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Etiological Evaluation of Non-resolving Pneumonia: Our Experience in a Tertiary Care Center of Telangana

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Abstract

Introduction: Non-resolving or slowly resolving pneumonia is not uncommon, affecting 10–20% of patients admitted with community-acquired pneumonia (CAP). Non-resolving pneumonia is a challenging clinical problem. Incidence of non-resolving pneumonia was found to be 10–15% among hospitalized patients with CAP and of them 6% developed progressive pneumonia. This study aims to evaluate the patients of non-resolving or slowly resolving pneumonias to establish the cause of it.

Methodology: It is a prospective, observational study taken up by the Department of Pulmonary Medicine of SVS Medical College and Hospital, Mahabubnagar, Telangana. All the enrolled cases of non-resolving or slowly resolving pneumonia which satisfy the inclusive criteria were taken into the study from June 2017 to December 2018. A total of 28 patients were satisfying the inclusion criteria and were further studied for evaluating the causative factors. The study was started after taking the approval of the Institutional Ethics Committee, SVS Medical College and Hospital, Mahabubnagar, Telangana.

Observation and Results: The mean age of the patients was 48.2 years. Of 28 patients, 18 (64.2%) were male and 10 (35.7%) were female with a male:female ratio – 1.8:1. Fever (81%) and cough (86%) were the most common symptoms. Smoking was the most common comorbidity noted (60.7%) followed by alcoholism (46.6%), diabetes (39.28%), hypertension (25%), and chronic obstructive pulmonary disease (21.4%). The most common cause of non-resolution of pneumonia in this study was tuberculosis 11 (39.28%) followed by bacterial pneumonias 9 (32.1%) which were caused by drug-resistant organisms. Other causes were malignancy 6 (21.4%), foreign body 1 (3.57%), and fungal pneumonia 1 (3.57%).

Key words: Non-resolving pneumonia, Fiberoptic bronchoscope, CT scan chest

INTRODUCTION

Pneumonia is defined as inflammation and solidification of lung parenchyma due to an infectious agent. Normal resolution of pneumonia is variable and depends on the causative agent and host response to the invading

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agent. In as many as half of cases, the pathogen remains unidentified which greatly hampers the evaluation of slowly resolving/non-resolving pneumonia. Non-resolving or slowly resolving pneumonia is not uncommon, affecting 10–20% of patients admitted with community-acquired pneumonia (CAP).^[1]

There is lack of uniformity regarding the definition for neonatal resuscitation program (NRP). The term NRP has been used to refer to "Persistence of radiological abnormalities beyond expected time of course." Most of the researchers defined slow resolving pneumonia (SRP) as pulmonary consolidation persisting for more than 21 days.^[2]

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Kirtland and Winterbauer defined SRP in immune competent patients based on radiological criteria; <50% clearing by 2 weeks or less than complete clearing by 4 weeks.^[3]

Non-resolving pneumonia is also defined as pneumonia with a slow resolution of radiologic infiltrates or clinical symptoms despite adequate antibiotic therapy.^[4]

Non-resolving pneumonia is a challenging clinical problem. Incidence of non-resolving pneumonia was found to be 10–15% among hospitalized patients with CAP and of them 6% developed progressive pneumonia.^[5]

Aim

This study aims to evaluate the patients of non-resolving or slowly resolving pneumonias to establish the cause of it.

METHODOLOGY

It is a prospective, observational study taken up by the Department of Pulmonary Medicine of SVS Medical College and Hospital, Mahabubnagar, Telangana. All the enrolled cases of non-resolving or slowly resolving pneumonia which satisfy the inclusive criteria were taken into the study from June 2017 to December 2018. A total of 28 patients were satisfying the inclusion criteria and were further studied for evaluating the causative factors. The study was started after taking the approval of the Institutional Ethics Committee, SVS Medical College and Hospital, Mahabubnagar, Telangana.

Inclusion Criteria

Any case of pneumonia, not responding to the treatment and fitting into the operational case definition of non-resolving pneumonia and willing to participate in the study, was taken into the study. Non-resolving or slowly resolving pneumonia was defined in this study by the presence of persistence of clinical symptoms and signs, failure of resolution of the radiographic features by 50% in 2 weeks or completely in 4 weeks on serial chest X-ray, in spite of antibiotic therapy for a minimum period of 10–14 days and sputum for acid-fast bacilli (AFB) smear negative, cartridge-based nucleic acid amplification (CBNAAT) – no *Mycobacterium tuberculosis* detected.

Exclusion Criteria

Any patient of pneumonia who was critically ill with poor general condition, who was already suffering with malignancies, who was positive for tuberculosis and HIV/AIDS, and the patients who were not willing to participate in the study were not enrolled into the study.

PROCEDURE

The patient underwent complete physical examination with written informed consent after complete demographic and detailed clinical history was taken. All the routine baseline investigations such as complete blood count, random blood sugar, blood urea, and serum creatinine and sputum for microbiological tests (AFB smear, Gram stain, pyogenic culture and sensitivity, fungal smear and culture, and sensitivity) were done. Chest X-rays were taken and were repeated again after 2 weeks of empirical antibiotics therapy. Contrast-enhanced computed tomography (CT) chest was done in necessary patients.

Fiber-optic bronchoscopy was done in all patients, by which macroscopic appearance of trachea-bronchial tree was noted. Bronchial wash, brushings, and biopsy were taken whenever they were found necessary. Those samples were sent for microbiological and cytological analysis.

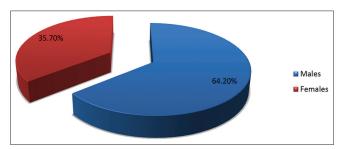


Figure 1: The gender distribution of the study population

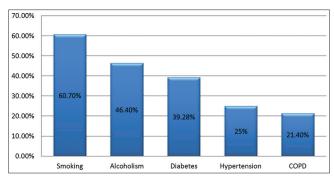


Figure 2: The comorbidities of the study population

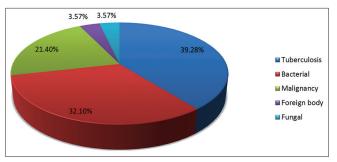


Figure 3: The etiology of non-resolving pneumonia

Table 1: The comorbidities of the study population

Comorbidities	Frequency (%)**
Smoking	17 (60.7)
Alcohol abuse	13 (46.4)
Diabetes	11 (39.28)
Hypertension	7 (25)
COPD	6 (21.4)

^{**}Total percentage exceeds 100% as many patients had more than one comorbidities. COPD: Chronic obstructive pulmonary disease

Table 2: The etiology of non-resolving pneumonia

Etiology	Frequency (%)
Tuberculosis	11 (39.28)
Bacterial	9 (32.1)
Malignancy	6 (21.4)
Foreign body	1 (3.57)
Fungal pneumonia	1 (3.57)

In suspected cases of tuberculosis, bronchoalveolar lavage was done and was sent for CBNAAT, AFB culture.

OBSERVATION AND RESULTS

A total of 28 patients who were satisfying the inclusion criteria were enrolled in the study. The mean age of the patients was 48.2 years. Of 28 patients, 18 (64.2%) were male and 10 (35.7%) were female with a male:female ratio – 1.8:1. Fever (81%) and cough (86%) were the most common symptoms.

Smoking was the most common comorbidity noted (60.7%). Among 17 smokers, 12 were male and 5 were female. Smoking was followed by alcoholism (46.6%), diabetes (39.28%), hypertension (25%), and chronic obstructive pulmonary disease (21.4%). Smoking was more common among patients suffering with malignant etiology. Diabetes mellitus was noted in patients with infective etiology. Tuberculosis was the most common etiology among diabetics.

The most common cause of non-resolution of pneumonia in this study was tuberculosis 11 (39.28%) followed by bacterial pneumonias 9 (32.1%) which were caused by drug-resistant organisms. Other causes were malignancy 6 (21.4%), foreign body 1 (3.57%), and fungal pneumonia 1 (3.57%).

DISCUSSION

It is a prospective, observational study taken up by the Department of Pulmonary Medicine of SVS Medical College and Hospital, Mahabubnagar, Telangana. A total of 28 patients were satisfying the inclusion criteria and were further studied for evaluating the causative factors. Patients

with non-resolving pneumonia are usually subjected to many investigations for diagnostic evaluation. Hence, knowledge regarding the spectrum of diseases which cause non-resolution and the frequency of their occurrence, so as to consider the investigative path will be of enormous value for the treating physician.

In our study, tuberculosis (39.28%) was the leading cause of non-resolution of pneumonias. Among 11 tuberculosis patients, seven patients had good clinical and radiological response and four patients had good clinical but partial radiological response. In a study was done by Jayaprakash *et al.*, [6] tuberculosis was the most common cause of non-resolving pneumonia. Chaudhuri *et al.* [7] reported that 16.7% of the causes of non-resolving pneumonia are due to tuberculosis. Ramesh and Saravanan [8] reported that bacterial pneumonias are major cause of non-resolving pneumonia.

The second most common cause was bacterial pneumonias (32.1%) caused by Gram-negative bacilli. *Klebsiella pneumoniae* and *Pseudomonas aeruginosa* were the two most common organisms isolated. *Klebsiella* was isolated more among diabetics. Begamy has also reported increased occurrence of *Klebsiella pneumoniae* in thoracic infections in diabetic patients. Fein also shared similar observation of increased occurrence of Gram-negative etiology of pneumonia in elderly patients with comorbidities. [10]

Incidence of malignancy was found to be high among smokers compared to non-smokers. Among malignancy, squamous cell carcinoma was common. Chaudhuri *et al.*^[7] reported that squamous cell cancer was common among all the other types of lung malignancies causing non-resolving pneumonias.

Performing CT chest before fiber-optic bronchoscopy was extremely useful in localizing the segment involved and to know the extent of the disease.

CONCLUSION

Non-resolving pneumonia is a problem not only for the patient but also to the treating physician because establishing the cause for the non-resolution of pneumonia takes time and requires invasive investigations. Tuberculosis and CAP not responding to empirical antibiotics and malignancy contribute major cause for non-resolution. So, coming to a particular diagnosis is very crucial for appropriate treatment in non-resolving pneumonia.

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Current Trends of Various *Candida* Coinfection using KB006Hi Candida Kit and CHROM Agar in Pulmonary Tuberculosis Patients at a Tertiary Health Care Center in Patna

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Abstract

Introduction: The various *Candida* species have long been associated with pulmonary tuberculosis (TB). These Candida have assumed significance as emerging pathogen in these TB patients with some degree resistance to antifungal therapy thus complicating the disease and its treatment. Early identification of *Candida* species and instituting appropriate treatment therapy is important in reducing the morbidity and mortality in patients with TB.

Aim: The aim is to study trends and prevalence of various Candida coinfection using KB006Hi Candida kit and CHROM agar in pulmonary TB patients and evaluating usefulness of these candida identification kit.

Material and Methods: This study was done in the Department of Microbiology at Indira Gandhi Institute of Medical Sciences, Patna, Bihar, over a period of 1 year in seventy patients of pulmonary TB. Prior Institutional Ethical Committee approval was also obtained for this study.

Results: Out of a total of 200 patients, 70 patients (35%) whose sputum samples were positive for acid-fast bacilli were included in the study. Candida coinfection was observed in 26 (37.14%) patients which included 16 male and 10 female patients. The ratio of male to female in Candida infection group was 1.6:1. *Candida albicans* was the most common isolate among *Candida* species in pulmonary TB patients which was isolated in 50% of the patients.

Conclusion: Candida coinfection in pulmonary TB patient is common, and synergistic growth between *Candida* species and TB exists. Along with *C. albicans*, the prevalence of non-albicans species is also increasing with variable degree of resistance. Prompt measures need to be taken for routine identification and treatment of these opportunistic Candida infections in TB patients.

Key words: Candida albicans, CHROM agar, Non-albicans Candida, Prevalence, Pulmonary tuberculosis

INTRODUCTION

Close to 200 species of genus *Candida* exist out of which almost two dozen has been associated with pathology



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in human and animals.^[1] Respiratory Candida infection involving the lungs or bronchial system is associated with secondary infections in tuberculosis (TB) patients. *Candida* species are one of the most potentially pathogenic fungal agents in patients with bronchopulmonary disease. Whenever the host resistance is lowered as in immunocompromised patients, cancer patients on chemotherapy, long-term steroid use, and the unrecognized opportunistic fungi affect the progression of disease and may even prove fatal. The synergistic growth promoting the association of *Candida* and *Mycobacterium tuberculosis* is

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well documented by various authors all over the world, but still, the sputum isolates of pulmonary TB patients are ignored for fungal studies which might prevent morbidity and mortality resulting from the disease as Candida species are innocuous throat commensals. [2,3] The effect of polysaccharide fraction of Candida albicans for enhancement of the growth as well as reduction of the generation time of tubercle bacilli is confirmed by different studies. [4] Most of the individuals affected with mycoses have a history of receiving long-term antibiotics and corticosteroids therapy, other immunodeficiency such as AIDS, and majority of them have severe pulmonary diseases such as TB. Concerning immunocompromised patients, C. albicans is the most frequently isolated pathogen, but the increasing incidence of infections due to non-albicans Candida such as Candida tropicalis, Candida glabrata, Candida krusei, and Candida parapsilosis is a cause of perturb. [5,6] Out of various isolation media available commercially for identification of fungal pathogens such as candida, CHROM agar serves as a medium for detection and identification of major Candida species with accuracy and reduces the time of identification and its characterization from poly fungal specimens.[7] CHROM agar Candida is a selective and differential medium which allows simultaneous isolation and identification of yeast based on the color and colony morphology. [8] Hence, these chromogenic media for Candida detection are an alternative to the older conventional techniques which used to take more time and were unwieldy. Species identification is pivotal when treating candidiasis as prolonged use of azoles in treatment has led to the emergence of drug resistance in C. albicans and other species. [9] This type of study will not only be helpful in screening patients for coinfection with Candida in pulmonary TB patients but can also be worthwhile in treating patients with improper response to antitubercular medications.

Objectives of the Study

- To determine the prevalence of Candida coinfections among TB patients.
- To differentiate Candida to the species level due to pathogenicity variation.
- Evaluating the usefulness of CHROM agar and KB006 identification kit.
- Early identification of *Candida* species and instituting appropriate treatment therapy thus reducing the morbidity and mortality in patients with TB.

MATERIALS AND METHODS

This prospective analytical study was done at Indira Gandhi Institute of Medical Sciences, Patna, Bihar, over a period of 1 year in seventy patients. Samples were collected from in and outpatients from the Department of Pulmonary Medicine



Figure 1: Growth of Candida species on CHROM agar



Figure 2: KB006 HI identification kit (sugar assimilation reaction)

and Revised National TB Control Program (RNTCP) designated microscopic center for acid-fast bacilli (AFB) staining of sputum. Prior Institutional Ethical Committee approval was also obtained for this study. Clinically diagnosed cases of pulmonary TB of all age groups and AFB smear positive or negative in Ziehl–Neelsen staining were included in the study. Repeat samples from the same patient, non-cooperative patients, and patients on antifungal therapy were excluded from the study.

Clinical specimens such as sputum and pleural effusion fluid were collected from pulmonary medicine department, and spot samples or morning two samples were collected from DMC, RNTCP after proper instructions to the patients. All the clinical specimens were Gram stained and observed under the microscope for yeast cells. In doing culture for primary isolation, Sabouraud dextrose agar was used for primary isolation of *Candida* species. The culture plates were incubated at 37°C for 48 h. Candida isolates were speciated by the following features -

- Morphology and culture characteristic (less informative)
- Germ tube test
- Cornmeal agar for chlamydospore formation
- Color of the colonies on CHROM agar [Figure 1]
- KB006 HiCandida Identification kit (sugar fermentation) [Figure 2].

Characterization of organisms - All pure cultures were characterized to species level using different tests confirming with required standard diagnostic criteria. [10,11] The criteria included will be morphological and cultural characteristics and small and large surface pellicle formation.

Study Methods

- KB006 HiCandida Identification kit It is a standard test system that can be used for identification and differentiation of *Candida* species. It can also be used for validating known laboratory strains. Principle of test Each KB006 kit is a standardized colorimetric identification system utilizing 12 conventional biochemical tests. The tests are based on the principle of pH change and substrate utilization. On incubation, organisms undergo metabolic changes which are indicated by spontaneous color change in the media.
- Germ tube test A rapid method of identifying *C. albicans* based on its ability to form germ tubes within 2 h when incubated in human serum at 37°C (Reynolds–Braude phenomenon).
- CHROM agar CHROM agar Candida (CHROM agar company, Himedia) - Identification of *Candida* spp. on CHROM agar culture produce different color of colonies.
- Cornmeal agar for chlamydospore formation Culture on cornmeal agar at 20°C produce chlamydospores by C. albicans and C. dubliniensis.

RESULTS

Out of a total of 200 patients in whom pulmonary TB was suspected, sputum specimen was sent and in which 70 patients (35%) whose sputum samples were positive for AFB by Zieh-Neelsen method were included in the study. Out of 70 patients in sputum-positive pulmonary TB, 42 were males and 28 were females. These seventy patients were screened for Candida coinfection. Candida coinfection was observed in 26 (37.14%) patients out of the 70 patients of pulmonary TB which included 16 male and 10 female patients. The ratio of male to female in Candida infection group was 1.6:1. Maximum number of Candida coinfection was observed in age group 61-80 years (57.7%) which was followed by age group 41-60 years (23.07%) and age group 21–40 years (19.23%), respectively [Table 1]. In various cases of pulmonary TB, identification of Candida species was done by CHROM agar and Candida identification kit. In this study, it was found that *C. albicans* was the most common isolate among *Candida* species in pulmonary TB patients which was isolated in 50% of the patients (13/26). Next common *Candida* species detected was *C. tropicalis* which was present in 23.08% patients (6/26) followed by *C. glabrata* present in 15.38% of patients (4/26). One patient each of *C. parapsilosis*, *C. krusei*, and *Candida haemulonii* was isolated in sputum samples of pulmonary TB patients [Table 2].

DISCUSSION

Respiratory fungal infections are the emerging pathogen complicating pulmonary TB, and Candida infection is one of the most common pathogenic fungi implicated in these patients. The diseases which are immunosuppressive in nature have led to increase in the incidence of opportunistic fungal infections. In the present study, the number of patients suffering with Candida coinfection in pulmonary TB patients was 37.14% which is quite similar to various studies done by other researchers [Table 3]. [2,12-15]

Considering gender, in our study, there is not much difference, and male preponderance was slightly more than females with the ratio being 1.6:1. Even other studies suggest

Table 1: Age- and sex-wise distribution of Candida speciation among TB patients

Age group (years)	Male	Female	Total Candida species (n=26) (%)
21–40	3	2	5 (19.23)
41–60	3	3	6 (23.07)
61–80	10	5	15 (57.70)
TB: Tuberculosis			

Table 2: Distribution of various *Candida* spp. (n=26) from patients with TB

Candida species	Number isolated (%)
Candida albicans	13 (50)
Candida tropicalis	6 (23.07)
Candida glabrata	4 (15.38)
Candida parapsilosis	1 (3.85)
Candida krusei	1 (3.85)
Candida haemulonii	1 (3.85)

TB: Tuberculosis

Table 3: Showing incidence of Candida coinfection in pulmonary TB patients in various study

Authors	Candida species isolated (%		
Baradkar et al.(2009)	26/100 (26%)		
Kali et al. (2013)	30/75 (40%)		
Mathavi et al. (2014)	19/107 (17.7%)		
Kavitha et al. (2017)	41/121 (33.89%)		
Nandihal et al. (2018)	32/100 (32%)		
Present study (2019)	26/70 (37.14%)		

that there is variability with regard to males and females as more males are having Candida coinfection in pulmonary TB patients, but some studies have also reported more female preponderance. [2,15] Less number of females in our study could only be due to the fact that most women are homemaker prefer to stay indoor and less literacy rate among females which emphasize the need of health education of the society. Patients of old age more than 60 years of age were affected maximally (more than 50%) with the Candida infection. People in the old age group are more vulnerable to fungal infections as the aging process leads to decline and variable changes in the physiologic and morphological functions in these people. [16] Another important factor could be less saliva production which limits production of peptide and presence of protein in the oral cavity, and the lack of substances with broad antimicrobial activity, such as lysozyme, contributes to oral candidiasis. [17] C. albicans is the most common fungal pathogen in patients of pulmonary TB and this is also evident from the present study where the common fungal pathogen was C. albicans in half of the cases. The various non-albicans Candida comprised other half of cases which were C. tropicalis (most common nonalbicans candida) followed by C. glabrata. One patient each of C. parapsilosis, C. krusei, and C. haemulonii were found in this study. Past studies done by various researchers showed C. albicans to be the principal isolate followed by C. tropicalis which correlates also with the present study. [2,12,18,19] C. albicans is a commensal organism, but it can be infectious and proves to be menacing in immunocompromised individuals under a variety of conditions as well as TB.[20]

This percentage of pulmonary TB patients coinfected with Candida is perturbing and might interfere and complicate the treatment of TB.^[21] There should be adequate guidelines, and steps should be taken for the treatment and prevention of the opportunistic candidiasis in pulmonary TB patients.

CONCLUSION

Candida from being a normal commensal in human can attain pathogenic forms and can even prove to be lethal in patients where it coexists with pulmonary TB. Detection of the various *Candida* species will aid in instituting prompt antifungal treatment for candidiasis along with the treatment of TB. There had been emerging resistance to antifungal therapy mostly in non-albicans candida in recent times, so this type of study where pulmonary TB patients are coinfected with *Candida* species will be worthwhile to the patients.

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Clinical Study using Urinary Albumin/Creatinine Ratio as an Early Predictor of Prognosis in Critically III Septic Patients

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Abstract

Background: Sepsis following surgery or trauma remains one of the leading causes of morbidity and mortality in hospital populations, especially in populations in intensive care units (ICUs). The key to successful control of sepsis-associated infections is early prediction and rapid treatment of the disease. Standard clinical and laboratory parameter testing estimate the levels of expression of interleukin-1 β (IL-1 β), IL-6, IL-8, and IL-10, tumor necrosis factor- α , FasL (Fas ligand is a type-II transmembrane protein), and CCL2 (C-C Motif Chemokines Ligand 2) mRNA and growth differentiation factor-15. These are a few measured by real- time reverse transcriptase polymerase chain reaction.

Aim of the Study: In this study, evaluation of the urinary albumin/creatinine ratio (ACR) was used as a prognostic predictor in critically ill sepsis patients.

Materials and Methods: In a prospective observational study, 365 adult critically septic patients were included. After clinical evaluation, urine spot samples were collected on admission and 24 h later for ACR1 and ACR2. Admission Acute Physiology and Chronic Health Evaluation (APACHE) IV score and the highest recorded Sepsis-related Organ Failure Assessment (SOFA) score of their daily estimation were considered. The need for mechanical ventilation was assessed in addition to inotropic and/ or vasoactive support, renal replacement therapy (RRT), and in-hospital mortality.

Observations and Results: A total of 365 patients who were critically ill with sepsis were initially recruited to this study. The patients included in this study were aged between 28 and 87 with a mean age of 62.37 ± 9.15 years. There were 235 (64.38%) males and 130 females (35.61%). The highest SOFA score was 7.4 (4.0-14.0) ranging from 1 to 17 and APACHE IV score recorded within the first 24 h of ICU admission was 76.8 (58.8-98.0) ranging from 46 to 118. Of 365 patients, 191 (52.32%) required ventilator support, 201 (55.06%) needed inotropic and/or vasoactive support to maintain hemodynamics, and 71 (19.45%) needed RRT. The mean length of hospital stay in the present study was 17.65 ± 8.60 days.

Conclusions: Evaluating the urinary ACR values regularly in all critically ill sepsis patients was a simple, rapid, non-invasive, inexpensive, easy to perform, and interpret test for early prognosis and prediction of mortality.

Key words: Microalbuminuria, Mortality, Sepsis, Urinary albumin/creatinine ratio

INTRODUCTION

Sepsis occurs in 1%–2% of all hospitalized patients and sepsis is a major cause of morbidity and mortality and the



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second leading cause of death worldwide. [1] Epidemiological studies are based on community or hospital studies, and the nature of data collection such as retrospective chart review, discharge diagnoses, diagnosis in death certificates, or prospective observational studies gives different figures. A robust epidemiological study methodology should be prospective in nature conducted over a prolonged period and should include heterogeneous case mix representative of the disease, thus allowing scope for generalizing the observed data. Epidemiological data on sepsis come mostly from western literature. [1-6] Data from India are sparse and in the form of epidemiology of infection

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(both community and hospital acquired) rather than sepsis which is a host response to infection. [7-10] Moreover, literature and surveys conducted in India concentrate on the microbiological profile, resistance pattern, antibiotic usage, and outcome rather than sepsis epidemiology. In the United States, sepsis causes more than 200,000 deaths each year. [2] Sepsis is characterized by a severe host defense response that involves triggering of potent inflammatory cascades which release a plethora of pro-inflammatory and anti-inflammatory molecules into the circulation.[11] The endothelial dysfunction is a milestone in sepsis pathogenesis. An early feature of sepsis is the loss of endothelial barrier integrity, leading to systemic capillary leak.[12] This enhanced capillary permeability causes increased glomerular excretion of albumin in the urine.^[13] Microalbuminuria has been accordingly seen by several studies to occur early after severe inflammatory process and to persist in more severe cases.[14-17] Early prediction of mortality among critically ill sepsis patients and early institution of intensive therapy are of paramount importance. Various ICUs scoring systems such as the APACHE II, APACHE IV, and Simplified Acute Physiology II scores to predict mortality are in current use. These scoring systems require a large number of variables derived from the patient's history, examination, and initial laboratory data. Microalbuminuria was shown to be promising as a predictor of organ failure, vasopressors requirement, and mortality prediction. It was shown to be even better than APACHE II and SOFA scores in some studies. [18-20] In the present study, an attempt was made to evaluate the prognostic value of urinary ACR in patients with sepsis and to compare this prognostic value with the APACHE IV and SOFA scoring systems.

Type of Study

This was a prospective, cross-sectional, and observational and analytical study.

Institute of Study

This study was conducted at Kannur Medical College, Anjarakandy, Kannur, Kerala, India.

Period of Study

The study duration was from May 2017 to April 2019.

MATERIALS AND METHODS

In this prospective observational and analytical study, 365 critically ill patients with sepsis who were admitted to surgical/medical ICUs were included. Kannur Medical College Hospital was a 750-bed tertiary care hospital attaché to a teaching institute. An ethical committee clearance was obtained before the commencement of the study. An ethical committee approved consent form signed

by the patient or his/her attendant was obtained before collecting the data.

Inclusion Criteria

- Patients with diagnosis of sepsis syndrome with the presence of systemic inflammatory response syndrome based on the diagnostic criteria of 1992 ACCP^[21] were included
- 2. Patients with [22] Society of Critical Care Medicine criteria with its update in 2001 "International Sepsis Definition Conference," exhibiting two or more of the following signs: (1) Temperature of >38°C or 90 beats/min, (3) respiratory rate of >20 breaths/min or hyperventilation with a PaCO2 of 12,000 lL1, or 10% immature cells were included. The presence of infection was defined according to the clinical and microbiological criteria of the Centers for Disease Control and Prevention definitions^[23] and was held as a gold standard.

Exclusion Criteria

1. Patients aged <18-year-old, patients with anuria or hematuria, patients with preexisting chronic kidney disease, patients with diabetes mellitus, patients with proteinuria due to renal or post-renal causes, patients with urinary tract infection, and patients with ICU length of stay (LOS) <24 h were excluded. All the patients were examined and determined by two independent experts who examined the patients daily for the first 48 h of admission. All the patients included in the study were subjected for clinical evaluation including history, physical examination, routine laboratory investigations (capillary blood glucose, coagulation profile, arterial blood gases, liver function tests, kidney function tests, random blood sugar, and serum electrolytes), and cultures from suspected sources of infection including sputum and urine. For all the patients at least two blood cultures obtained from different venipunctures were obtained before antibiotic administration. APACHE IV score was calculated in an integer score form that is web-based computed by applying worst values of the measurements observed during 24 h following ICU admission, with a maximum score of 286. Other parameters of disease severity that were studied included need for mechanical ventilation, need for inotropic and/or vasoactive support, and need for RRT. Outcome was evaluated by ICU-LOS and the in-hospital mortality. Urinary ACR urine spot samples were collected at the time of ICU admission for ACR1 and 24 h following ICU admission for ACR2. Urinary microalbumin was measured by the immunoturbidimetric method and urinary creatinine by modified kinetic Jaffe reaction (Dimension RxL Max, Dade Behring Inc., U. S. A.). A trend of microalbuminuria was assessed as the change from ACR1 to ACR2. The difference between those values represents the delta ACR (D ACR) and is calculated as D ACR = ACR2 ACR1. When D ACR is negative, it is defined as decreasing ACR and when it is positive, it is defined as increasing ACR. SOFA score was calculated in all the patients right from the admission to the time of discharge or demise. All the data were analyzed using standard statistical methods.

OBSERVATIONS AND RESULTS

A total of 365 patients who were critically ill with sepsis were initially recruited to this study. The patients included in this study were aged between 28 and 87 with a mean age of 62.37 ± 9.15 years. There were 235 (64.38%) males and 130 females (35.61%). Table 1 shows the various causes and sources of infection in the present study subjects. The highest SOFA score was 7.4 (4.0–14.0) ranging from 1 to 17 and APACHE IV score recorded within the first 24 h of ICU admission was 76.8 (58.8-98.0) ranging from 46 to 118. Of 365 patients, 191 (52.32%) required ventilator support, 201 (55.06%) needed inotropic and/ or vasoactive support to maintain hemodynamics, and 71 (19.45%) needed RRT. The mean length of hospital stay in the present study was 17.65 ± 8.60 days. One hundred and thirty-seven (37.53%) patients died and the remaining survived their ICU course (Figure 1). ACR measurements: ACR measured on admission (ACR1) was 116.7 (79.1–153.9) with a range from 27 to 221 mg/g and the 24 h ACR (ACR2) was 138.3 (65.2–193.2) ranging from 23 to 245 mg/g. The ACR was decreased in 160 patients

Table 1: The different sources of infection in the study group (n=365)

Source of sepsis	n (%)
Chest infection	220 (60.27)
Peritonitis	072 (19.72)
Infected bed sores	027 (07.39)
Wound infection	046 (12.60)

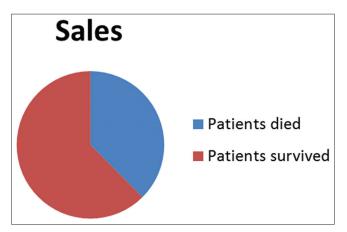


Figure 1: The mortality rate in the study (Blue: 37.53, Pink: 62.46%)

(43.83%) by 31 (24.1–38.9) mg/g and it was increased in 205 (56.16%) by 36.7 (25.7–58.95) mg/g. ACR in relation to disease severity, the ACR1 was not significantly correlated with SOFA (r = 0.216, P = 0.143) or APACHE IV (r =0.178, P = 0.301) scores while the ACR2 was positively correlated with SOFA score (r = 0.315, P = 0.023) but not with APACHE IV score (r = 0.277, P = 0.076), (p significant at < 0.05). The SOFA score was significantly higher in patients with increased ACR trend 13 (4.15–15.35) than in patients with stationary or declining trend 5.2 (3–8) (P = 0.01). Meanwhile, there was no significant difference in APACHE IV between patients with increased ACR trend 89.15 (57.7–99.03) and those with stationary or declining ACR trend 64 (53–81) (P = 0.201). The ACR1 was not statistically different in patients who needed and those who did not need mechanical ventilation; 113.8 (96.25–184.14) versus 83.40 (71.8–140.70), respectively (P = 0.09), while ACR2 was significantly higher in patients who required mechanical ventilation compared to those who did not need 137.40 (122.80–201.3) versus 64.05 (46.03–171.15).

Considering the change in ACR, it was observed in this study that the increase in ACR was a predictor of the need of mechanical ventilation. Of the 205 patients with increased ACR, 155 (75.60%) needed mechanical ventilation while 50 (24.39%) did not (P = 0.010). A similar relation was found between ACR1 and ACR2 and the need of inotropic and/or vasoactive support. ACR1 was not significantly different in patients who needed and those who did not need inotropic and/or vasoactive support (112.65 [96.3–200.80] vs. 98.5 [72.0–135.6], respectively, P = 0.040) while ACR2 was significantly higher in patients who needed inotropic and/or vasoactive support compared to those who did not need (151.15 [125.85-218.2] vs. 73.3 [51.7–159.5], respectively, P = 0.018). Considering the change in ACR, we found that the increase in ACR was a predictor of need of inotropic and/or vasoactive support. Of the 205 patients with increased ACR, 136 patients (66.34%) needed inotropic and/or vasoactive support while 69 patients (33.65%) did not (P = 0.015). Neither ACR1 nor ACR2 was significantly related to the need for RRT in this study. ACR1 was 111.05 (96.4-140.70) versus 113.2 (83.09–171.60) for those who needed and did not need RRT, respectively, P = 0.712 and ACR2 was 137.40 (121.3-163.8) versus 133.05 (55.24-193.0), P = 0.431. Even the increase in ACR overtime was not significantly associated with the need for RRT. Of the 205 patients with increased ACR, 56 patients (27.31%) needed RRT while 149 patients (72.68%) did not (P = 0.340).

ACR and Outcome

The ACR1 and ACR2 revealed significantly positive correlation with ICU-LOS (r = 0.5, P = 0.007 for ACR1 and r = 0.4, P = 0.05 for ACR2). Both ACR1 and ACR2

were a significant predictor for mortality in our patients' population. ACR1 and ACR2 were 120.83 (101.3–184.31) mg/g and 191.0 (136.4–216.8) mg/g in non-survivors compared to 90.8 (72.3–128.4) mg/g and 69.1 (49.3–132.5) mg/g for survivors (P = 0.009 and <0.001 for ACR1 and ACR2, respectively).

DISCUSSION

Sepsis is not only a great health problem but also an important socioeconomic challenge worldwide. It lowers patients' living quality and increases the mortality significantly.[1] Identification of sepsis, its prognosis, and outcome prediction are of paramount importance in medical practice. At present, available tools for prediction of prognosis in ICU are the APACHE scores, [24] which predict mortality, and the SOFA score, [25] which predicts morbidity. These scoring systems rely on several physiological indices and chemical analyses. In addition to difficulty in estimation, several drawbacks and limitations have been shown to these scoring systems. [26] No definite laboratory biomarkers had been definitively demonstrated to correlate with severity of illness and mortality in ICU patients. Several clinical studies on critically ill patients with severe endothelial and renal involvement showed that microalbuminuria may be a beneficial marker of disease severity and mortality prediction^[18,19] and it may indirectly quantify changes in systemic vascular permeability. [13] Few authors had identified microalbuminuria as a significant prognostic marker of morbidity and mortality.[23] The level of microalbuminuria starts to increase within hours of an inflammatory insult as against delayed increases in levels of many other mediators.^[27] In the present study, an attempt was made to evaluate the prognostic value of urinary ACR in sepsis in the intensive care setting and to compare this prognostic value with the APACHE IV and SOFA scoring systems. The commonly known factors that may cause increased ACR and that might be confounding are the diabetes mellitus and chronic kidney disease; accordingly, hence, these conditions were excluded. Sepsis is characterized by widespread endothelial dysfunction arising from the effects of cytokines, and other inflammatory mediators released during the intense inflammatory responses, leading to systemic increase in capillary permeability.[11] The increased capillary permeability in the pulmonary circulation contributes into ARDS, [26] in systemic circulation contributes into sepsis-induced hypotension, [27] and in renal circulation causes increased amounts of albumin to escape into the glomerular ultrafiltrate. The tubular reabsorptive mechanism for albumin from the ultrafiltrate is exceeded beyond its threshold capacity, leading to increased excretion of albumin in the urine. [28] As a marker of increased

permeability, microalbuminuria was supposed to indicate the development of ARDS, hemodynamic compromise, and acute kidney injury. Accordingly, in this study, observation of the use of mechanical ventilation, inotropic and/or vasoactive support, and RRT as severity indicators were done. Here was no significant correlation between ACR1 obtained on admission and either SOFA or APACHE IV scores while ACR2 obtained 24 h later significantly correlated with SOFA score and had a statistically nonsignificant tendency for correlation with APACHE IV score. It was also found that the SOFA score while not APACHE IV score is higher in patients with an increasing trend of ACR. In a medical/surgical critically ill patients, Basu et al. found that ACR 6 and 24 h after admission were correlated with APACHE II score. [28] De Gaudio et al. [14] reported an increasing ACR to be positively correlated with an increasing SOFA score in 55 post-operative patients with sepsis. It was observed in this study that the ACR2 and the Δ ACR and not the ACR1 are associated with a higher incidence of need of mechanical ventilation and need of inotropic and/or vasoactive support. Other authors also found that ACR is inversely associated with the PaO2/FiO2 ratio in post-trauma patients and was associated with significantly more duration of mechanical ventilation in patients with initially normal lung function. [29] The mean length of hospital stay in the present study was 17.65 ± 8.60 days. There was a positive correlation between the ACR on admission and 24 h later and the ICU-LOS. Gosling et al. found that ACR values positively correlate with ICU-LOS.[29] In Gosling's study, the ACR was measured on admission and 6 h later. APACHE IV, ACR1, and ACR2 were found to be predictors for mortality in this study. The AUC for ROC analysis was highest for APACHE IV score (0.905) followed by ACR2 (0.876) and then ACR1 (0.755). We found an APACHE IV score of 72.5 to have 100% sensitivity and 80% specificity, ACR1 of 86.3 mg/g to have 100% sensitivity and 50% specificity, and ACR2 of 110.5 mg/g to have 100% sensitivity and 86.2% specificity to predict mortality. It was also observed that the trend of ACR overtime is a predictor of mortality with higher mortality in those with an increase in ACR2 compared to ACR1. The increase in ACR was associated with 89% sensitivity and 68% specificity for detection of mortality in sepsis patients.

