominal muscles in response to peritoneal irritation, from the leaking gastroduodenal contents.

Obliteration of liver dullness: Of the 30 cases, liver dullness was obliterated in 28 cases. In two cases, the liver dullness was present in the mid-axillary line.

Bowel sounds: On auscultation, bowel sounds were absent in majority of cases and sluggish in two cases.

Table 1: Age incidence

Name of the author	Year	Peak age incidence
Turner	1951	30–40
James Hardy and Walker	1961	30–50
Jamieson	1947	20–35

Table 2: Sex incidence

Name of the author	Year	Percentage in males
DCM Rao *et al.*	1984	100
Kumar and Ghose	1969	99
Minhas	1987	80
Thompson	1937	94.25
Judin	1939	98.1

Table 3: Seasonal incidence

Months	No. of patients	Percentage
January–March	4	13.3
April–June	6	20.0
July–September	12	40.0
October–December	8	26.7

Table 4: Associated complications

Disease	No. of patients	Percentage
Chronic bronchitis	6	20
Anemia with emphysema	2	6.6
Osteoarthritis	2	6.6
No other problem	20	66.8

Table 5: Type of treatment

Type of treatment	No. of patients	Mortality
Conservative	1	1
Surgical management	29	0

Table 6: Post-operative complications

Complications	No. of patients
Pneumonitis	1
Wound infection	2
Wound dehiscence	1
Biliary leak	1
None	25

Systemic Examination

Associated medical illness: About 66.8% of patients had no other systemic problems. Out of the remaining 33.2% who had systemic problems – 6 patients (20%) had associated chronic bronchitis, one patient had anemia, and one had osteoarthritis.

Associated medical problems are one of the major factors in deciding of the major factors in deciding the line of treatment (conservative or operative) and type of surgery if operative line of treatment is decided.

Plain X-ray of abdomen: In all the cases, plain X-ray was taken in erect position. In two cases, there was gas under both domes of diaphragm, in one case, gas under left dome of diaphragm and rest of the cases there was gas under the right dome of diaphragm.

The amount of gas under the diaphragm will give a clue to the size of the perforation. In cases of massive collection of gas under the diaphragm, there was large perforation, whereas small amount of gas indicated smaller size of perforation. In the present series, the average height of gas under the diaphragm was 2.1 cm–3.3 cm.

Treatment

In the present series, out of 30 cases, 29 cases subjected to surgical management and one patient was treated on conservative basis because he had a 2-day-old perforation. He presented with shock and dehydration and he also had associated medical problems such as chronic bronchitis and emphysema. The patient never recovered from the shock and died next day.

Pre-operative Treatment

In all cases, immediately after the admission, a thorough clinical workup was done, intravenous fluids started, antibiotics given, and nasogastric aspiration started. Tetanus toxoid given, preparation of part done, and blood drawn for blood grouping and cross-matching. Appropriate measure taken to correct the shock [Tables 1-6].[6-10]

CONCLUSION

Duodenal ulcer perforation is common in the 4th decade, in males and related to heavy smoking, anxiety, chronic alcoholism, intake of nonsteroidal anti-inflammatory drugs (NSAIDs), and also long-standing untreated duodenal ulcer. Even with the advent of laparoscopic surgery, open surgery like simple closure with Graham's patch is the most common procedure done and is the most effective treatment. The post-operative complications are usually very less.

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Original Article

A Comparative Evaluation of Blood Sugar and Glycosylated Hemoglobin in Clinically Manifested Diabetic Neuropathy

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Abstract

Introduction: According to the International Diabetes Federation (IDF), the worldwide prevalence of diabetes mellitus (DM) has risen dramatically over the past two decades from an estimated 30 million cases in 1985 to 415 million in 2017. Based on current trends, the IDF projects that 642 million individuals will have diabetes by the year 2040.

Aims and Objectives of the Study: The aims of the study were to assess the efficacy of metabolic control of diabetes in the development of diabetic neuropathy and to identify the predisposing factors for the development of diabetic neuropathy.