CONCLUSIONS

Evaluating the urinary ACR values regularly in all critically ill sepsis patients was a simple, rapid, non-invasive, inexpensive, easy to perform, and interpret test for early prognosis and prediction of mortality. Late ACR after 24 h from ICU admission and ACR trend overtime might be more important than the earlier admission ACR. Thus,

together with conventional illness severity scores, the measurement of ACR on admission to the ICU, and 24 h later, can provide additional information on patient outcome.

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Evolving a System of Classification for Scalp Defects and Methods of Reconstruction

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Abstract

Background: Scalp wound closure requires good understanding of scalp anatomy, knowledge of a algorithm for reconstruction of scalp defects, good planning, adequate debridement, proper execution and proper post-operative care. **Aim and objective:** The aim of the study was to use a simple algorithm to reconstruct scalp defects of various sizes and to study the efficacy of the algorithm in reconstruction of scalp defects. **Materials and Methods:** All patients with scalp defect who presented to the Department of Burns Plastic and Reconstructive surgery at Kilpauk government medical college were studied. Reconstruction of scalp defect was planned based on the algorithm. All patients were followed up for a period of 1 year post operatively. **Results:** The scalp defects were reconstructed based on the algorithm. Smaller defects were managed with primary closure and SSG. Larger size defects and defects without periosteum were given local or distant flap. All patients recovered well with lesser rate of complications. **Conclusion:** Reconstruction of scalp defect is made easy with the use of the algorithm for choice of treatment based on the defect size.

Key words: Distant flap, Free flaps for scalp wound, Local flaps, Primary suturing, Regional flaps, Scalp wound, Skin grafting

INTRODUCTION

Scalp defects can occur due to varied causes ranging from congenital (aplasia cutis) to acquired (trauma, burns, infection, and neoplasm). When scalp and forehead reconstruction is considered, several factors are important in the development of a treatment plan. ^[1] The evaluation of the defect is critical in the management of the patient. The factors assessed are size, site, depth of wound, laxity of scalp, and nature of available tissue and patient factors such as age and comorbidities are also taken into account. The effect of reconstruction on nearby mobile structure such as hairline and eyebrow is to be considered. The goals of reconstruction are to restore the scalp with hair-bearing skin by redistribution of local tissues and a good esthetic outcome. ^[2]

Objectives

To use a simple algorithm to reconstruct scalp defects of various sizes.



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MATERIALS AND METHODS

This is an observational retrospective study of patients admitted with scalp defects in the Department of Burns, Plastic and Reconstructive Surgery at Government Kilpauk Medical College and Hospital from January 2015 to January 2018.

Based on the size of the defect, an algorithm was created and patients were planned for the scalp defect reconstruction [Table 1].

Inclusion Criteria

All patients with scalp defect who presented to the Department of Burns, Plastic and Reconstructive Surgery at Kilpauk Medical College and Hospital were included in the study.

Exclusion Criteria

Patients with concurrent head injuries were excluded from the study.

Method of Study

The patients were categorized based on the scalp defect size [Table 2]. Reconstruction of the defect was planned based on the algorithm. All patients were followed up for

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Defect size

| Smooth and and elastic atrophic | presence of pericranium | primary closure | flaps | SSG | local flaps (rotation) | SSG | local flaps (rotation) | SSG | local flaps (rotation) | SSG | local flaps (distant flaps distant flaps

Table 1: Algorithm for scalp defect reconstruction

Table 2: Patient statistics

Defect size	Periosteal involvement	Reconstructive method	Number of patients
<3 cm	-	Primary closure	9
3–6 cm	With periosteum	SSG	7
3-6 cm	Without periosteum	Flap	32
6-9 cm	With periosteum	SSG	4
6–9 cm	Without periosteum	Flap	3
>9 cm	-	Flap	3

SSG: Split skin grafting

a period of 1 year postoperatively. Immediate and late post-operative complications were noted.

RESULTS

In this study, patient with aplasia cutis was managed conservatively allowing the raw area to heal by secondary intention. This patient recovered without any complications. Nine patients presented with scalp defect size <3 cm and underwent primary closure [Figure 1]. All patients recovered uneventfully. Split skin grafting was done in 11 patients with size of defects ranging from 3 to 9 cm with intact periosteum [Figure 2]. Of this, two patients had minimal graft loss, which were managed conservatively and healed with dressings alone. Thirty-two patients with defect size between 3 cm and 6 cm without periosteum were managed with local flaps (14 rotation flaps [Figures 3 and 4] and 18 transposition flaps [Figure 5]). For patients with scalp defects of size 6-9 cm without periosteum (three patients) were managed with distant flaps (two supraclavicular flaps [Figure 6] and one vertical trapezius flap). Patients who presented with a scalp defect size of >9 cm (three patients) underwent free flap cover of raw area (two anterolateral thigh free flap [Figure 7] and one latissimus dorsi free flap [Figure 8]) [Table 3].



Figure 1: Primary closure for scalp defect

DISCUSSION

Scalp and forehead share five anatomic layers: skin, subcutaneous tissue, loose areolar tissue, and pericranium. The skin of the scalp is the thickest in the body. The underlying galea apneurotica is a broad fibromuscular layer that covers the cranium from the forehead to the occiput. Scalp has two muscles — occipitalis and frontalis. The scalp and forehead are supplied by five paired arteries that form rich interconnections: Supraorbital and supratrochlear arteries, superficial temporal artery, post-auricular artery, and occipital artery.

Etiology of scalp defects [Table 4] varied from congenital defects like aplasia cutis to acquired defects like trauma, thermal electrical chemical and radiation burns, infection, and neoplasm. [Figures 9 and 10].

Evaluation of the scalp defect was based on the following factors; size, site, depth of wound, laxity of scalp, nature of available tissue, and patient factors.^[3]

59

Table 3: Reconstructive methods			
Reconstructive methods Number of patients			
Conservative	1		
Primary closure	9		
Split skin graft	11		
Rotation flap	14		
Transposition flap	18		
Distant flap			
Supraclavicular flap	2		
Vertical trapezius flap	1		
Free flap			

Table 4:	Etiology	of scalp	defects
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Anterolateral thigh flap Latissimus dorsi flap

Total

Etiology	Number of patients		
Congenital			
Aplasia cutis	1		
Acquired			
Trauma	18		
Burns	29		
Infection	5		
Neoplasm	6		
Total	59		

Table 5: Complications

Complications	Number of patients
Minimal graft loss	2
Anterolateral thigh free flap failure	1
Minimal flap necrosis	4

Scalp defects classified based on the size of the defect:

- 1. <3 cm small
- 2. 3–6 cm moderate
- 3. 6-9 cm large
- 4. >9 cm extensive.

Reconstructive options of scalp defect are primary closure, skin grafting, local flaps, distant flaps, free flaps, and tissue expander.

In the case of the scalp, the repair of even small defects is complicated. The goals of reconstruction are to restore the scalp with hair-bearing skin by redistribution of local tissues and for a good esthetic outcome. If the skin defect does not exceed 3 cm in diameter, it can be closed primarily. If primary closure is not possible without tension, the surrounding loose connective tissue can be undermined to attain more mobility. In larger defects with a vascularized bed and intact pericranium, split skin grafting is the choice for reconstruction. This is technically easier but has poor cosmetic results and is unstable. Local flaps are indicated in moderate- and large-sized defects exposing cranial bone



Figure 2: Split skin grafting for scalp defect



Figure 3: Double rotation flap cover for scalp defect



Figure 4: Rotation flap for scalp defect

without pericranium.^[4] Distant flaps are preferred when there are an extensive defects with unavailable local tissues. Regional musculocutaneous flap such as the trapezius flap and latissimus dorsi flap can be used in reconstruction. Free flaps are indicated in larger to extensive defects with unavailable local tissues and absent pericranium. With scalp defect more than 9 cm defect and availability of technical expertise, free flaps are the choice for reconstruction.^[5] Regional musculocutaneous flap like the trapezius flap and latissimus dorsi flap can be used in reconstruction.



Figure 5: (a) Transposition flap for scalp defect.
(b) Transposition flap cover for scalp defect



Figure 6: Supraclavicular flap cover for scalp defect



Figure 7: Anterolateral thigh flap for scalp defect

Free flaps are indicated in larger to extensive defects with unavailable local tissues and absent pericranium. [6] With scalp defect more than 9cms defect and availability of technical expertise, free flaps are the choice for reconstruction. [7] Scalp reimplantation can be considered only when complete or near complete avulsion of the scalp has occurred. It is contraindicated when the patient is hemodynamically unstable. It is absolutely contraindicated in severely macerated scalp part and in patients with concomitant severe life threatening injuries. As a secondary procedure, tissue expansion can be considered to provide hair bearing scalp. [8]



Figure 8: Latissimus dorsi free flap for scalp defect

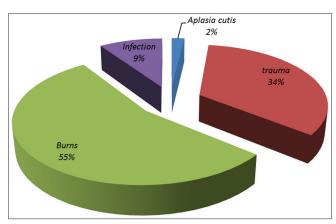


Figure 9: Etiology of scalp defects

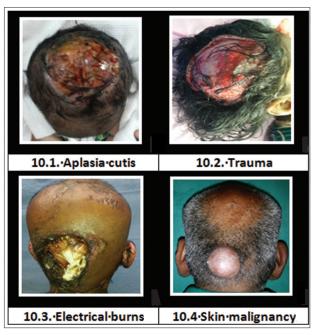


Figure 10: Etiology of scalp defects

Complications

The most common complications following scalp defect reconstruction are bleeding, wound dehiscence, infection, flap necrosis, graft loss, and flap loss. The complications encountered in this study [Table 5] were minimal graft loss in two patients who were managed conservatively. Minimal flap necrosis developed in four patients that were debrided and sutured primarily. Complete failure one anterolateral thigh free flap was encountered which was managed with wound debridement and distant flap cover.

CONCLUSION

Successful reconstruction of the scalp requires careful preoperative planning, adequate debridement, precise intraoperative execution, and proper post-operative care. [9] Detailed knowledge of scalp anatomy, skin biomechanics, hair physiology, and the variety of available local tissue rearrangements allows for excellent esthetic reconstruction. [10] Reconstruction is made easy with the use of the algorithm for choice of treatment based on the defect size.

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Thoracoscopy and its Role in Evaluating Undiagnosed Pleural Effusions

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Abstract

Introduction: Definition of undiagnosed pleural effusion was considered as the failure to achieve an etiologic diagnosis by initial pleural fluid microbiological, biochemical analysis, and at least three pleural fluid cytologies negative for malignant cells or other definite causes. Medical thoracoscopy also referred to as pleuroscopy is an endoscopic evaluation of the pleural space. Thoracoscopy was mainly used in the etiological diagnosis of pleural effusions and therapeutic procedures such as pleurodesis and adhesiolysis. In around 20%–30% of cases, etiology remains unclear and in this context, thoracoscopy becomes an important investigation modality.

Materials and Methods: It is a prospective, interventional study taken up as a pilot project by the Department of Pulmonary Medicine of SVS Medical College and Hospital, Mahabubnagar, Telangana, India. A total of 30 patients were satisfying the inclusion criteria and were further studied for their thoracoscopic and histopathological findings from January 2018 to November 2018.

Results: A total of 30 patients out of whom 19 patients were male (63.3%) and 11 patients (36.6%) were female. The most common respiratory symptom was shortness of breath in 18 patients (60%) and cough in 12 patients (40%). Out of the total 30 cases, 23 (76.66%) were malignant and 7 (23.33%) were diagnosed to be having tuberculosis (benign). According to the histopathological diagnosis, 20 (66.6%) had metastatic adenocarcinoma, 7 (23.3%) had tuberculosis and malignant lymphoma, and metastatic squamous cell carcinoma and sarcoma were detected in 1 (3.3%) patient. According to thoracoscopic findings, 13 (43.3%) patients had mass lesion, 12 (40%) patients had nodule, 3 (6.6%) patients had adhesions, and 2 (10%) patients had plaques. Majority of the mass lesions 11 (36.66%) were metastatic adenocarcinomas and majority of nodules 5 (16.66%) were diagnosed as tuberculous lesions.

Key words: Histopathology, Pleural effusion, Thoracoscopy

INTRODUCTION

Medical thoracoscopy also referred to as pleuroscopy is an endoscopic evaluation of the pleural space. It is minimally invasive procedure invented in 1910 by

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Hans Christian Jacobeus who is regarded as "Father of Thoracoscopy." Thoracoscopy was mainly used in the etiological diagnosis of pleural effusions and therapeutic procedures such as pleurodesis and adhesiolysis. In around 20%–30% of cases, etiology remains unclear and in this context, thoracoscopy becomes an important investigation modality. Thoracoscopy, mainly rigid thoracoscopy, is useful to get large tissues where we can go for relevant investigations.

Thoracoscopy-guided biopsy and adhesiolysis today is a minimally invasive procedure performed by interventional pulmonologists. Results are excellent and

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severe complications are extremely rare. Thoracoscopy is a valuable tool as the pleural space can be visualized and representative sample can be picked.

Histopathology is the microscopic examination of the tissue to study the manifestations and type of disease. The tissue for histopathological examination is obtained after surgery or biopsy or autopsy. Later, it is sent for laboratory for confirmation by the pathologist. This is the gold standard investigation for confirmation. Whenever there is difficulty in confirming the diagnosis, histopathological examination remains the standard procedure of choice.

Definition of undiagnosed pleural effusion was considered as the failure to achieve an etiologic diagnosis by initial pleural fluid microbiological, biochemical analysis and at least three pleural fluid cytologies negative for malignant cells or other definite causes.^[3]

In Indian scenario, there are fewer studies that have been done on the role of thoracoscopy in cases of undiagnosed pleural effusion. [4-6] This study was taken up to find out the thoracoscopic gross appearance in undiagnosed exudative pleural effusion cases and its final histopathological diagnosis.

MATERIALS AND METHODS

It is a prospective, interventional study taken up as a pilot project by the Department of Pulmonary Medicine

Table 1:Types of cases according to gender

Type of cases	Male (%)	Female (%)	Total (%)
Malignancy	14 (46.66)	09 (30)	23 (76.66)
Tuberculosis	05 (16.66)	02 (6.66)	07 (23.33)
Total cases	19 (63.33)	11 (36.66)	30 (100)

Table 2: Histopathological diagnosis of cases

Histopathological diagnosis	Frequency (%)
Metastatic adenocarcinoma	20 (66.6)
Malignant lymphoma	1 (3.3)
Metastatic squamous cell carcinoma	1 (3.3)
Sarcoma	1 (3.3)
Tuberculosis	7 (23.3)

of SVS Medical College and Hospital, Mahabubnagar, Telangana, India. All the enrolled cases of exudative pleural effusion which satisfy the inclusive criteria were taken into the study from January 2018 to November 2018. A total of 30 patients were satisfying the inclusion criteria and were further studied for their thoracoscopic and histopathological findings. The study was started after taking the approval of the Institutional Ethics Committee, SVS Medical College and Hospital, Mahabubnagar, Telangana, India.

The inclusion criteria include any case of exudative pleural effusions of age 45–75 years, which remained undiagnosed after initial and repeated biochemical, cytological analysis of pleural fluid and who have given the consent for participating in the study.

The exclusion criteria included the pleural effusions where microbiological or cytological or biochemical confirmation of diagnosis has been achieved. The patients who are unfit for the procedure, those who are suffering from bleeding diathesis, and those who are not willing to participate in the study were excluded from the study.

The patient underwent complete physical examination with written informed consent after detailed clinical history was taken. All the necessary baseline investigations were done including prothrombin time to assess the fitness of the patient. Radiological investigations included chest X-ray, contrast-enhanced computed tomography chest, and ultrasound chest.

For thoracoscopic procedure, the patient should be nil by mouth for at least 6 h before the procedure. During the procedure, the patient is asked to lie down in the lateral decubitus position with the affected side facing upward. Locoregional anesthesia is given on the desired site of affected side. Throughout the procedure, conscious sedation with benzodiazepine and opioid was given and blood pressure, oxygenation, and pulse were monitored.

Incision was given at the desired site and pleural cavity was entered with blunt dissection. A trocar and cannula were introduced along with rigid thoracoscope. Inspection of

Table 3: Thoracoscopic findings and histopathological diagnosis

Histopathological diagnosis	Mass lesion (%)	Nodule (%)	Plaque (%)	Adhesion (%)
Metastatic adenocarcinoma (n=20)	11 (55)	5 (25)	2 (10)	2 (10)
Malignant lymphoma (n=1)	0	1 (100)	0	0
Metastatic squamous cell carcinoma (<i>n</i> =1)	0	1 (100)	0	0
Sarcoma (n=1)	1 (100)	0	0	0
Tuberculosis (n=7)	1 (14.2)	5 (71.5)	0	1 (14.2)
Total (<i>n</i> =30)	13 (43.3)	12 (40)	2 (6.6)	3 (10)

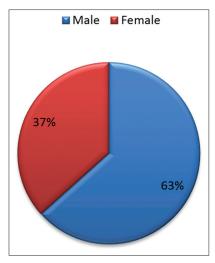


Figure 1: Distribution of the study population according to gender

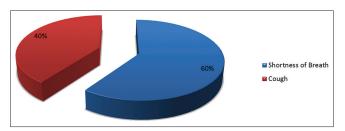


Figure 2: Distribution of the study population according to symptoms

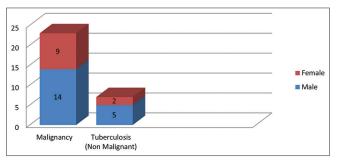


Figure 3: Types of cases according to gender

the pleural cavity was done and at selected sites, pleural biopsies were also taken simultaneously. The findings of thoracoscopy were recorded and the biopsy specimen was sent for histopathological examination. Adhesiolysis was also in patients in whom adhesions were present. Six to 10 biopsies are taken with pinch and peel method from the mass lesions, nodules, and plaques. Chest tube was inserted and connected to underwater seal and secured with suture. Biopsies were also sent for CBNAAT and acid-fast bacilli culture.

The data were entered using Microsoft Excel and analyzed using Microsoft Excel and Epi info software. Univariate analysis was done.

RESULTS

A total of 30 patients out of whom 19 patients were male (63.3%) and 11 patients (36.6%) were female. The most common respiratory symptom was shortness of breath in 18 patients (60%) and cough in 12 patients (40%). Out of the total 30 cases, 23 (76.66%) were malignant and 7 (23.33%) were diagnosed to be having tuberculosis (benign). Malignancy was present in 14 (46.66%) male patients and 9 (30%) female patients. Tuberculosis was diagnosed in 5 (16.66%) male patients and 2 (6.66%) female patients.

According to the histopathological diagnosis, 20 (66.6%) had metastatic adenocarcinoma, 7 (23.3%) had tuberculosis and malignant lymphoma, and metastatic squamous cell carcinoma and sarcoma were detected in 1 (3.3%) patient each.

According to thoracoscopic findings, 13 (43.3%) patients had mass lesion, 12 (40%) patients had nodule, 3 (6.6%) patients had adhesions, and 2 (10%) patients had plaques. Majority of the mass lesions 11 (36.66%) were metastatic adenocarcinomas and majority of nodules 5 (16.66%) were diagnosed as tuberculous lesions.

Of seven patients diagnosed to be tuberculosis, all were AFB positive and their histopathological examination suggested tuberculosis. Six were CBNAAT positive.

DISCUSSION

This prospective, interventional study was taken up as a pilot project by the Department of Pulmonary Medicine of SVS Medical College and Hospital, Mahabubnagar, Telangana, India.

In our study, majority of the patients were male and the most common symptom of presentation was shortness of breath. These findings are in concurrence with the study conducted by Patil *et al.*,^[3] where the majority of the cases were male and presented with shortness of breath. In a study done by Yousef *et al.*,^[7] male and female patients were in equal number and dyspnea was the presenting feature in all of them.

In this study, histology revealed that majority (76.66%) of the cases of undiagnosed exudative pleural effusion are malignant. These findings are in line with the study conducted by Patil *et al.*^[3] and Prabhu and Narasimhan,^[6] where majority of the patients were diagnosed with malignancy on histopathological examination. Other studies also reported that majority of the histopathological findings as malignancies.^[4,5,8,9]

In this study, mass lesions and nodules were the most common thoracoscopic findings. However, in the study

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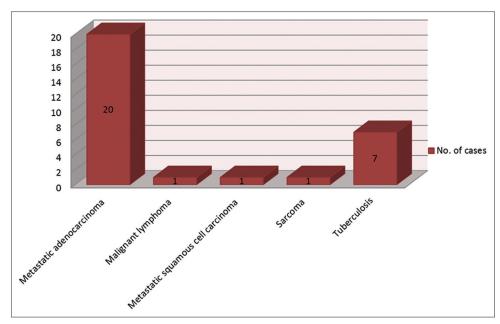


Figure 4: Histopathological diagnosis of cases

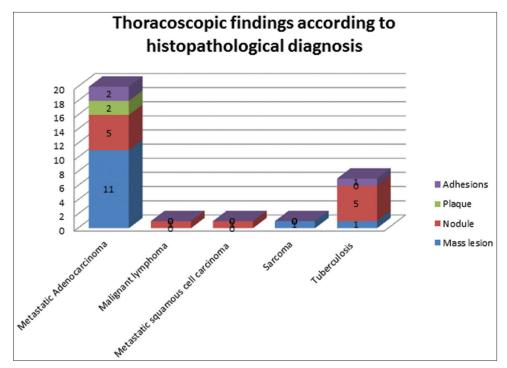


Figure 5

conducted by Yousef *et al.*, almost 75% of them presented as nodules.

In this study, metastatic adenocarcinoma was the most common histolopathological finding. This finding of our study is in concurrence with the study done by Patil *et al.*^[3]

The complications after the procedure were nil. However, in the study conducted by Prabhu and Narasimhan, [6] 5%

of them had minor complications such as subcutaneous emphysema and prolonged air leak. Similarly, in the studies conducted by Menzies and Charbonneau,^[10] Blanc *et al.*,^[11] Munavvar *et al.*,^[12] and Law *et al.*^[13] reported minor complications after the procedures.

CONCLUSION

• In this study, adenocarcinoma (66.6%) is most common

 In this study, mass lesions were the most common gross finding in patients who were diagnosed with adenocarcinoma.

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Effect of Pleurodesis with 2% Povidone-lodine in a Tertiary Care Centre, Mahabubnagar, Telangana

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Abstract

Background: Tetracycline, talc, and bleomycin have been proved to be effective in recurrent spontaneous pneumothorax and malignant pleural effusion. Recent studies have shown the efficacy of 2% betadine in pleurodesis.

Objective: The objective of this study was to find out the success rate of 2% betadine in pleurodesis in patients with recurrent spontaneous pneumothorax and malignant pleural effusions.

Materials and Methods: The study was conducted in SVS Medical College, Mahabubnagar Dist., Telangana, during the period of May 2016 - Feb 2019. Patients with malignant pleural effusion and recurrent spontaneous pneumothorax were taken into consideration. About 2% betadine with xylocaine was used in this study.

Results: A total of 26 patients underwent pleurodesis. Eighteen patients had malignant pleural effusion and eight patients had recurrent spontaneous pneumothorax. Of 26 patients, 23 (88.5%) patients had successful pleurodesis. Among 23 patients who had underwent successful pleurodesis, 16 had malignant pleural effusion and seven had recurrent spontaneous pneumothorax.

Conclusion: In our observation, we have seen that pleurodesis with 2% betadine is very effective and inexpensive in pleurodesis without many complications.

Key words: Pleurodesis, 2% povidone iodine, Pneumothorax, Malignant effusion

INTRODUCTION

Pleurodesis is a procedure to achieve symphysis between the two layers of pleura aimed at preventing accumulation of either air or fluid in the pleural space. [1] It is usually done in recurrent malignant effusions and recurrent pneumothorax cases. Pleurodesis can be achieved by either a chemical agent or by physical abrasion of the pleural surfaces during thoracotomy or thoracoscopy.



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Various agents are used, but no agent till now is considered to be an ideal agent for pleurodesis. Talc till now is considered to be the most effective agent for chemical pleurodesis in both spontaneous pneumothorax and malignant effusion. [2,3] Tetracycline and bleomycin are also used in pleurodesis.

Betadine is being used for pleurodesis from the year 1991^[4] and various studies are going onto prove efficacy of 2% betadine.^[5-8]

Aim

The study was conducted to know the efficacy of pleurodesis with 2% betadine for recurrent malignant pleural effusions and recurrent pneumothorax cases.

METHODOLOGY

The study was conducted in SVS Medical College, Mahabubnagar Dist., Telangana, during the period of

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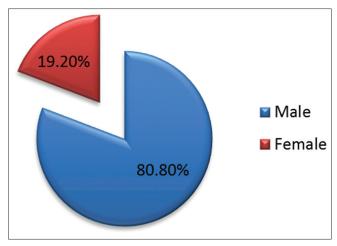


Figure 1: Gender distribution

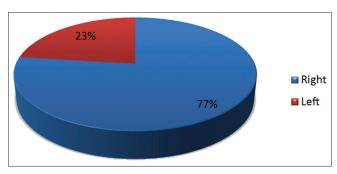


Figure 2: Lung involvement

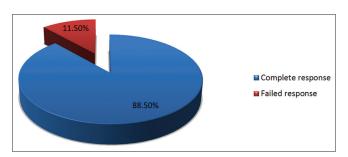


Figure 3: Response after the procedure (success rate)

March 2016–February 2019. A total of 26 patients were included in the study, of which 18 were suffering from malignant pleural effusions and eight had recurrent pneumothorax. An informed consent was taken after explaining the complete procedure with side effects.

Procedure

The use of nonsteroidal anti-inflammatory drugs and other anti-inflammatory drugs should be stopped 24 h before pleurodesis till 12 h after the procedure. An inter costal drain (ICD) was inserted in the patients. Pleurodesis was done in patients with drain <100 ml and in the absence of air leak, and chest X-ray showing complete expansion of lung. Distal end of tube was clamped and 20 ml of 2% xylocaine was injected into the pleural cavity through ICD, percussion was

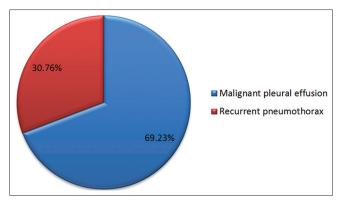


Figure 4: Diagnosed condition among patients

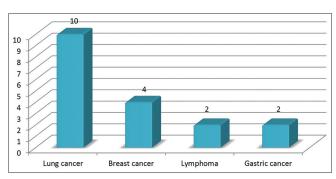


Figure 5: Primary sites in malignant pleural effusion (16 cases)

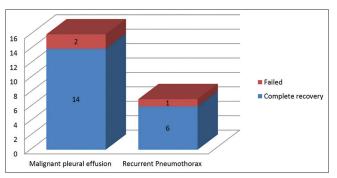


Figure 6: Complete recovery according to the diagnosis

done while changing patient to different positions. Then, 70 ml of 2% betadine mixed with 10–20 ml of normal saline was injected. Then, percussion was done changing patient to different positions. Then, ICD was kept clamped for 6 h following an ultrasonography chest and X-ray was done after releasing the clamp and repeated after 7 days. The response to this procedure, treatment failure, and the complaints of the patients were evaluated.

Inclusion Criteria

The patients who were diagnosed to have the following conditions and those who were willing to participate in the study by giving a written informed consent were enrolled for the study.

- 1. Diagnosed with primary malignancy
- 2. Recurrent symptomatic malignant effusion

- 3. Recurrent spontaneous pneumothorax
- 4. Evidence of complete expansion of lung after drainage of air/fluid
- 5. Absence of bronchial obstruction.

Exclusion Criteria

The patients who had the following conditions and those who were not willing to participate in the study were excluded from the study.

- 1. Cardiac disease
- 2. Trapped lung
- 3. Loculated effusions.

RESULTS

A total of 26 patients were studied. The mean age of patients was 63.6 ± 5 (45–80) years. Out of the total 26 patients, 21 (80.8%) patients were men and 5 (19.2%) were women. The right lung was involved in 20 (77%) patients and the left lung in 6 (23%) patients.

Out of the total 26 patients, 18 (69.23%) had malignant pleural effusion. The most common primary diseases associated with malignant pleural effusion were lung cancer (n = 10, 55%) followed by breast cancer (n = 4, 22%), lymphoma (n = 2, 11%), and gastric cancer (n = 2, 11%). Rest 7 (30.76%) patients had recurrent pneumothorax.

Of 26 patients, 23 patients (88.5%) achieved confirmed complete response. In three patients (11.5%), pleurodesis failed to achieve complete response.

Among 18 patients who had malignant pleural effusion, pleurodesis was successful in 16 (88.9%) patients and was unsuccessful in 2 cases (11.1%). Among eight patients suffering with recurrent pneumothorax, 7 (87.5%) were successful and 1 (n = 1, 12.5%) failed.

There were no complications reported by the patients except for one case of recurrent pneumothorax which reported pain. Injection tramadol was given and pain subsided. No other mortality and morbidity were reported in this study.

DISCUSSION

Chemical pleurodesis is the procedure of choice in the management of recurrent pleural effusions^[9] and a recognized treatment option in the management of patients with primary or secondary spontaneous pneumothorax.^[10] The question is the choice of the sclerosing agent, which is determined by the efficacy of the agent, its cost, accessibility, safety, ease of administration, and the number of administrations needed to achieve a complete response.

The precise mode of action of iodopovidone remains unclear.^[11] It may be related to the low pH (pH 2.97) of the sclerosing solution, or to the strong oxidative and cytotoxic properties of iodine, which can induce a potent inflammatory response.

Agarwal et al.^[7] obtained complete response rate of 86.5% in pleural effusion group and 92.6% in pneumothorax group with povidone-iodine in a study including 37 patients with pleural effusion and 27 patients with pneumothorax.

In a review of six studies, 265 patients underwent chemical pleurodesis with povidone-iodine, and the mean success rate was 90.6%. In this meta-analysis, pleurodesis with povidone-iodine was performed for recurrent pleural effusion in 157 patients and pneumothorax in 108 patients.^[8]

Agarwal *et al.*^[8] reported that all the patients in their study experienced chest pain and noted that the only clinically important side effect of povidone-iodine was pain and chemical pleurodesis did not cause death in these patients. The other side effects reported were fever in seven patients and empyema in one patient.

The results of the present study affirm that 2% betadine pleurodesis is associated with high success rates, with efficacy rate of 87.5% and 85.5% in malignant pleural effusions and recurrent pneumothorax, respectively.

There were no serious adverse events including acute respiratory distress syndrome or deaths associated with the procedure.

CONCLUSION

This study supports iodopovidone as an effective, inexpensive, safe, and feasible agent for chemical pleurodesis in patients with pleural effusions and recurrent pneumothorax.

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Comparative Study between Ropivacaine and Ropivacaine Plus Fentanyl for Spinal Anesthesia

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Abstract

Introduction: Spinal anesthesia is preferred over general anesthesia due to the ease of administration, minimal systemic effects, and reduced post-operative morbidity. A number of anesthetic agents and adjuvants have been tried over the years, to achieve optimal effects. This study compares the efficacy of ropivacaine versus ropivacaine plus fentanyl as spinal anesthetics.

Materials and Methods: This study was carried out on 100 American Society of Anaesthesiologists Grades I and II patients, having no comorbidities and scheduled for surgery of up to 200 min. They were randomly divided into two Groups: Group I (Ropivacaine) and Group II (Ropivacaine and Fentanyl). Intraoperative and post-operative vitals, analgesic parameters, and side effects were monitored.

Results: The onset of both sensory and motor blockade was faster, and the duration of the blockade was longer with the addition of fentanyl to ropivacaine. Ropivacaine is a safe drug in terms of cardiorespiratory stability and other side effects. The addition of fentanyl did not alter the beneficial side effect profile of ropivacaine.

Conclusion: Ropivacaine is a safe anesthetic in terms of cardiorespiratory stability and side effects. The addition of fentanyl to ropivacaine significantly potentiates the block, both sensory and motor, without altering the beneficial effects of cardiorespiratory stability and side effect profile.

Key words: Fentanyl, Motor blockade, Pruritus, Ropivacaine, Sensory blockade, Spinal anesthesia, Two-segment regression

INTRODUCTION

Cerebrospinal fluid (CSF) was discovered by Demenico Cotugno in 1764 and its circulation was described F. Magendie in 1825.^[1] J. Leonard Corning 1885, a neurologist injected cocaine in between two spinous processes and found to have sensory as well as motor blockade in the dog.^[2]

Spinal anesthesia was introduced for the 1st time in clinical practice by German Surgeon August Karl Gustav Bier in 1898. He performed a lumbar puncture as described by Quincke (1891) and injected 3 cc of 0.5% cocaine into the spinal theca on himself. Tuffier in 1899 was the first one to try cocaine intrathecally to relieve the pain of the leg in

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Month of Submission : 04-2019 Month of Peer Review : 05-2019 Month of Acceptance : 05-2019 Month of Publishing : 06-2019 the young man.^[3] The first drug used for local anesthesia was cocaine in 1855.

Since then, a number of drugs have been tried in the zest to achieve optimal anesthesia. Identification of specific opiate receptors in the cord was a breakthrough. Yaksh and Rudy^[4] were the first to report the intrathecal administration of morphine in 1976.

Spinal anesthesia has passed through phases of overly enthusiastic acceptance followed by phases of complete rejection; each phase frequently being based more on emotional reaction and clinical impression rather than on scientific observation. It is less frequently practiced in western countries due to the introduction of neuromuscular blocking agents and newer inhalation anesthetic agents. However, in our country, it is used commonly for many surgical procedures below the umbilicus. Particularly, in rural areas, it is preferable and economical to use spinal anesthesia as there is a lack of sophisticated anesthetic equipment, drugs, and compressed anesthetic gases to administer general anesthesia. Spinal anesthesia has maintained its

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popularity because it provides profound muscle relaxation, decreases operative blood loss, and causes minimal systemic effects if executed cautiously. At the same time, improvement in the technique and supportive management have lessened the incidence of complications.

The subarachnoid block requires minimal pre-operative preparation and is safe and satisfactory if performed with the knowledge of its physiological consequences. In many instances, a subarachnoid spinal block is the choice in the best interest of the patient and provides ideal operating conditions for the surgeon.

Solutions for spinal anesthesia can be classified as hyperbaric, isobaric, or hypobaric depending on their density in relation to CSF. Bupivacaine has been a standard agent for spinal anesthesia for a long time, which like all amide anesthetics has been associated with cardiotoxicity when used in high concentration or accidental intravascular injection. Ropivacaine is a long-acting regional anesthetic structurally related to bupivacaine developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles.

In the present study, the efficacy of intrathecal isobaric ropivacaine was compared with ropivacaine with fentanyl for infraumbilical surgeries.

Aims and Objectives

The principal aim of this study was to determine the efficacy of 0.5% isobaric ropivacaine (17.5 mg) and compare it with 0.5% isobaric ropivacaine with fentanyl (15 mg + 10 mg) for subarachnoid block.

- 1. The speed of onset of sensory blockade.
- 2. The speed of onset of motor blockade.
- 3. Extent of sensory blockade.
- 4. Duration of action of motor blockade.
- 5. Two segment regression.
- 6. To compare the incidence of cardiorespiratory changes, if any.
- 7. To compare the incidence of side effects of both drugs if any.

MATERIALS AND METHODS

This study was undertaken after approval from the Hospital Ethical Committee. This was a randomized, double-blind, non-crossover type interventional study carried out in Padmashree Dr. D. Y. Patil Medical College, Hospital and Research Centre, Pune, on American Society of Anaesthesiologists (ASA) Grades I and II patients of 18–60 years of age, of either gender, weighing 40–80 kg, having height of 140–170 cm and scheduled for surgery of up to 200 min. However, the patients refusing to participate,

having spine deformity, neurological deficiency, deranged coagulation profile, local skin infection, history of drug abuse, or opioid-tolerant patients were excluded from the study. A total of 100 patients (as per Figure 1) scheduled to undergo elective arthroscopy and anterior cruciate ligament (ACL) repair surgeries, lower abdominal surgeries as hernia, gynecology surgeries such as vaginal hysterectomy, total abdominal hysterectomy, and urological surgeries, were enrolled in this study. A written, informed, and signed consent was obtained from all the participants.

Detailed history, clinical examination, and relevant investigations were done. Patients were asked to remain nil by mouth overnight. Preoperatively pulse rate, blood pressure, respiratory rate, and SpO2 were recorded. No premedication was given. Preloading was done. Patients were randomly divided into two groups of 50 each:

- Group I: Received intrathecal 0.5% isobaric ropivacaine (17.5 mg).
- Group II: Received intrathecal 0.5% isobaric ropivacaine (15 mg) mixed with 10 mcg fentanyl.

Accordingly, spinal anesthesia was given. The adequate level of spinal anesthesia was achieved. Intraoperatively no sedation or analgesia was given to any of the patients.

During surgery, patients were monitored with basic monitoring devices electrocardiography, pulse oximeter, and NIBP monitor. Any episode of intraoperative hypotension was treated with fluid administration, head low position, and small bolus of injection ephedrine if required. Supplemental oxygen was given only if indicated. Any episode of bradycardia intraoperatively was treated with injection atropine.

Following parameters were assessed.

- 1. Pre-spinal hemodynamic baseline or 0 mins parameters.
 - a. Heart rate
 - b. Blood pressure
 - c. Oxygen saturation
- 2. Intraoperative hemodynamic at 5, 10, 15, 30, 45, 60, 75, 90, 105, 120, and 150 min.
- 3. Post-operative hemodynamics up to 24 h.
- 4. Total duration of surgery.
- 5. Onset of sensory analgesia taken as loss of pin-prick sensation at dorsum of foot.
- 6. Level of the sensory blockade achieved in minutes.
- 7. Duration of motor blockade according to Bromage scale.
- 8. Two segments dermatomal regression level of sensory block.
- 9. Any adverse effects neurological changes such as motor and sensory deficits, bowel and bladder dysfunction were checked before discharge.