Materials and Methods: The present study was conducted at Mahatma Gandhi Memorial Hospital, Warangal. The study was undertaken between June'2019 and May'2020, both in inpatient and outpatient department.

Results: Symptoms of sensory system involvement were the most common in 47 (78.3%) patients followed by motor symptoms 20 (33%) cases. Autonomic symptoms 10 cases and cranial nerve symptoms 2 cases. Distal symmetric sensory neuropathy was the most common type of clinical neuropathy.

Conclusion: Longstanding diabetes and poor glycemic control are particularly associated with an increased risk of neuropathy in DM. It also provides a conceptual framework for the pathogenesis of the long-term complications of diabetes.

Key words: Blood sugar, Diabetes, Glycosylated hemoglobin

INTRODUCTION

According to the International Diabetes Federation (IDF), the worldwide prevalence of diabetes mellitus (DM) has risen dramatically over the past two decades from an estimated 30 million cases in 1985 to 415 million in 2017. Based on current trends, the IDF projects that 642 million individuals will have diabetes by the year 2040. Although the prevalence of both type 1 and type 2 DM is increasing worldwide, the prevalence of type 2 DM is rising much more rapidly because of increasing obesity, reduced activity levels as countries become more industrialized, and the aging of the population. In 2015, the prevalence of diabetes in individuals aged 20–79 ranged from 7.2% to 11.4%. The countries with the greatest number of individuals with diabetes in 2015 are China (109.6 million), India (73 million), United States (30.3 million), Brazil (14 million), and the Russian Federation (9 million). The prevalence of DM increases with age.

The spreading diabetes epidemic is a major health concern for India and a great threat to the nation. According to recent estimates presently, India has 62 million diabetic subjects, and this is projected to increase to 100 million, that is, rise by 250% by the year 2035.

In the urban population study, 12% of individuals above age of 20 years in Chennai were found to be diabetic in the year 1997. The prevalence of diabetes is increasing rapidly and it is estimated that the number of diabetics in worldwide will double by the year 2020 projection published. In the year 1997, International Diabetes Institute stated that there will be more than 400 million people with diabetes by 2020, with the majority of them suffering with

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Type-2 Diabetes.[1] More than 95–97% of elderly diabetics are of Type II disease.

The metabolic syndrome is a deadly combination of hypertension, diabetes, heart disease, and dyslipidemia due to abdominal obesity. The causes are due to both bad genes and bad environment. Vascular complications of both micro- and macro-vascular predominate the features of Indian diabetes due to delayed diagnosis and late presentation of the syndrome. Diabetic foot accounts for one of the largest in-patient admissions in India. Diabetic nerve-related disorders directly or indirectly contribute to morbidity and mortality in a big way. Simple measures such as good glycemic control and neuroadjuvants, visual inspection of feet, and foot care can save and salvage feet at risk. Diabetic neuropathy is one of the most common troublesome complications of DM.

The prevalence of neuropathy is related to age, duration of diabetes, and the quality of metabolic control. By the time a diabetic patient has severe neuropathy, retinopathy and albuminuria are also usually present. It is the most common form of neuropathy in the developed countries of the world and accounts for more hospitalization than all the other diabetic complications and accounts for 50–70% of non-traumatic amputation.

The introduction of Insulin in the year 1922 by BANTING and BEST seemed to offer the ideal therapy for the treatment of DM and replacement of the missing hormone. Indeed in the past 50 years, the judicious use of Insulin has made it possible to control the symptoms of hyperglycemia and to avoid death from Diabetic Ketoacidosis. However, despite the continuous use of Insulin many pathological changes (e.g., retinopathy, angiopathy, nephropathy, and neuropathy) can develop and now account for the major morbidity and mortality associated with the disease.

One of the main difficulties to establish whether there is a relation between the degree of hyperglycemia and long-term complications of diabetes is the lack of reliable and objective method for assessing diabetic control. The clinician at present has no quick and simple way of ascertaining whether his patient is well controlled or not. Whether the modification of therapeutic regimen has altered control for better or worse.

Blood and urine glucose testing and urine ketone testing provide useful information for the day-to-day management of diabetes. However, these tests cannot provide the patient and healthcare team with a quantitative and reliable measure of glycemia over an extended period of time and these tests have a drawback in the demands of patient's compliance or frequent measurement.

Measurements of glycated proteins such as primary hemoglobin and serum proteins have added new dimensions in the assessment of glycemia. With a single measurement of each of these tests can quantitate the average glycemia over weeks and months, thereby complementing day-to-day testing. Expert opinion recommends glycosylated hemoglobin (HbA1c) testing at least 2 times a year in patients who have stable glycemic control.[2]

Lately, KEONTG and GABBAY and their coworkers have suggested measurement of HbA1C as an indicator of diabetic control. HbA1C is formed by the post-transcriptional glycosylation of HbA at the amino terminal valine of beta chain. This is a slow irreversible chemical reaction which occurs throughout the life span of the RBC, the prevailing plasma glucose concentration being the most important factor governing the quantity of HbA1C formed. HbA1C can be separated from the major hemoglobin fraction by virtue of its fast movement through action exchange resin.

When properly assayed, HbA1C level in a blood sample gives an estimate of diabetic control for the preceding 3–4 month period (i.e., life span of RBC).[2,3]

Diabetic control and complications trial study proved that allocated hemoglobin (HbA1c) reduction from 9% to 7% for a mean follow-up of 6.5 years was able both to reduce the onset of diabetic neuropathy (from 9.6% to 2.8%) and to slow its progression.[4,5] Euglycemia is only able to halt the progression, rather than reverse it, once the nerve damage has been established.[6,7]

Diabetic neuropathy has been defined by the consensus conference of San Antonio as peripheral neuropathy either clinically evident or sub-clinically that occurs in the setting of DM without other causes.[8] The present combination of the triad of neuropathy, retinopathy, and nephropathy in the course of the lifelong disease regarded this "Triopathy" as consequences rather than complication.[9]

Diabetic neuropathy is one of the most common long-term complication of DM and is clinically present in 30–50% of all diabetes patients.[10,11]

The primary pathological role of hyperglycemia in diabetic complications is well established. With the increasing knowledge that maintenance of euglycemia greatly reduces, if not prevents, the risk of diabetic complications and at times helps even in regression of such complications, monitoring the control of diabetes is essential for the successful management of diabetes. The responsibility of the patient and his physician in close monitoring control of diabetes and tailoring the various components in their management have assumed greater significance.[12]

The present study has been undertaken to monitor the levels of blood sugar and HbA1C in diabetic neuropathy. The study of diabetic neuropathy has been undertaken for many reasons. Diabetes is a frequent cause of peripheral neuropathy. It affects almost every part of nervous system and produces, various type of neuropathy. It has significant morbidity and mortality. Its incidence increases when the control of diabetes is poor.[13]

It is very well established that tight control of diabetes reduces, if not prevents, the risk of neuropathy. The benefit of other modes of therapy like myo-inositol supplementation and all doses of reductive inhibitors remain to be established. Until then, the clinician should monitor the patient's neurological status by routine methods and assess the control of diabetes by the available parameters and give practical advice that may save a limb and life.

Aims and Objectives of the Study

The aims of the study were as follows:

1. To assess the efficacy of metabolic control of diabetes in the development of diabetic neuropathy
2. To compare the value of estimation of blood sugar and HbA1c in monitoring the control of diabetes in diabetic neuropathy
3. To identify the predisposing factors for the development of diabetic neuropathy.

MATERIALS AND METHODS

The present study was conducted at Government Medical College, Suryapet, Telangana State , Study period June 2019- May 2020, both in inpatient and outpatient department. Diabetic patients seeking consultation for the symptoms suggestive of neuropathy were screened and labeled as suffering from diabetic neuropathy based on the inclusion and exclusion criteria described by PIRAR.

Inclusion Criteria

The following criteria were included in the study:

1. Loss of knee/ankle jerk
2. Sensory deficits
3. Other neurological abnormalities.

Exclusion Criteria

The following criteria were excluded from the study:

1. Other causes of neuropathy, especially alcoholism
2. Generalized areflexia without signs of neuropathy, and
3. Unilateral reflex loss.