Assessment of Motor Blockade

This was assessed by Bromage scale. The time interval between injection of the drug into subarachnoid space to the patient's inability to lift the straight extended leg was taken as onset time. Duration of motor block was recorded from onset time to time when the patient was able to lift the extended leg.

Bromage scale^[5]

- 0 Full flexion of knees and feet.
- 1 Just able to flex knees, full flexion of feet.
- 2 Unable to flex knees, but some flexion of feet possible.
- 3 Unable to move legs or feet.

Bromage index for the degree of block

- I no block (scale 0)
- II partial block (scale 1)
- III almost complete block (scale 2)
- IV complete block (scale 3).

Statistical Analysis

Data were analyzed by SPSS. *P*-value was calculated using the Z-test. P < 0.05 was considered as significant.

RESULTS

Both the groups were comparable in terms of mean age, gender, mean height, mean weight, ASA grades, and duration of surgery as there was no statistically significant difference. The hemodynamics (heart rate, systolic, and diastolic BP), respiratory rate, and oxygen saturation (SpO2) were almost same throughout the study in both the groups (measured at 5 min interval till 15 min, 15 min interval till 120 min, 30 min interval till 270 min, and 60 min interval till 480 min) and there was no statistically significant difference (P > 0.05). The onset of sensory blockade was significantly earlier in Group II as compared to Group I. The peak sensory blockade was achieved much earlier in Group II than in Group I and this was statistically significant [Table 1]. Similarly, the motor blockade had a delayed start and a short lasting effect in Group I than in Group II, which was statistically significant [Table 2]. The two-segment regression time (sensory) was earlier in Group I than in Group II, and it was statistically significant [Table 3]. There was a single incidence of pruritus in Group II. However, it was not statistically significant (P > 0.05). No other side effects were observed.

DISCUSSION

Spinal/regional anesthesia is preferred over general anesthesia, [6] as the adrenergic responses and the neuroendocrine changes occurring in response to

Table 1: Comparison of onset and peak sensory blockade in the study groups

Sensory	• • • • • • • • • • • • • • • • • • • •		P	Significance	
blockade (min)	Group I	Group II			
Onset	3.84±0.47	3.27±0.52	<0.0001	Significant	
Peak	6.15±0.59	3.92±0.49	<0.0001	Significant	

SD: Standard deviation

Table 2: Comparison of onset and recovery of motor block in the study groups

Parameter	Mean±SD (n=50)		P	Significance
	Group I	Group II		
Onset motor (min) Complete motor recovery (min)		3.61±0.47 165.4±11.30		0

SD: Standard deviation

Table 3: Comparison of two-segment regression time (sensory) in study groups

Parameter	Mean±S	D (n=50)	P	Significance
	Group I	Group II		
Two-segment regression time (sensory) (min)	67.28±7.96	75.38±7.83	<0.0001	Significant

SD: Standard deviation

surgical stress are minimal under spinal anesthesia. A survey of anesthetists in Scotland^[7] suggested that many preferred intradural block in the presence of pulmonary or cardiovascular insufficiency or poor risk patients. The reason may be that it avoids the inhalation of potentially irritant vapors which may initiate coughing, laryngospasm, or bronchospasm in those who are susceptible. There is also no need for tracheal intubation which itself provides stimulation of bronchial reflexes.^[8]

It is interesting to speculate on the reasons for the increased interest in spinal anesthesia. Many preferred to inject the solution extradurally, hoping thereby to avoid the common and sometimes distressing complication of spinal headache resulting from puncture of the dura mater as well as the rarer but catastrophic possibility of direct neural damage and permanent paralysis. There are now a number of reports of serious neurological complications following extradural block, showing that mere avoidance of dural puncture is no guarantee of safety, while the use of narrow gauge spinal needle has reduced the incidence of a spinal headache to acceptable levels. [8]

Various drugs such as procaine, etidocaine, tetracaine, lidocaine, and bupivacaine have been tried for spinal anesthesia. Etidocaine is twice as toxic as lidocaine,



CONSORT 2010 Flow Diagram

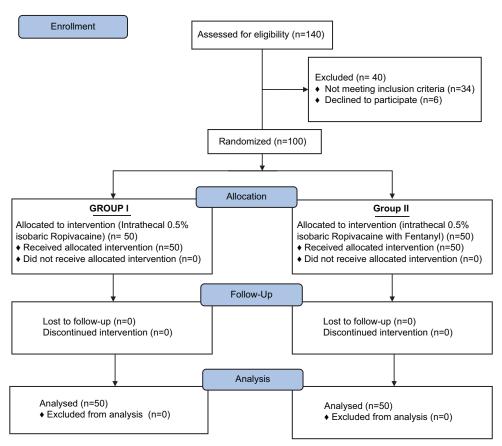


Figure 1: CONSORT 2010 Flow Diagram

tetracaine has a longer duration of action but has a narrow margin of safety, bupivacaine has a slow onset of action and the sensory and motor blockade produced by bupivacaine is often long which is not necessary for operations of short duration. ^[9] Thus, every drug has some disadvantage in it which prevents it from becoming an ideal agent for spinal anesthesia. ^[10]

Ropivacaine is a new long-acting local anesthetic drug belonging to the same class as bupivacaine and mepivacaine. Although bupivacaine and mepivacaine have been in use for more than 30 years, ropivacaine is unique. The name ropivacaine refers to both the racemate and the marketed S-enantiomer. Historically, bupivacaine was used clinically as it had a long duration of action. Subsequently, it was found that "propyl" derivatives of pipecoloxylidides were less toxic than butyl derivatives (bupivacaine). Ropivacaine is a pure S (–) enantiomer, unlike bupivacaine, which

is a racemate, developed for the purpose of reducing potential toxicity and improving relative sensory and motor block profiles. Cardiotoxicity of ropivacaine is less than bupivacaine as ropivacaine causes lesser depression of cardiac contractility.

Factors which are believed to influence the extent and duration of intradural spinal anesthesia include gravity and the baricity, volume, and concentration of the injected local anesthetic solution. [12] Barker, in 1907, demonstrated that hyperbaric anesthetic solutions spread rapidly under the influence of gravity and are collected in the lowest part while isobaric solutions remained localized at the site of injection.

Opioids have been commonly used as an adjuvant for spinal anesthesia. Combination of an opioid with local anesthetic reduces local anesthetic requirement, hastens the onset of action and provides intense analgesia. However, such opioids are not devoid of side effects such as pruritus, somnolence or may be distressing such as nausea, and vomiting, or respiratory depression.^[13-15]

In the present study, both the groups were comparable in terms of demographic variables, physical attributes of height and weight, ASA Grade, and duration of surgery.

Onset and Peak Sensory Block

The onset and peak of the sensory blockade were attained faster when fentanyl was added to ropivacaine, thus, suggesting that adding fentanyl might potentiate block.

The results are similar to study by Yegin *et al.*^[16] where it was observed that the addition of 25 mcg added to 18 mg of hyperbaric ropivacaine in TURP significantly improved the quality and prolonged the duration of analgesia without causing a substantial increase in the frequency of major side effects.

The results were also comparable to the study conducted by Biswas and Rudra,^[17] which showed that fentanyl 12.5 mg prolongs the duration of bupivacaine-induced sensory blockade (sensory regression to L1 dermatome).

The results were also comparable to the study by Akhtar *et al.*,^[18] where it was observed that the onset was faster and the duration of analgesia was longer when fentanyl was added to ropivacaine.

However, it was, in contrast, to a study conducted by Boztug *et al.*^[19] which concluded that 25 mcg fentanyl added to 8 mg ropivacaine provided shorter sensory blockage duration then 10 mg ropivacaine alone. Furthermore, the study by Sanli *et al.*^[20] did not find any significant difference in the attainment of peak sensory action.

Administration of fentanyl intrathecally is an established method for intraoperative anesthesia and to supplement post-operative analgesia.

Two-segment Regression

The two-segment regression time was more when fentanyl was added to ropivacaine, indicating the prolonged duration of anesthesia.

The results were comparable to the study conducted by Biswas and Rudra,^[17] which showed that fentanyl 12.5 mg prolonged the duration of bupivacaine-induced sensory blockade (sensory regression to L1 dermatome).

Similarly, studies by Sanli *et al.*,^[20] Murali and Narsaiah,^[21] and Seetharam and Bhat^[22] showed that delayed regression on addition of fentanyl to ropivacaine.

Motor Block

The onset of motor block was earlier with the addition of fentanyl. Furthermore, the addition of fentanyl did prolong the duration of motor block. Thus, clearly, fentanyl potentiates the motor block induced by ropivacaine.

This was similar to the study by Akhtar *et al.*,^[18] it was observed that the onset was faster and the duration of motor block was longer when fentanyl was added to ropivacaine.

This is, in contrast, to a study conducted by Boztug *et al.*^[19] who evaluated the effects of low dose intrathecal isobaric ropivacaine with or without fentanyl and concluded that 25 mcg fentanyl added to 8 mg ropivacaine provided shorter motor blockage duration than 10 mg ropivacaine alone. Similarly, in the studies by Sanli *et al.*,^[20] Murali and Narsaiah,^[21] and Seetharam and Bhat,^[22] no significant differences were seen in the onset and recovery of motor action on addition of fentanyl to ropivacaine.

Cardiorespiratory Stability

The pulse rate, blood pressure, respiratory rate, and SpO2 were almost the same throughout the study. There were minor differences between the groups, which were not statistically significant. There was no incidence of bradycardia, hypotension, or respiratory depression in any Group.

This was similar to the study by McNamee *et al.*,^[23] who concluded that intrathecal ropivacaine provided a higher degree of cardiovascular stability with low incidence of bradycardia.

Similarly, Boztug *et al.*,^[19] in their study of intrathecal ropivacaine versus ropivacaine plus fentanyl for out-patient arthroscopic knee surgery, postulated that none of the patients in either group had episodes of hypotension or bradycardia. Mean arterial pressure and heart rate changes were similar between the two groups.

However, in the study by Akhtar *et al.*,^[18] intraoperative bradycardia was observed in 3% of patients in the ropivacaine group and the incidence of hypotension was 27% in the ropivacaine group and 10% in the ropivacaine with fentanyl group. However, it was not statistically significant. Similarly studies by Murali and Narsaiah,^[21] Seetharam and Bhat^[22] and Koltka *et al.*^[24] reported incidences of bradycardia and hypotension.

Thus, ropivacaine is safe for spinal anesthesia in terms of cardiorespiratory stability.

Side Effects

There was one incidence of pruritus in the ropivacaine with fentanyl group. However, it was not statistically significant.

This is in contrast to the study by Akhtar *et al.*,^[18] where it was observed that the onset was faster and the duration of analgesia was longer when fentanyl was added to Ropivacaine.

Similarly, Murali and Narsaiah^[21] in their study reported the incidence of shivering and pruritus. The incidence of pruritus was more in the ropivacaine with fentanyl group. Seetharam and Bhat^[22] also reported incidences of shivering and pruritus.

Limitations

The study was limited to the OPD attendance in indoor admission of the patients undergoing a few elective surgeries such as elective arthroscopy and ACL repair surgeries, lower abdominal surgeries as hernia, gynecology surgeries such as vaginal hysterectomy, total abdominal hysterectomy, and urological surgeries. Therefore, the results may not be generalized.

CONCLUSION

Thus, from the present study, it can be effectively concluded that ropivacaine is a safe anesthetic in terms of cardiorespiratory stability and side effects. The addition of fentanyl to ropivacaine significantly potentiates the block, both sensory, and motor, without altering the beneficial effects of cardiorespiratory stability and side effect profile.

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Clinicopathological Study of Cancer Larynx

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Abstract

Background: In India, laryngeal cancer contributes to approximately 3-6% of all cancers in men.

Objective: The aim of this study was to study the clinicopathology of cancer larynx with respect to age, sex, site, complaints, histology, staging, and predisposing factors.

Materials and Methods: The study population consisted of 100 patients who were suffering from cancer larynx. A complete clinical history was taken from the patients. After the clinical diagnosis of growth larynx, the patients were prepared for direct laryngoscopy under general or local anesthesia. The lesions were visualized, the extent of growth defined, and biopsy taken and then sent for histopathological examination. The staging of cancer larynx was done according to tumor, node, and metastasis classification.

Results: There were 80 male (80%) and 20 female (20%) patients. Maximum patients were in the age group of 51–60 years (40%). 54% showed supraglottic cancer, 45% had glottic cancer, and only 1% had subglottic cancer. In cases of supraglottic cancer, the most common complaint was difficulty in swallowing seen in all 54 patients; in cases of glottis cancer, the most common complaint was hoarseness of voice seen in 88.88%. There was only 1 patient of subglottic cancer who presented with difficulty in swallowing and difficulty in breathing. Out of 100 cases, there were 99 cases of squamous cell carcinoma whereas there was only 1 case of adenocarcinoma. Out of total 100 patients, overall most common stage was Stage 2 (34%), followed by Stage 3 (25%), Stage 4a (16%), Stage 1 (15%), and Stage 4b (10%). Smoking was found to be the most common predisposing factor (92%), followed by alcohol intake (78%) and tobacco chewing (50%).

Conclusion: Early diagnosis and treatment of laryngeal cancer is important to reduce the morbidity and mortality of patients.

Key words: Cancer, Smoking, Squamous cell

INTRODUCTION

The larynx is divided anatomically into supraglottis, glottis, and subglottis. The supraglottis and glottis are divided by a line passing through the ventricle, which separates the true cords from the false cords. The subglottis extends from approximately 1 cm below the level of the cords to the trachea inferiorly. ^[1] In patients with laryngeal disorders, most commonly, the presenting symptom is hoarseness of voice. In patients with benign lesions, hoarseness is often the only presenting symptom while patients with malignant

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lesions may have associated dysphagia, odynophagia, dyspnea, and secondaries in the neck due to lymph node metastasis. Other symptoms may include lump in the neck, foreign body sensation in the throat, sore throat, referred earache, and bad breath. [2]

The diagnosis of the laryngeal lesion is usually made by acquiring the biopsy of the tumor by direct laryngoscopy under general or local anesthesia, allowing a careful and thorough direct examination of the tumor. The biopsy material is important for definitive diagnosis of malignancy, identification of type of tumor, and degree of differentiation.^[3]

Histologically, squamous cell carcinoma is the most common malignancy involving the larynx, arising from the non-keratinizing squamous epithelial lining. Other malignancies comprising <5% of all cancerous lesions include carcinoma *in situ*, sarcoma, lymphoma,

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and adenocarcinoma. Adenocarcinoma is aggressive malignancies. [4] Although rare, they are the most common glandular carcinoma to affect the larynx and comprise <1% of all laryngeal malignancies. Undifferentiated carcinomas and verrucous carcinomas are the major variants of squamous cell carcinomas, lymphoepithelial carcinoma, and spindle cell carcinoma. [5]

Men are traditionally more commonly affected, but the incidence among women is increasing as smoking in this group has become more common. Besides, smoking and alcohol, laryngopharyngeal reflux, and vocal abuse have also been implicated. [6]

Specific treatment of malignant tumors of larynx depends on the location, type, and stage of the tumor and includes surgery, radiation therapy, and chemotherapy in conjunction with radiotherapy.^[7]

MATERIALS AND METHODS

This study was conducted in the Department of Otorhinolaryngology and Head and Neck Surgery of SMGS Hospital, Government Medical College, Jammu, between June 2016 and April 2019. The study included 100 patients of cancer larynx of either sex presenting in ENT outpatient department.

Inclusion Criteria

 Patients of laryngeal cancer irrespective of age and sex.

Exclusion Criteria

- Refusal by the patient
- Recurrent cases of laryngeal cancer.

After the selection of patients, informed written consent was taken. A complete clinical history was taken from the patients. Clinical history included chief complaints, duration of symptoms, presenting illness, past history, addiction history (mainly smoking, tobacco chewing, and alcohol consumption), occupational history, family history, and socioeconomic status of the patients.

After the clinical diagnosis of growth larynx, the patients were prepared for direct laryngoscopy under general or local anesthesia. The lesions were visualized, the extent of growth defined, and biopsy taken and then sent for histopathological examination. The results were then noted in a prescribed performa. The staging of cancer larynx was done according to tumor, node, and metastasis classification.

RESULTS AND OBSERVATIONS

A 100 patients of cancer larynx were included in the study. The following observations were made.

Age and Sex Distribution

There were 80 male (80%) and 20 female (20%) patients. The male:female ratio was 4:1. Maximum patients were in the age group of 51–60 years (40%). There were two patients of age <30 years. One of them was 28 years old. The mean age was 52 years. Figure 1 shows age distribution of patients.

Site of Cancer

Out of 100 patients of cancer larynx, 54% showed supraglottic cancer, 45% had glottic cancer, and only 1% had subglottic cancer. Figure 2 shows the site of involvement of cancer.

Chief Complaints

In cases of supraglottic cancer, the most common complaint was difficulty in swallowing seen in all 54 patients

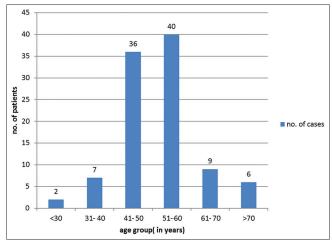


Figure 1: Age distribution of patients

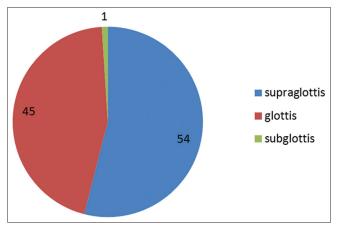


Figure 2: Site of cancer

(100%), followed by foreign body sensation in throat (81.48%), hoarseness of voice (42.59%), difficulty in breathing (40.74%), and pain in ear (22.22%).

In cases of glottis cancer, the most common complaint was hoarseness of voice seen in 88.88% followed by difficulty in breathing (84.44%), foreign body sensation in throat (55.55%), difficulty in swallowing (44.44%), and pain in ear (13.33%).

There was only 1 patient of subglottic cancer who presented with difficulty in swallowing and difficulty in breathing. Table 1 shows the incidence of various symptoms according to the site of involvement.

Histology of Cancer

Out of 100 cases, there were 99 (99%) cases of squamous cell carcinoma whereas there was only 1 (1%) case of adenocarcinoma. Out of these 99 cases of squamous cell carcinoma, 57% were moderately differentiated, 24% were well differentiated, and 18% were poorly differentiated. Table 2 shows distribution of patients according to histology of tumor.

Stage of Cancer

Out of total 100 patients, overall most common stage was Stage 2 (34%), followed by Stage 3 (25%), Stage 4a (16%), Stage 1 (15%), and Stage 4b (10%).

In supraglottic cancer, most common stage was Stage 3 (58%), whereas in glottis cancer, it was Stage 2 (45%). There was only 1 patient of subglottic cancer and he presented at Stage 4b. Figure 3 shows distribution of patients according to staging.

Predisposing Factor

On careful history taking of the patients, smoking was found to be the most common predisposing factor (92%), followed by alcohol intake (78%) and tobacco chewing (50%). Figure 4 shows the distribution of patients according to predisposing factor.

DISCUSSION

In our study, 54% showed supraglottic cancer, 45% had glottic cancer, and only 1% had subglottic cancer. This

is in concordance with most of the studies, in which the supraglottis is the most common site of involvement, followed by glottis and subglottic regions.

Thompson *et al.*^[8] studied 104 cases of tumors of larynx of which 30% were supraglottic, 46% were glottic, 3% were subglottic, and 21% were transglottic cancer. Bakshi *et al.*^[9] in a study of 690 cases of laryngeal malignancy found that 56% tumors were supraglottic, 17% glottis, 3.6% subglottic, and 13% transglottic which is similar to our results. In all these studies, the subglottis was the least common site of involvement.

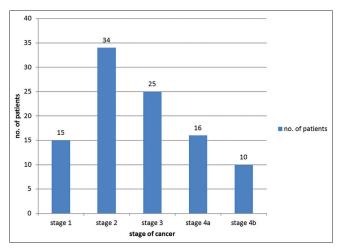


Figure 3: Staging of cancer

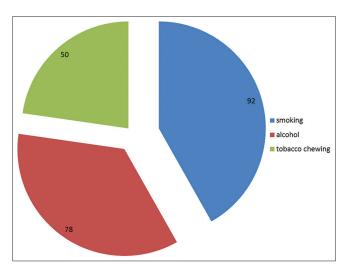


Figure 4: Predisposing factor

Table 1: Incidence of	presenting	symptoms	depending	on the site o	f cancer
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Site of cancer Hoarseness of voi		f voice		Difficulty in swallowing		Difficulty in breathing		Foreign body sensation in throat		Pain in ear	
	No. of cases	%age	No. of cases	%age	No. of cases	%age	No. of cases	%age	No. of cases	%age	
Supraglottis	23	42.59	54	100	22	40.74	44	81.48	12	22.22	
Glottis	40	88.88	20	44.44	38	84.44	25	55.55	6	13.33	
Subglottis	0	0	1	100	1	100	0	0	0	0	

Table 2: Distribution of patients according to histological type of cancer

Туре	Number of patients	Percentage
Well-differentiated squamous cell carcinoma	24	24
Moderately differentiated squamous cell carcinoma	57	57
Poorly differentiated squamous cell carcinoma	18	18
adenocarcinoma	1	1
Total	100	100

In our study, maximum patients were in the age group of 51–60 years (40%). There were two patients of age <30 years. One of them was 28 years old. The mean age was 52 years. Similar results were observed by Thompson *et al.*^[8] in his study of exophytic and papillary squamous cell carcinoma of larynx. According to 3-year report of population-based cancer registries 2009–2011 in India, the maximum number of cases of laryngeal carcinoma were reported in the age group of 60–69 years.^[10]

In cases of supraglottic cancer, the most common complaint was difficulty in swallowing seen in all 54 patients (100%), followed by foreign body sensation in throat (81.48%), hoarseness of voice (42.59%), difficulty in breathing (40.74%), and pain in ear (22.22%). In cases of glottis cancer, the most common complaint was hoarseness of voice seen in 88.88% followed by difficulty in breathing (84.44%), foreign body sensation in throat (55.55%), difficulty in swallowing (44.44%), and pain in ear (13.33%). There was only 1 patient of subglottic cancer who presented with difficulty in swallowing and difficulty in breathing. Bakshi *et al.*^[9] in their study also found that hoarseness was the most common complaint while other complaints were sore throat, neck nodes, and hemoptysis.

Out of 100 cases, there were 99 (99%) cases of squamous cell carcinoma whereas there was only 1 (1%) case of adenocarcinoma. Out of these 99 cases of squamous cell carcinoma, 57% were moderately differentiated, 24% were well differentiated, and 18% were poorly differentiated. These findings are consistent with the findings of the studies by Kaufman and Burke, Kumar *et al.*, Jaiswal and Hoang, Domanowski, and Wang *et al.* in which the percentage of squamous cell carcinoma were 90%, 96%, 95%, 99%, and 99%, respectively.^[11-15]

In our study, smoking was found to be the most common predisposing factor (92%), followed by alcohol intake (78%) and tobacco chewing (50%). A significant association of laryngeal cancer with smoking and alcohol

was observed by Elwood *et al.*^[16] and Dosemeci *et al.*^[17] in case—control studies conducted to evaluate risks of laryngeal cancer as in men by subsite and cell type in relation to smoking and alcohol. Bakshi *et al.*^[9] found that smoking was a predisposing factor in 87.8% of the cases and additionally or otherwise alcohol consumption was found in 75% of the cases. Menvielle *et al.*^[18] in their hospital-based study also observed the synergistic effect of alcohol and tobacco in etiology of laryngeal cancer. Kapil *et al.*^[19] in their study of 305 laryngeal cancer patients observed alcohol and tobacco consumption to be a major risk factor in laryngeal cancer.

CONCLUSION

On the basis of present study, it can be concluded that laryngeal cancers of different subsites produce different symptoms. Smoking and alcohol are most common predisposing factors. Early diagnosis of laryngeal cancer is important for effective treatment and hence to decrease morbidity and mortality arising from the disease.

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Results of Open Reduction and Internal Fixation of Humeral Shaft Fractures using Locking Compression Plate

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Abstract

Introduction: Fractures shaft of the humerus is common in an orthopedic practice. Open reduction and plating of these fractures allow anatomical reduction without affecting elbow and shoulder function but involve extensive soft tissue stripping. We treat 22 cases of humeral shaft fractures using locking compression plate (LCP).

Objective: The objective of this study was to measure the clinical outcome which includes fracture healing, radial nerve recovery, infection, and functional range of motion in the shoulder and elbow. Radiographic measurements included fracture alignment, time to healing, delayed union, and non-union.

Materials and Methods: Twenty-two skeletally mature patients with acute humeral shaft fractures requiring surgical stabilization as indicated by the fracture pattern, failure to maintain reduction by conservative method, and associated injuries were treated by open reduction and internal fixation (ORIF) using LCP. Follow-up was possible only on 20 patients.

Results: Nineteen Humeral shaft fractures united completely, one fails to unite necessitating subsequent procedure which was united afterwards within 1½ years. Two superficial wound infections in patients with an open fracture and one transient post-operative radial nerve palsy were the only complications. A functional range of motion in the elbow and shoulder was regained in all except in one patient who had severe bone and soft tissue injuries in the same extremity.

Conclusion: ORIF with locking compression plating becomes the treatment of choice with increased popularity for humeral shaft fracture as it can give good results by providing both biologic and mechanical advantages.

Key words: Humeral shaft, Internal fixation, Locking compression plate, Treatment outcome

INTRODUCTION

Humeral shaft fractures account for 3–5% of all fractures. [1] Although most closed fractures of the humeral shaft can be treated successfully with closed method, open reduction and internal fixation (ORIF) with direct fracture exposure often yields near anatomic alignment without affecting elbow and shoulder function. [2,3] It



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is advocated that compression plating offers the best treatment for humeral shaft fractures that require surgical intervention. [4] The rates of non-union and hardware failure necessitating revision range from only 0% to 7%. [5] Locking the screws to the plate allows the plate to sit at a distance offset from the underlying bone surface providing a biologic advantage for bone fracture healing by preserving the periosteal blood supply underlying the plate. [6-8] The functional range of motion of the elbow and shoulder predictably returns after plate fixation when complete motion is not obtained; it is often the case that other associated skeletal or neurologic injuries exist.[9] The two approaches that we used for fracture exposure and plate fixation are the anterolateral and posterior approach. Fractures in the proximal third often require the anterolateral approach.[10]

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Evidence also suggests that immediate weight-bearing on an upper extremity that has been treated with ORIF has little or no deleterious effect.^[11] The most common complications associated with plating procedures are infection and iatrogenic nerve palsy (2–5%), with most cases being a transient problem that requires no further intervention (0–6%).^[12,13] Some surgeons prefer not to plate humeral shaft fractures due to the difficulties of dealing with fracture exposure, the technical aspects of plating and complex fracture patterns, as well as due to concerns about radial nerve injury.^[14] This paper presents the results obtained after internal fixation of fractures of the humeral shaft using locking compression plate (LCP).

MATERIALS AND METHODS

Over the 3-year period from February 2011 to January 2014, 22 patients with acute fractures of the humeral shaft treated by ORIF using LCP were included in the study. Informed written consent of all the patients was obtained before clinical and radiographic assessment. There were 15 male patients and seven female patients, and the average age was 37 years (range, 16–71 years) [Table 1]. The left humerus was fractured in 16 patients and the right in six. The fractures were located in the proximal third of the shaft in six patients, in the middle third in 12, and distal third in four [Table 2].

Ten of the fractures were comminuted and the remainder was either transverse or short oblique. The cause of injury was road traffic accident in 14 patients, a fall in five, direct assault in two, and following arm wrestling in one [Table 3].

Five patients had a neural injury in the extremity when they were first seen. These included an injury of the radial nerve in four patients, an injury of the posterior interosseous nerve with an associated Monteggia fracture in one. In still another patient, a radial nerve palsy developed after attempted closed manipulation of the fracture.

The indication for ORIF in this series was as follows:

- Fracture in proximal third of the humerus that remains displaced and angulated despite manipulation and immobilization by functional cast brace in six patients
- Comminuted fracture in the mid and distal third of the humeral shaft that remains completely displaced in 10 patients, of which four patients had initial radial nerve palsy
- Loss of radial nerve function after closed manipulative reduction in one patient
- In the remaining five patients, either an open fracture or associated injury or both were the indications for internal fixation.

The associated injury group included one patient who also had an injury of the head, an abdominal injury with splenic rupture in another patient and an additional injury in the same or opposite upper extremity in the remaining. The additional injury in the same upper extremity included an ipsilateral fracture of the forearm or elbow or neurovascular compromise or a soft tissue injury for which skeletal stability was needed to allow soft tissue reconstruction.

The ORIF was performed between 4 h and 21 days after the injury. We used either anterolateral approach or posterior approach depending on the site of fracture and condition of the soft tissues. In upper one-third of the humeral shaft fracture, we used anterolateral approach, and in middle and lower third fracture, we used posterior approach if the condition of soft tissue allowed. Utmost care was taken intraoperatively not to injure the radial nerve by careful exposure and inspection of the nerve. Interfragmentary compression by means of lag screws was used if possible. In general, an LCP that permitted screw fixation to at least six cortices, that is, three in the proximal and another three in the distal fragment was used [Figure 1]. A 4.5 mm

Table 1: Age and sex variation in the study group (n=22)

Age	Male (n)	Female (n)	Total (n)
<40	9	4	13
40-60	6	2	8
>60	0	1	1
>60 Total	15	7	22

Table 2: Site of humeral fracture (n=22)

Humeral site	n (%)
Proximal one-third	6 (27.3)
Middle one-third	12 (54.5)
Distal one-third	4 (18.2)

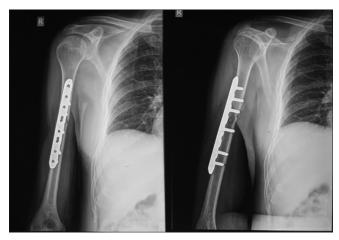


Figure 1: X-ray of fracture shaft right humerus (AP and lateral view) fixed with LCP in a 36-year-old male

Table 3: Characteristics of fracture included in the study

Clinical details of fracture							
Sex/age	Occupation	Sides	Presentation (days)	Mechanism	Classification	Associated injury	Radial N Palsy
Male/58	MW	L	2	RTA	Prox/spiral/close	Nil	Nil
Female/42	HW	R	1	RTA	Prox/trans/close	Nil	Nil
Male/16	Student	L	3	*Fall in sports	Prox/obl/close	Nil	Nil
Male/30	MW	L	4	Direct blow	Prox/trans/close	Nil	Nil
Male/40	MW	L	16	RTA	Prox/obl/close	Nil	Nil
Female/23	Student	L	3	RTA	Prox/trans/close	Nil	Nil
Male/24	Student	R	1	*Arm wrestling	Mid/spiral/close	Nil	Nil
Male/38	MW	L	1	RTA	Mid/obl/open	Head injury	Nil
Female/52	HW	R	4	RTA	Mid/trans/close	Nil	Nil
Male/45	MW	L	3	RTA	Mid/com/close	Nil	Р
Male/53	MW	L	1	RTA	Mid/com/open	Nil	Nil
Male/51	MW	L	1	RTA	Mid/trans/close	Abdominal injury (splenic rupture)	Nil
Female/26	HW	L	5	RTA	Mid/com/close	Nil	Р
Male/21	Student	L	1	RTA	Mid/spiral/open	Elbow injury (opp)	Nil
Female/71	HW	L	6	Fall	Mid/com/close	Nil	Nil
Male/34	MW	L	2	*Direct blow	Mid/obl/close	Nil	Р
Female/29	MW	R	2	RTA	Mid/com/close	Nil	Nil
Male/46	MW	L	3	Fall	Mid/spiral/close	Nil	Nil
Male/39	MW	L	1	RTA	Dis/trans/close	Monteggia #(ips)	Nil
Female/28	HW	R	2	Fall	Dis/com/close	Nil	P
Male/31	MW	R	1	RTA	Dis/obl/open	Elbow injury (lps)	Nil
Male/18	Student	L	1	*Fall from height	Dis/com/close	Nil	Nil

N=Nerve, MW=Manual worker, HW=House worker, RTA=Road traffic accident, Prox=Proximal, Mid=Middle, Dis=Distal, Trans=Transverse, Obl=Oblique, Com=Comminuted, L=Left, R=Right, P=Palsy

narrow LCP was used in these fractures as the size of the humerus was not large enough to use large fragment broad plate construct [Figure 2]. In three patients, cancellous bone grafts were placed about the fracture site at the time of fixation. Bone grafts were used when the continuity of the cortex of the humeral shaft could not be completely restored due to bone loss or comminution, especially if a defect was present in the cortex opposite the plate. The limb was put on an arm pouch and no post-operative immobilization given and physiotherapy instituted as soon as the pain subsided, usually within 72 h. Active hand, wrist mobilization along with assisted shoulder and elbow exercises was commenced from the 3rd day itself. Patients were follow-up at monthly interval till radiographic union was seen. Functional assessment was done as per system of the American Shoulder and Elbow Surgeons (ASES) score as adopted by KcCormack et al.[15] and visual analog pain score was recorded.

RESULTS

Of the 22 patients, only 20 patients were followed until the fracture had healed. The time to the union was determined as the time when the fracture line was no longer visible radiographically, but in two patients, the fracture line remained visible long after consolidation of the bone grafts. Thirteen fractures healed within 4 months; four within 6 months; and two delayed but unite within 1 year. One required subsequent operation for hypertrophic non-union



Figure 2: X-ray of fracture shaft left humerus (AP and lateral view) fixed with LCP in a 50-year-old male

with implant failure due to immediate weight-bearing activity done by the patient; replating and autogenous bone grafting were performed and the fracture united within 6 months from the second operation [Table 4].

Prolonged time to healing did not seem to correlate with clinical symptoms, function, or severity of the initial injury. There was no case of non-union in our study. In the series, three of the patients with an open fracture both internal fixation and wound closure were delayed up to 3 weeks. Immediate internal fixation after debridement with delayed wound closure was used in the other two patients

with an open fracture. Both methods were successful in achieving union. Fifteen patients recovered full motion of the shoulder and elbow. Four patients had full motion of the shoulder, but motion of the elbow was from 15° to 125° of flexion. Two of these four patients had an associated skeletal or soft tissue injury in the extremity. The remaining one patient with associated injury of the elbow and forearm had >60° of flexion of the elbow. To assess function, we used the ASES shoulder score for 13 activities of daily living requiring full shoulder and elbow movement [Table 5]. The maximum possible score is 52 points. The average score was 48.5 (range, 40–52). Pain was quantified using visual analog scales, with zero being no pain and 10 as extreme pain.

There was one transient post-operative radial nerve palsy, which we attributed to excessive retraction during the procedure. Of the four patients who had a radial nerve palsy when they were first seen, one was found to have a partially lacerated nerve; two had contusion of the nerve at the level of the fracture; and in one, the nerve appeared normal. In the patient who lost radial nerve function after closed manipulation, the nerve was found within the fracture site.

Nerve function was restored in all five patients who had a radial nerve palsy initially as well as in the one patient whose palsy developed after manipulation. Posterior interosseous nerve palsy with an associated Monteggia fracture of ipsilateral forearm also recovered after stabilization of the fracture. The details of the results in this study are shown in Table 6.

Two patients with an open fracture; one treated with delayed and one with immediate internal fixation had a superficial infection that resolved after administration of the third-generation cephalosporin. There were no deep infections and no patients had osteomyelitis.