Among those diagnosed to be suffering from diabetic neuropathy, further exclusion of the factors which would lead to falsely abnormal values for HbA1C was done before proceeding further.

1. Anemia (Hb <10 g%)
2. Acute metabolic complications
3. Ingestion of antibiotics and aspirin
4. Alcohol intake
5. Uremia
6. Hemoglobinopathies
7. Recent Blood Transfusion
8. Hyperlipidemia.

In all, 60 patients of diabetic neuropathy who satisfied the above criteria were selected and were subjected to a thorough evaluation as per working pro forma A battery of tests of cardiovascular autonomic function as described in Hutchison's clinical method was performed in all patients normal and abnormal values in tests were described by Ewing and Clarke (1982) given below.

Laboratory Investigations Done in all Patients Include

1. Urine – Sugars and Ketone bodies
   - Albumin
   - Microscopy
2. Fasting blood sugar (FBS) and postprandial blood sugar test (Folin-Wu method).
3. Blood
   - Hb%
   - Urea
   - Creatinine
   - Cholesterol
4. HbA1C by ion exchanges chromatographic method.
5. Electrocardiogram, X-ray chest, and other investigations whenever necessary were done. HbA1C was estimated in blood sample taken for FBS estimation.

Ion Exchange Resin Chromatographic Method of Estimation of HbA1C

(GlycoHb) (KYNOCK and LEHMANN 1977)

It is a rapid and simple method; total time required is <30 min.

Principle

Whole blood is mixed with a lysing reagent to prepare a hemolysate. This is then mixed with a weakly binding cation exchange resin. The non-glycosylated hemoglobin bind stores in, leaving HbA1C free in the supernatant. The HbA1C is determined by measuring the absorbance of the HbA1C fraction and of the total Hb.

Reagents and Apparatus

1. Ion exchange Resin (Bio-Rex 70)
2. Hemolyzing Reagent
   - 0.3 g white saponin
   - 0.5 g potassium cyanide

   Dissolved in a buffer pH 6.7 to make 1 L.

3. Control (lyophilized)
4. Apparatus – plastic tubes and resin separators.

Specimen

Whole blood collected in EDTA bulb. Heparin may also be used. HbA1C in blood is found to be stable for 1 week at 2–8°C.

Equipment Required

1. Spectrophotometer/photocolorimeter
2. Cuvettes
3. Test tubes
4. Vortex mixer
5. Pipettes and micropipette.

Reagent Preparation

Reagents 1 and 2 are ready to use. HbA1C control (3) is dissolved in 1 ml of deionized water by inverting/swirling. Reconstituted control is stable for 30 min only at room temp or 15 days at −20°C.

Procedure

Assay temperature: 23 ± 2°C.

Wavelength: 415 nm (Hg 405 nm).

Step 1: Hemolysate preparation

1. 0.5 ml of lysing reagent (2) was pipetted into a test tube
2. To it, 0.1 ml of well-mixed whole blood sample was added
3. Mixed and allowed to stand at room temperature for 5 min.

Step 2: Hb A1C separation and assay

1. 3.0 ml of ion exchange resin (1) was pipetted into the plastic tube. Mixed well before use.
2. 1.0 ml of the hemolysate was added (from step 1)
3. The resin separates or was positioned in the plastic tube so that the rubber sleeve was approximately 2 cm above the liquid level.
4. Plastic tube was placed on vortex mixer and was mixed for 5 min
5. The resin separator was pushed down in the plastic tube until therein was firmly packed
6. The supernatant was poured directly into a cuvette and absorbance was measured against deionized water within 60 min.

Step: 3 total hemoglobin (THB) assay

1. 5.0 ml of deionized water was pipetted into test tube
2. 0.02 ml of hemolysate (from step 1) was pipetted into it
3. Mixed and absorbance was read against deionized water within 60 min.