DISCUSSION

At present, open reduction and compression plating remain the treatment of choice for humeral shaft fractures that require operative intervention. Locking the screws to the plate allows the plate to sit at a distance offset from the underlying bone surface providing a biologic advantage for bone fracture healing by preserving the periosteal blood supply underlying the plate. [6-8] Mechanically this provides stability without the need for the plate to match the curvature of the bone surface and without the need to compress and maintain friction between the plate and bone surface. [8] Nowadays, all of the locking plates modeled were offset 1 mm from the cortex avoiding undue stress

Table 4: Time of union of fracture

Number of patients
Time of union

13
Within 4 months
Within 6 months
Within 1 year
Within 1½ years
Loss follow-up

Table 5: Details of the American Shoulder and Elbow Surgeons score

Back pocket	Perineal care
Wash opposite axilla	Eat with utensil
Comb hair	Use arm at shoulder level
Carry 10 lb at side	Dress
Sleep on affected side	Pull
Use hand overhead	Throw
Lift	

4: Normal, 3: Mild compromise, 2: Difficulty, 1: With aid, 0: Unable, NA: Not available

Table 6: Details of the results in the study

Overall assessment	Outcome
ASES functional score (52 points)	48
Visual analog scale for pain (0–10)	1.0
Impingement symptoms	0
Primary bone graft	3
Secondary surgery with bone grafting	1
Radial N palsy	
Pre-operative – 4 no.	Recovered fully
Post-operative – 1 no.	
Deep infection	Nil

ASES: American Shoulder and Elbow Surgeons

shielding and contact below the plate. This advantage with locked plates has been suggested to prevent local bone necrosis.^[16] It is, therefore, advocated that compression plating offers the best treatment for humeral shaft fractures that require surgical intervention.^[4,17] However, the risks of any musculoskeletal procedure cannot be overlooked and in the case of compression plating include extensive dissection, iatrogenic radial nerve injury, an increased risk of infection, and non-union.^[17]

Surgical stabilization is considered to be better treatment for bilateral fractures of the humerus and ipsilateral fractures of the humerus and forearm, as well as in cases of polytrauma, progressive neurological deficit, vascular injury, and failed conservative treatment. [18] The most frequent indication for operative treatment is the presence of associated multiple injuries. [19] In a comparative study of dynamic compression plating versus locked intramedullary nailing for humeral shaft fractures shows significant association with a higher risk of infection and post-operative nerve palsy in those fixed by plating, but there is no difference with respect to non-union and revision rate. [20]

The posterior approach allows for direct observation of the fracture and posterior and lateral plate placement but requires the nerve to be dissected out because it is in the middle of the operative field. In contrast, the anterolateral approach avoids direct observation of the nerve and allows for anterior and lateral plate placement.^[21]

Fractures of the middle and middle-distal parts of the shaft had a significantly higher association with radial nerve palsy than those in other parts. Transverse and spiral fractures were more likely to be associated with radial nerve palsy than oblique and comminuted patterns of fracture. [22] The surgical approach and plate fixation technique are of immense importance to avoid radial nerve injuries and achieve a high degree of absolute stability. [23]

Pal *et al.* described modified functional cast brace as one of the options in treatment for humeral shaft fractures as it can be applied on the 1st day of the presentation in most of the situations also mentioned about the usefulness of simple objective scoring system, particularly in uneducated patients.^[24]

One of the disadvantages of conservative treatment being a constant contraction of the surrounding muscles and the pull of gravity which tends to distract the fracture fragments. Other disadvantages of conservative treatment include joint stiffness, edema, muscle atrophy, and osteoporosis. Inadequate immobilization may lead to delayed union and non-union, whereas prolonged immobilization may lead to stiffness of elbow and shoulder joint. Therefore, transverse fractures should be treated with a compression plate, as it aids achieving bone-to-bone contact, and dynamic compression screws can pull opposite fracture fragments together when tightened.^[25]

The attractive theoretical advantages of locking humeral nails have not been borne out in clinical studies by Bhandari *et al.*, but complications such as shoulder pain, delayed union or non-union, fracture about the implant, iatrogenic fracture comminution, and the difficulty in the reconstruction of failures have diminished their usefulness. The precise role of locking nails in the treatment of humeral shaft fractures has yet to be defined. Furthermore, when surgical treatment is contemplated, it is still generally believed that intramedullary nailing may not be the best choice. [26] The suitability of antegrade interlocking humeral nailing by flexible nailing technique has been described by some authors due to their non-requirement of extensive soft tissue dissection, bone grafting, and external immobilization in case of comminuted and segmental fracture patterns. [27]

Demirel et al. in their studies shown additional advantage of retrograde locked nailing by sparing the rotator cuff and subacromial bursa, thus preserving the shoulder functions. [28] Although nailing and plating are effective treatments for fractures of shaft of humerus, antegrade nailing may not be suitable in elderly patients, as it can cause significant shoulder dysfunction. [29,30] The patients operated with interlock nailing underwent more number of secondary bone grafting procedures. [30]

Various methods of the treatment of humeral shaft have been described, some author mentioned about minimally invasive plate osteosynthesis (MIPO) giving a good and reproducible results with few risks, but MIPO is a complex technique, requiring a relatively long learning curve. The plate placement and indirect reduction require experience. [31] Ilizarov method is another treatment option, the main disadvantages of Ilizarov fixation include the presence of a bulky implant on the arm, pin-tract infection, painful impingement of the frame on the chest wall, and the possibility of neurovascular injury due to the wires. [32,33]

Thus, LCP is a reliable option to achieve union of humeral shaft fractures even in younger patients with higher physiological demands and elderly group with poor bone quality. LCP seems to be the implant of choice even in the presence of significant bone loss requiring strut grafts. Along with LCP, corticocancellous iliac crest grafts are adequate in the treatment of segmental bone defects. Thus, plating is still the gold standard for fracture shaft humerus.

CONCLUSION

The locking compression plating is the preferred method in the majority of fractures of the shaft of the humerus with better preservation of joint function. When indicated, ORIF of the diaphysis of the humerus using LCP followed by early physiotherapy of shoulder and elbow joint is a safe and efficacious procedure.

LCP is reliable in achieving union even in patients belonging to the younger age group with higher activity levels as well as elderly group with poor bone quality as it offers both biologic and mechanical advantages. The second episode of bone grafting may be necessary to accelerate union in some patients. The LCP should probably be the implant of choice and it has been associated with excellent outcomes.

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Original Article

Comparison of Wound Closure using Octylcyanoacrylate Tissue Adhesive versus Subcuticular Suture in Inguinal Hernia Surgery

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Abstract

In our study, we have compared inguinal hernia skin closure with octylcyanoacrylate tissue adhesive and subcuticular suture with 4-0 Monocryl. We found that time require for closure is significantly less with using glue. Hospital stay are less in glue group compare to subcuticular group but not significant. Incidence of infection is more in subcuticular group. Cosmetic outcome of scar is equally good in glue as compared to sutures. Post op pain is less in glue group. Inguinal hernia is a common surgical problem and the usual treatment is Lichtenstein mesh hernioplasty. Wound closure is usually done by interrupted sutures, subcuticular sutures, or staples. Tissue adhesive octylcyanoacrylate is an alternative method for skin closure, which is a new generation long chain tissue adhesive. In this study, we will be comparing the outcome of tissue adhesive octylcyanoacrylate with subcuticular suture for closure of inguinal hernia surgery in adults in terms of time efficiency, cosmesis, pain, and wound complications.

Key words: Inguinal hernia, Octylcyanoacrylate tissue adhesive, Subcuticular suture

INTRODUCTION

Hernia is defined as a protrusion of viscus or a part of a viscus through an abnormal opening in the wall of its containing cavity. It is a common disease with lifetime risk of 27% for males and 3% for females.^[1] The external abdominal hernia is the most common form, out of which inguinal hernia accounts for more than 75% of the cases.^[2,3]

There are different types of techniques for the repair of inguinal hernia. The most commonly used technique for inguinal hernia is the Lichtenstein technique. Precise approximation of the skin incision with wound closure devices is critical for a favorable cosmetic and functional surgical result. The main focus of wound closure is to minimize tension on the wound and to bring the skin edges together in an everted orientation.



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The ideal incision closure should be simple, effective, safe, rapid, inexpensive, painless, cosmetic, and bactericidal. [4-6] Sutures, staples and adhesive tapes are the traditional methods of wound closure, while tissue adhesives have entered clinical practice more recently. [7]

Recently, few studies have been conducted which have compared these various methods of closure. Application of sutures requires passage of foreign material through the skin, which is usually left in place for 5–10 days. If sutures are tied too tight or left in too long, they may leave permanent suture scars on tracts. If sutures are removed before adequate healing, the loss of tensile strength may result in wound dehiscence or a widened scar. Although suture removal usually causes minimal discomfort, the procedure is often associated with increased patient anxiety. Surgical glue is an option for sutureless wound closure, which will overcome these difficulties. The introduction of tissue adhesives heralded the era of suture free closures, which led to better results.^[8]

MATERIALS AND METHODS

This will be an 18 months prospective study conducted in the Department of General Surgery, Christian Medical

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College and Hospital, Ludhiana. The study will include all patients above 18 years of age undergoing elective inguinal hernia repair from October 1, 2012, to March 30, 2014. The patient will be randomized into two groups in a block of 2 and 4 by block randomization.

- Group-1. Those patients who will undergo closure of skin incision by subcuticular suture
- Group-2. Those patients who will undergo closure of skin incision by octylcyanoacrylate tissue adhesive.

A detailed history of each patient will be obtained, a thorough physical examination and local examination will be done.

Statistical Analysis

All data will be collected in individual patient protocols and analyzed using t-test and Chi-square test as a test of significance.

Informed Consent

All patients will be informed about the purpose of the study before enrolment and written consent will be taken.

Technique

All patients will receive pre-operative dose of antibiotic. Skin preparation by povidone-iodine scrub will be done the previous night and on the morning of the surgery. Hair removal by clippers will be done on the table. After reconstructing the posterior wall of the inguinal canal by mesh repair, external oblique aponeurosis is sutured with continuous sutures of 1.0 prolene and the subcutaneous fat with 3.0 Vicryl interrupted sutures. The skin will be closed by glue or subcuticular sutures based on randomization.

For Group-1

The subcuticular suture is a four-step method using 4.0 Monocryl suture. With the first step, the skin is gently everted using an Adson Forceps to visualize the dermalepidermal junction. Step two consists of introducing the needle at a 90° angle at the dermal-epidermal junction and pronating the wrist to take a deep horizontal bite parallel to the skin surface. In step three, the needle is stabilized with the Adson Forceps, being mindful of not touching the tip, and advanced through the skin. In this step, it is important to emphasize that the Adson Forceps can be used more effectively by firmly gripping the needle at more of a right angle to it, allowing more contact and thus success with grasping the needle, without dulling the needle by manipulating the tip. Finally, in step four, while continuing to stabilize the needle with the Adson Forceps, the needle is replaced in the needle holder in the appropriate position for the next throw. It should be highlighted that in this step the operator should stabilize the hand holding the needle with the Adson Forceps on the patient's body close to the area from the last throw while releasing and reloading with the needle holder, minimize the difficulty in reloading the needle holder in the correct position for the next throw.

For Group-2

After closing the subcutaneous layer, achieving proper hemostasis of the wound achieved. The two skin edges will be approximated with the help of forceps or skin hooks. Following this, using the glue applicator glue will be applied topically over the wound edges extending 5–10 mm beyond the incision. Initial layer applies act as a barrier, which minimize any heat dissipation to the tissue. There is a delay of 10–30 s between the two applications to prevent pooling of the glue. The wound edge will be held together for 60–90 s to allow the glue to polymerize, thus taking care that glue does not enter the wound. The time required for skin closure will be recorded using a stopwatch.

For both the groups, non-occlusive dressing will be given.

Postoperatively, the patients will receive one dose of antibiotic and injectable analgesics for 1 day. On the 2nd post-operative day, the patients will be started on oral analgesics. Patients will be evaluated postoperatively on the day of discharge for evidence of inflammation, infection, and wound gaping. The total hospital stay will be noted. Patients will be re-evaluated for infection/gaping/inflammation/cosmesis during follow-up on the 15th day, 1 month, and at 3 months.

The wounds will be evaluated according to the Hollander wound evaluation scale (HWES) by a senior surgeon who will be blinded to the method of closure.

The wound score will address six clinical variables.

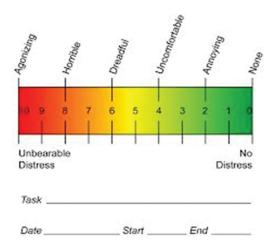
- 1. Step off borders (0 for yes, 1 for no)
- 2. Contour irregularities puckering
- 3. Scar width > 2 mm
- 4. Inflammation redness, discharge
- 5. Edge inversion sinking, curling
- 6. Overall cosmetic appearance (0 = poor, 1 = acceptable).

Each of these categories is graded on 0 or 1 patient scale. A total cosmetic score is derived by the addition of scores of the six variables.

A score of six will be considered optimal, while five or less will suboptimal. The percentage of wounds from each group that attained cosmesis will be compared.

The visual analog scale (VAS) is presented as a 10-cm line, anchored by verbal descriptors, usually "no pain" and "worst imaginable pain". The patient is asked to mark a 10-cm line to indicate pain intensity. The score is measured from the zero anchor to the patient's mark.

This score will be measured postoperatively at 0 h, 2 h, 6 h, 12 h, and 24 h. Pain from each group will be compared.



RESULTS AND ANALYSIS

A total of 30 cases satisfying the selection criteria were included in the study which was carried out at Christian Medical College and Hospital, Ludhiana, Punjab. The age of the patient above 18 years. Their relative proportion age is shown in the following table. Majority of patients were >50 years 25 patients (166.67%).

Table 1 shows the age of the patient above 18 years. Their relative proportion age is shown in the following table. Majority of patients were >50 years 25 patients (166.67%).

Table 2 shows that all samples were males.

Table 3 shows that out of 30 patients, 17 (113.33%) patients had direct hernia, 13 (73.33%) had indirect hernia, and 2 (13.33%) patients had pantaloons hernia.

According to Table 4, 16 (53.33%) of 30 patient had right-sided hernia while 14 (46.66) had left-sided hernia.

Table 5 shows all patients (100%) underwent mesh plasty. Out of 30 patients, the glue was used for skin closure in 15 patients and subcuticular sutures for skin closure in 15 patients.

Table 6 shows that average time of 141 s was taken for closure of incision with glue An average time of 572 s was taken for closure of incision with subcuticular suture. The difference between the groups in closure time was statistically significant (P < 0.001).

Table 7 at post-operative 0 h follow-up; all patients in both group had no pain.

Table 8 at post-operative 2 h follow-up, 15 patients had mild pain in glue group, but 5 and 10 patients had mild and moderate pain, respectively, in the subcuticular group, which was significant.

Table 9 at post-operative 6 h follow-up, 6 and 9 patients had no and mild pain, respectively, in glue group, but 2, 12, and 1 patients had no, mild, and moderate pain, respectively, in the subcuticular group, which was not significant (P = 0.18).

Table 10 at post-operative 12 h follow-up, 11 and 4 patients had no and mild pain in glue group, but in subcuticular

Table 1: Age group					
Age group	Glue (%)	Suture (%)	Total (%)	P value	
18–30	1 (6.67)	0 (0.00)	1 (6.67)	0.499	
31–40	0 (0.00)	1 (6.67)	1 (6.67)		
41-50	2 (13.33)	1 (6.67)	3 (20.00)		
>50	12 (80.00)	13 (86.67)	25 (166.67)		
Total	15 (100.00)	15 (100.00)	30 (200.00)		

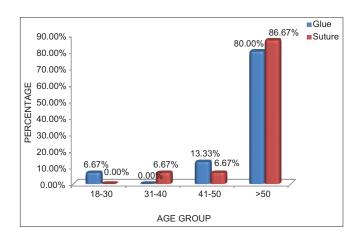


 Table 2: Sex

 Sex
 Glue (%)
 Suture (%)
 Total (%)

 Male
 15 (100.00)
 15 (100.00)
 30 (200.00)

 Total
 15 (100.00)
 15 (100.00)
 30 (200.00)

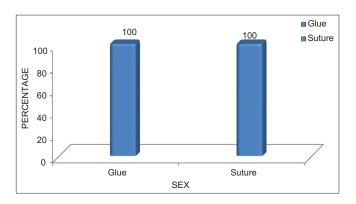


Table 3: Type of hernia

Type of hernia	Glue (%)	Suture (%)	Total (%)	P value
Direct	8 (53.33)	9 (60.00)	17 (113.33)	0.341
Indirect	5 (33.33)	6 (40.00)	11 (73.33)	
Pantaloon	2 (13.33)	0 (0.00)	2 (13.33)	
Total	15 (100.00)	15 (100.00)	30 (200.00)	

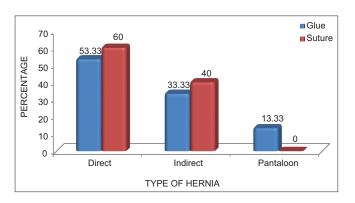


Table 4: Side of hernia

Side of hernia	Glue (%)	Suture (%)	Total
Right	8 (53.33)	8 (53.33)	16
Left	7 (46.66)	7 (46.66)	14
Total	15	15	30

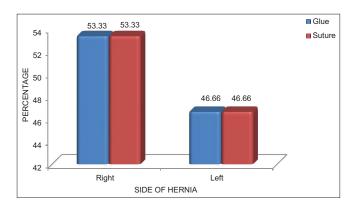


Table 5: Surgery

Type of surgery	Glue (%)	Suture (%)	Total
Mesh plasty	15 (50)	15 (50)	30

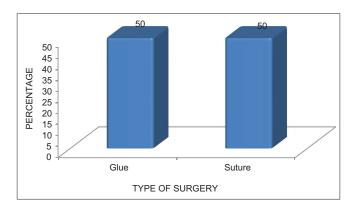


Table 6: Time of skin closure

Skin closure	Mean±SD	Median	Min-Max	P value
Glue	141±9.67	140	130–165	<0.001
Suture	572±22.42	570	540-600	

SD: Standard deviation

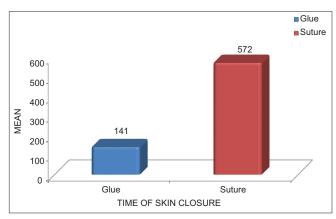
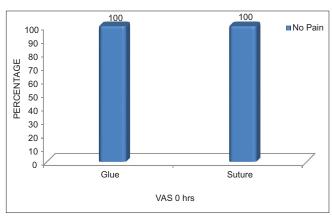


Table 7: VAS 0 h

VAS		Glue (%)	Suture (%)	Total (%)
VAS 0 h	No pain	15 (100.00)	15 (100.00)	30 (200.00)
Total		15 (100.00)	15 (100.00)	30 (200.00)

VAS: Visual analog scale



group, it was 2 and 13 patients, respectively, which was significant (P = 0.003).

Table 11 at post-operative 24 h follow-up, 8 and 7 patients had no and mild pain in glue group, but in subcuticular group, it was 6 and 9 patients, respectively, which was not significant (P = 0.715).

Table 12 shows that mean VAS score at post-operative 0 h was zero in both groups. After that, all follow-up re-evaluation of mean VAS score in the glue group was less than the subcuticular group. At 2 h and 12 h follow-up, the mean VAS score of glue group was statistically significant compared to the subcuticular group.

Table 8: VAS 2 h				
VAS 2 h	Glue (%)	Suture (%)	Total (%)	P value
Mild pain	15 (100.00)	5 (33.33)	20 (133.33)	<0.001
Moderate pain	0 (0.00)	10 (66.67)	10 (66.67)	
Total	15 (100.00)	15 (100.00)	30 (200.00)	

VAS: Visual analog scale

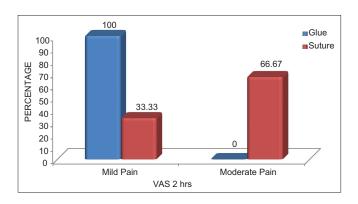


Table 9: VAS 6 h				
VAS 6 h	Glue (%)	Suture (%)	Total (%)	P value
Mild pain	9 (60.00)	12 (80.00)	21 (140.00)	0.18
Moderate pain	0 (0.00)	1 (6.67)	1 (6.67)	
No pain	6 (40.00)	2 (13.33)	8 (53.33)	
Total	15 (100.00)	15 (100.00)	30 (200.00)	

VAS: Visual analog scale

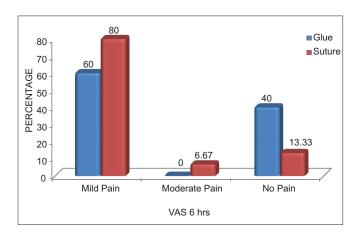


Table 13 shows that out of 30 patients, 29 (193.33%) patients had no complications and 1 (6.67%) patient developed a wound infection. In subcuticular group total, 1 (6.67%) patient developed post-operative complication, all of which had wound infection. There was no complication in the glue group. Prevalence of wound infection though more common in the subcuticular group was not statistically significant (P = 1).

Table 14 shows that HWES: In the glue group, 11 (73.33%) patients have an optimal score of six while 4 (26.67%) patients had \leq 5. In the subcuticular group, 7 (46.66%) had a score of six,

Table 10	: VAS 12 h			
VAS 12 h	Glue (%)	Suture (%)	Total (%)	P value
Mild Pain	4 (26.67)	13 (86.67)	17 (113.33)	0.003
No Pain	11 (73.33)	2 (13.33)	13 (86.67)	
Total	15 (100.00)	15 (100.00)	30 (200.00)	

VAS: Visual analog scale

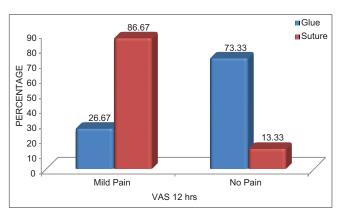
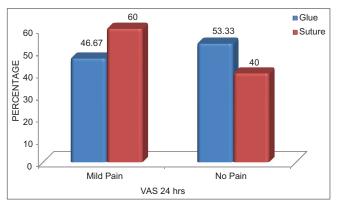


Table 11: VAS 24 h				
VAS 24 h	Glue (%)	Suture (%)	Total (%)	P value
Mild pain	7 (46.67)	9 (60.00)	16 (106.67)	0.715
No pain	8 (53.33)	6 (40.00)	14 (93.33)	
Total	15 (100.00)	15 (100.00)	30 (200.00)	

VAS: Visual analog scale



while 8 (53.33%) had a score of \leq 5. Even though the difference between 2 groups is present, it is not significant (P = 0.264).

Table 15 shows, most of the patients of both groups were discharged on hospital day 4 after first wound evaluation. Average hospital day of patients in the glue group was 4.47±2.1.

One patient in subcuticular group had wound infection and was discharged on 8th post-operative day. Average hospital day of patients in the subcuticular group was 5.13±2.23.

Difference of hospital stay between the two groups was statistically not significant (P = 0.401).

Table 12: VAS score

VAS		Glue			Suture		P value
SCORE (h)	Mean±SD	Median	Min-max	Mean±SD	Median	Min-Max	
VAS 0	0±0	0	0–0	0±0	0	0–0	-
VAS 2	1.53±0.52	2	1–2	2.73±0.59	3	2–4	< 0.001
VAS 6	0.6±0.51	1	0–1	1.2±0.77	1	0–3	0.018
Vas 12	0.27±0.46	0	0–1	0.87±0.35	1	0–1	< 0.001
VAS 24	0.47±0.52	0	0–1	0.6±0.51	1	0–1	0.481

SD: Standard deviation, VAS: Visual analog scale

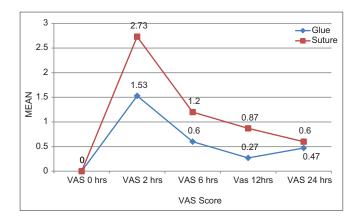


Table 13: Wound complications

Wound complications	Glue (%)	Suture (%)	Total (%)	P value
Infection	0 (0.00)	1 (6.67)	1 (6.67)	1
No complications	15 (100.00)	14 (93.33)	29 (193.33)	ı
Total	15 (100.00)	15 (100.00)	30 (200.00)	

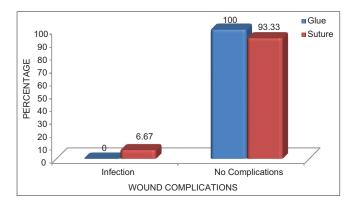


Table 16 cost factors, the cost of glue was RS 450.00 while that of suture was RS 370.00.

DISCUSSION

Proper healing of incisions/wounds so as to restore the structural integrity and strength of the wound has always been the most important factor on surgeon's mind.

With the advent of modern surgical technology and improvement in surgical skills, use of newer and higher antibiotics, maintaining high level of surgical asepsis thus decreasing the incidence of wound complications, the onus is now on obtaining good cosmetic scar.

There are many factors, which affect the cosmetic outcome of scars.

Among the local factors, surgical skill and type of material used to close the incisions are of much importance.

Conventionally, low-tension skin incisions like groin incisions have been closed by subcuticular sutures (continuous) with absorbable (polydiaxone) or non-absorbable materials (Polypropylene/nylon).

The advantage that the absorbable suture material has over the nonabsorbable material is the avoidance of suture removal, which may be slightly painful for the patient. However, the problem associated with it is that this material is not easy to insert in the subcuticular region as compared to polypropylene.

Again it lies at the discretion of the surgeon as to what material to be used.

The problem associated with suturing of the wound is as follows:

- Needlestick injuries to the surgeon
- Stitch abscess may develop
- Injury to the blood vessels in the skin resulting in hematoma.

Other alternative for skin closure is cyanoacrylate glue.

Numerous clinical reports have shown that N-butyl cyanoacrylate can be used as a successful alternative to sutures for topical skin closure of low-tension incisions.

In the present study, 30 patients undergoing inguinal hernia repair were included and studied. Fifteen cases underwent skin closure in N-butyl cyanoacrylate glue while 15 cases underwent skin closure with subcuticular sutures by polypropylene (prolene 2-0)

The comparison of these two groups was done in relation to

Table 14: Cosmetic evaluation

Cosmetic evaluation	Glue (%)	Suture (%)	Total	P value
HWES (optimal) 6/6	11 (73.33)	7 (46.67)	18 (120.00)	0.264
≤5/6	4 (26.67)	8 (53.33)	12 (80.00)	
Total	15 (100.00)	15 (100.00)	30 (200.00)	

HWES: Hollander wound evaluation scale

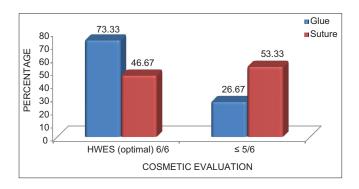


Table 15: Hospital stay

Skin closure	Mean±SD	Median	Min-max	P value
Glue	4.47±2.1	4	3–11	0.407
Suture	5.13±2.23	4	3-12	

SD: Standard deviation

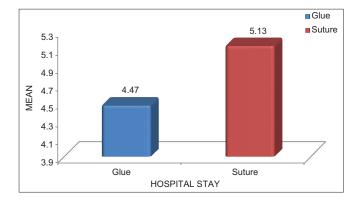
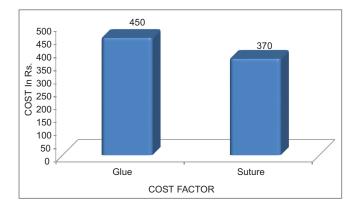


Table 16: Cost factor

Price	Glue	Suture	P value
Cost	450.00	370.00	<0.001



- 1. Time taken for closure
- 2. Post-operative complications
- 3. Cosmetic outcome.

All the patients were males and were between the age group above 18-year direct hernia (17) was more common than indirect (11) and pantaloon hernia (2).

Time Taken

The time taken glue closure was 140 s (average) which was significantly less than the time taken for the subcuticular group, which was 570 s (average) P = (0.001).

The average length of incision was 5–7 cm in the glue group, after approximating the edges with skin hooks, glue was applied topically over the edges.

Thus, according to the literature, longer the incision greater is the difference between the two groups.

Toruimi *et al.* took 55 s for closure of lacerations with glue and 235 s for sutures with the difference being significant (P < 0.0001)

CCP ONG *et al.* did not find any time difference between skin closure of pediatric herniotomies with glue meantime (181 s) and subcuticlar sutures (161 s) P = 0.18. This may be because the herniotomy incision was small in length about 2–3 cm. As the incision length increases, the time difference between the two groups also increases.

Bruns conducted a trial for the closure of lacerations in children's emergency department in 1995 and concluded that there was a significant time difference between glue application and suturing with glue needing lesser time for closure.

Wound Complications

Wound complications are as follows:

- 1. Inflammation
- 2. Wound infection
- Wound gape.

Out of 30 patients, 29 (193.33%) patients had no complications and 1 (6.67%) patient developed a wound infection.

In subcuticular group total, 1 (6.67%) patient developed post-operative complication, all of which had wound infection. There was no complication in glue group. Prevalence of wound infection though more common in the subcuticular group was not statistically significant (P = 1).

Infection of wound is the presence of serosanguinous discharge or frank pus from incision site, which was present in 1 (6.67%) in subcuticular group.

It is known that octylcyanoacrylate glue has antibacterial properties Quinn 1995 has shown the antibacterial property of glue in a contaminated wound model.

The exact mechanism of antibacterial property is not known, but it is likely to be a cell wall mechanism because the sensitivities are restricted to Gram-positive organisms. Gram-negative organisms are relatively less affected.

All these patients with wound infection were treated conservatively. Patients were discharged in 8–9 days. All patients were evaluated during follow-up on the 15th day, 1 month, and 3 months. No evidence of complication presents.

As octylcyanoacrylate glue causes mild histotoxicity to the vascularized tissue, this histotoxicity may be the cause of mild inflammation seen patients in glue group. This may be due to leakage of glue within the tissues. This histotoxicity may be the cause of mild inflammation seen in patients in the glue group. This may be due to leakage of glue into the tissues. However, in our study, there was no wound complication such as inflammation and wound infection.

Toruimi *et al.* did not find any evidence of gaping in both groups of glue and sutures for laceration repair. Amiel *et al.* found that post-operative complications following glue usage in pediatric herniotomies as follows: Inflammation in 5.5%, wound dehiscence in 1.1%, and wound infection 1.9%.

Hospital Stay

Most of the patients of both groups were discharge on hospital day 4 after 1st wound evaluation.

Average hospital day of patients in glue group was 4.47±2.1.

One patient in in subcuticular group had wound infection was discharge on 8th post-operative day. Average hospital day of patients in the subcuticular group was 5.13±2.23.

The difference of hospital stay between the two groups was statistically not significant (P = 0.401).

Cosmesis

All patients were called for follow-up after 3 months when photographs were taken of the scar for cosmetic evaluation. Photographs were evaluated by a senior surgeon who has blinded the method of closure.

Cosmetic outcome was evaluated on HWES it has been proved that 3-month follow-up evaluation provides a good measure of long-term cosmetic outcome.

HWES evaluation showed comparable results with no significant difference between the two groups (P = 0.264) at 3 months follow-up. Our finding is similar to other studies in literature.

CCP ONG *et al.* compared tissue glue versus subcuticular suture for pediatric herniotomies and concluded that tissue glue is easy and safe, with no complications and results equality good cosmesis.

Simon *et al.* found that cyanoacrylate is an ideal alternative to conventional suturing for the cutaneous closure of low tension lacerations in children with long-term cosmetic outcome comparable to conventional sutures.

Keng *et al.* found that glued wounds had consistently better cosmesis mean score (4.7) than sutures (4) (P < 0.5) at 4 weeks follow-up for groin incisions.

Toruimi *et al.* also found no significant difference between the two groups, glue and sutures in closure of skin incisions of facial plastic surgery.

Pain VAS Score

Mean VAS score at post-operative 0 h was zero in both groups. After that, all follow-up re-evaluations of mean VAS score in glue group were less than the subcuticular group. At 2 h and 12 h follow-up, the mean VAS score of glue group was statistically significant compared to the subcuticular group.

In our study, at all follow-up re-evaluation of pain was less in glue group as compared to the subcuticular group.

Toruimi *et al.* found no significant difference in VAS between the two groups, glue and subcuticular suture in closure of skin incision of facial plastic surgery.

Cost Factor

An incision of 5–6 cm requires about (0.25-ml), i.e., one ampoule of glue. Each ampoule of glue costs Rs. 450.00 while a single 4–0 Monocryl suture costs Rs. 370.00. We have used new suture material for every patient discarding the used suture. Ever though the cost of glue per patient is more than

suture, the cost of follow-up and suture removal has not been taken into consideration. Thus, we conclude that even though the cost of glue is more than suture, the overall cost of the suture group will be more or less equal to the glue group.

Limitation of Study

Our sample size was less; we have studied only 30 patients of inguinal hernia. Long-term follow-up that is 1 year for cosmetic evaluation could not be achieved.

Tissue adhesives are more convenient for patients and practitioners than sutures or staples. They fall off spontaneously in 5–10 days and do not require a return visit for their removal. However, patients should be cautioned about frequent exposure to moisture and use of any topical ointments or creams that may result in premature sloughing of the tissue adhesive.

Use of tissue adhesives avoids unnecessary needle stick injuries with sutures. In addition, tissue adhesives also have antimicrobial properties, especially against Gram-positive organisms that are responsible for most wound infections.

SUMMARY

Surgeons have becomes aware of the patient's need for the minimal and esthetic scar. With anincrease in the control of wound infections, the onus is now on the cosmetic appearance of wound scar.

Several methods of skin closure are available to close the skin incisions in place of sutures such as staples, clips, steristrips, and glue adhesives.

In our study, we have compared inguinal hernia skin closure with octylcyanoacrylate tissue adhesive and subcuticular suture with 4–0 Monocryl.

We found that,

- Time require for closure is significantly less with using glue
- 2. Hospital stay is less in glue group compare to subcuticular group bur not significant

- 3. Incidence of infection is more in the subcuticular group
- 4. Cosmetic outcome of the scar is equally good in glue as compared to sutures
- 5. Post-operative pain is less in glue group.

Hence, we conclude that use of glue in low tension incisions is easy, time-saving, less post-operative pain with good cosmetic outcome, low incidence of complications and equally cost effective as sutures and thus recommend its use in surgical practice.

ACKNOWLEDGMENTS

Dedicated to almighty god, loving parents, revered teachers, and my wife.

I pay sublime obeisance to my esteemed parents who have always been a source of motivation and encouragement in my life. My brothers, sisters, and my wife for their support and perseverance that have always been a source of inspiration.

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A Prospective Study Comparing No Antibiotic versus Antibiotic Prophylaxis in Patients Undergoing Elective Laparoscopic Cholecystectomy

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Abstract

Laparoscopic cholecystectomy is one of the most common operations performed in general surgery. Elective laparoscopic cholecystectomy has a low risk for infective complications, and standard guidelines do not recommend prophylactic antibiotic use for low-risk cases. However, the use of antibiotic prophylaxis is very prevalent and the duration and dosage are inconsistent and varies widely among surgeons. This study is being done to assess the role of no antibiotic prophylaxis in the prevention of wound infection in a patient undergoing elective laparoscopic cholecystectomy.

Study Design and Period: The study was conducted in the Department of General Surgery at Christian Medical College, Ludhiana. This was an open labeled study conducted from the period of January 1, 2014, to December 31, 2014.

Results: 92 patients suffering from chronic calculous cholecystitis undergoing elective laparoscopic cholecystectomy were included in the study. Group A with 23 cases without prophylactic antibiotic. Group B with 69 cases with two doses of prophylactic antibiotics Inj. cefuroxime 1.5 gram 30 min prior to induction and after 6 h. The majority of our 81 patients (88.04%) were females. The male to female ratio was 1:8. 3 patients (3.27%) in Group B had associated comorbidities except for diabetes mellitus. The majority of patients 14 (60.86%) in Group A had taken 1-2 h of operative time while 58 patients (84.05%) patients in Group B with statistical insignificant P = 0.05. There was no fever in Group A patients while in Group B 2 patients (2.89%) had fever on second post-operative day which was not related to surgical site infection and that was due to superficial thrombophlebitis. In Group A 18 patients (78.26%) were discharged on second postoperative days while 46 patients (66.67%) patients in Group B were discharged on second postoperative days. There was no statistical difference in the duration of hospitalization between the two groups with P = 0.22. The overall incidence of postoperative infective complications were nil in both groups either with patients having no prophylactic antibiotic or those having prophylactic antibiotics.

Key words: Calculous cholecystitis prophylactic Antibiotics, Comorbidities, Infective complications, Laparoscopic cholecystectomy

INTRODUCTION

Cholecystectomy is one of the most common surgeries done today and laparoscopic cholecystectomy is the gold standard procedure due to its advantages to the patient such as reduced pain, reduced hospital stay, lesser

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analgesics required, and earlier return to work and better cosmesis.^[1,2]

Surgical antimicrobial prophylaxis refers to a very brief course of antimicrobial agent initiated 1/2 h before an operation begins. It is not an attempt to sterilize tissue, but a critically timed adjunct used to reduce the microbial burden of intraoperative contamination to a level that will not overwhelm host defense. [3] The concept of prophylactic antibiotics was introduced in the early 1960s. [4]

The success of laparoscopic surgery has led to the re-evaluation of many long-accepted surgical doctrines.

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A lower incidence of complication and a better postoperative outcome have been observed with laparoscopic surgery compared with conventional open operation.^[5]

The infective complications following laparoscopic cholecystectomy are low, was further supported by study analysis of 1702 patients undergoing laparoscopic cholecystectomy and revealed an overall infections rate of 2.3% and surgical site infection rate 0.4%. [6] Observing the low incidence of infections following laparoscopic cholecystectomy, the need for prophylactic antibiotics is now frequently questioned. The overuse of antibiotics can result in rising frequency of adverse effects, emergence of drugresistant organisms, as well as excessive costs. [7] A number of studies and meta-analysis show different results in the context of surgical site infection in elective laparoscopic cholecystectomy and it ranges from 0.4% to 7.9%. [8-12]

Antibiotic prophylaxis includes the pre-operative administration of a wide spectrum antibiotic against the most frequent bacteria involved in surgical site infections, trying to get high tissue levels of the antibiotic at the surgical wound to avoid colonization and the growing of microorganisms.^[13,14]

It is advisable to use prophylactic antibiotics to reduce the incidence of wound infection in laparoscopic cholecystectomy.^[15] On the other hand, eliminating the unnecessary use of prophylactic antibiotics would result in a cost reduction; moreover, it would lower the risk of adverse reactions and reduce microbial resistance.

Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) provided a guideline for antibiotic prophylaxis as follows:

- 1. Antibiotics are not required in low-risk patients undergoing laparoscopic cholecystectomy
- Antibiotics may reduce the incidence of wound infection in high-risk patients (age >60 years, the presence of diabetes, acute colic within 30 days of operation, jaundice, acute cholecystitis, or cholangitis)
- 3. If given, they should be limited to a single pre-operative dose given within 1 h of skin incision.

The aim of this study was to compare the efficacy of no prophylaxis with antibiotics prophylaxis with regard to post-operative infections in elective laparoscopic cholecystectomies performed in the Department of General Surgery at Christian Medical College, Ludhiana.

MATERIALS AND METHODS

Study Setting

The study was conducted in the Department of General Surgery at Christian Medical College, Ludhiana.

Study Design and Period

This was an open labeled study conducted from the period of January 1, 2014, to December 31, 2014.

Study Population

All patients undergoing elective laparoscopic cholecystectomy were included in the study as per inclusion and exclusion criteria after taking written informed consent for participation. To make it a statistically significant study with the expected difference of infection rate being 15% with alpha of 95% and power of 80%, with an unequal allocation ratio being 1:3, the sample size was calculated as 23 cases without antibiotic prophylaxis (Group A) and 69 cases with antibiotic prophylaxis (Group B).

- Group A: Patients in this group received no antibiotics prophylaxis
- Group B: Patients in this group received prophylactic antibiotic Inj. cefuroxime 1.5 g 30 min before induction and after 6 h.

Methods

A detailed history and general physical examination followed by routine investigations were done. Informed consent for laparoscopic/open cholecystectomy had taken. Group A patients had not received antibiotic prophylaxis before surgery. At the time of surgery, the site was cleaned with 10% povidone-iodine solution. Nasogastric tube was inserted after induction of anesthesia. Laparoscopic cholecystectomy was performed with standard four-port technique. The gallbladder was extracted through subxiphoid or umbilical port. The umbilical port sheath was closed with no.1 nylon. The skin incisions were closed with nylon 4–0.

Group B patients were received prophylactic antibiotic Inj. Cefuroxime 1.5 g 30 min before induction and after 6 h. All the patients received analysesic, steam inhalation, and nebulization postoperatively.

The patients were watched for infective complications which were defined as follows:

- 1. Pyrexia of >38°C (Excluding the 1st post-operative day)
- 2. Evidence of infections
 - Wound infections
 - Erythema
 - Induration
 - Pus discharge and
 - Serous discharge with bacteriological evidence of infection.
 - b. Major infections
 - Intra-abdominal collections or abscess.

Inclusion Criteria

All patients undergoing elective laparoscopic cholecystectomy at the Department of General Surgery, Christian Medical College for chronic calculous cholecystitis were included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

- Age more than 60 years
- Antibiotic use within 48 h
- Diabetes mellitus
- H/O Steroid use
- Patients with acute cholecystitis
- Conversion to open cholecystectomy
- Cholangitis
- Intraoperative cholangiogram
- Jaundice
- Post-endoscopic procedure such as endoscopic retrograde cholangiopancreatography
- Patient getting antibiotics post-operative for any intervention
- Cardiac prosthesis
- Rheumatic heart disease.

Follow-up

The patients were discharged 48–72 h postoperatively and were followed up in the outpatient department on 1st, 2nd, and 4th weeks postoperatively. The patients were examined to rule out any infective complications. If present, a wound swab from the infected site was taken to document the infection.

Statistical Analysis

The results obtained were statistically analyzed using SPSS software version 16 and subjected to frequency, proportion, Chi-square, and *t*-test for significance.

RESULTS AND ANALYSIS

Table 1 shows the mean age of patients and perioperative assessment of blood biochemistry of the patients in both groups. The mean age in Group A was 37.83 years with a standard deviation of 10.83 while in Group B the mean age was 42.80 years with a standard deviation of 10.75.

The mean hemoglobin was 12.01 g% with a standard deviation of 1.71 in Group A while the mean hemoglobin was 12.47 g% with a standard deviation of 1.58 in Group B with a statistically insignificant P = 0.241.

The mean total leukocyte count was $7713.04/\text{cm}^3$ with a standard deviation of 2489.12 in Group A while the mean total leukocyte count was $7487.88/\text{cm}^3$ with a standard deviation of 2397.99 in Group B with a statistically insignificant P = 0.70.

The mean random blood sugar was 123 mg/dl with a standard deviation of 20.37 in Group A while the mean random blood sugar was 124.72 mg/dl with a standard

deviation of 23.02 in Group B with a statistically insignificant P = 0.75.

The serum creatinine was 0.66 mg/dl with a standard deviation of 0.19 in Group A while the serum creatinine

Table 1: Pre-operative assessment in both groups

Parameters	Group A	Group B	P value
Age			0.061
Sample size	23	69	
Mean±SD	37.87±10.83	42.80±10.75	
Median	37	44	
Min-max	18–60	22-60	
Interquartile range	30.25-47.5	33-51.25	
Hb			0.241
Sample size	23	69	
Mean±SD	12.01±1.71	12.47±1.58	
Median	12.4	12.5	
Min-max	8.1-15.2	9-17.6	
Interquartile range	11.125-13.150	11.275-13.525	
TLC			0.7
Sample size	23	69	
Mean±SD	7713.04±2489.12	7487.88±2397.99	
Median	7100	7200	
Min-max	3800-12400	64-14500	
Interquartile range	6025-9800	6025-8525	
RBS			0.75
Sample size	23	69	
Mean±SD	123±20.37	124.72±23.02	
Median	117	122	
Min-max	86-178	81-189	
Interquartile range	112-135.5	111.75-136.5	
Creatinine			0.067
Sample size	23	69	
Mean±SD	0.66±0.19	0.74±0.27	
Median	0.6	0.7	
Min-max	0.4-1.1	0.1-2.1	
Interquartile range	0.57-0.7	0.6–0.8	
CD. Ctandard doviation			

SD: Standard deviation

Table 2: Age distribution of patients

Age	Age Group		Total (%)	P value
grouping	A (%)	B (%)		
18-20	1 (4.35)	0 (0.00)	1 (1.09)	0.121
21-30	5 (21.74)	10 (14.49)	15 (16.30)	
31-40	9 (39.13)	17 (24.64)	26 (28.26)	
41-50	5 (21.74)	21 (30.43)	26 (28.26)	
51-60	3 (13.04)	21 (30.43)	24 (26.09)	
Total	23 (100.00)	69 (100.00)	92 (100.00)	

χ²=7.299, df=4

Table 3: Comorbidities among the patients

Co morbidity	Group		Total (%)	P value
	A (%)	B (%)		
Bronchial asthma	0 (0.00)	1 (1.45)	1 (1.09)	0.793
HTN	0 (0.00)	1 (1.45)	1 (1.09)	
Hypothyroidism	0 (0.00)	1 (1.45)	1 (1.09)	
Nil	23 (100.00)	66 (95.65)	89 (96.74)	
Total	23 (100.00)	69 (100.00)	92 (100.00)	

 $\chi^2 = 1.034$, df = 3

was 0.74 mg/dl with a standard deviation of 0.27 in Group B with a statistically insignificant P = 0.067.

Table 2 and Figure 1 shows the distribution according to the age of patients included in both the group separately. Nine patients (39.13%) were in the 4th decade and 5 patients (21.74%) were in the 5th decade of life in Group A, whereas 17 patients (24.64%) were in the 4th decade and 21 patients (30.43%) were in the 5th decade of life in Group B. There was no statistically significant difference between the two groups in terms of age distribution (P = 0.121).

Table 3 and Figure 2 in Group A, none of the patients have comorbidities while 3 patients (4.35%) in Group B have comorbidities. There was no statistically significant difference between the two groups (P = 0.793).

Table 4 and Figure 3 shows that 3 patients (13.04%) required <1 h, 14 patients (60.87%) required 1–2 h, and 6 patients (26.09%) required more than 2 h of operative

Table 4: Duration of operation

Duration of	Gre	oup	Total (%)	P value
operation (h)	A (%)	B (%)		
<1	3 (13.04)	5 (7.25)	8 (8.70)	0.054
1–2	14 (60.87)	58 (84.06)	72 (78.26)	
>2	6 (26.09)	6 (8.69)	12 (13.04)	
Total	23 (100.00)	69 (100.00)	92 (100.00)	

 $\chi^2=5.852$, df=2

Table 5: Distribution of patients according to post-operative hospital stay

Duration of hospital	Gro	oup	Total	P value
days (days)	A (%)	B (%)	No (%)	
1	5 (21.74)	15 (21.74)	20 (21.74)	0.22
2	18 (78.26)	46 (66.67)	64 (69.57)	
3	0 (0.00)	8 (11.59)	8 (8.69)	
Total	23 (100.00)	69 (100.00)	92 (100.00)	

Table 6: Distribution of wound complication in both groups

Complications	Group A	Group B
Fever		
Present	00	02
Absent	23	67
Erythema		
Present	00	00
Absent	23	69
Induration		
Present	00	00
Absent	23	69
Discharge (Pus/serous)		
No discharge	23	69

time in Group A while in Group B 5 patients (7.25%) required <1 h, 58 patients (84.06%) required 1–2 h, and 6 patients (8.69%) required more than 2 h of operative time. There was no statistically significant difference between the two groups with P = 0.054.

Table 5 and Figure 4 shows that 5 patients (21.74%) were discharged on 1st post-operative day while 18 patients (78.26%) were discharged on 2nd post-operative day in Group A whereas 15 patients (21.74%) discharged on 1st post-operative day, 46 patients (66.67%) were discharged on 2nd post-operative day, and 8 patients (11.59%) were discharged on 3rd post-operative day in view of high drain output in Group B. The difference was not statistically significant with P = 0.22.

Table 6 shows that there was no fever in Group A patients whereas 2 patients (2.89%) in Group B had a fever on the 2nd post-operative day due to superficial thrombophlebitis and were cured with antipyretic. No any

Table 7: Distribution of wound complications in both groups

Complications with time duration	Group A	Group B
Bacteriological evidence of infection		
Absent	23	69
Infection at other site		
Absent	23	69
Infection at the surgical site		
1 st week		
Absent	23	69
2 nd week		
Absent	23	69
4 th week		
Absent	23	69

Table 8: Status of the wound in the two groups

Status of wound	Group		
	A (%)	B (%)	
Healed	23 (100)	69 (100)	
Wound complication	0	0	

Table 9: Infection at the surgical site after discharge

Infections		Gro	oup	Total (%)
		A (%)	B (%)	
Infection at surgical site 1st week	NO	23 (100.00)	69 (100.00)	92 (100.00)
Infection at surgical site 2 nd week	NO	23 (100.00)	69 (100.00)	92 (100.00)
Infection at surgical site 4 th week	NO	23 (100.00)	69 (100.00)	92 (100.00)
Total		23 (100.00)	69 (100.00)	92 (100.00)

other wound complication noticed in both groups. There is no statistically significant difference noticed between the two groups.

Table 7 shows that there is no bacteriological evidence of infection in both groups as well as there is no infection at other site in both groups. Following follow-up at 1st, 2nd, and 4th weeks, there was no evidence of infection at the surgical site in both groups.

Table 8 and Figure 5 shows that there were no wound complications noticed in both groups and all patients had completely healed the wound in both groups.

Table 9 and Figure 6 shows no evidence of infection at the surgical site after discharge on follow-up.

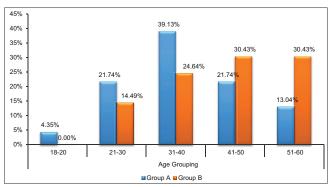


Figure 1: Age distribution

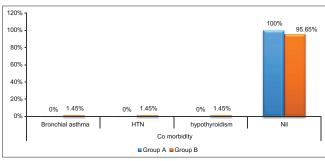


Figure 2: Comorbidities

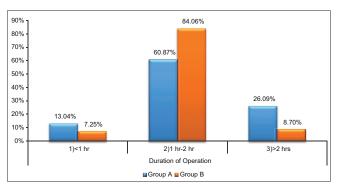


Figure 3: Duration of operation * group

DISCUSSION

Laparoscopic cholecystectomy is now considered as the "gold standard" treatment for symptomatic cholelithiasis. ^[16] The infective complication following this procedure is significantly less compared to open cholecystectomy. ^[17-19] It has been shown to be associated with decreased pain, shorter hospital stay, reduced pulmonary complications, decreased wound infection, and faster recovery. ^[1,2] The systemic immune response for surgery, in general, may not apply to laparoscopic surgery. The body response to laparoscopy is one of lesser immune activation as opposed to immunosuppression. ^[20] The smaller biological impact induced by laparoscopy is followed by greater preservation of the immune response, than that after the

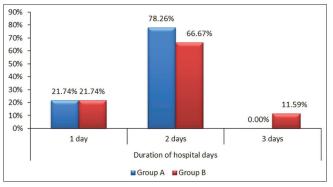


Figure 4: Duration of hospital days * group

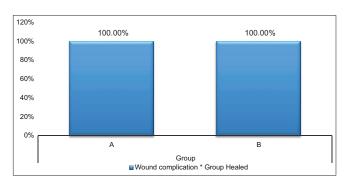


Figure 5: Status of the wound

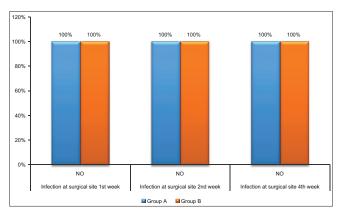


Figure 6: Infection at the surgical site after discharge

open operation, consequently lowering the incidence of infectious complications.^[5]

Antibiotic therapy has played a major role in the treatment of general and biliary septic complication in biliary surgery. The administration modalities of these drugs have progressively been changed, with pre-operative prophylaxis preferred to post-operative treatment, based on a number of studies that documented the efficacy of the former in controlling septic complications.^[21]

It is well documented that prophylactic antibiotic coverage of most clean-contaminated surgical procedure can significantly prevent infectious complications, including wound infection, thereby affecting the overall rates of morbidity and mortality. However, the benefit of antibiotic prophylaxis in other clean surgical procedure such as laparoscopic cholecystectomy has been considered questionable.[22] The low rate of wound infections and the straight forward treatment, if they occur at all are the main arguments against routine antibiotic coverage during laparoscopic cholecystectomy. Laparoscopic cholecystectomy is an elective clean operation and the post-operative wound infection rate been shown to be of value in other areas of surgery such as trauma^[23] and vascular surgery, [24,25] but in laparoscopic cholecystectomy, its benefits remain uncertain. [22] Due to the unknown impact on bacterial resistance, Waldvogel et al. suggested that the routine use of antibiotic prophylaxis should be discouraged. [26] SAGES also advocate no prophylactic antibiotics in low-risk patient undergoing laparoscopic cholecystectomy.

We have carried out a prospective open labeled study which included patients with an unequal allocation ratio being 1:3, considering statistically significant study with the expected difference of infection rate being 15% with alpha of 95% and power of 80%. The sample size was calculated as 23 cases without antibiotic prophylaxis (Group A) and 69 cases with antibiotic prophylaxis (Group B).

Patients in Group A not received prophylactic antibiotic while patients in Group B received prophylactic antibiotic intravenous Cefuroxime 1.5 g, 30 min before induction and after 6 h.

Comparison of mean age in our study with other studies

Study	Mean age (years)
Peters and associates[27]	46
Gordan and associates[28]	47
Lipman and associates[29]	45
Present study	45.5

The mean age in our study (45.5 years) is consistent with the mean age in the above-mentioned studies.

Comparison of % of female in our study with other studies

Study	% of females
Kambouris and associates[30]	72.6%
Schirmer and associates[31]	78.2%
Bailey and associates[32]	80.7%
Present Study	88.04%

The percentage of females in our study 88.04% is consistent with the percentage of females in the abovementioned studies.

Thus, the mean age at presentation (45.5 years) and female preponderance obtained in our study are similar to most of the other studies, thereby implying that symptomatic cholelithiasis most commonly presents in the 5th decade of life, with a significant female preponderance.

Presenting Symptoms

In this study, pain abdomen associated with chronic calculous cholecystitis was 72.83% of patients.

Comparison of % of patients with pain abdomen in our study with other studies

Study	% of patients with pain abdomen
McMahon and associates[33]	32-82%
Singh and associates[34]	40%
Present study	72.83%

Pain abdomen associated with chronic calculous cholecystitis is the most common presenting symptoms in our study, which is consistent with the result obtained in the abovementioned studies.

Associated Comorbidities

In this study, 3 patients in Group B has associated comorbidities, but none of them are significantly associated with an increased incidence of infective complications following elective laparoscopic cholecystectomy.

Duration of Hospitalization

In our study, all patients in Group A were discharged within the 1st week of operation, maximum within 2 days (78.26%). As similar, all patients in Group B were discharged within the 1st week of operation, maximum within 2 days (66.67%). The corrected P = 0.22 which is statistically insignificant.

Our study is comparable to a study conducted by Tocchi *et al.*, [10] in which all 84 patients were discharged within the 1st week of surgery.

Post-operative Wound Status

In our study, 23 out of 23 patients (100%) in Group A had completely healed wound postoperatively without any evidence of surgical site infections. In Group B, 69 patients out of 69 also had completely healed wound postoperatively without any evidence of surgical site infections. This illustrates that patients in Group A without antibiotic prophylaxis and patients in Group B with antibiotic prophylaxis have no difference in outcome in terms of surgical site infections.

Elective laparoscopic cholecystectomy has a low risk of infective complications. [8] In a randomized controlled trial on 417 patients undergoing laparoscopic cholecystectomy, conducted by Gaur and Pujaharr, they reported an overall infection rate of 2.2%, which is consistent with the results obtained in our study. [35]

Chang *et al.* conducted a prospective randomized study to demonstrate the impact of prophylactic antibiotics on post-operative infective complications in elective laparoscopic cholecystectomy. They demonstrated that no prophylactic antibiotics are necessary after wound closure, i.e., postoperatively in an effort to decrease the incidence of superficial wound infections in elective laparoscopic cholecystectomy.^[36]

Kuthe et al. carried out a prospective study to define the role of prophylactic antibiotics in elective laparoscopic cholecystectomy to prevent post-operative infection. Ninety-three patients were randomly placed in two groups. Group A comprised 40 while Group B consisted of 53 patients. Patients in Group A received 1.5 g of second generations cephalosporin (cefuroxime sodium) diluted in 100 ml of normal saline, at the time of induction of anesthesia. Group B patients received an equal volume of normal saline only. In Group A, one patient (2.5%) had post-operative wound infection and in Group B, two patients (3.8%) had post-operative infections which were statistically similar (P > 0.1). Therefore, the study concluded that prophylactic antibiotic did not have a significant role to play in the prevention of post-operative wound infection in elective laparoscopic cholecystectomy this result is consistent with the results obtained in our study.^[37]

Mehmet *et al.* conducted a double-blind prospective, randomized, controlled study comparing the prophylactic use of cefazolin (Group 1) versus placebo (Group 2). One hundred fifty patients undergoing elective laparoscopic cholecystectomy were selected for study. After all exclusion Groups 1 and 2 included 68 and 76 patients, respectively. The study showed that the incidence of SSI in patients was 3.47% for the total study group. Nearly 4.41% for Group 1 and 2.63% for Group 2 and there was no

significant difference in infection rate between the groups. They concluded that antibiotic prophylaxis did not seen to affect the incidence of SSI and is not necessary for elective laparoscopic cholecystectomy in low-risk patients which is consistent with our study too.^[38]

Qahtani carried out a study to determine the necessity of a single dose prophylactic antibiotic in preventing the post-operative infective complications in patients undergoing elective laparoscopic cholecystectomy. Patients who were included in this study were prospectively randomized into two groups, those receiving single dose of intravenous cefuroxime 1.5 g, 30 min before surgery (Group A) and those not receiving any pre-operative antibiotic (Group B). One hundred two patients in Group A received antibiotic and 109 patients in Group B did not received any antibiotics. In this study, the overall post-operative infective complications were 3.62% (2.7% in Group A and 4.6% in Group B) with no significant statistical difference between the two groups.^[39]

They concluded that elimination of prophylactic antibiotics in patients undergoing elective laparoscopic cholecystectomy increases the incidence of post-operative infective complications but not to a statistically significant degree. In our study, the post-operative wound infections in both groups were statistically not significant.

Choudhary *et al.* in their meta-analysis to evaluate the efficacy of prophylactic antibiotics in low-risk patients undergoing laparoscopic cholecystectomy concluded that prophylactic antibiotics before laparoscopic cholecystectomy resulted in no statistically significant benefit for wound infection. This difference, though, can be attributed to the exclusion criteria used by Choudhary *et al.*, who excluded all patients with cholelithiasis or cholangitis from their study. They went onto state that future multicenter randomized controlled trials with adequate statistical power and involving a higher number of patients, particularly those at high risk for infections are needed to complete the evaluation of prophylactic antibiotics before laparoscopic cholecystectomy. [40]

In another study conducted by Mahmoud *et al.* to assess the role of antibiotic prophylaxis in elective laparoscopic cholecystectomy, they stated that antibiotic prophylaxis does not prevent wound infection in elective laparoscopic cholecystectomy. This is probably due to the fact that Mahmoud *et al.* excluded all patients with associated comorbidities, such as diabetes mellitus and hypertension from their study.^[410]

They also concluded that the use of antibiotic prophylaxis is preferred to be restricted to high-risk patients such as patients with associated comorbidities like diabetes mellitus.

The rate of post-operative wound infection in our study was nil in both groups and there is no difference in surgical site infections in patients those who received no prophylactic antibiotics versus those who received prophylactic antibiotics.

This can be attributed to the following reasons:

- Proper selection of patients
- Strict adherence to aseptic precautions
- Good surgical technique
- Better handling of tissues
- Experienced laparoscopic surgeons.

SUMMARY AND CONCLUSIONS

This was an open label prospective study and has been conducted in the Department of General Surgery, Christian Medical College, Ludhiana, Punjab. Ninety-two patients suffering from chronic calculous cholecystitis undergoing elective laparoscopic cholecystectomy were included in the study.

- Ninety-two patients underwent elective laparoscopic cholecystectomy for chronic calculous cholecystitis
- Patients were randomized with an unequal allocation ratio of 1:3 into two groups
- Group A with 23 cases without prophylactic antibiotic
- Group B with 69 cases with two doses of prophylactic antibiotics Inj. cefuroxime 1.5 g 30 min before induction and after 6 h
- Laparoscopic cholecystectomy was done by the standard four port technique
- Patients were discharged between 48 and 72 h postoperatively and were followed on 1st, 2nd, and 4th weeks for the development of infective complications
- Maximum incidence of cholelithiasis was found in between 4th and 5th decade of life, 38 patients (56.52%).
 The mean age of our patients was 40.33 years with a range from 18 to 60 years
- The majority of our 81patients (88.04%) were females. The male to female ratio was 1:8
- Three patients (3.27%) in Group B had associated comorbidities except for diabetes mellitus
- The majority of patients 14 (60.86%) in Group A had taken 1–2 h of operative time while 58 patients (84.05%) patients in Group B with statistical insignificant *P* = 0.05
- There was no fever in Group A patients while in Group B 2 patients (2.89%) had a fever on 2nd post-operative day which was not related to surgical site infection and that was due to superficial thrombophlebitis
- In Group A, 18 patients (78.26%) were discharged on 2nd post-operative days while 46 patients (66.67%)

- patients in Group B were discharged on the 2nd postoperative day. Eight patients (11.59%) in Group B were discharged on 3rd post-operative days
- There was no statistical difference in the duration of hospitalization between the two groups with P = 0.22.
- The overall incidence of post-operative infective complications was nil in both groups either with patients having no prophylactic antibiotic or those having prophylactic antibiotics
- There was no statistical difference in the incidence of post-operative infective complications in lowrisk patients underwent elective laparoscopic cholecystectomy with or without prophylactic antibiotics.

CONCLUSION

Based on the finding of our study, it may be concluded that not giving prophylactic antibiotic does not increase the post-operative infective complications. Prophylactic antibiotic is not necessary for low-risk patients undergoing elective laparoscopic cholecystectomy.

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Scabies: Its Treatment Futile

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Abstract

Introduction: Scabies is a ectoparasitic infestation casued by the mite *Sarcoptes scabiei*. Its mainifestation includes itching, excoriations, papular lesions and burrows. It is highly contagious, affecting usually all the members of a family staying together or inmates of a hostel. It is convenient to treat the affected ones but treating all the contacts is difficult, resulting in reinfection.

Aims and Objectives: In this study we try to evaluate if application of topical scabicidal creams such as permentrin 5% is effective in curing the disease.

Materials and Methods: A total of 56 patients who presented to our Out patient department were included for the study. They were prescribed permetrin 5 % cream. Advice regarding the proper application of the cream and treatment of contacts was give. They were followed up at the OPD at 2 weeks, 1 and 2 months for assessment of response.

Results: Our study showed that although effective initially in a significant number of patients, there was a considerable relapse of the infestation. Only 11 patients (19.64%) showed complete response with failure in the rest (80.36%).

Conclusion: Although scabies is a common parasitic infestation, its treatment is complex. The difficulty in treating scabies is identification and treatment of all of the contacts, many of whom are asymptomatic. The average cost of permetrin 5% cream is around Rs 90, the cost involved in treating all the contacts such as family members and inmates in hostels would be far more than what the common man can afford. This makes the treatment of scabies unfeasible especially in developing countries like India. Hence scabies which is a self limiting infestation, is best treated symptomatically.

Key words: Infestation, Mite, Parasite, Permetrin 5%, Scabies

INTRODUCTION

Scabies is a highly infectious parasitic infection caused by the mite *Sarcoptes scabiei* var. *hominis*. It spreads mainly by direct skin-to-skin contact. Worldwide, incidence is about 300 million (Maan *et al.*, 2015).^[1] It occurs mainly in settings of overcrowding such as hostels bunkers, and shelter homes. Other predisposing factors include poverty and poor nutritional status (Shimose and Munoz-Prize, 2013).^[2] It is mainly characterized by severe itching, multiple excoriated papules, and typical burrows. It has an incubation period of 1 month (Shimose and Munoz-Prize, 2013).^[2] Diagnosis is mainly clinical although the gold standard for diagnosis would be the

identification of mites, eggs, or feces in skin scrapings of skin or identification of burrows (Andrews *et al.*, 2009).^[3] The mainstay of treatment is topical scabicidal agents. Although there are a number of topical scabicidal agents, the most effective one is considered to be topical permethrin (Karthikeyan, 2005).^[4] Often, overlooked is the high contagiousness of the infestation, resulting in the presence of asymptomatic persons who can again reinfect the treated individual if the carriers themselves were not treated (Golant and Levitt, 2012).^[5] Hence, the goal of treatment can be achieved if all the contacts are treated. In this study, we try to evaluate if the standard regime for scabies, which is topical application of permethrin cream, is effective in curing the disease.

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MATERIALS AND METHODS

A total of 56 patients were included in the study which included men, women, and children. The study was conducted at Ganga skin clinic between February 2017 and July 2017. They were evaluated if they were infected with the scabies mite based on the following criteria:

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The presence of itching with one of the features:

- Multiple excoriations and papular lesions over the body
- Burrows over the interdigital spaces
- Nocturnal itching
- Involvement of other family/roommates

Exclusion Criteria

Patients who were allergic to permethrin, pregnant and lactating patients were excluded from the study.

The patients were given permethrin 5% cream and advised to apply it topically all over the body below the neck. The application must be a single overnight application followed by taking a bath the next morning. All contacts including family members and roommates were advised to take the same treatment. They were to advised to wash their clothes in warm water and not to wear the same clothes the next day.

Follow-up

All patients, irrespective of resolution of symptoms, were asked to report to the outpatient department after 2 weeks, 1 month, and 2 months for follow-up. The patients were evaluated for resolution of symptoms and signs. Those patients who still had symptoms were asked to reapply permethrin cream for a 2nd time at the 2nd week. Further, follow-up was done at the end of 1 and 2 months.

RESULTS

A total of 56 patients were included for the study, of which 36 patients (64.28%) were male and 20 patients (35.71%) were female (P < 0.01). The age distribution is shown in Table 1.

The majority of the patients were below 50 years (92.83%) (P < 0.01) with maximum in the age group of 10–20 years (32.14%). The ratio of males-to-females was 2.6:1.

Occupation and Residence

The majority of patients were students who were either residing in their homes, as hostel mates or paying guests along with other students. This was followed by housewives, office workers, coolies, and agricultural workers.

History of Involvement of Other Room/Family Members

A history of the involvement of other family members was seen in 15 patients (26.78%). Similarly, the involvement of other members in hostels or as roommates in paying guest was seen in 20 patients (35.71%).

Response to Treatment

A complete resolution of symptoms after 2 weeks was seen in 15 patients (26.78%). Forty-one patients (73.21%)

continued to have generalized itching (P < 0.01). They were prescribed another course of topical permethrin 5% on the 2^{nd} week. At the end of 1 month, 20 patients (35.71%) had persistent symptoms. At the end of 2 months, symptoms and signs of infestation were present in 45 patients (80.35%) (P < 0.01), complete cure was seen in only 11 patients (19.64%) [Table 2].

Compliance

Of all the 56 patients who were advised to treat their contacts either roommates, family members, or friends with similar complaints, 8 patients (14.28%) failed to do so. Of the 56 patients who were patiently told about the need to apply the cream as 1 time whole body application, 5 patients (8.92%) failed to follow the instructions and instead applied small amounts of the cream on a daily basis

DISCUSSION

Scabies is a contagious parasitic infestation. Although there are many topical medicines for treatment, permethrin 5% is considered to be the most efficacious and most widely used modality of treatment Usha and Nair. [6] However, considering the highly contagious nature of the disease and the presence of asymptomatic carriers, there is a high chance of reinfection. This is especially so in an Indian setting where there is a large occurrence of overcrowding, poverty, poor nutritional status, and inhygiene in houses, slums, and hostels, due to the high population density (Sharma and Singal, 2011). [7] Our study results are contradictory to studies by Ranjkesh et al.[8] who reported a cure rate of 96.8% after 2 weeks of application of permethrin 5%. It is also contradictory to other studies by Chhaiya et al.[9] who reported a cure rate of 100% after 2 weekly applications of permethrin 5%. Our results at

Table 1: Age distribution

Age (years)	Number (%)
1–10	6 (10.70)
10–20	18 (32.14)
20-30	10 (17.85)
30-40	8 (14.28)
40–50	10 (17.85)
50-60	4 (7.14)
>70	Nil

Table 2: Results

Follow-up period	2 weeks	1 month	2 months
Number of patients with resolution of symptoms	15	21	11
Number of patients with persistent symptoms	41	35	45

1 week are comparable to that of Taplin and Meinking^[10] who reported 30% cure rate after a single treatment with permethrin 5%.

CONCLUSION

Our study was conducted to assess if permethrin 5% cream which is considered the first line treatment of scabies is as effective as it is claimed. Our study showed that although there was a significant improvement of symptoms after 2 weekly treatment of scabies, there was a high rate of reinfection from asymptomatic carriers.

Hence, based on the study, we suggest that a symptomatic treatment of scabies should be given such as topical application of calamine lotion or other emollients and antihistamines instead of scabicidal agents. This is especially true for patients reporting from hostels and other crowded settings where it is very hard to treat all the contacts. It is also true for patients coming from poor socioeconomic backgrounds as the cost of permethrin is high.

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Clinical Study and Analysis of Kidney Disease in Patients with Hematological Malignancies

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Abstract

Background: Blood-related malignancies are the most common non-renal neoplasms affecting the kidneys. Renal involvement in patients with hematological malignancies varies according to the type of malignancy. The pathogenesis is either due to direct involvement of the kidney or related to its treatment and/or effects of chemotherapy.

Aim of the Study: This study aims to study and analyze the prevalence of kidney involvement in blood-related malignancies and to observe the clinical and laboratory profile of patients in various hematological malignancies.

Materials and Methods: A total of 93 consecutive patients of various hematological malignancies were included such as Hodgkin's disease, non-Hodgkin's lymphoma, acute and chronic leukemias, and multiple myeloma. The renal involvement was judged on analysis of patient's clinical parameters, urine analysis, biochemical, radiological, and when necessary, histological parameters. All the patients were investigated and treated on an established protocol described in literature. Patients were advised to give informed written consent followed by a detailed history taking and relevant physical examination. Patients were asked about special emphasis on urinary symptoms and usage of nephrotoxic drugs.

Observations and Results: A total of 93 consecutive patients of various hematological malignancies presenting to oncology and medicine departments were included. There were 62 (66.66%) were male and 31 (33.33%) were female with a male-to-female ratio of 2:1. The youngest patient was aged 11 years and the eldest one was 81 years with a mean age of 43.13 ± 16.2 years. Among 93 patients, 46/85 (49.46%) were diagnosed as leukemias, 27/93 (29.03%) patients had lymphomas, and 20/93 (21.50%) patients were diagnosed as multiple myelomas. Acute leukemias were seen in 27/46 (58.69%) of the patients and chronic leukemias in 19/46 (41.30%) of the patients. Forty-six patients with leukemias acute lymphatic leukemia were 7 in males (25.92%) and 3 (11.11%) in females making it a total of 10/27 (37.03%), acute myeloid leukemia was 6 (22.22%) in males and 3 (11.11%) in females with a total of 9/27 (33.33%). Acute basophilic leukemia was observed in 5 (18.51%) male patients and 3 (11.11%) female patients; total 8/27 (29.62%). Chronic myeloid leukemia was seen in 5/19 (26.31%) male and 2/19 (10.52%) female patients; 7/19 (36.84%).

Conclusions: All patients with hematological malignancies should be periodically evaluated for renal dysfunction and necessary preventive measures should be undertaken in such patients, especially when initiated on chemotherapy.

Key words: Acute leukemia, Chronic leukemia, Lymphoma, Multiple myeloma, Renal failure, Renal involvement

INTRODUCTION

Hematological malignancies are the most common non-renal neoplasms affecting the kidney.^[1] These malignancies may directly infiltrate, obstruct, or can interfere with renal function by causing metabolic and

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immunological changes. [2] Chemotherapy-induced renal involvement is another preventable but important cause of renal failure in these patients. [3] Clinical sequelae of renal involvement are usually not prominent even though many solid and hematological malignancies involve kidneys. [4] The most common cancers involving the kidneys are lymphomas, leukemias, and multiple myeloma. [5] Compared to the world literature, the data on renal involvement in hematological malignancies from the Indian subcontinent are scanty. [6] Multiple myeloma-related renal failure is a particularly important cause of renal failure and end-stage renal disease (ESRD). [7] Nearly 20% of patients with myeloma have renal failure, and such patients have more advanced disease at diagnosis and shortened survival. [8] Although

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it causes only 1% of all cancers, myeloma-related ESRD accounted for 58% of all malignancy-related cases between 1997 and 2001.[9] "Tumor lysis syndrome" is described as the metabolic complication of either rapid tumor cell turnover or chemotherapy-induced tumor cell lysis. This syndrome is characterized by hyperuricemia, hyperphosphatemia, hypocalcemia, hyperkalemia, and ARF.[10,11] Tumor lysis syndrome may arise with a variety of tumors but is most commonly associated with poorly differentiated lymphomas such as Burkitt's or with leukemias, particularly acute lymphoblastic leukemia. [12] Chronic lymphocytic leukemia (CLL) can cause impaired renal function in different ways such as direct infiltration of the kidney, ureteral obstruction by lymphadenopathy, and treatment-related tumor lysis syndrome (uric acid nephropathy). Rarely, CLL has also been reported to be associated with light chain nephropathy, renal amyloidosis, membranoproliferative glomerulonephritis, granulomatous interstitial nephritis, and minimal change disease. The present study was planned to evaluate the renal involvement in 85 consecutive patients with hematological malignancies (leukemia, lymphoma, and multiple myeloma).

Type of Study

This was a prospective cross-sectional and analytical study.

Duration of Study

The study period was from September 2017 to April 2019.

Institute of Study

This study was conducted at Viswabharathi Medical College, RT Nagar, Penchikalapadu, Kurnool, Andhra Pradesh.

MATERIALS AND METHODS

In the present study, it was observed that was conducted in the departments of oncology and medicine in a tertiary care teaching medical college and hospital of Andhra Pradesh. A total of 93 consecutive patients of various hematological malignancies diagnosed in the department of oncology and medicine of the hospital were included in the study. The different hematological malignancies included were Hodgkin's disease, non-Hodgkin's lymphoma, acute and chronic leukemias, and multiple myeloma. An ethical committee clearance certificate was obtained before the commencement of the study. An ethical committee cleared consent form was used during the study. Inclusion criteria: (1) Patients of all aged with hematological malignancies were included. (2) Patients with the diagnosis of Hodgkin's disease, non-Hodgkin's lymphoma, acute and chronic leukemias, and multiple myeloma were included. (3) Patients diagnosed earlier or after the admission to the hospital were included. Exclusion criteria: (1) Patients with terminal illness were excluded. (2) Patients with immunosuppression were excluded. (3) Patients with associated malignancies were excluded. The final diagnosis was based on clinical findings, hematological findings, and bone marrow examination or other relevant investigations. The renal involvement was judged on analysis of patient's clinical parameters, urine analysis, biochemical, radiological, and when necessary, histological parameters. All the patients were investigated and treated on an established protocol described in literature. Patients were advised to give informed written consent followed by a detailed history taking and relevant physical examination. Patients were asked about special emphasis on urinary symptoms and usage of nephrotoxic drugs. All patients were subjected to a complete hemogram, routine urine examination (especially for proteinuria, hematuria, glycosuria, urinary pH, and crystalluria), blood urea, serum creatinine, serum sodium, serum potassium, serum calcium, serum phosphorus, serum uric acid, serum protein, and serum albumin. X-rays and ultrasound abdomen were carried out. Fine-needle aspiration cytology, renal biopsy, and computed tomography scan were carried out wherever indicated. All the patients diagnosed at the time of admission were followed-up for 3 months for evidence of any renal dysfunction. All the data obtained were analyzed using standard and specific statistical methods such as percentage, mean and standard deviation, and appropriate tests such as Student's t-test and P < 0.05was considered as statistically significant.

OBSERVATIONS AND RESULTS

A total of 93 consecutive patients of various hematological malignancies presenting to oncology and medicine departments were included in the present study. These patients were followed up over a period of 3 months and clinical and renal profiles were studied. Among 93 subjects, 62 (66.66%) were male and 31 (33.33%) were female with a male-to-female ratio of 2:1. The youngest patient was aged 11 years and the eldest one was 81 years with a mean age of 43.13 ± 16.2 years. Among 93 patients, 46/85 (49.46%) were diagnosed as leukemias, 27/93 (29.03%) patients had lymphomas, and 20/93 (21.50%) patients were diagnosed as multiple myelomas. Acute leukemias were seen in 27/46 (58.69%) of the patients and chronic leukemias in 19/46 (41.30%) of the patients [Table 1].

The incidences of acute lymphatic and acute myeloid leukemia (AML) were almost equal in this study [Table 2]. Observing the distribution of cases according to the type of hematological malignancy in this study showed among the total of 46 patients with leukemia, acute lymphatic leukemia was 7 in males (25.92%) and 3 (11.11%) in females making it a total of 10/27 (37.03%), AML was 6 (22.22%) in males and 3 (11.11%) in females with a total

of 9/27 (33.33%). Acute basophilic leukemia was observed in 5 (18.51%) male patients and 3 (11.11%) female patients; total 8/27 (29.62%). Chronic myeloid leukemia was seen in 5/19 (26.31%) male and 2/19 (10.52%) female patients; 7/19 (36.84%). CLL was seen in 5/19 (26.31%) male and 1 (05.26%) female patients; total 6/19 (31.57%). Chronic hairy cell leukemia was seen in 2 (10.52%) male and 1 (05.26%) female patients; total 3/19 (15.78%). Chronic eosinophilic leukemia was seen in 2 (5.26%) male and 1 (5.26%) female patients; total 3/19 (15.78%), [Table 2].