Good: 6–8 g%

Fair: 8–10 g% Calculations

$$\text{HbA1C\%} = \frac{\text{Absorbance of}}{\text{Absorbance of THb}} \times 10\text{X Temp.factor}\left(\text{Ff}\right)$$

Tf for assay at 23± 20°C=1.0 Tf for assay at 300°C= 0.7.

The pooled information was analyzed using appropriate statistical methods. HbA1C estimation done by ion exchanges chromatographic method.

The interpretation of GlycoHb test in our study is as follows:
Normal: <6. g%
Poor: >10 g%.

RESULTS

History

Of the 60 cases studied, 36 (62.6%) were male and 24 (38%) were female.

Average age group was 52.18 years.

Diabetic neuropathy was common in the age group of 56–65 years in both male and female (33.3%).

Average duration of diabetes was 8.7 years. NIDDM was more common (58 out of 60).

Ten patients were not on any treatment at the time of evaluation. Out of these, 6 patients were detected to be diabetic when they were admitted to this hospital for evaluation of neuropathy. Diabetic neuropathy was commonly observed in those patients with irregular treatment.

None of the patients had previous medical records documenting their diabetic status (urine sugar, blood sugar, and HbA1C estimation) before this evaluation except 5 patients who had previous admission record and record documenting glycemic status. Hence, diabetic control status could be assessed as either good or poor depending on symptoms of diabetes, regularity or otherwise of treatment and previous hospital admissions for their complications of diabetes, excluding the 6 patients who were detected on admission 46 patients were classified as "poor" controlled diabetics either because of failure to take treatment or persistence of symptoms in spite of treatment. Remaining 8 patients were judged to be "good" controlled with minimal parameters. Out of 60 patients, 26 patients were smokers and 34 were non-smokers.

Degree of control	Blood sugar (No of cases)	Glycosylated hemoglobin (No of cases)
Normal	9 (15%)	1 (1.9%)
Good control	14 (23.3%)	6 (20%)
Fair control	25 (41.6%)	14 (23%)
Poor control	12 (20%)	39 (68%)

P<0.001 Highly significant

Thus HbA1C showed evidence of poor control more frequently than blood sugar estimation in these patients. The difference between this parameter as a measure of poor control of diabetic was statistically significant.

When these patients were evaluated for their diabetic control status depending on the presence of symptoms of diabetes, regularity or otherwise of the treatment, history of the previous hospitalization for the complications, only 8 patients were judged to be under good control.

When these patients were analyzed for control status based on blood sugar and HbA1C, following observation was made. When 46 patients, thought to be "poorly" controlled diabetics using the same criteria, were further analyzed, taking blood sugar and HbA1C criteria into consideration, following observation was obtained.

Thus, it can be seen that in those patients who were on regular treatment and asymptomatic for glycosuria, HbA1C estimation revealed evidence of poor control in 6 patients. In contrast, blood sugar estimation revealed acceptable levels for diabetic control in these patients.

Even in those patients who were designated to be "poorly" controlled diabetics (n = 46), estimation of HbA1C revealed supportive evidence of the same more frequently (n = 30) than blood sugar estimation (n = 7). This difference was highly statistically significant ($P < 0.001$).

Patients with both retinopathy and neuropathy in this study had DM for periods 2 months–20 years (Mean 8.2 years). Whereas, patients with neuropathy alone had DM which was either detected on admission or was there for periods up to 10 years (Mean 8.2 years).

Thus, it is clear that the longer the duration of diabetes, more is the chance for the development of complications of diabetes.

Sixteen patients had abnormal autonomic nervous system function as per the criteria laid down by Ewing and Clarke and two patients showed evidence of diabetic gastroparesis. Out of these 18, only 2 (11%) patients had blood sugar in the "poorly" controlled category as compared to 11 (61%) patients in whom the HbA1C showed evidence of poor control. This difference was statically significant.

After establishing the efficacy of the estimation of HbA1C, the influence of the other parameters such as age, sex, duration, and mode of therapy on its estimation was analyzed. The following observations were made:

There were 19 patients aged <45 years and 41 patients aged more than 45 years.

HbA1C estimation indicated poor control in 12 patients in the former group as compared to 27 patients in the later. This difference was not statistically significant ($P > 0.05$).

Twenty-four out of the 36 male patients had evidence of poor control of diabetes; similarly, 15 out of the 24 females had evidence of poor control. There was no statistically significant difference between the value of HbA1c ($P > 0.05$) [Tables 1-3].

DISCUSSION

The exact mechanism in the development of neuropathy in diabetes is uncertain. Whether a poor control of the diabetic state hastens the progression of neuropathy is a question that yet to be answered, one of the earlier studies to establish relationship between glycemic control and neuropathy performed by Pirart, which showed that poor control was associated with a higher incidence of neuropathy. Intensive glycemic control in the DCCT study showed decreased incidence of diabetic neuropathy to 3% in intensively treated patients compared to 10% in the group that received conventional treatment.[4] Holman *et al.* concluded that tight control of diabetes retarded or reversed the progression of neuropathy.

On the other hand, Service *et al.* found no such correlations. However, majority of the authorities, Dyck *et al.* favor the view that poor control of diabetes is associated with an increased risk of neuropathy.

In the present study, the accurate classification regarding control of the diabetic state as laid down by the recommendations of the American Diabetes Association (1988) could not be done. There as on, has been elaborated earlier. However, patients who could be grossly classified as having poor metabolic control outnumbered those who could be classified as having good control (46 vs. 8) in this study.

Although considerable controversy exists regarding the etiopathogenes is of neuropathy in diabetes. It has been conclusively shown by Pirart that the incidence of neuropathy increases with the duration of diabetes. Heal so showed that there was a positive correlation between the occurrence of neuropathy and retinopathy. Tesfaye *et al.* showed a significant or relationship between diabetic neuropathy, age, duration of diabetes, diabetic retinopathy,

cigarette smoking, and prevalence of cardiovascular disease in IDDM patient.[14] This fact was brought out in this study.

In the present study, 33 (55%) neuropathy patients had retinopathy and the duration of diabetes was long. Furthermore, 16 neuropathy patients showed evidence of myocardial infarction and smoking habit observed in 26 neuropathy patients.

As noted by various authors (Thomas and Brown) as well as various (Holzer *et al.*) studies shown that symmetric distal sensory polyneuropathy is the most common form of diabetic neuropathy; this is supported by our study where the incidence of is more than any other type (61.2%); as documented by many workers earlier, the sensory disturbances follow a "Length related pattern" with the lower limb fibers being involved earlier than upper limb fibers.

This has been observed in our study. All patients who exhibited sensory changes did so in lower limbs. No patients showed sensory loss to touch (large fiber neuropathy) and yet to be firmly established. The existence of sensorimotor polyneuropathy was doubted by Thomas and Brown (1984), who feel that it is just a variation of the sensory neuropathy with minor motorabnormalities. However, Dycketal (1985) tends to classify this as a separate entity and the incidence of this particular form of neuropathy in our study is 40.8% (24 cases).

Prepared from pig and cattle pancreases and human insulin, synthesized by recombinant DNA technology, are now available which are superseding the older preparations. They are less likely to cause insulin allergy and lipodystrophy which prevent the potential hazards of patients non-compliance. Example includes Humulin S, Humulin I, actrapid MC, Actrapid HM, Neusilin, etc.

In summary, better method of soft treatment such as better delivery system and better insulin offers the hope of better control of diabetes and thereby better quality of life.

A recent study by MALIK suggested that the ACE inhibitor quinapril shows improvement in autonomic neuropathy. In 12 month's study of trandolapril treatment showed significant improvement in peripheral nerve function; however, this role of angiotensin-converting enzyme inhibitors as neuroprotective agents remains to be clearly delineated.

A recent meta-analysis by Nicoluccietal of randomized control trial involving acute respiratory infections demonstrated a modest benefit of treatment in only one aspect, improving the median nerve motor conduction velocity.

A recent 1 year multicentre trial of GLA administration to patients with diabetic neuropathy reported improvement in clinical and electrophysiological nerve function. Clinical trials regarding, use of alpha-lipoic acid in diabetic neuropathy is undergoing in the USA. The role of recombinant NGF remains uncertain in the treatment of diabetic neuropathy.