Table 1: Distribution of patients according to the type of malignancies

Type of malignancy (%)	Nu	mber
	Male (%)	Female (%)
Leukemias – 46 (49.46)		
Acute - 27 (58.69)	22 (81.48)	5 (18.51)
Chronic – 19 (41.30)	11 (57.89)	8 (42.10)
Lymphomas - 27 (29.03)		
NHL – 23 (85.18)	19 (82.60)	4 (17.39)
Hodgkin's - 4 (14.81)	3 (75)	1 (25)
Multiple myelomas – 20 (21.50)	14 (70)	6 (30)

NHL: Non-Hodgkin's lymphoma

Table 2: The distribution of leukemia in the study group (n-37)

Leukemias – 46 (%)	Male (%)	Female (%)
Acute lymphatic – 10 (37.03)	7 (33.33)	3 (11.11)
Acute myeloid leukemia – 9 (33.33)	6 (22.22)	3 (11.11)
Acute basophilic leukemia – 8 (29.62)	5 (26.31)	2 (10.52)
Chronic myeloid leukemia – 5 (26.31)	3 (11.11)	2 (10.52)
Chronic lymphocytic leukemia – 6 (31.57)	5 (26.31)	1 (05.26)
Chronic hairy cell leukemia – 3 (15.78)	2 (05.26)	1 (05.26)
Chronic eosinophilic leukemia – 3 (15.78)	2 (05.26)	1 (05.26)

Observing the presenting clinical symptomatology in the present study revealed that 63/93 (67.74%) of the patients had fever, 32/93 (34.40%) had symptoms suggestive of azotemia, and 22/93 (23.65%) had oliguria and weight loss. Bleeding tendencies were present in 17/93 (18.27%) of the patients. Mean value of calculated glomerular filtration rate (GFR) was 73.09 ± 47.52 ml/min. 30/93 (32.25%) patients had GFR of >90 ml/min, 24/93 (25.80%) 60-89 ml/min, 21/93 (22.58%) had GFR of 30-59 ml/min, and 18/93 (19.35%) had GFR of 15–29 ml/min. Mean blood urea and serum creatinine were $68.34 \pm 79.10 \text{ mg/dl}$ and $3.52 \pm 2.62 \text{ mg/dl}$, respectively. 6/93 (6.45%) patients had serum creatinine values at >8 mg/dl and required renal replacement therapy in the form of hemodialysis. Mean serum sodium was 136.12 \pm 5.93 Meq/l and mean serum potassium value was 4.13 \pm 0.66 Meg/l. Mean serum calcium was $11.06 \pm 3.15 \text{ mg/dl}$. 19/93 (20.43%) patients had values of hypercalcemia (Ca++>10.5 mg/dl) and 14/20 (70%) of them belonged to multiple myeloma group. Mean value for uric acid was $8.14 \pm 3.90 \text{ mg/dl}$. Hyperuricemia (uric acid >7.0 mg/dl) was observed in 51/93 (54.83%) of the patients. Out of these, 16/27 (59.25%) patients were diagnosed as lymphoma, 21/46 (27.63) had leukemia, and 17/20 (80%) patients had multiple myeloma [Table 3].

Mean value for serum protein and serum albumin was 6.16 ± 2.01 g/dl and 3.42 ± 0.91 g/dl, respectively. Hyperproteinemia (S. protein >8.0 g/dl) was observed in 15/93 (16.12%) patients. Proteinuria was present in 47/93 (50.53%) and it ranged from 0.4 to 1.7 g/day. However, none of the patients had nephrotic range of proteinuria. More than 50% of the patients with multiple

Table 3: The clinical and laboratory data of the study group (n-93)

Observation	Lymphoma	Leukemia	Multiple myeloma	P value
Age (mean±SD)	46.32±18.27	42.65±21.40	56.72±11.62	0.012
Etiology	NHL-23 HL-04 Acut	e leukemias-27 Chronic leukemias-1	9	
Sex distribution (M:F) 26:7	4.75:1 3:1	4.4:1 1.3:1	2.33:1	0.020
Weight loss 22 (23.65%)	9/93 (9.67%)	10 (10.7%)	3 (3.22%)	0.001
Symptomatology				
Fever	34 (53.96%)	19 (30.15%)	10 (15.87%)	0.031
Azotemia	18 (56.25%)	9 (28.12%)	5 (15.62%)	0.071
Oliguria	9 (40.90%)	6 (27.27%)	8 (36.36%)	0.601
Bleeding tendency	7 (41.17%)	5 (29.41%)	5 (29.41%)	0.712
Mean of calculated GFR	71.17±35.32	74.40±21.50	72.11±16.35	0.050
Mean blood urea	69.20±12.40	66.50±11.20	67.60±20.10	0.049
Mean serum creatinine	4.02±0.87	3.28±0.82	3.31±0.76	0.630
Mean serum sodium	133.45±6.25	138.80±4.12	137.91±3.43	0.044
Mean serum potassium	4.02±0.68	4.00±0.55	4.34±0.64	0.532
Mean serum calcium	10.86±1.30	11.20±1.55	10.98±0.71	0.072
Mean serum uric acid	7.98±2.10	8.30±1.05	8.10±1.00	0.810
Mean serum protein	6.02±0.78	5.80±1.02	6.31±0.99	0.570
Mean serum albumin	3.12±0.68	3.61±0.48	3.11±0.36	0.921
Mean urinary PH	5.87±1.10	5.91±0.73	6.0±0.28	0.735

GFR: Glomerular filtration rate

myeloma and lymphoma had proteinuria on urine examination. Moreover, nearly 41.86% of the patients with leukemia showed proteinuria. Glycosuria was present in 7/93 (7.52%) of the patients. The mean urinary pH among these patients was 5.59 ± 0.74 and majority of the patients 49/93 (52.68%) had urinary pH between 6.0 and 8.0 [Table 3]. 15/93 (16.12%) patients had evidence of pyuria (pus cells >5/high-power field [HPF]) and 2/93 (2.15%) of these had Escherichia coli urinary tract infection. No patient had hematuria, while microscopic hematuria was seen in 13/93 (13.97%) of the subjects. Renal failure was present in 26/93 (27.95%) and out of these, 16/26 (61.53%) of the patients had multiple myeloma. Around one-third of patients of lymphomas and one-fourth of patients of leukemias had renal failure at the time of presentation. Acute urate nephropathy was present in 5/93 (5.37%) patients, of which three cases were of acute leukemia and two had multiple myeloma. In all these cases, uric acid levels were >25 mg% and urinary uric acid to creatinine ratio was >1. Three cases had tumor lysis syndrome and all these patients had multiple myeloma.

DISCUSSION

The present study was conducted in a tertiary teaching hospital attached with an oncology department in Andhra Pradesh. In this study, among 93 patients, 46/85 (49.46%) were diagnosed as leukemias, 27/93 (29.03%) patients had lymphomas, and 20/93 (21.50%) patients were diagnosed as multiple myelomas. In this study, it was observed that the maximum number of patients (49.46%) had leukemia followed by lymphoma (29.03%) and multiple myeloma in (21.50%). In a similar study conducted by Khanna et al.[13] done on 30 patients with hematological malignancies, it was observed that there were 12 patients (40%) of multiple myeloma, 11 of lymphoma (36.6%), and 7 of leukemia (23.3%). In another study in which analysis of 83 patients with malignancies, occurrence of lymphomas and leukemias was showed as 48% and 46% of the patients, respectively.^[14] However, the patients with multiple myeloma were only 6%.[14] The present study showed a male preponderance with 62 (66.66%) males and 31 (33.33%) females with a male-to-female ratio of 2:1 which was similar to the study by Banday et al.[14] However, the mean age in their study was 31.2 years, which is probably due to the fact that proportion of patients with multiple myeloma was only 6.2%, as compared to 21.50% in the present study. Renal failure was present in 26/93 (27.95%) and out of these, 16/26 (61.53%) of the patients had multiple myeloma. Around one-third of patients of lymphomas and one-fourth of patients of leukemias had renal failure at the time of presentation. Acute urate nephropathy was present in 5/93 (5.37%) patients, of which three cases were of acute leukemia and two had multiple myeloma. In all these cases, uric acid levels were >25 mg% and urinary uric acid to creatinine ratio was >1. Three cases had tumor lysis syndrome and all these patients had multiple myeloma. Multiple myeloma is a disease of elderly adults; as such, in our study as well, the median age of the 20 patients with multiple myeloma was $56.72 \pm$ 11.62 years with only one patient with age <40 years. 16/26 (61.53%) patients with renal failure were found to have multiple myeloma in this study. Similar observations were made by Kyle et al.[15] who also found that anemia was present initially in 73% of patients, hypercalcemia in 13%, and elevated creatinine in 48% of patients. Only 2% of patients in their study were younger than 40 years. [15] Review of literature showed another study analyzing 26 patients of multiple myeloma with acute renal failur; the mean age of patients was 59.3 ± 7.4 years. The clinical manifestations of myeloma included were anemia (100%), Bence-Jones proteinuria (80%), "M" peak in serum electrophoresis (69%), lytic bone lesions (62%), and "M" peak in urine electrophoresis (54%).[16] Similarly, in this study also, 83.3% of the patients showed M band on electrophoresis and 37.5% showed lytic lesions on skeletal survey. 19/93 (20.43%) patients had values of hypercalcemia (Ca++>10.5 mg/dl) and 14/20 (70%) of them belonged to multiple myeloma group. Mean value for uric acid was $8.14 \pm 3.90 \text{ mg/dl}$. Hyperuricemia (uric acid >7.0 mg/dl) was observed in 51/93 (54.83%) of the patients. Out of these, 16/27 (59.25%) patients were diagnosed as lymphoma, 21/46 (27.63) had leukemia, and 17/20 (80%) patients had multiple myeloma [Table 3]. Various studies have reported varying incidences of renal failure ranging from 7% to 49.5%, and hypercalcemia has been found to be the most common precipitating factor for renal failure. [17-20] High incidence of renal failure observed in this study was probably due to the usage of low threshold definition of renal failure (S. creatinine >1.4 mg%). Studies which have reported higher figures have tended to include patients with milder degrees of azotemia without taking into consideration whether factors like dehydration had been corrected. [21-23] Tubular dysfunction has been reported in patients with myeloma and Bence Jones proteinuria. In this study, glycosuria was present in 7/93 (7.52%) of the patients. 2/20 (10%) patients with multiple myeloma in this study showed glycosuria. Analysis of 27 lymphoma patients of this study showed 23/27 (85.18%) males and 4/27 (14.81%) were female with a male-to-female ratio of 5.75:1. The mean age of this group was 46.32 ± 18.27 years. Both Hodgkin's disease and NHL lesions were found to be involving kidneys as extranodal metastatic lymphomas in 5/27 (4.62%) cases, which could have caused renal infiltration as cited by Richmond et al.[24] Renal involvement occurred in 3/5 (60%) cases from NHL in this study. Hypercalcemia has been found to be a cause or contributing factor for acute kidney injury (AKI) and mean level of calcium in this study was $11.06 \pm 3.15 \,\text{mg/dl}$. $19/93 \,(20.43\%)$ patients had values of hypercalcemia (Ca++>10.5 mg/dl) and 14/20 (70%) of them belonged to multiple myeloma group. In the present study, one-third of patients of lymphomas and one-fourth of patients of leukemias had renal failure at the time of presentation. Acute urate nephropathy was present in 5/93 (5.37%) patients, of which three cases were of acute leukemia and two had multiple myeloma. In all these cases, uric acid levels were >25 mg% and urinary uric acid to creatinine ratio was >1. Christiansen et al.[25] reported incidence of AKI and defined as 50% elevation of baseline serum creatinine. In a study by Khalil et al., [26] the incidence of AKI was found to be 31.8% and they opined that the discrepancy between various studies could be explained by the variable criteria for inclusion adopted in various studies. Recently, Li et al.[27] in their analysis of 20 NHL patients with renal dysfunction and/or proteinuria found proteinuria in all the patients and impaired renal function (estimated GFR <60 ml/min) in 75% of patients. No patient had hematuria in this study, while microscopic hematuria was seen in 13/93 (13.97%) of the subjects. In this study, 15/93 (16.12%) patients had evidence of pyuria (pus cells >5/HPF) and 2/93 (2.15%) of these had E. coli urinary tract infection. Hyperproteinemia (S. protein > 8.0 g/dl) was observed in 15/93 (16.12%) patients. Proteinuria was present in 47/93 (50.53%) and it ranged from 0.4 to 1.7 g/day. However, none of the patients had nephrotic range of proteinuria. More than 50% of the patients with multiple myeloma and lymphoma had proteinuria on urine examination. Lower incidence of proteinuria in this study when compared with the study of Li et al.[27] was probably due to the fact that the study conducted by Liu et al. included only those patients who had renal involvement either in the form of proteinuria or AKI. Most patients with lymphomatous infiltration have no clinical evidence of renal involvement. Urinalysis usually reveals mild proteinuria, few red and white blood cells, and occasional hyaline and granular casts.^[28] Most of the patients in our study were also asymptomatic pertaining to symptoms suggestive of renal infiltration. In a largest series in medical literature, renal parenchyma involvement was identified in 34% of 696 autopsy cases. Out of 142 patients for whom antemortem data were available, 14% had lymphomatous infiltration diagnosed before death. [26] Acute leukemias occurred in 32/93 (34.40%) of the patients in this study accounted for 32 of 43 patients. Leukemic process can cause renal impairment^[29] either due to disease itself or due to their treatment and complications. Nephrotoxicity secondary to antibiotic treatment/ chemotherapy or triggered by tumor lysis syndrome can occur which can produce uric acid nephropathy, hypophosphatemia, or hypercalcemia with renal failure. [30]

The leukemic patients had mean serum calcium of 11.20 ± 1.55 and mean serum uric acid levels of 8.30 ± 1.0 in this study and renal failure was present in 8/27 (29.6%) of them. Microscopic infiltration of the genitourinary tract has been considered as a cause of hematuria in these patients. While comparing patients with and without renal failure, male sex, multiple myeloma, and hyperuricemia were found as statistically significant factors contributing to renal failure (P < 0.05).

CONCLUSIONS

A significant number of patients with hematological malignancies have renal involvement. Multiple myeloma was the most common malignancy resulting in renal failure. Male sex, multiple myeloma, and hyperuricemia were significant factors contributing to renal failure. Although proteinuria was observed in around half of the patients, none of the patients had nephrotic range proteinuria. Many of the acute urate nephropathy cases were noted in acute leukemias, whereas all cases of tumor lysis syndrome had multiple myeloma. Hence, all the patients with hematological malignancies should be evaluated for renal involvement and all prophylactic measures against acute renal failure should be used in all hematological malignancies on chemotherapy.

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Spectrum of Congenital Heart Disease in a Tertiary Care Center

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Abstract

Background: Congenital heart disease (CHD) is not an uncommon entity in our country. The prevalence of CHD is 9.3 Per 1000 life birth in Asia which is found to be highest globally. Not much of Indian data is available particularly from south part of the country. So we conduct a retrospective study to know the spectrum of congenital heart disease in our set up.

Methods: This is a retrospective hospital based study carried out over a period of 12 months (2018 January – 2019 January) where all suspected children (< 12 years) of CHD were subjected to echocardiographic study. The age, sex, clinical presentation and echo findings were well documented.

Results: The total number CHD diagnosed were 124 and were more common among males (54.5%) with male to female ratio is 1.2:1. Congenital heart diseases were diagnosed more commonly between 1 month to 1 Year (45.9%). The commonest type of acyanotic CHD in our study was ventricular septal defect (VSD) (32.3%) and cyanotic CHD is tetralogy of Fallot (8.06%). The major clinical finding was a detection of a murmur (84.4%) followed by tachycardia (41.5%) and tachypnea (36.3%).

Conclusions: In this era of most accurate diagnostic modalities, any clinical suspicion of congenital heart disease should be confirmed by echocardiography to hasten the diagnosis, timely management and prevention of complications.

Key words: Congenital heart disease, Echocardiograph, Prevalence

INTRODUCTION

Congenital heart disease (CHD), in a definition proposed by Mitchell *et al.*, is "a gross structural abnormality of the heart or intra-thoracic great vessels that is actually or potentially of functional significance.^[1]" The detection of congenital heart diseases in India is improved due to more accurate diagnostic modalities and awareness among parents. The reported incidence of CHD is 8–10/1000 live births.^[2,3] The frequency of different major forms of CHD also differs greatly in various studies. The clinical presentation of CHD varies according to the type and severity of the defect. The purpose of this study was to know the burden of heart diseases in children under 12 years of age.



MATERIALS AND METHODS

This is a retrospective study carried out in a teaching hospital to determine the spectrum of CHD. The cases included all patients attending the outpatient or inpatient of pediatric department as well as the neonatal and pediatric intensive care units within the age range of 0–12 years over a period of 12 months (January 2018–January 2019). All cases suspected of having a CHD on clinical examination were included in the study. Patients from the neonatal intensive care unit were subjected to echocardiography due to the appearance of murmur, cyanosis, and tachypnea. The usual presentation of patients from infancy was failure to thrive, breathlessness, cyanosis, presence of murmur, and arrhythmias. The presence or absence of CHD and its character were confirmed by echocardiography. The data of all patients regarding the age of presentation, gender, signs and symptoms, clinical features, and echo findings were documented.

RESULTS

The total number of CHD diagnosed was 124. CHD is more common among males (54.5%) with the

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male-to-female ratio is 1.2:1 [Figure 1]. CHD is diagnosed more commonly between 1 month and 1 year (45.9%) [Figure 2]. The most common CHD in our study was ventricular septal defect (VSD) (32.3%), followed by atrial septal defect (ASD), tetralogy of fallot (TOF), and patent ductus arteriosus (PDA) and in that order.

The most common cyanotic CHD is TOF (11.25%) and is the fourth in frequency in our study [Figure 3]. The major clinical finding was a detection of a murmur (84.8%), followed by tachycardia (41.5%) and tachypnea (36.3%) [Table 1].

DISCUSSION

A recent systemic review pointed out the highest prevalence of CHD reported from Asia (9.3/1000 live birth) and least from Africa (1.9/1000 live birth). [4] Contrast to other developed countries, there are few Indian studies showing the prevalence of CHD. Available Indian studies had reported a wide variation in the prevalence of CHD from 2.25 to 26/1000 live birth. [5,6]

There are few scattered studies from North and South part of country, but there is a paucity of data from this part of country. This is a hospital-based retrospective study having the prevalence of CHD 4.81/1000 live birth though it does not reflect the true prevalence in the community.

CHD is more common between 1 month and 1 year (45.9%) similar to the study at other parts of our country. In our study, highest number of cases were seen in infancy which could be explained because of a large number of referrals from peripheral health center. In the present study, 84.8% of the patients presented with murmur, followed by tachycardia (41.5%) and tachypnea (36.3%) unlike other studies where tachypnea is more common. In Tachycardia, in our study, may be explained because of prevalence of anemia and malnutrition which are more common in children of this part of India. In this index study of total 124 cases, the isolated acyanotic heart disease is 76.1% and cyanotic is 20.34%.

Table 1: Clinical findings of the congenital heart disease cases (*n*=124)

	,							
Clinical findings	Number of cases	Percentage						
Murmur	104	84.8						
Tachycardia	51	41.5						
Tachypnea	45	36.3						
Cyanosis	23	19.04						
Enlarged liver	21	17.7						
Crepitations	17	14.7						
Anemia	18	15.5						
Clubbing	14	12.1						
Rhonchi	13	11.2						
Edema	11	9.09						

The most common type of acyanotic heart disease is VSD (32.3%) which is quite similar to other Indian data. [9] We have also observed an increase in the number of ASD (27.41%) as the second common CHD. This may be attributable to overdiagnosis of patent foramen ovale as ASD. PDA is the fourth in the list (7.44%) of CHD in our study.

TOF is the most common type of cyanotic CHD (18.06%) as reported by several studies.^[9] Some studies show the

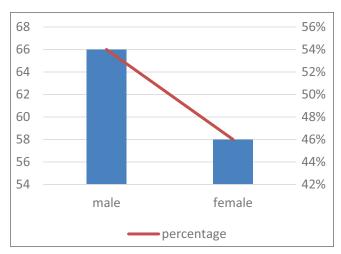


Figure 1: Sex-wise distribution of congenital heart disease

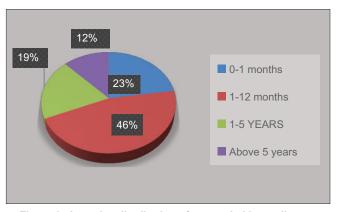


Figure 2: Age-wise distribution of congenital heart disease

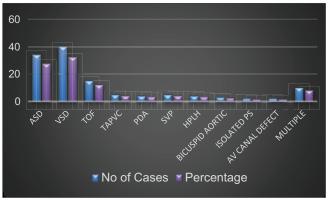


Figure 3: Types of congenital heart disease

male preponderance of 2.08:1 and 1.78:1, but we did not get a significant gender disparity (1.2:1).^[10,11] This small disparity may be explained on the basis of social issue in our country, which may be due to high health-seeking behavior in parents for male child.

CONCLUSION

In this era where we have the most accurate diagnostic modalities, any clinical suspicion of CHD should be confirmed by echocardiography. More doctors should be trained in diagnosing CHD by echocardiograph, so that children can be treated earlier there by reducing morbidity and mortality. Fetal echocardiography should be advised liberally to the expectant mothers when one of the siblings is known to have complex CHD.

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A Morphological Study of Position of Nutrient Foramen in Dry Human Femur

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Abstract

Aim: The aim of the study is to determine the variations in diaphyseal nutrient foramen(NF) of femur with respect to their number, location, direction and size in Jharkhand state population.

Materials and Methods: 70 dry adult femora (38 Right side and 32 Left side) were collected from the department of Anatomy, Mahatma Gandhi Memorial Medical College, Jamshedpur, Jharkhand. Femora were examined for mean length of femur, number, position including foraminal index, direction and size of nutrient foramina.

Result:- Mean length of femur was 42.27cm. According to Foraminal Index the location of nutrient foramina were 72.34% in right side and 86.84% were located in left side in middle 1/3 of bone. Most common position was between two lips of Linea aspera(42.35%). Single nutrient foramen was 64.70%.

Conclusion:- The knowledge of anatomical variation in diaphyseal nutrient foramen of femur is important for bone ossification, bone healing and it also give additional information to orthopedicians for microvascular bone grafting.

Key words: Femur, Nutrient artery, Nutrient foramen, Foraminal index

INTRODUCTION

The nutrient foramina are cavities that conduct the nutrient arteries and the peripheral nerves on the shaft of long bones. The femur is supplied principally by the diaphyseal nutrient artery (DNA) which enters the bone through the diaphyseal nutrient foramen (DNF) with little contribution from the metaphyseal and epiphyseal arteries. Adequate knowledge of the location of nutrient foramen (NF) is important for the process of bone ossification, growth, and healing. Surgically aided bone defect repair such as microvascular bone graft relies greatly on the vascularity of the femur for survival of donor and recipient bones. Knowledge of location and relevant anatomy of nutrient foramina is important in surgical procedures to preserve circulation. The DNA usually originates from profunda femoris artery

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as a branch of the second perforating artery, enters the DNF to run through the nutrient canal characteristically directed away from the growing epiphysis. At the medullary end of the nutrient canal, the nutrient artery divides into ascending and descending branches which anastomose with epiphyseal and metaphyseal arteries.

MATERIALS AND METHODS

A total of 70 dried, adult human femora of unknown sex (38 of right and 32 of left side) were taken for morphological study of nutrient foramina from the Department of Anatomy, Mahatma Gandhi Memorial Medical College, Jamshedpur, Jharkhand, India. Bones with gross structural abnormalities were excluded from the study. The instruments used were osteometric board, 18, 20, 22, and 24 gauge hypodermic needles, magnifying hand lens, measuring tape, Vernier digital scale, and divider. Photographs were taken with the digital camera. With the help of osteometric board, determination of the total length of the individual bones was done by taking the measurement between the superior aspect of the head of the femur and the most distal aspect of the medial condyle. The value was recorded in centimeter.

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The nutrient foramina were observed in all the bones carefully with the help of hand lens and the total number of foramina present on any surface was recorded. After side determination, the NF was studied with regard to number of foramen on bone shaft; location of foramen in relation to segment was studied using foraminal index formula:

For aminal index = $(DNF/TL) \times 100$

Where, DNF = The distance from the proximal end of the bone to the NF.

TL = Total bone length.

Subdivisions of foraminal position according to the foraminal index can be grouped into three types.

- Type 1: From 1 up to 33.33: The foramen is in the proximal third of the bone.
- Type 2: From 33.34 up to 66.66: The foramen is in the middle third of the bone.
- Type 3: Above 66.67: The foramen is in the distal third
 of the bone. Caliber of NF was measured using 18–24
 gauge hypodermic needles and direction of foramen
 was also noted.

RESULTS

A total of 70 femora were examined, of which 38 were of the right side and 32 were of the left side. A total range of length of femur of the right side was from 36.3 cm to 46.9 cm and femur of the left side ranged from 35.6 cm to 47.9 cm.

DISCUSSION

Anatomical characteristics of the NF, such as its number, position, size, and direction, are important factors considered in orthopedic surgeries including bone grafting and fracture repair. These characteristics also contribute to the prognosis after a fracture because they are essential to blood flow. Gray's anatomy textbook describes that the

foramina for the nutrient arteries are situated close to the linea aspera (LA).[1] They vary in number and position. One is usually at the upper end of the LA, and a second, which is not always present, near its lower end [Figure 1]. The foramina are directed upward through the compact bone. The nutrient artery of the femur usually comes from the second perforating artery, which is one of the three perforating branches from the profunda femoris artery. When two nutrient foramina exist [Figure 3], they usually come from the first and third perforating branches of above artery. Kizilkanat et al.[2] stated that the position of the nutrient foramina was directly related to the requirements of a continuous blood supply to specific aspects of each bone, for example, areas of some major attachments such as flexors require more blood supply as compared to extensors due to more activity. Many theories have been put forward to account for the direction of foramina and also the anomalously directed ones. The present study of femur obeys the growing end theory of Mysorekar^[3] that opinioned the direction of nutrient foramina is determined by the growing end of the bone. The growing end is supposed to grow at least twice as fast as the other end. The nutrient artery runs away from the growing end as the growing bone might pull and rupture the artery. Hence, the nutrient foramina are directed away from the growing end. Laing examined 10 femora, Murlimanju BV, [4] Kizilkent et at studied in 100 femora, Gupta AK et al^[5] studied 100 femora, Sendemir^[6] examined 102 femora, Bridgmen et al used 108 femora, Motabagani studied 130 femora, Gupta Pk et al studied



Figure 1: Nutrient foramen on linea aspera

Table 1: Mean length of femur								
Total number of femur	Side	Total length (range) (cm)	Mean length (cm)	Mean length of femur (cm)				
38	Right	36.3–46.9	41.85	42.27				
32	Left	35.6-47.9	42.69					

Table 2: Total number of nutrient foramina present [Figure 1]								
Total number of femur	Side	Nun	ber of nutri	ent foramina pre	sent in one femur	Total number of foramina		
		Absent	One	Two	Three	_		
38	Right	0	29	9	0	47		
32	Left	0	26	6	0	38		

with 312 femora, Present study was done in 70 femora under following parameters.

Length of Femur

In the present study, the average mean length of both sides of femur was 42.27 cm [Table 1], which resembles with the previous study done by Kizilkanat *et al.*;^[2] Roopam *et al.*;^[7] Kirshner *et al.*;^[8] Gupta *et al.*;^[5] and Nagel.^[9]

Author	Mean total length of femur (cm)
Kizilkanat et al.	42.58
Roopam et al.	43.23
Kirschner et al.	40.8
Gupta et al.	41.22
Nagel	40.10
Present study	42.27

Number of Nutrient Foramina

The present study shows 64.70% single NF and 35.29% having double nutrient foramina [Tables 2-4]. This study is almost similar with the previous study done by Kizilkanat *et al.* and Collipal E^[10] and Oladayo^[11] and Laing^[12] and and and Gupta *et al.*, but the result is more than Roopam *et al.*^[7] and Bridgement *et al.* This study indicates that majority of femur is supplied by single source of nutrition.

Position of Nutrient Foramina

According to present study, position of nutrient foramina was present predominantly on middle 1/3 of femur (78.82%) [Table 5] which is almost similar with the authors Mysorekar;^[3] Kizilkanat *et al*;^[2] Longia *et al*;^[13] Nagel^[9], Kirschner *et al*, Kumar *et al*;^{14]} and Gupta *et al*. reported that the nutrient foramina are mostly located in the middle one-third of the diaphysis. Forriol

Table 3: Position and number of nutrient foramina observed in femur [Figure 2-6]

Position of nutrient foramina	Number of nutrient foramina	Percentage of nutrient foramina
Medial lip of LA	22	25.88
Lateral lip of LA	08	09.41
Medial surface	15	17.64
LA	04	04.70
Between two lips of LA	36	42.35
Upper posterior surface	00	00

LA: Linea aspera



Figure 2: Nutrient foramen in between lips of linea aspera



Figure 3: Single and double foramina



Figure 4: Nutrient foramen on medial and lateral lip of linea aspera



Figure 5: Nutrient foramen on distal 1/3



Figure 6: Nutrient foramen on medial surface

Table 4: Comparative study of Number of nutrient foramina in %

Author	Number of bone	Bone % with 0 NF	Bone % with 1 NF	Bone % with 2 NF	Bone % with 3 NF	% of Dominant NF
Kizilkanat et al.	100	0	75	25	0	80.64
Motavagani	130	3.07	48.46	48.46	0	
Roopam et al.	312	0	44.60	49.40	6.10	77.10
Laing	10	0	60	40	0	
Gupta et al.	100	3	71	25	1	64.50
Bridgeman et al.	109	2.75	44.03	53.21	0	
Present study	70	0	64.70	35.29	0	68.27

NF: Nutrient foramen

Table 5: Observation about the location of nutrient foramina in relation to segment according to foraminal index formula

Total number of bones	Side	Proximal 1/3 (%)	Middle 1/3 (%)	Distal 1/3 (%)	Total number of foramina
38	Right	12 (25.53)	34 (72.34)	01 (2.12)	47
32	Left	05 (13.15)	33 (86.84)	00	38

Table 6: Comparative study of Position of nutrient foramina in %

Author	Total bones	Total nutrient foramina	Medial surface	Between two lips of LA	Lateral lip	Medial lip	LA	Upper posterior surface
Mysorekar et al.	180	270	14.4%		_	_	_	_
Roopam et al.	312	511	16.6%	-	12.1%	40.9%	53%	-
Kizilkanat et al.	100	124	39.8%	-	-	-	44.3%	-
Gupta et al.	100	124	26.6%	_	12.95	1.65	00	_
Present study	70	85	17.64%	42.35%	9.41%	25.88%	4.70%	00

LA: Linea aspera

Table 7: The size of the foramina observed with gauge needle

Total number of foramina	SIDE	Small (24 gauge) (%)	Medium (20 and 22 gauge) (%)	Large (18 gauge) (%)
47	Right	18 (38.29)	23 (48.93)	06 (12.76)
32	Left	12 (31.57)	22 (57.89)	04 (10.52)

All nutrient foramina (100%) in the femur were directed proximally (upper end) away from the growing end

Campos F et al¹⁵ studied the diaphysial nutrient foramina in the femur at between 25 and 58%. According to our present study 82.34% [Table 6] of nutrient foramina was located on whole posterior surface including linea aspera and its two lips (42.35% between two lips, 25.88% on medial lip, 9.41% on lateral lip, 4.70% on linea aspera), which is again similar with the Mysorekar et al, Roopam et al and Kizilkanat et al while Gupta et al reported more frequency on lateral surface.48.93% of right side and 57.89% of left side foramina observed by gauge needle was medium size [Table 7].

CONCLUSION

Knowledge of anatomical variation in detail for DNF of femur with respect to their number, location, direction, and size is important. The single foramina were more common as compared to double. All the foramina were located on or near the LA, especially in middle one-third. Adequate knowledge of the location of dominant NF is important for bone ossification, bone healing, and microvascular bone grafting.

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A Study of Two-field, Three-field, and Four-field Techniques using Rainbow and Thermoluminescent Dosimetry for Radiotherapy Treatment of Cervix Cancer

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Abstract

The aim of the present study is to investigate the rectal dose during three different radiotherapy techniques of dosimeter cervical cancer. The study was carried out using a Anderson Rando female phantom. The thermoluminescent dosimetry (TLD) capsules and detectors of rainbow dosimeter were employed for rectal and target volume dose determination. Several techniques of external beam radiation therapy such as two field (AP-PA), three field, and four field with equal applied dose were planned. During application of different radiotherapy techniques, the maximum dose received by rectum is due to the two-field technique. The results of two dosimetry types were compared with each other. The mean and standard deviation values of two field, three field, and four field for cervix are 2.03 ± 0.05 , respectively, whereas the mean and standard deviation values of two field, three field, and four field for cervix are 2.03 ± 0.01 , 1.98 ± 0.02 and 1.92 ± 0.01 , respectively. The results were evaluated by the paired t-test. The P values calculated from data are as follows: Two field, cervix, P = 0.02; three field, cervix, P = 0.0016; and four field, cervix, P = 0.0026, demonstrates that four field significantly reduces the rectum dose. This study showed that using TLD and rainbow dosimetry during radiotherapy could have a useful role as a predictor of choosing appropriate technique for preventing future rectal complications. Dose limitation to the rectum could possibly be achieved by using three-field and four-field techniques with equal tumor dose while maintaining a high dose to the tumor.

Key words: Dosimetry, Phantom, Rectum, Cervix cancer, Radiotherapy

INTRODUCTION

Cervical cancer is a serious health problem, with nearly 500,000 women developing the disease each year worldwide. Most cases occur in less developed countries where no effective screening systems are available. Risk factors include exposure to human papillomavirus, smoking, and immune-system dysfunction. Most women with early stage tumors can be cured although long-term morbidity from treatment is common. The results of

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randomized clinical trials have shown that for women with locally advanced cancers, chemoradiotherapy should be regarded as the standard of care; however, the applicability of this treatment to women in less developed countries remains largely untested. Many women with localized (Stage IB) tumors, even now, receive various combinations of surgery and radiotherapy, despite unresolved concern about the morbidity of this approach compared with definitive radiotherapy or radical surgery.

It is estimated that by the year 2020, there will be almost 20 million new cases. Worryingly, it is not only in the number of new cases that will increase but also the proportion of new cases from the developing countries such as India will also rise to around 70%. The magnitude of the problem of cancer in the Indian subcontinent is alarming. Although the cancer incidence rate in India is less than that of the Western countries due to the large

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population size, the number of cases is more prevalent at any time. [2] The most common cancers among females are cervix, breast, ovary, esophagus, and mouth. Of this, cervical cancer is the second most common cancer among women worldwide after breast cancer. According to the WHO report, globally, cervical cancer comprises 12% of all cancers in women and it is the leading gynecological malignancy in the world.[3] Carcinoma of the uterine cervix is the most common malignancy to affect females in developing countries. In developing countries, it accounts for about 3.4 lakh new cases and 1.6 lakh deaths every year. [4] It is a leading cause of death among women between 35 and 45 years. [5] Cervical cancer is the second most common cancer in females in the world with around 500,000 new cases occurring annually, but the first in the developing countries with a high mortality if not diagnosed early.[6] In India, about 1.25 lakh new cases and 80,000 deaths are reported every year from this disease. At present, the ageadjusted incidence rates for cervical cancer range from 19 to 44/lakh women in various cancer registries of India. The lifetime risk of cancer cervix would be estimated at 3.7% in the absence of screening. Either surgery or radiotherapy alone can be used to treat early stages of cervix cancer. The main objective of radiotherapy is to deliver lethal dose to tumor cells without inducing irreparable or unacceptable damage to the surrounding normal tissues.

Radiotherapy plays an important role in the treatment of cancers. It treats cancer using high-energy rays which destroy the cancer cells while doing as little harm as possible to normal cells. Radiotherapy for cancer of the cervix can be given externally or internally and often as a combination of the two. It is usually given if the cancer has spread beyond the cervix and is not curable with surgery alone and may also be used after surgery if there is a high risk that the cancer may come back. It is often given in combination with chemotherapy. External beam radiotherapy (EBRT) plays an important role in the management of patients with carcinoma cervix. EBRT treats the whole pelvis, including clinically and radiologically apparent tumor, uterine corpus, upper part of the vagina, parametrium, and the draining lymph nodes. EBRT is best utilized for tumors that are geometrically defined, isolated, and hard to treat surgically.

Radiotherapy of cervix carcinoma often results in high doses to the surrounding structures, such as rectum and bladder. Therefore, these organs should be closely monitored. The late complications manifesting on these organs, as a result of radiotherapy, can lower the therapeutic ratio and significantly decrease patient quality of life. [7-9] The most important treatment-related factors that could lead to creation of late complications on the rectum include total dose to the rectum and the volume of irradiated rectum. Of those, the dose delivered to the rectum is

particularly important.^[10] Researchers try to develop new treatment techniques by which increasing patients' survival and concomitantly minimizing morbidity.^[11,12] Apart from accuracy of the dose at the point concerned, a uniform dose distribution within the target volume is also crucial for successful radiotherapy. It is generally accepted that variance in the dose delivered to the patient should not be greater than 5% at the reference point.^[13] More recently, a tolerance of 3.5% has been suggested.^[14] Subsequently, the International Commission on Radiation Units and Measurements report No. 50 has recommended dose homogeneity of between –5% and +7% of the prescribed dose throughout the planned target volume.^[15]

MATERIALS AND METHODS

Alderson Rando female phantom was used as a patient for determining the received dose. The phantom is transacted horizontally into 2.5-cm thick slices. Each slice has holes which are plugged with bone equivalent, soft-tissue equivalent, or lung tissue equivalent pins which could be replaced by thermoluminescent dosimetry (TLD) capsules and detectors of rainbow dosimeter and are ordered separately. Figure 1 shows an Alderson Rando female phantom.