Asbury metal has noted that third nerve palsy is the most common cranial mononeuropathy encountered in diabetics. This feature has been documented in our study also where 2 cases had third nerve involvement. They have also noted that inspite of total paralysis of the extraocular muscles supplied by this nerve; there will be sparing of the pupillary reflex, more frequently in those who were aged above 50 years. Both the suspects were documented significantly in the present study.

Kurezyn suggested that Bell's Palsy (LMN facial Palsy) occurs greater than expected frequency in diabetics; however, only one case was observe in the present study.

In the present study, 30% of neuropathy patients had coexisting autonomic dysfunction. The duration of diabetes was long and level of glycemic control was poor (mean value GlycoHb– 11.05%). Ewing and Clarke have reviewed various series and suggested that the incidence of such abnormalities may vary from 17% to 40% in diabetes. Pfeifer *et al.* and Youne *et al.* (1986) have also documented the occurrence of autonomic abnormalities in patients with somatic neuropathy.

Elevated HbA1C was observed in diabetic neuropathy suggestion hyperglycemia or a related metabolic abnormality as an important factor in establishing neuropathy (Boulton *et al.*, 1982).

Several studies showed a position correlation between HbA1C and retinopathy, neuphropathy, and platelet aggregation. Even in those patients who were thought to have poor metabolic control, levels of HbA1C were more consistent in indicating poor metabolic control than blood sugar levels. This difference was statistically significant ($P < 0.01$). Zonen *et al.* but also a more sensitive and reliable indicator in monitoring the control (Koenig and Gabbay *et al*).

Boulton *et al.* (1982) observed an increased level of HbA1C in patients with diabetic neuropathy. Mcdonal *et al.* (1979) noted elevation level of HbA1C causes a shift of the oxygen dissociation curve to the left resulting in tissue hypoxia and this forms one of the hypothesis for the pathogenesis of neuropathy and other microvascular complication associated with diabetes.

Part of the examination included an assessment of neurological function, including neuropathic symptoms and physical signs, vibration perception threshold, tests of autonomic function, and the prevalence of impotence. The prevalence of diabetic neuropathy across Europe was 28% with no significant geographical differences.

Significant correlations were observed between the presence of diabetic peripheral neuropathy with age ($P < 0.05$), duration of diabetes ($P < 0.001$), quality of metabolic control ($P < 0.001$), height ($P < 0.01$), the presence of background or proliferative diabetic retinopathy ($P < 0.01$), cigarette smoking ($P < 0.001$), high-density lipoprotein cholesterol ($P < 0.001$), and the presence of cardiovascular disease ($P < 0.05$), thus confirming previous associations. New associations have been identified from this study – namely with elevated diastolic blood pressure ($P < 0.05$), the presence of severe ketoacidosis, an increase in the levels of fasting triglyceride ($P < 0.001$), and the presence of microalbuminuria ($P < 0.01$). All the data were adjusted for age, duration of diabetes, and HbA1c. Although alcohol intake correlated with the absence of leg reflexes and autonomic dysfunction, there was no overall association of alcohol consumption and neuropathy.

The reported problems of impotence were extremely variable between centers, suggesting many cultural and attitudinal differences in the collection of such information in different European countries. In conclusion, this study has identified previously known and new potential risk factors for the development of diabetic peripheral neuropathy.

"Matsumoto *et al.* showed the FBS is a major determinant of neuropathy independent of age, body mass index, and duration of diabetes. The fasting hyperglycemia was observed in 83.3% (50) of patients, while post-prandial hyperglycemia was observe in 33.3% of patients in the study. As Perice, Detal 1991 showed, erectile dysfunction was a common complication observed in diabetic men and was related to the many other complication, sexual dysfunction was observed in 72.2% of diabetic men in the study (26 out of 36 diabetic male patients). The duration of diabetes was longer in these patients and the estimated glycosylated hemoglobin clearly showed a poor controlled state.