The Rando phantom was placed on the Co-60 teletherapy machine table. Total dose of 5000 cGy is given in 25 fractions with a dose of 200 cGy per fraction. Several techniques of external beam radiation therapy such as two field (AP-PA), three field, and four field were planned. Three-field technique consisted of two lateral fields and one anterior field. Four-field arrangement consists of two laterals and one anterior and one posterior field with equal applied dose to each field. Treatment fields were simulated using a simulator. The dosimetry results based on TLD and rainbow dosimeter measurements were compared with each other.



Figure 1: Alderson Rando female phantom

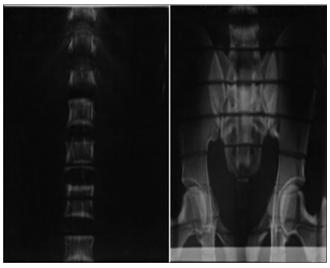


Figure 2: Radiograph of the pelvis of the phantom

The detectors of rainbow dosimeter were employed for the measurement of radiation doses. The dosimeter has applications for relatively low doses and dose rate independent up to 10–8 Gy s-1. The system is also independent of relative humidity and can be used over a broad temperature (0 to 5°C). The integrated radiation effect that is used for the measurement is the shift in threshold voltage due to trapped charge in the multilayered device. This threshold voltage is evaluated in the measurement of the channel (drain) current as a function of gate voltage at a constant supply voltage to the device. Three detectors were put at the points of interest in irradiation volume.

A TLD reader system together with some TLDs of CaSO₄ was used for dose measurement. TLD capsules in the size with diameter 0.4 cm and with length 1.4 cm were used for dose measurement. For annealing procedures, the TLDs were heated to 400°C and maintained at that temperature for 1 h, followed by 100°C for 2 h and then cooled to room temperature. For dose measurement, TLDs were inserted by vacuum tweezers in a sequential order of labeled TLDs at the pre-determined sites in slice 31 of the phantom. The position was determined by the fact that the cervix is the lower part of the uterus. Figure 2 shows the radiograph of the pelvis of the phantom. Three TLD capsules were used at each measurement site.

RESULTS

The comparison of the mean absorbed dose by TLD and rainbow dosimeter in all techniques following cervix cancer treatment is given in Table 1. The calculated dose for the rectum by TLD was as follows: 1.97 Gy with two field, 1.62 Gy with three field, and 1.33 Gy with equal applied dose, and the calculated dose for the rectum by rainbow

Table 1: Comparison of the mean absorbed dose by thermoluminescent dosimetry and rainbow dosimeter for treatment of cervix cancer in different techniques with Co-60 teletherapy unit

Techniques	Dose			
	Rectum	Cervix	t-test	
	Mean±SD	Mean±SD		
Two field	1.97±0.01	2.03±0.01	P=0.02	
Three field	1.68±0.026	1.89±0.02	P=0.0016	
Four field	1.35±0.05	1.92±0.01	<i>P</i> =0.0026	

dosimeter was as follows: 2.03 Gy with two field, 1.87 Gy with three field, and 1.69 Gy with equal applied dose.

The results obtained from the TLD and rainbow dosimeters were grouped according to their location points of interest in the irradiation volume. Three points were selected for dosimetry on the phantom slice (slice 32). The results were evaluated by the paired t-test. The mean and standard deviation values of two field, three field, and four field for the rectum are 1.97 ± 0.01 , 1.68 ± 0.026 , and 1.35 ± 0.05 , respectively, whereas the mean and standard deviation values of two field, three field, and four field for the cervix are 2.03 ± 0.01 , 1.98 ± 0.02 , and 1.92 ± 0.01 , respectively. The results were evaluated by the paired t-test. The P values calculated from data are as follows: Two field, cervix, P = 0.02; three field, cervix, P = 0.0016; and four field, cervix, P = 0.0026, demonstrates that four field significantly reduces the rectum dose.

CONCLUSIONS

By using multiple fields, the ratio of the tumor dose to the normal tissue dose was increased. Although multiple fields could provide good distribution, there are some clinical and technical limitations in these methods. For example, certain beam angulations were practically impossible due to the presence of critical organs. Furthermore, the setup accuracy of a treatment may be better with parallel opposed than with multiple angles beam arrangement. The results were evaluated by paired *t*-test. The P values calculated from data are as follows: Two field, cervix, P = 0.02; three field, cervix, P = 0.0016; and four field significantly reduces the rectum dose. As far as comparison of point measured dose is concerned, the following conclusions could be drawn:

- Maximal rectal dose was obtained using two-field technique.
- Considering similar target volume, best normal tissue sparing was obtained using the three-field and four field techniques with equal tumor dose.

- There is a uniform dose distribution throughout the tumor volume.
- In comparison of the TLD and rainbow dosimetry results with the prescribed dose, it was demonstrated that there was significant difference between the measured and prescribed dose by tumor volume and rectum.

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Conventional Radiotherapy with Hypofractionated Radiotherapy in Post-Mastectomy Breast Cancer Patients: A Prospective Comparative Study

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Abstract

Aim: The aim of this study is to assess the efficacy, toxicity, and feasibility of hypofractionated radiotherapy in post-mastectomy breast cancer patients compared with conventional radiotherapy.

Materials and Methods: A total of 80 post-mastectomy breast cancer patients were randomized into two groups for adjuvant radiotherapy. Control group of 40 patients received conventional radiotherapy of 50 GY in 5 weeks. Study group of 40 patients received hypofractionated radiotherapy of 42.72 GY in 3.1 weeks.

Results: The statistical analysis of the study was performed in terms of tolerability, radiation toxicities, and feasibility of the hypofractionated radiotherapy over conventional radiotherapy. There was found to be no significant difference between the two groups.

Conclusion: In breast cancer patients after post-mastectomy, hypofractionated radiotherapy in comparison to conventional radiotherapy finds comparable outcomes without any significant difference in radiation-induced toxicities.

Key words: Carcinoma breast, Hypofractionated radiotherakpy, Post-mastectomy radiotherapy, Toxicities

INTRODUCTION

Carcinoma breast being the most common cancer in females usually presents as a locally advanced disease which makes the treating oncologist difficult in taking treatment decisions. [1,2] Hence, radical mastectomy is more often performed than breast conservative surgeries such as lumpectomy, quadrantectomy in developing countries like India, where people do not give much importance to cosmetic outlook. [3,4] Nearly, all of these post-mastectomy patients require adjuvant radiotherapy to prevent locoregional recurrence and distant metastasis. [5-7]

For long, conventional radiotherapy is being delivered to the chest wall and drainage area. In the recent past, most of the

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centers are trying various methods of delivering different types of fractionations in the adjuvant radiotherapy. [8,9] The most tested regimen of adjuvant radiotherapy in carcinoma breast is hypofractionated radiotherapy with a total dose of 42.72 GY, 2.67 GY per fraction in 16 fractions. The other fractionation protocols are 42.9 GY in 13 fractions, 39 GY in 13 fractions, 40 GY in 15 fractions, 28.5 GY in 5 fractions, and 30 GY in 5 fractions. [10-13]

In this study, we compare conventional fractionation 50 GY, 200 CGY per fraction, 5 fractions per week, 25 fractions in 5 weeks, with the hypofractionation regimen 42.72 GY, 2.67 GY per fraction, 5 fractions per week, and 16 fractions in 3.1 weeks. Post-operative radiotherapy is aimed at eradicating subclinical disease, superior locoregional control, and acceptable risk of normal tissue reactions, for example, lungs and heart. [14,15] Post-mastectomy radiotherapy is indicated in patients with 1–3 positive axillary lymph nodes and tumor size equal to or more than 5 cm or positive/unknown pathological margins. [16] Conventional fractionation modality requires a lengthy hospitalization or commuting to the hospital

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for radiotherapy for a prolonged period. The probability of missing radiotherapy is higher with older patients and those living farther away from radiotherapy centers. This also applies to patients with disabilities or those who cannot rely on their families support.^[17,18]

Hypofractionation is a strategy allowing shortening the time of radiotherapy. Hypofractionated radiotherapy is gaining momentum, which delivers a higher dose per fractions for a biologically equivalent dose while maintaining the same toxicity and locoregional control. [2,10] Hypofractionated regimen for post-operative breast cancer is also radiobiologically justified. Since the sensitivity of breast cancer to radiotherapy is similar to that of healthy tissues responding with late reactions, high fraction doses may be more efficient in destroying tumor cells. [2]

Aim

The aim of this study is to assess the efficacy, toxicity, and feasibility of hypofractionated radiotherapy in post-mastectomy breast cancer patients compared with conventional radiotherapy.

MATERIALS AND METHODS

This prospective study was carried out in the Department of Radiotherapy, Thanjavur Medical College Hospital from June 2018 to May 2019. Post-mastectomy patients were randomized into two groups – the control group and study group with 40 patients in each group: Control group – Arm A – 40 patients, conventional fractionation radiotherapy regime, 5000 CGY, 200 CGY per fraction, 5 fractions per week, and totally 25 fractions in 5 weeks.

Study group – Arm B – 40 patients, hypofractionated radiotherapy regime, 4272 CGY, 267 CGY per fraction, 5 fractions per week, and totally 16 fractions in 3.1 weeks.

All patients should have undergone modified radical mastectomy with axillary node dissection followed by chemotherapy with or without hormonal therapy. Moreover, the patients should present for adjuvant radiotherapy within 1 month of the last cycle of chemotherapy. The other inclusion criteria were as follows:

- 1. Histological proof of breast cancer
- 2. Age 30–60 years
- 3. Pathological stage T2/T3 No/N1/Mo
- 4. Tumor size ≥5 cm
- 5. Axillary node positive
- 6. ECOG performance status 0–2
- 7. Written consent of the patient
- 8. Unilateral breast cancer
- 9. Estrogen/progesterone receptor Positive/Negative
- 10. Her 2 Negative.

Exclusion Criteria

- 1. History of previous irradiation
- 2. Recurrent breast cancer
- 3. Active systemic lupus or scleroderma
- 4. Comorbid conditions such as cardiac disease, diabetes mellitus, hypertension
- 5. Pregnancy
- 6. Breast conservation surgery such as lumpectomy and quadrantectomy
- 7. Evidence of metastasis.

Preradiotherapy Examination of Patients

Before the execution of radiotherapy, all the patients were evaluated with:

- 1. Complete clinical examination
- 2. Detailed cardiac evaluation
- 3. Thoracic medicine opinion
- 4. Blood test and HIV
- 5. CT scan chest
- 6. CT scan abdomen.

Radiotherapy

In Arm A of control group, 40 patients of conventional fractionation regimen were given a total dose of 50 Gy/2Gy/per fraction/5 days a week/25 fractions/in 5 weeks. In Arm B of the study group, 40 patients of hypofractionated radiotherapy were given a total dose of 42.72 GY/2.67 GY/per fraction/5 days a week/16 fractions/in 3.1 weeks. The patients were delivered radiation in telecobalt machine to the chest wall and drainage area. The chest wall received radiation with bilateral tangential fields [Table 1].

Monitoring of Patients during Radiotherapy

Patients on radiation treatment are regularly examined for:

- 1. Tolerance
- 2. Maintenance of general condition
- 3. Acute toxicities
- 4. Dysphagia and oral intake
- 5. Pulmonary symptoms
- 6. Cardiac symptoms
- 7. Arm edema
- 8. Appearance of metastasis
- 9. Psychological status.

Follow-up

After completion of treatment, patients were advised for strict follow-up which included:

- 1. Routine clinical examination monthly
- 2. Chest radiography every month
- 3. Mammography every 3 months
- 4. Ultrasonogram of the abdomen every year
- 5. Bone scan whenever necessary.

RESULTS

Going to the statistical analysis of our study, the follow-up period of patients ranged from 3 to 14 months. All patients tolerated radiotherapy well and completed the treatment protocol in the scheduled duration, with 1–2 days interruption of radiation, which was seen in eight patients in conventional fractionation radiotherapy (CFRT) and 13 patients in hypofractionated radiation therapy (HFRT) due to toxicities [Table 2].

Table 1: Radiation treatment

Variables	CFRT	HFRT
Number of patients	40	40
Total dose	5000 CGY	4272 CGY
Fractions	25	16
Dose per fraction	200 CGY	267 CGY
Treatment days per week	5 days a week	5 days a week
Total treatment period	5 weeks	3.1 weeks

HFRT: Hypofractionated radiation therapy, CFRT: Conventional fractionation radiotherapy

Table 2: Characteristics of patients

<u> </u>					
Characteristics	CFRT (%)	HFRT (%)			
Age (years)					
30–40	14 (35)	18 (45)			
40-50	17 (43)	12 (30)			
50-60	9 (23)	10 (25)			
ECOG score					
0	4 (10)	8 (20)			
1	17 (43)	20 (50)			
2	19 (47)	12 (30)			
Menopausal status					
Pre	14 (35)	22 (55)			
Post	18 (45)	13 (33)			
Peri	8 (8)	5 (12)			
Hormone therapy					
ER+	15 (38)	16 (40)			
PR+	16 (40)	12 (30)			

HFRT: Hypofractionated radiation therapy, CFRT: Conventional fractionation radiotherapy

Table 3: Characteristics of tumor

Characteristics	CFRT (%)	HFRT (%)	
Anatomical side			
Left	20 (50)	18 (45)	
Right	20 (50)	22 (55)	
Involved breast quadrant			
Upper outer quadrant	24 (60)	23 (58)	
Other quadrants	16 (40)	17 (42)	
Tumor stage			
II	22 (55)	25 (63)	
III	18 (45)	15 (37)	
Tumor grade			
1	5 (13)	2 (5)	
II	18 (45)	24 (60)	
_ III	17 (42)	14 (35)	

HFRT: Hypofractionated radiation therapy, CFRT: Conventional fractionated radiotherapy

Regarding toxicities, Grade I–II acute skin reactions were observed in 19 patients (48%) of CFRT and 22 patients (55%) of HFRT. Grade III skin toxicities were observed in 6 patients (15%) in CFRT and in 16 patients (40%) of HFRT. Acute radiation-induced pneumonitis was noticed in 2 patients (5%) in CFRT and in 4 patients (10%) of HFRT. The development of dysphagia was equal in both groups, in 9 patients and did not cause much disturbance to the patients in continuation of the treatment, managed with Ryle's tube and other supportive measures. Anemia was noticed in 18 patients (45%) of CFRT and 23 patients (58%) of HFRT. Febrile neutropenia was observed in 4 patients (10%) of CFRT and in 7 patients (18%) of HFRT [Tables 3-5].

Lymphedema is a common late complication resulting from both axillary nodal dissection and radiotherapy. One year of follow-up, 8 patients (20%) in CFRT and 13 patients (33%) in HFRT presented with lymphedema. Restricted arm and shoulder movement were noticed in almost all patients in both groups with varying intensity. Lymphedema and restricted shoulder movement were reduced with regular exercises. Some patients developed transient hypertension after 3 months of completion of treatment. One patient in HFRT with left-sided breast cancer developed minimal pericardial effusion at 6 months of follow-up. At 1 year of follow-up, two patients presented with lung metastasis and one patient with bone metastasis in the CFRT group. In

Table 4: Acute skin reactions

Acute skin reactions	CFRT (%)	HFRT (%)	
Grades I and II	48	55	
Grade III	40	15	

HFRT: Hypofractionated radiation therapy, CFRT: Conventional fractionated radiotherapy

Table 5: Development of anemia and febrile neutropenia during radiation

Complication	CFRT	HFRT
Anemia (%)	45	58
Neutropenia	10	18

HFRT: Hypofractionated radiation therapy, CFRT: Conventional fractionated radiotherapy

Table 6: Late complications at 1 year of follow-up

Toxicity	CFRT (%)	HFRT (%)
Lymphedema	8 (20)	13 (33)
Chest wall recurrence	2 (5)	1 (3)
Axillary nodal recurrence	1 (3)	0 (0)
Lung metastasis	2 (5)	0 (0)
Liver metastasis	0 (0)	1 (3)
Bone metastasis	1 (3)	1 (3)

HFRT: Hypofractionated radiation therapy, CFRT: Conventional fractionated radiotherapy

HFRT group, one patient presented with liver metastasis and one patient with bone metastasis. Regarding chest wall recurrence, one patient presented at 6 months and two patients at 1 year in CFRT. In HFRT, one patient had chest wall recurrence at 1 year of follow-up. Recurrence in axillary nodes was observed in one patient in CFRT, 1 year after completion of treatment [Table 6].

The other possible chronic toxicities are as follows:

- 1. Skin changes
- 2. Damage to rib bones
- 3. Pain and numbness in the arm
- 4. Hypothyroidism
- 5. Radiation-induced second cancers such as leukemia, thyroid, and breast.

These changes will occur months to years after treatment. Some of the toxicities and other complications may be related to mastectomy induced the cosmetic appearance of the chest wall, side of the breast cancer and the breast quadrant of the tumor. However, there is no concrete evidence for this association. The statistical analysis of all the characteristics of the patients, results, and toxicities is discussed in the following tables and figures.

DISCUSSION

Adjuvant local or locoregional radiation treatment improves locoregional control and survival for women treated with breast-conserving surgery and in patients with the high-risk disease treated with mastectomy. Standard or conventional fractionation radiotherapy for breast cancer is generally defined as 1.8-2 Gy per fraction to total doses of 50-50.4 Gy. Early experiences of hypofractionated radiation regimen using higher fraction sizes to deliver radiotherapy over shorter durations were far from positive. Investigators from Manchester and Denmark have reported an unexpected high rate of late effects, including severe fibrosis among women treated with over 12 fractions.^[19] The routine use of HFRT in breast radiotherapy is supported by the results of five large randomized controlled trials (RCTs) in women with early breast cancer. [20-23] These studies demonstrate that HFRT yields equivalent or improved outcomes in all essential endpoints: Efficacy, toxicity, cosmesis, and cost-effectiveness. HFRT also results in greater patient convenience and resource efficiency. Nevertheless, the optimal fractionation schedule is not well established, but existing evidence suggests that shorter schedules may be equivalent with regard to local control and cosmesis. In 2010, a Cochrane review concluded that HFRT did not seem to decrease safety and efficacy, but the longer followup was needed for a more comprehensive assessment. [24]

Recently, some newly original trials reported the research results^[23-27] and several key RCTs update the results with longer periods of follow-up.[28] Thus, we performed this systematic review and meta-analysis to determine the efficacy and safety of altered radiation fraction size on outcomes for women with early breast cancer and to further facilitate clinical decision-making. Studies have evaluated correlations between lungs dose-volume histogram metrics (Vx: Volume of lungs receiving at least x dose, mean lungs dose, etc.) and risk of radiation pneumonitis.^[29] In the last quantitative analyses of normal tissue effects in the clinic review, it was concluded that recommendations for dose-volume limits for lungs are challenging as there is no clear and consistent threshold for metrics. [30] One of the valid concerns with using hypofractionation for locoregional radiotherapy is that there may be an increased risk of nerve injury; particularly, radiation-induced brachial plexopathy. One older study reported that the risks of radiation-induced brachial plexopathy and paralysis were high and that the risks increased over long-term follow-up.[31]

CONCLUSION

From this prospective study, it is clearly evident that hypofractionated radiotherapy in post-mastectomy breast cancer patients is not inferior to conventional radiotherapy and can be considered a safe and feasible alternative treatment protocol. Skin toxicities are slightly higher in hypofractionated radiotherapy. All other adverse effects are nearly comparable to conventional radiotherapy. A shorter course of treatment in a broader range of patients may improve patient compliance and decrease resource utilization. Completion of uninterrupted radiation treatment in a shorter duration increases the biological effects of radiation. Most of the studies having a long follow-up of patients after completion of radiation treatment provide strong evidence of non-inferiority of this approach compared with conventional fractionation. We can also argue that acute toxicities should not be a limiting factor for hypofractionated radiotherapy considering other benefits over the conventional regime. The optimal modality for treating breast cancer is still a challenge, despite several studies being conducted in many centers worldwide. In particular, the best adjuvant radiation protocol after post-mastectomy breast cancer patients is still an open issue in the era of customization of cancer therapy. Considering all aspects of adjuvant radiotherapy, we can conclude that this trial will substantially contribute to the understanding of the hypofractionated regimen is not only aiming at obtaining an optimal disease control but also preserving the patient quality of life and this kind

of adjuvant treatment is highly suitable for patients in developing countries like India.

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Radiopathological Correlation of Thyroid Masses: A Prospective Study

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Abstract

Background: Diseases of the thyroid continue to be a common clinical problem having a prevalence rate of 4–7% in the general population. It affects patients in all age groups and the treatment modalities include either a conservative management or a surgical excision of the gland. Fine-needle aspiration cytology (FNAC) is a minimally invasive, accurate diagnostic tool which can differentiate neoplastic from non-neoplastic lesions and, hence, reduces the number of unnecessary thyroidectomy. Ultrasonography (USG) is the most common and the most useful way to image the thyroid gland and its pathology. The study was conducted with the objective of evaluating the applicability of Doppler USG in diagnosing thyroid pathologies, established its superiority over clinical palpation, and correlated histopathologically using FNAC. The type of thyroidectomy can be planned based on the type of the thyroid swelling and thereby preventing the surgical complications. Thyroid gland is afflicted by various pathologies ranging from diffuse enlargement (goiter) to nodular lesions, thyroiditis, and malignancies.

Materials and Methods: This was a prospective study done on 98 patients that came to the outpatient department of the Department of Radiodiagnosis of Sukh Sagar Medical College, Jabalpur, from August 2018 to May 2019. All the patients with thyroid swelling/mass/enlargement were studied under color Doppler USG and then FNAC was performed.

Results: The present study had a total of 98 cases. Cytologic diagnosis was classified under benign, malignant, inconclusive, suspicious, and malignant categories. Among 98 cases, 86 cases were non-neoplastic and 12 were neoplastic. The ratio of non-neoplastic to neoplastic is 7.16:1. Majority of the patients were females in the age group of 41–60 years. USG was found to be more sensitive than clinical palpation. Differences were found when the results of USG were correlated with FNAC.

Conclusion: Ultrasound was found to be more reliable than palpation. The addition of color flow imaging has added value to the prediction of thyroid, but definitive diagnosis can be reached only with FNAC/biopsy. Multinodular goiter was the most common non-neoplastic lesion and papillary carcinoma was the most common neoplastic lesion. Thus, fine-needle aspiration is a very useful and indispensable test in the diagnosis of thyroid lesions.

Key words: Color Doppler, Fine-needle aspiration cytology, Thyroid, Ultrasonography

INTRODUCTION

Thomas Wharton first coined the term "thyroid" due to the organ's close proximity to the thyroid cartilage (120–200 A.D). The word thyroid is derived from the Greek "thyros" meaning "shield" because it was originally considered to protect the larynx. [1] Thyroid disease indicated by the presence of single or multiple nodules within the

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thyroid gland remains a common clinical problem and has a reported prevalence of 4%–7% in the general population. [2]

The incidence of thyroid diseases is increasing in recent years due to goitrogens and changing food habits. Thyroid gland is afflicted by various pathologies ranging from diffuse enlargement (goiter) to nodular lesions, thyroiditis, and malignancies. The development and application of fine-needle aspiration cytology (FNAC) has been helpful in distinguishing benign from malignant nodules and in screening patients for surgery. The fine-needle aspiration method for studying the thyroid was first developed in Sweden in the Rudiunhelmet hospital of Stockholm in the 1950s. [3] Frable, in 1983, used the FNAC as a means of diagnosing most thyroid masses as either neoplasm or goiter nodules. [4] Histopathological examination remains

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the "gold standard" method for the confirmation of the pre-operative diagnosis of FNAC.

At present, high-resolution ultrasound with color Doppler is the primary imaging modality of choice in morphological evaluation of the thyroid gland. [5,6] Ultrasonography (USG) gives good graphic representation of regional anatomy, has high resolution, small expense, simplicity, and it depicts the internal structure of the thyroid gland and the regional anatomy and pathology without using ionizing radiation or iodine-containing contrast medium. [7,8]

USG, the most common and the most useful way to image the thyroid gland and its pathology, as recognized in guidelines for managing thyroid disorders, published by the American Thyroid Association.^[9]

It is used to define the nature of the lesion, whether solid or cystic, to differentiate thyroid from extrathyroidal masses, assessment of blood flow pattern in and around lesion, to differentiate between benign and malignant thyroid nodule, invasion in nearby structures, and to identify additional nodular lesions or enlarged lymph nodes.^[5,6]

The drawback of ultrasound is that it may reveal thyroid swellings that are not clinically relevant that leads to unnecessary further investigations, but in experienced hands, USG allows more targeted sampling and is highly reliable.^[10]

Fine-needle aspiration cytology (FNAC) is the investigation of choice in discrete thyroid swellings. FNAC has excellent patient compliance, is simple and quick to perform in the outpatient department (OPD), and is readily repeated. Ultrasound may be used to guide the needle for more accurate sampling. The results of FNAC are reported using the terminology given in Table 1.^[10]

The study was conducted with the objective of evaluating the applicability of Doppler USG in diagnosing thyroid pathologies, establish its superiority over clinical palpation, and correlate histopathologically using FNAC.

Aims and Objectives

The aim of the study is to evaluate the spectrum of diseases in thyroid swellings, to know the accuracy of USG and FNAC in the diagnosis of thyroid swellings.

MATERIALS AND METHODS

This was a prospective study done on 98 patients of thyroid swellings who visited surgical OPD of Sukh Sagar Medical College, Jabalpur, from August 2018 to May 2019. General examination of the patient was done and looked for thyroid

functional abnormality followed by local examination which was carried out to locate and identify the site of the swelling, shape, size, and consistency of the thyroid swelling and clinical diagnosis was made. All thyroid swellings were sent to the Radiodiagnosis Department of Sukh Sagar Medical College for USG. After USG, the patients were sent to the Department of Pathology, City Hospital and Research Centre, Jabalpur, Madhya Pradesh, for FNAC. The cases were subjected to FNAC as outpatient procedure after explaining the details of the procedure to the patient and taking an informed written consent. Several air-dried and wet mount smears were made and are stained with May-Grunwald-Giemsa and papanicolaou stains, respectively.

Inclusion Criteria

Patients with thyroid swelling/mass or thyroid gland enlargement (diffuse or nodular) were included in the study.

Exclusion Criteria

Patients undergoing treatment or recovery after proper diagnosis were not included in the study.

Patients name, age, sex, and presenting complaints were noted.

The investigations were performed using GE VOLUTION P6 USG and GE-VIVID-E USG machine, with a high-frequency probe of 12 MHz. FNAC was done under all aseptic precautions, using a gauge spinal needle and a 10 ml syringe for proper suction.

International ovarian tumor analysis scoring system, RI and PI value, was applied to differentiate benign and malignant masses.

USG of the thyroid gland was performed with the patient in supine position with dorsally extended head. The echotexture of the whole thyroid gland was assessed by subjectively comparing the echo pattern of the lesion with characteristics adjacent neck musculature. Thyroid abnormalities were classified as diffuse or nodular. Vascularity was evaluated using color Doppler flow imaging.

RESULTS

Of the 98 patients that were reviewed in our study, 74 were female (75.5%) and 24 were male (24.5%).

Maximum patients in our study (35%) were found to be in the age group of 41–60 years. The age distribution of patients is shown in Table 2.

Apart from swelling/mass/enlargement, some patients came with the complaints of tremors, weight loss,

menorrhagia, etc. The frequency of such complaints is shown in Table 3.

Of the 98 patients, palpation and clinical examination demonstrated 11 cases of multiple nodules. The number was found to be 41 when USG was performed. Palpation demonstrated 45 cases of solitary nodules and the number of the same on USG was found to be 26. The findings of palpation versus USG are shown in Figure 1. There is gross difference in the findings of USG and clinical examination. Histopathological correlation was done using FNAC samples. The results are shown in Table 4.

The masses that were detected by USG were categorized further based on their echogenicity and color flow patterns. The findings are shown in Figures 2 and 5.

Table 1: Classification of FNAC reports

Thy 1	Non-diagnostic
Thy 1c	Non-diagnostic cystic
Thy 2	Non-neoplastic
Thy 3	Follicular
Thy 4	Suspicious of malignancy
Thy 5	Malignant

FNAC: Fine-needle aspiration cytology

Table 2: Age distribution

Age (years)	Number of patients	Percentage (%)
0–20	09	9.2
21-30	23	23.4
31-40	25	25.5
41-60	32	32.6
61+	07	7.3
	98	100

Table 3: Clinical presentations

Clinical presentation	Number of patients	Percentage (%)		
Tremors	3	3		
Difficulty in breathing	1	1		
Difficulty in swallowing	6	6		
Weight gain/menorrhagia	6	6		
Weight loss	3	3		
Voice change	1	1		

Table 4: USG versus FNAC

Pathology	USG	FNAC
Follicular adenoma	14	16
Thyroiditis	32	32
Hyperplastic nodule	3	1
Colloid goiter	40	37
Carcinoma	9	4
Inflammatory cells	-	1
RBS'c only	-	7
Total	98	98

USG: Ultrasonography, FNAC: Fine-needle aspiration cytology

DISCUSSION

The thyroid gland is uniformly hyperechoic on ultrasound in comparison to the adjacent strap muscles and is best seen with the use of high-resolution linear array transducers having frequency ranging from 5 to 10 MHz, and having color flow capability and low flow sensitivity. The use of color flow imaging identifies multiple small vessels within and adjacent to the thyroid. [11] A total of 100 cases were studied, of which 74 were female (74%) and 2 were male (26%), the female:male ratio is 3:1. Most of the patients were more than 20 years of age and <60 years of age, maximum in the age group of 41–60 years (35%). Ezzat et al., [16] 1994, in a prospective study of 100 subjects in North America, found abnormal ultrasound findings of the thyroid in 67 patients, with prevalence being greater in women (72%) than in men (41%), and mean age range being 43-50 years.[8] Ultrasound screening of thyroid gland in a random adult population of 253 subjects in Finland, was goiter, is not endemic, and was carried out by Brander, in 1992. Echo abnormalities were detected in 27.3%. The prevalence showed an increase in the age group of 40-50 years. Women showed significantly more lesions (34.6%) than men (19.5%).[9] It can be safely said that women, after 40 years of age, are highly prone to developing thyroid abnormalities.

Our study shows significant differences in the findings of USG and palpation. As opposed to an actual of 67% of cases of nodular thyroids, only 56% could be picked up by palpation. Only 11 % of these were appreciated as multiple nodules, in contrast to 44% appreciated by ultrasound. This shows that USG is much more sensitive as compared to clinical palpation, especially multiple small non-palpable nodules. Tan et al. showed that clinical palpation is less sensitive than ultrasound in identifying multiple nodules and that a palpable solitary nodule represents a multinodular gland in 50% of patients.^[12] In their study of 72 patients in 1992, Brander found that only one-third of clinically solitary nodules proved to be solitary by ultrasound. Of 77 separate nodules, 43 escaped detection on clinical examination. They reported that nodules smaller than 1 cm in diameter are impossible to detect clinically, unless they are hard and superficial. These observations clearly demonstrate the clinical superiority of USG over clinical palpation.

Forty-one cases of 100 in our study were reported as colloid goiter on USG, of which 39 proved to be colloid goiter on FNAC. The most common echo patterns seen on ultrasound were anechoic, with normal vascularity on color flow imaging. Of 100 cases, 32 came out to

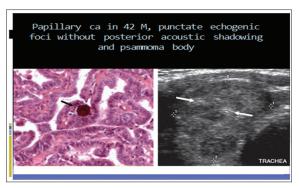


Figure 1: Papillary Ca in 42 M, punctate echogenic foci without posterior acoustic shadowing and psammoma body.

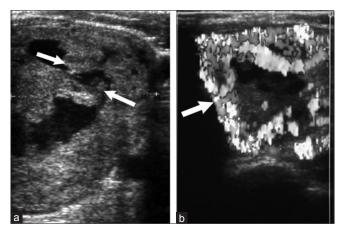


Figure 2: (a and b) Hurthle cell (follicular) carcinoma in a 60-F. Transverse USG of the left lobe of the thyroid shows a partially cystic tumor with solid internal projections and thick walls.

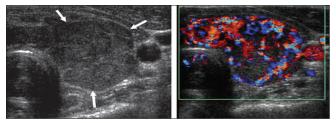


Figure 3: Diffuse follicular variant of papillary thyroid ca in 37 F with thyrotoxicosis mistaken for graves

be thyroiditis on USG and the number was confirmed on FNAC. The most common echo pattern seen on ultrasound was heteroechoic. Langer *et al.* reported that lesion that was lymphocytic thyroiditis on FNAC appears as solid hyperechoic nodules with ill-defined margins on USG.^[13] Hiromastu *et al.* showed that in patients with acute subacute thyroiditis show low echogenicity without increased tissue vascularity in the affected swollen thyroid and in the recovery stage, isoechogenecity with slight increased vascularity.^[14] Diffuse hyperechoic thyroid associated with reduced thyroid volume was found in 53 of 55 (96%) patients with atrophic thyroiditis by Vitti *et al.* These findings correlate with our study that shows the most common

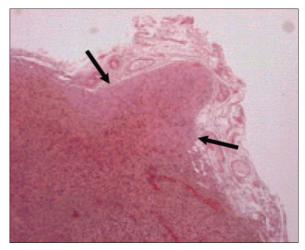


Figure 4: Arrow showing Tumor invasion beyond capsule.

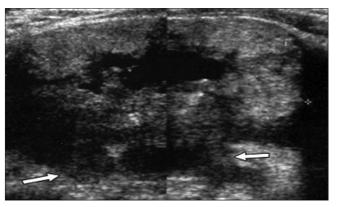


Figure 5: Anaplastic carcinoma in 84 F. Transverse USG of the left lobe of the thyroid shows an advanced tumor with infiltrative posterior margins (arrows) and invasion of prevertebral muscle.

echo pattern seen on ultrasound in thyroiditis was heterogeneous with diffuse vasculature.^[15]

Of 100 thyroid nodules studied, 15 were detected as adenoma on USG (hyperechoic) and 16 were confirmed adenomatous on FNAC. Katz *et al.* (1984) prospectively examined 28 cadaver thyroid glands. The most common echo pattern seen on USG was hypoechogenicity.

CONCLUSION

Ultrasound was found to be more reliable than palpation in differentiating nodular from diffuse gland and especially so for detection of non-palpable nodules. Colloid goiter was the most common presentation on ultrasound and it showed a wide spectrum of appearance, majority being nodular and anechoic. It can reliably differentiate toxic goiter, adenoma, or thyroiditis. The addition of color flow imaging has added value to the prediction of thyroid, but definitive diagnosis can be reached only with FNAC/ biopsy.

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Evaluation of Hard Tissue Cephalometric Norms for Maharashtrian Population using Downs Analysis

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Abstract

Aim: Based on Downs analysis, the present study aims to evaluate hard tissue cephalometric norms for the Maharashtrian population.

Materials and Methods: The digital lateral cephalograms of 100 subjects with Maharashtrian ethnicity within the age range of 18–30 years with normal occlusion were obtained. Downs analysis was performed using Dolphin software. The obtained values were statistically analyzed to evaluate hard tissue norms for the Maharashtrian population.

Results: Statistically significant differences were observed in hard tissue norms between Maharashtrian population and Caucasian norms.

Conclusion: Ethnic differences exist between Maharashtrian population and Caucasian population, which should be considered when formulating an orthodontic treatment plan.

Key words: Caucasians, Cephalometrics, Downs, Ethnic group, Hard tissue

INTRODUCTION

Downs (1948) was among the pioneers who established cephalometric standards to be used as guidance for treatment planning for orthodontic patients.^[1] A cephalometric radiograph in diagnosis and treatment planning is an essential tool in orthodontics to assist research workers and orthodontic clinicians.^[2]

Various cephalometric analysis for orthodontic treatment has been designed, but these cephalometric norms were specific to one ethnic group White subjects of European American ancestry. Cephalometric norms derived from the Caucasian population are routinely used for investigations.

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As these norms show a great degree of variation when applied to different ethnic groups, it becomes necessary to establish the norms for every ethnic group with a standard method for effective orthodontic treatment (all articles).

One of the commonly used hard tissue analyses is Downs analysis given by D. W. Downs.^[1] Since India is a subcontinent with a large number of racial subgroups and several religious and interracial mixtures, it was proposed, therefore, to study only the individuals derived from Maharashtra origin using Downs analysis (Nanda).

Thus, the present study was designed to derive norms for the Maharashtrian population, which would be comparable in diagnosis and treatment planning to the Holdaway cephalometric analysis.

Aim

The aim of the study is to evaluate the mean cephalometric norms for Downs analysis in the Maharashtrian population.

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Objective

The objective of the study is as follows:

- 1. To evaluate the mean cephalometric norms for Downs analysis in the Maharashtrian population
- 2. To compare standards derived with the earlier established norms for other population.

MATERIALS AND METHODS

Source of Data

The sample of 100 subjects was selected, 50 males and 50 females were included. The sample was selected based on age, sex, and straight pleasing profile. A signed informed consent form was taken in Marathi and English language.

Selection Criteria for Subjects

Inclusion criteria

The following criteria were included in this study:

- 1. Subject should be Maharashtrian origin traced back to two generations
- 2. The age range of 18–30 years
- 3. Permanent dentition
- 4. Class I molar relation
- 5. Class I skeletal jaw bases
- 6. Normal overjet and overbite.