Elevated levels of HbA1C were observed in most of the patients of diabetic neuropathy in the present study which supports the above outcomes.

The effect of various other parameters on the efficacy of HbA1C estimation as an indicator of poor metabolic control was also analyzed.

During optimal diabetic control, the blood sugar concentration was 84 mg per deciliter (range, 70–100) and HbAIc concentration 5.8% (range, 4.2–7.6). HbAIc concentration appears to reflect the mean blood sugar concentration best over previous weeks to months.

The periodic monitoring of HbAIc levels provides a useful way of documenting the degree of control of

Table 1: Ormal and abnormal values in tests of autonomic neuropathy

Test	Normal	Borderline	Abnormal
Parasympathetic (heart rate response).			
Valsalva ratio	≥1.21	1.11–1.20	≤1.10
Deep breathing (max: min HR)	≥15 beats/min	11–14 beats/min	≤10 beats/min
Standing 930:15 ratio RR)	≥1.04	1.01–1.03	≤1.00
Sympathetic (blood pressure response)			
Standing (↓systolic)	≥10 mm hg	11–29 mm hg	≥30 mm hg
Exercise (↑diastolic)	≥16 mm hg	11–15 mm hg	≤10 mm hg

Table 2: The age and sex distribution of these cases is as below

Age in years	Male	Female	Total	Percentage
<25 years	0	3	3	5
26–35 years	1	1	2	3.33
36–45 years	11	3	14	23.3
46–55 years	7	4	11	1.6
56–65 years	12	8	20	33.3
66 and above	5	5	10	16.6
Total	36	24	60	100

Table 3: Depicts the duration of diabetes in these patients varied from freshly detected cases to 25 years. Patient with IDDM and NIDDM could be further sub-classified depending upon the duration of diabetes as under

Duration of diabetes in years	No of type 1 DM patients	No of type 2 DM patients	Total no of diabetes	Percentage
<5 years	0	18	18	30
6–10 years	1	23	24	40
11–15 years	0	13	13	21.6
>15 years	1	4	5	8.4
Total	2	58	60	100

glucose metabolism in diabetic patients and provides a means whereby the relation of carbohydrate control to the development of sequelae can be assessed. From the Laboratory of Medical Biochemistry, Rockefeller University, Cornell University Medical College and the Beth Israel Medical Center Ronald J. Koenig at Rockefeller University, 1230 York Ave., New York, NY 10021.

Whereas, in the present study, it has been demonstrated that the sequelae of DM, especially diabetic neuropathy, has been the cornerstone for this study and thus the study indicated that Hba1c levels are directly related to the management of diabetic neuropathy.

The study of Koenig *et al.* was conducted only in the inpatients, whereas the present study was concentrated on both inpatients and outpatients.

Natural Progression of Diabetic Peripheral Neuropathy in the Zenarestat Study Population by Bird *et al.* to report the baseline and natural progression of diabetic peripheral neuropathy over 12 months in a large mild-to-moderate neuropathy population concluded that neurologic decline over 12 months is evident when measured by nerve conduction studies and cool thermal quantitative sensory testing (QST). Other measures, vibration QST, neuropathy rating scores, and monofilament examination, are insensitive to changes over 12 months in a mild-to-moderate affected population of this size.

CONCLUSION

1. Longstanding diabetes and poor glycemic control are particularly associated with an increased risk of neuropathy in DM
2. Estimation of HbA1C is a simple, rapid, and objective procedure to assess diabetic control
3. It serves both as a screening test for uncontrolled diabetes and as an indicator of the efficacy of various therapeutic regimens
4. It also provides a conceptual framework for the pathogenesis of the long-term complications of diabetes.
5. Its estimation gives a relatively precise reflection of the state of diabetic control as compared to blood glucose estimation. Therefore, it is now possible to estimate more accurately and with greater sensitivity the degree of glucose intolerance, particularly in cases associated with diabetic complications. It represents an accurate technique to evaluate new ways of controlling blood glucose.

Thus, as an integral of diabetic control, HbA1C estimation is superior to the conventional measures in the assessment of control.

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