Exclusion criteria

The following criteria were excluded from the study:

- 1. Previous or current orthodontic treatment
- 2. Severe crowding
- 3. Missing tooth other than the third molar
- 4. Obvious periodontal disease
- 5. Evidence of previous trauma/surgery
- 6. Facial asymmetry or deformity
- 7. Presence of deciduous/retained teeth
- 8. Presence of any pathological conditions
- 9. Presence of deciduous or over retained teeth.

Initially, each subject was thoroughly examined clinically according to inclusion and exclusion criteria. A digital lateral cephalometric radiograph was taken of all subjects. Downs cephalometric analysis was performed and studied.

Radiographic Unit Detail

The Pax-I (PCH2500), Vatech Global, digital radiographic unit from the Department of Oral Medicine and Dental Radiology, Bharati Vidyapeeth Dental College and Hospital, Sangli, was used to take the lateral digital cephalometric radiographs of the subjects involved in the study [Figure 1].

Cephalometric Tracing

The digital radiographs obtained from Pax-I machine were then transferred to Dolphin Imaging 11.9 Software (Dolphin Imaging and Management Solutions, Chatsworth,



Figure 1: Patient position for lateral cephalogram

Calif.). In our study, Downs cephalometric analysis was performed and studied [Figures 2 and 3].

Statistical Analysis

- The measurements were statistically analyzed by calculating their means and standard deviations
- Then, the means of the Maharashtrian population were compared with means of the Caucasian population with the help of unpaired *t*-test
- A comparison was also made between males and females within the present study.

RESULTS

Facial Angle

In our study, the mean value was 86.64 while in Caucasian population was 87.8. The mean difference was -1.10 which was statistically significant ($P \le 0.001$).

Angle of Convexity

In our study, the mean value was 4.72 while in Caucasian population was 0.0. The mean difference was 4.70 which was statistically significant ($P \le 0.001$).

AB Plane Angle

In our study, the mean value was -4.26 while in Caucasian population, the angle was -4.6. The mean difference was 0.33 which was statistically insignificant (P = 0.353).

Mandibular Plane Angle

In our study, the mean value was 22.40 while in Caucasian population, the angle was 21.9. The mean difference was 0.50 which was statistically insignificant (P = 0.338).

V-Avis

In our study, the mean value was 59.97 while in Caucasian, it was 59.4. The mean difference was 0.57 which was statistically insignificant (P = 0.583).

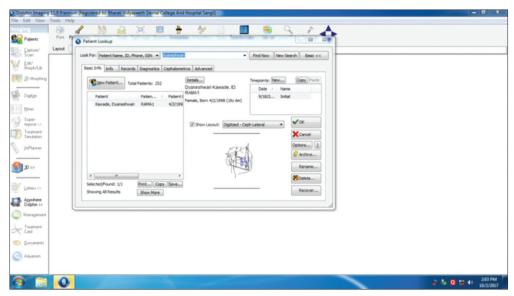


Figure 2: Dolphin Imaging 11.9 Software

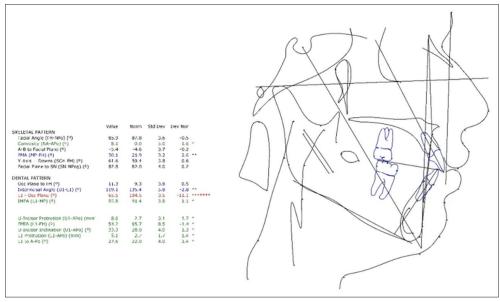


Figure 3: Downs analysis tracing

SN-Npog

In our study, the mean value was 81.07 while in Caucasian, it was 82. The mean difference was -0.92 which was statistically insignificant (P = 0.444).

Occlusal Plane Angle

In our study, the mean value was 9.65 while in Caucasian, it was 9.3. The mean difference was 0.35 which was statistically insignificant (P = 0.685).

Interincisal Angle

In our study, the mean value was 121.8 while in Caucasian, it was 135.4. The mean difference was -13.54 which was statistically significant ($P \le 0.001$).

Incisor Mandibular Plane Angle

In our study, the mean value was 97.01 while in Caucasian, it was 91.4. The mean difference was 5.61 which was statistically significant ($P \le 0.001$).

Protrusion of Max Incisors

In our study, the mean value was 8.65 mm while in Caucasian, it was 2.7 mm. The mean difference was 5.95 which was statistically significant ($P \le 0.001$).

Frankfort Mandibular Incisor Angle (FMIA)

In our study, the mean value was 97.01 while in Caucasian, it was 91.04. The mean difference was -7.91 which was statistically significant ($P \le 0.001$).

Degree of Maxillary Incisor Protrusion

In our study, the mean value was 27.86 while in Caucasian, it was 28. The mean difference was -0.137 which was statistically insignificant (P = 0.835).

Linear Measurement for Lower Incisor Protrusion

In our study, the mean value was 3.60 mm while in Caucasian, it was 2.7 mm. The mean difference was 0.91 which was statistically significant ($P \le 0.001$).

Angular Measurement for Lower Incisor Protrusion

In our study, the mean value was 27.40 while in Caucasian, it was 22. The mean difference was 5.40 which was statistically significant ($P \le 0.001$).

DISCUSSION

In a country like India, where the intra-country variation in the population is found to a great extent morphogenetically as well as linguistically, developing a specific normative standard for the entire population can be erroneous in nature.^[3]

Hard tissue comparative analysis such as Burstone analysis^[4] and Steiner analysis^[5] has been performed by many authors. In our study, we used Downs analysis for analyzing hard tissues of the Maharashtrian group.

The mean value for Indian adults was not similar in most of the measurable parameters when compared to the means of downs norms. Cephalometric studies on Indian adult ethnic group indicate there were some measurable skeletal and dental differences when compared to the Caucasian population. Facial angle, interincisal angle, FMIA, and lower incisor protrusion showed more variation compared to other variables. Indian adults showed a more convex profile when compared with Caucasians. The interincisal angle was more acute in Indians than in Caucasians, which revealed that Indians have more proclined teeth when compared with Caucasians. FMIA was greater which indicated that the degree of lower incisor in

Comparison of	boys versus Caucasian						
Parameter	Number of samples	Mean	SD	Downs value	Mean difference	t-value	P-value
FH-NPo (°)	50	86.34	2.72	87.8	-1.41	-3.74	0.001
NA-Apo (°)	50	4.32	13.21	0.0	4.32	2.29	0.026
AB-NA (°)	50	-4.20	3.29	-4.6	0.39	0.842	0.404
FMA (°)	50	22.51	5.37	21.9	0.61	0.803	0.426
Y-axis	50	62.42	10.21	59.4	3.02	2.072	0.044
SN-NPog	50	83.76	7.07	82	1.76	1.743	0.088
OP-FH (°)	50	8.58	3.04	9.3	-0.71	-1.645	0.107
U1-L1 (°)	50	123.43	18.11	135.4	-11.96	-4.625	0.001
L1-OP (°)	50	64.74	11.90	104.5	-39.75	-23.375	0.001
IMPA (°)	50	96.89	15.04	91.4	5.49	2.557	0.014
U1-Apo (mm)	50	8.63	14.39	2.7	5.93	2.885	0.006
L1-FH (°)	50	59.11	8.22	65.7	-6.58	-5.599	0.001
U1-Apo (°)	50	27.17	6.55	28	-0.82	-0.883	0.382
L1-Apo (mm)	50	3.55	1.91	2.7	0.85	3.137	0.003
L1-Apo (°)	50	26.43	4.84	22	4.43	6.408	0.001

SD: Standard deviation

Comparison of	girls versus Caucasian						
Parameter	Number of samples	Mean	SD	Downs value	Mean difference	t-value	<i>P</i> -value
FH-NPo (°)	50	87.04	3	87.8	-0.75	-1.7	0.082
NA-Apo (°)	50	5.12	15.46	0.0	5.12	2.35	0.023
AB-NA (°)	50	-4.3	3.88	-4.6	-0.75	-1.7	0.082
FMA (°)	50	22.30	5.21	21.9	0.46	0.54	0.58
Y-axis	50	57.57	9.94	59.4	-1.83	-1.30	0.199
SN-NPog	50	78.44	14.86	82	-3.55	-1.69	0.097
OP-FH (°)	50	10.69	11.70	9.3	1.39	0.84	0.403
U1-L1 (°)	50	120.30	20.66	135.4	-15.10	-5.16	0.001
L1-OP (°)	50	67.25	9.90	104.5	-37.24	-26.58	0.001
IMPA (°)	50	97.14	13.82	91.4	5.74	2.93	0.005
U1-Apo (mm)	50	8.68	14.38	2.7	5.98	2.94	0.005
L1-FH (°)	50	56.47	9.91	65.7	-9.22	-6.57	0.001
U1-Apo (°)	50	28.53	6.53	28	0.538	0.58	0.563
L1-Apo (mm)	50	3.65	4.01	2.7	0.95	1.68	0.098
L1-Apo (°)	50	28.34	6.04	22	6.34	7.42	0.001

SD: Standard deviation

Comparison of	all subjects versus Cauca	sian					
Parameter	Number of samples	Mean	SD	Downs value	Mean difference	t-value	P-value
FH-NPo (°)	100	86.69	2.87	87.8	-1.10	-3.811	0.001
NA-Apo (°)	100	4.72	14.29	0.0	4.72	3.290	0.001
AB-NA (°)	100	-4.26	3.58	-4.6	0.33	0.933	0.353
FMA (°)	100	22.40	5.26	21.9	0.50	0.962	0.338
Y axis	100	59.97	10.31	59.4	0.57	0.551	0.583
SN-NPog	100	81.07	11.92	82	-0.92	-0.769	0.444
OP-FH (°)	100	9.65	8.61	9.3	0.35	0.407	0.685
U1-L1 (°)	100	121.8	19.40	135.4	-13.54	-6.947	0.001
L1-OP (°)	100	66.01	10.95	104.5	-38.48	-34.94	0.001
IMPA (°)	100	97.01	14.36	91.4	5.61	3.891	0.001
U1-Apo (mm)	100	8.65	14.31	2.7	5.95	4.140	0.001
L1-FH (°)	100	57.78	9.17	65.7	-7.91	-8.588	0.001
U1-Apo (°)	100	27.86	6.54	28	-0.137	-0.209	0.835
L1-Apo (mm)	100	3.60	3.13	2.7	0.91	2.87	0.005
L1-Apo (°)	100	27.40	5.54	22	5.40	9.699	0.001

SD: Standard deviation

relation to basal bone was more in Indians and L_1 -APog was also greater which revealed that lower incisors where more protruded when compared with Caucasian population.^[1]

Even there were some measurable changes with the neighboring country like Bangladesh. The angle of convexity was straight when compared to Downs. The mandibular plane angle was increased when compared with Downs, which was decreased.^[6]

The study done in Korea by Douglas Bowman and Lewis Klapper revealed that the profile was more convex, the interincisal angle was increased in relation to the Caucasian population while mandibular plane angle was same as that of Caucasians.^[7]

Cephalometric evaluation of Mexican Americans done by Carlos J. Garcia using Downs and Steiner analysis showed increased facial convexity with protruded upper and lower incisors, and the interincisal angle was also decreased which stated that the incisors were proclined in relation to the Caucasian population. Thus, their results were comparable to our study.^[8]

SUMMARY AND CONCLUSION

According to Downs analysis carried out in this study, Maharashtrian adults had a more convex profile.

Dentally having protruded upper and lower anterior teeth with proclined upper and lower incisors and increased FMIA which indicated that the degree of lower incisor in relation to basal bone was more in Indians when compared with Caucasian.

It is legitimate and important for those undertaking orthodontic treatment for patients of the Maharashtrian population to use cephalometric norms for the Maharashtrian population.

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Accidental Blunt Abdominal Injury Causing Multiple Small Bowel Loops' Avulsion from the **Mesentery and Dismembered Colon**

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Abstract

A 50-year-old male, truck driver, met with an accident with blunt steering wheel injury to the abdomen with no external marks of injury over the abdominal wall. He had severe abdominal pain with tossing up in bed. As the abdomen showed no external marks of injuries, strikingly, abdominal palpatory findings were prominent with severe tenderness in the left side umbilical and pelvic regions. He had consumed heavy food with liquids within an hour before the accident. He collided with another stationary lorry; thus, he received massive blow to his abdomen with the steering wheel. He displayed the signs of hemorrhagic shock on arrival to the emergency care. Computed tomography scan confirmed moderate hemoperitoneum with multiple bowel perforations. On exploratory laparotomy, multiple jejunal and ileal loops were found completely avulsed from the base of the mesentery, making them completely devascularized along with dismembered descending colon from the sigmoid. Resection of nonviable small bowels and end-to-end jejunoileal anastomosis was done. Colocolic anastomosis was performed after adequate descending colon mobilization with protective loop ileostomy in the right lower quadrant. The patient had developed wound infection; hence, he was put on daily dressing. Gradually, the patient improved and was discharged with functioning ileostomy.

Key words: Avulsed bowels, Blunt abdominal injury, Deceleration and compressive force, Devascularized small bowel loop, Dismembered colon, Mesenteric base avulsion of small bowels, Resection and anastomosis, Traumatic bowel injury

INTRODUCTION

In 2020, 8.4 million people will die every year from injury, and injuries from road traffic accidents will be the third most common cause of disability worldwide and the second most common cause in the developing world.^[1] The reported incidence of bowel and mesenteric injuries after blunt abdominal trauma is approximately 1.3%.[2] It was observed that the proximal jejunum and distal ileum were more prone to perforation in such injuries.^[3] Devascularization is more common in small bowel than in large bowel.^[4] Accidental blunt abdominal trauma with steering wheel may cause extensive intra-abdominal hemorrhage with or without small bowel perforations. The

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A 50-year-old male, truck driver, met with an accident while driving, as he collided with another truck on the highway. He was brought to the emergency room with severe abdominal pain and hypotension. He got severe thrust to his abdomen with the steering wheel of the truck, and as per history, in his words, he had heavy food within an hour before the accident. On examination, he was restless but conscious. He did not

severity of such injury depends on the velocity of impact

and usage of safety aids such as wearing seat belts and

deployment of air bags. Underlying bowel perforations

and hemoperitoneum may obscure their manifestation

when presented early, particularly with no apparent

abdominal injury marks, but careful general and regional

examinations point out impending doom. Inadequacy of

surgical diagnosis and proper management affect morbidity

and mortality. Thus, early recognition, resuscitation, and

prompt surgical treatment appear to be within the capability

of surgeons, [5] which, in turn, improves the outcome.

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Figure 1: Devascularized small bowel loop due to avulsion from mesenteric supply



Figure 2: Colocolic anastomosis

show any signs and symptoms of head injury. His vitals were showing that he was in hypotensive shock (Temperature 96 degree Fahrenheit (units), pulse: 110, BP: 90/60 mmHg). However, his abdomen did not show up any external marks of injuries. Per abdominal palpatory findings showed tenderness in the left side umbilical and hypogastric regions. The patient was resuscitated and made hemodynamically stable with inotropic support and blood transfusions 2 units. Computed tomography (CT) scan of the abdomen with contrast study showed moderate hemoperitoneum with multiple jejunal perforations. No solid organ injuries were found; hence, he was taken for emergency exploratory laparotomy. Intraoperative, gross hemoperitoneum (>1 L) with multiple jejunal and ileal loops were entirely avulsed from the base of mesentery along with intervening normal loops along the entire length of the small bowel [Figure 1]. The descending colon was completely dismembered from the sigmoid, and the later was lying free into the pelvis. Bowel decompression and thorough peritoneal lavage were done. It was impossible to salvage the devascularized bowel loops; hence, the resection of jejunal and ileal loops of about 4 feet was done and end-to-end jejunoileal anastomosis was performed. The descending colon was anastomosed with sigmoid after adequate mobilization of the colon [Figure 2] and protective loop ileostomy created in the right lower quadrant. The patient had developed surgical site infection which was dealt with the appropriate usage of antibiotics and daily dressings. The patient was discharged in stable hemodynamic condition with functioning ileostomy.

DISCUSSION

Injury to the intra-abdominal structures can be classified into two primary mechanisms of injury - compression forces and deceleration forces. [6] Compression forces may result from direct blows or compression. These forces may deform hollow organs and transiently increase intraluminal pressure, resulting in rupture. Deceleration forces cause stretching and linear shearing between relatively fixed and free objects. In this case, few loops showed complete avulsion from the mesenteric blood supply causing them devascularized. Similarly, the junction of descending and sigmoid received the same forces and displayed complete sheared and dismembered sigmoid colon. The high mortality rates reflect the severity of the high-velocity impact and associated injuries. Such patients should be carefully monitored for related injuries and complications, [7] as early resuscitative measures and timely surgical management could reduce morbidity and mortality.

CONCLUSION

Detection of bowel and mesenteric injury can be challenging in patients after blunt abdominal trauma. Early diagnosis and treatment are critical to decrease patient morbidity and mortality. CT has become the primary modality for the imaging of these patients. [8] "Golden hour" concept is crucial in managing this case. Patient life was salvaged with a multidisciplinary approach with active involvement of other allied branch consultants.

Resection of a significant length of the small intestine may severely affect protein absorption which, in turn, reflects in poor collagen content at healing site and scar tissue^[9,10] and diminishes the quality of healing.^[11] High-protein diet and vitamin supplements are essential for a healthy later life.^[12,13]

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Case Report

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Hoffa Fracture of Medial Femoral Condyle in a 9-Year-Old Child: A Case Report

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Abstract

Hoffa fractures are intra-articular fractures of the distal femoral condyles in coronal plane. These fractures may be of either condyle but lateral condyle is most commonly affected and medial condyle is extremely rare. Non-operative treatment of unicondylar femur fractures, including Hoffa fractures, yields poor result. We present a case of 9-year-old child with Hoffa fracture of medial femoral condyle with understanding of the mechanism of injury and its further management. He had history of fall from height of about 5 feet on his right knee which was in flexed position at around 90°. X-ray of knee showed fracture of medial femoral condyle in coronal plane. Three-dimensional (3D) reconstruction of computed tomography (CT) scan confirmed the coronal fracture of medial femoral condyle and was classified as Type 33 B3 according to orthopedic trauma association classification and Type 1 as per Letenneur classification. Open reduction and internal fixation were performed with partially threaded cancellous screws. The fixation of coronal fracture of medial femoral condyle done through cancellous screws in anterior to posterior direction was adequate in giving stable fixation and aided in union without disturbing the physis of the child. At 1 year, the child could do full extension and 130° flexion. There was no posterior or varus, valgus instability of the knee. We believe that a medial condyle Hoffa fracture is extremely rare in children, and the diagnosis can be missed. ORIF using partially threaded cancellous screws in the epiphysis provides stable fixation and can lead to a good functional outcome in the long term. The mechanism of injury in this fracture pattern was found to be direct impact on the knee in flexed position of 90°.

Key words: Cancellous screw fixation, Fixation, Hoffa fracture, Mechanism of injury, Medial condyle, Type 23B-3

INTRODUCTION

Hoffa first described this fracture in 1904.^[1] These are intra-articular fractures of the distal femoral condyles in coronal plane. This injury is classified as a Type 33-B3 fracture by the orthopedic trauma association (OTA)/Arbeitsgemeinschaft für osteosynthesefragen (AO) classification. The Hoffa fracture may be of either condyle but lateral condyle is most commonly affected and medial condyle is extremely rare in occurrence, which has been presented twice in literature.^[2,3]

To the best of our knowledge, the Hoffa fracture of medial condyle in skeletally immature patient has been described

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only once in literature.^[3] The mechanism of injury of this type of fracture is not well understood.

We present a case of 9-year-old child with Hoffa fracture of medial femoral condyle with understanding of the mechanism of injury and the principles of management.

CASE REPORT

A 9-year-old child came with a history of fall from height of about 5 feet after which a brick fell on his right knee flexed at around 90°. The patient experienced severe sudden onset pain in the right knee and was unable to stand and bear weight. There were tenderness and swelling of right knee, and bony crepitus was felt on movement. The limb was immobilized in a long leg slab and elevated. The radiographs of knee in anteroposterior and lateral view were taken which showed fracture of medial femoral condyle in coronal plane [Figure 2]. A CT scan with 3D reconstruction was advised which revealed a coronal fracture of medial femoral condyle [Figures 1-3]. The fracture was classified as Type 3 Salter

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and Harris classification, Type 33-B3 according to OTA classification, and Type 1 as per Letenneur classification. [2] The patient was treated with open reduction and internal fixation with two cancellous-cannulated screws. In supine position under general anesthesia and tourniquet application, the knee was approached with medial parapatellar incision and fragment reduced and held with two guide wires over which cannulated drill holes were made, and two 4 mm cancellous screws were passed over them in anterior to posterior direction without crossing the physeal plate and screws were countersunk. Guide wires were removed and the integrity of the fracture checked [Figure 4]. A negative suction drain applied and wound was closed in layers. On post-operative day 1, static quadriceps exercise was started. On day 2, drain was removed. The patient was further seen at 2 weeks for suture removal, and above knee cast was applied. Further, radiological evaluation was done at 6 weeks post-operative. Partial weight bearing was delayed till radiological signs of union were seen at 10 weeks [Figures 5 and 6]. Moreover, full weight bearing allowed when union was visible at fracture site at 14 weeks [Figures 7 and 8]. Lewis et al. recommended



Figure 1: Axial CT with Hoffa's fracture

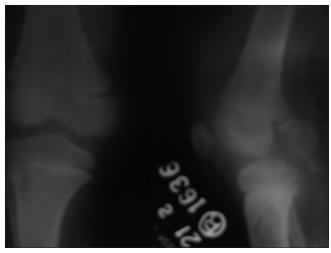


Figure 2: Pre-op Xray

plaster immobilization in full extension for 6 weeks^[4] because in such a position, the posterior joint capsule is tightened to provide splintage to the condylar fragment, and any axial loading can be borne by the anterior portion of the condyles. The patient was regularly followed up at monthly when he complained of pain in terminal flexion, and therefore, at 6 months of follow-up, the screws were removed through medial parapatellar approach. On Operation table (OT) table, the flexion was seen to be 120°. The mobilization of the knee was further started next post-operative day after removal of the screws.

At the final follow-up of 24 months, the patient had 120° flexion, complete extension without a lag, no varus/valgus instability, and no limb length discrepancy. X-rays showed no signs of osteoarthritis, avascular necrosis, or physeal bar formation. The patient is pain free and can carry out his daily sporting activities at school.

The fixation of coronal fracture of medial femoral condyle done through cancellous screws in anterior to



Figure 3: Saggital CT with Hoffa's fracture



Figure 4: Post-op Xray



Figure 5: Post-op Xray AP



Figure 6: Post-op Xray lateral

posterior direction was adequate in giving stable fixation and aided in union without disturbing the physis of the child. The patient complained of pain in terminal flexion, and therefore, at 6 months of follow-up, the screws were removed through medial parapatellar approach. On operating table, the flexion was seen to be 120°. The mobilization of the knee was further started next post-operative day after removal of the screws. The final range of movements achieved at 2 years documented to be flexion 130°, full extension, no varus valgus instability, and negative anterior and post-drawer test. The patient has joined his school and can run and play well. The pain on 1–10 scales was noted to be 1 and subsided with rest. There was no limb length discrepancy observed at the final follow-up.

DISCUSSION

Hoffa fracture is a fracture of posterior femoral condyle in coronal plane. These are rare injuries, with lateral



Figure 7: Complete extension clinical picture



Figure 8: Complete flexion

condyle more commonly involved than medial. These fractures are even rarer in children. They were classified according to the AO/OTA classification as Type 33-B3. Letenneur et al.^[2] classified it into 3 types as Type I is a vertical fracture involving the entire condyle parallel to the posterior cortex of the femur, Type II is a fracture of variable size, horizontal to the base of the condyle, and Type III is a fracture oblique to the femur. They reported the best results with internal fixation and the poorest results in Type III. Because of physiological valgum, lateral condyle is more likely to sustain a direct shearing force and is more likely to fracture. [6] A medial condyle Hoffa fracture is extremely rare in children, and the diagnosis can be missed. The mechanism of injury of these types of fracture is still not properly understood. Lewis et al.[4] suggested that direct impact, leading to an axial loading force to the femoral condyle, with the knee in 90° or more of flexion and possibly with an element of abduction, results in a typical Hoffa fracture. Some investigators have postulated direct impact with the knee in a flexed position as the mechanism of injury while others have attributed the fracture to simultaneous vertical shear and twisting forces.^[5,6]

These fractures are difficult to diagnose, clinically it may suggest a lower femoral fracture, but interpretation of radiographs can be difficult in minimally displaced fracture as the anterior part of the condyle is intact, and therefore, it needs 3D reconstruction of CT scan evaluation. [7] These fractures are notorious for displacement if treated conservatively and can lead to long-term social and economic consequences of malunion, non-union, and degenerative changes in the joint. Internal fixation using partially threaded cancellous screws in the epiphysis provides stable fixation and can lead to a good functional outcome in the long term and decrease the risk of these complications. A minimum of two screws is mandatory to provide rotational stability.[8] Insertion of screws through the articular cartilage is necessary to achieve the lag effect. The screws should be placed as far laterally as possible with their heads countersunk to avoid damage to the

opposing articular cartilage. [8] The mechanism of injury in this fracture pattern was found to be direct impact on the knee in flexed position of 90°.

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Retrocaval Ureter with Proximal Hydroureteronephrosis Presenting as Flank Pain in a Child: A Rare Case Report with Review of Literature

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Abstract

Retrocaval ureter also referred to as pre-ureteral vena cava or circumcaval ureter is a rare congenital anomaly with the ureter passing posterior to the inferior vena cava. Although it is a congenital anomaly, patients do not normally present with symptoms until the 3rd and 4th decades of life after a resulting hydronephrosis. We present the report of a 12-year-old male child with a history of right flank pain and associated right proximal hydroureteronephrosis. Diagnosis was confirmed with computerized tomography urography, and an open surgical repair was done for the anomaly. The case is discussed here along with review of recent literature.

Key words: Circumcaval ureter, Flank pain, Hydroureteronephrosis, Pre-ureteral vena cava retrocaval ureter

INTRODUCTION

Retrocaval ureter, also called circumcaval ureter or pre-ureteral vena cava, is a rare congenital anomaly in which ureter deviates medially passing behind the inferior vena cava (IVC) and winding around it before crossing anteriorly and laterally to resume its normal course distally. The condition usually becomes symptomatic in the 3rd or 4th decade of life due to hydronephrosis from kinking of the ureter, compression, or aperistaltic retrocaval segment. Most patients present with right flank pain, recurrent urinary tract infection (UTI), renal stones, and hydronephrosis. It is also one of the causes of pelviureteric junction obstruction. Retrocaval ureter may be asymptomatic and discovered during imaging or surgery for

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unrelated pathology or at autopsy. Repair usually involves resection of the redundant retrocaval ureteral segment and reanastomosis.^[3] The surgical approach for this entity has shifted from open to laparoscopic and robotic surgery [Table 1].

CASE REPORT

A 12-year-old boy presented with right flank pain for 8 months, and the pain was dull and intermittent. There was no other history related to urinary tract symptoms such as hematuria, burning micturition, and retention. No abnormality was found on general and abdominal physical examination. Complete laboratory evaluation including urinalysis, complete blood picture, urea, creatinine, and electrolytes was within normal limits. On ultrasonography (USG), moderate hydronephrosis and upper hydroureter were found. Contrast computerized tomography (CT) urography of the abdomen revealed hydronephrosis and dilatation of the right proximal ureter up to the level of L3. The ureter was found to be coursing medially posterior to the IVC, at this level with

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Tabl	Table 1: Published reports of operative repair of	orts of op	erative		retrocaval ureter	ureter						
S. No.	. Study	Period	No. of patient	Median age of Male/ diagnosis femal	: Male/ female	Presentation	Diagnostic investigation	Type of retrocaval ureter	Treatment approach	Operation	DJ remove	Follow
_	Fernendo <i>et al.</i> ^[20] 2018	3 2018	-	14 years	Male	Incidental diagnosed during UDT evaluation	USG then IVP	Type I	Open, flank incision retroperitoneal approach	DJ stent ureteroenteric anastomosis	1	12-week DTPA scan
7	Agarwal <i>et al.</i> ^[21] 2018	2018	~	33 years	Female	Flank pain	USG then IVP	Type I		Ureteroureterostomy		6 months
က	Tamhankar <i>et al.</i> ^[22] 2017	2013–2016	9	29.6 years (14–50 years)	All male	Flank pain	USG CE CT RCU, DTPA scan	Type I	Laparoscopic Ureterou transperitoneal DJ stent	Ureteroureterostomy DJ stent	6 weeks	1 year
4	Rehan <i>et al.</i> ^[23] 2017	2017	~	31 years	Female	Flank pain	USG DJ stenting CT, DTPA scan	Type I	Open subcostal incision	_	6 weeks	6-month DTPA
ro	Ahmed <i>et al.</i> ^[24] 2017	2010–2017	4	31.8 years (9-48 years)	2+2	Flank pain, hematuria-3 Incidental for APD	USG then IVP MRI	Type I	Open subcostal incion-3 One	Pyeloureterostomy, ureteroureterostomy		
9	Shah <i>et al.</i> [25] 2016	2016	_	19 years	Male	Flank pain	USG, IVP, CT		Open	Pyeloureterostomy	6 weeks	2 months
7	Bhattacharjee <i>et al.</i> ^[26] 2016	2016	-	40 years	Male	urograpny Cyclic abdominal USG, IVP, CT pain urography	urography I USG, IVP, CT urography	Type I	laparotomy Laparoscopic, transperitoneal	with DJ stenting Ureteroenteric anastomosis with DJ stent	6 weeks	ı
∞	Pradnaybendre <i>et al.</i> ⊵≀≀ 2016	2016	~	5 years	Male	Flank pain	USG, DTPA, CT IVP		Open, right transverse incision	Ureteroenteric anastomosis with DJ stent	6 weeks	3 months
O	Tuncer <i>et al.</i> ^[28] 2016	2013–2016	en	17.66 (13–24 years)	Male-2 Female-1	Lumber pain, hematuria	USG, IVP	Type I	Open, flank incision	Ureteroenteric anastomosis with DJ stent	6 weeks	3-month IVP
10	Fidalgo <i>et al</i> . ^[29] 2016	2016	~	40 years	Male	Flank pain	USG, CT, MAG 3 scan		Laparoscopic transperitoneal	Pyeloureterostomy	6 weeks	3 months
7	Deepak Pankaj <i>et al.</i> ^[30] 2015	2015	~	27 years	Female	Right flank pain, burning micturition	USG, IVP then CT		Open lumber abdominal approach	Ureteroenteric anastomosis with DJ stent	6 weeks	
12	Pradeep Kajal <i>et al</i> . ^[31] 2015	2015	~	6 years	Female	Right flank pain	USG, IVP, DTPA then CT		Open loin incision	Pyeloureteric anastomosis with DJ stent	3 weeks	
13	Ricciardulli e <i>t al.</i> ^[32] 2015	2002–2013	27	28 years (21–39 years)	20+7	Flank pain-10, haematuria-7, UTI-6 Asympt 4	USG, IVP then CT	Type I	Laparoscopic retroperitoneal	Ureteroureterostomy with DJ stent	4–6 weeks	12 months
4	Kamble <i>et al</i> . ^[33] 2014	2014	~	30 years	Male	<u> </u>	USG, IVP	Type	Open lumber incision	Ureteroenteric anastomosis with DJ stent	4 weeks	
72	Vs <i>et al</i> . ^[34] 2014	2014	-	45 years	Female	Right flank pain, dysuria	USG, IVP	Type I	Open loin incision retroperitoneal approach	Ureteroenteric anastomosis with DJ stent	6 weeks	

Table	Table 1: (Continued)											
S. No	S. No. Study	Period	No. of patient	Median age of Male/ diagnosis femal	f Male/ female	Presentation	Diagnostic investigation	Type of retrocaval ureter	Treatment approach	Operation	DJ remove Follow up	Follow
91	Bassiouny <i>et al.</i> ^[15] 2013	2012	2	Newborn	++	Antenatally detected hydronephrosis	USG, MCU, CT	Type I Type II	Open right subcostal approach conservative	Ureterourostomy		
17	Nayak <i>et al.</i> [35] 2012	2006–2009	c)	27.8 years	4+1		IVU, CT, MRI		Robotic transperitoneal	Robotic Ureteroureterostomy-3, transperitoneal pyelopylostomy 2	6 weeks	12.5 months
8	Kye <i>et al.</i> ^[9] 2010		7	38 years (36,40 years)	++	Flank pain	USG, retrograde Type II pyeloureterogram, CT	Type II	Open midline approach	Pyeloureterostomy with DJ stent	5 weeks	
6	Yarmohammadi <i>et al.</i> ^[10] 2006	1983–2005	73	23 years (12–27 years)	12+1	Pyelonephritis-7, IVU and flank pain-4, retrograc calcula-1, pyelogra hematuria-1	de phy	Type I	Open subcostal retroperitoneal approach	Ureteroureterostomy	0 >	6 months with IVP
20	Iqba and Ansari [®] 2006	2006	-	35 years	Male	Flank pain	USG, IVP, CT		Open subcostal retroperitoneal approach	Ureteroureterostomy	(y >	6 months with IVP
CT: Con	ηρυτεrized tomography, MRI: Ι	Magnetic resona	ance imagin	ng, USG: Ultrasonog	raphy, IVP: In	itravenous pyelogram,	DTPA: Diethylenetriam	ninepentaacetic	acid, MAG 3: Merca	CT: Computerized tomography, MRI: Magnetic resonance imaging, USG: Ultrasonography, IVP: Intravenous pyelogram, DTPA: Diethylenetriaminepentaacetic acid, MAG 3: Mercaptoacetyltriglycine, UDT: Undescended testis,	lescended testis	

normal caliber distal to it. Findings were consistent with retrocaval ureter [Figure 1].

Right kidney and ureter were approached by midline vertical incision and medial mobilization of ascending colon done. On exploration, right proximal ureter and pelvis were dilated. Dilated proximal ureter was curved medially then posterior to IVC. Finally, curved anterolaterally to IVC and took a downward course [Figure 2]. Distal ureter was normal. Ureter was dissected and separated anteriorly from IVC and transected at U curved site of ureter. Ureter was anteriorized, spatulated, and an oblique ureteroureteral anastomosis was performed over DJ stent using 5/0 Vicryl [Figure 3]. The patient recovered uneventfully. The patient was allowed orally on post-operative day, catheter remove on post-operative day 2 and was discharged on post-operative day 5. DJ stent [Figure 4] was removed after 3 weeks. An USG done 3 months after surgery showed regression of hydronephrosis and hydroureter.

DISCUSSION

MCU: Micturating Cystourethrogram

Retrocaval ureter is a rare congenital abnormality. It occurs in 1 in 1500 live births at autopsy, [4] with an overall incidence of about 0.006–0.17%. [5-7] It was first reported by Hochstetter in 1893. [6] It is more common in males, with a male-to-female ratio between 3 and 4:1. [8] In clinical practice, reported cases have also shown male preponderance [Table 1]. [5,9,10]

The anomaly is thought to occur because of the abnormal formation of infrarenal IVC from anteriorly located subcardinal instead of supracardinal veins which are located posteriorly.^[2] In normal circumstances, the infrarenal IVC originates from dorsally located supracardinal vein, but when it develops from ventrally located subcardinal vein, the ureter is trapped posteriorly leading to pre-ureteral vena cava.^[2] It mainly occurs on the right side but can be on the left side in patients with the very rare situs inversus, duplication of IVC, or persistent left subcardinal vein.^[11,12]

Associated anomalies with retrocaval ureter are reportedly up to 21% and are mainly related to the cardiovascular and urogenital systems (including duplication of IVC, situs inversus, horseshoe kidney, ureteral duplication ureteropelvic junction obstruction, congenital lack of the vas deferens, hypospadias, extra vertebra, diverticulum, anterior urethral calculus, kidney agenesis, syndactyly, intestinal malrotation, and Goldenhar syndrome). [10-12] None of these anomalies was seen in our patients.

Although it is congenital in origin, most of the reported cases presented in the 3rd or 4th decade because of the



Figure 1: Pre-operative #D reconstructive image of computerized tomography urography reveals right retrocaval ureter with proximal dilated pelvis and proximal ureter

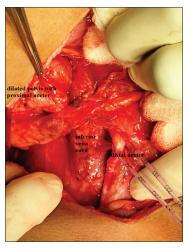


Figure 2: Intraoperative pic of retrocaval ureter with dilated pelvis and proximal ureter, vena cava, and distal ureter

gradual nature of the hydronephrosis. However, symptoms can occur earlier^[13,14] as in our case in which symptoms manifested at 12 years of age and also reported in neonatal period.^[15] Patients usually complain of right-sided flank pain and features of recurrent UTI, which typify the mode of presentation. In some cases, hematuria and renal stone may also be present. However, it should be noted that some cases remain asymptomatic and are only incidentally discovered during evaluation for unrelated disease conditions.

Bateson and Atkinson classified retrocaval ureter into two types based on radiological appearance and the site of narrowing of ureter in 1969. [11] Type I has the typical S-shaped, "fish hook," or "Shepherd crook" deformity and associated with extreme medial deviation in 50% of the cases at the level of third lumbar vertebral segment and moderate-to-severe hydronephrosis. This type accounts for

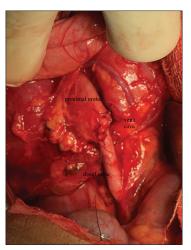


Figure 3: Operative picture of retrocaval ureter after correction as ureteroenteric anastomosis



Figure 4: Post-operative kidney, ureter and bladder X-ray with DJ stent

most of the symptomatic cases. Type II is associated with a more gentle curve appearing as J-shaped or "sickle"-shaped deformity with mild medial deviation at the level of renal pelvis, with mild or no hydronephrosis in 10% of the cases and most are asymptomatic.^[1]

Abdominal ultrasound can at best demonstrate the presence of hydronephrosis since it poorly delineates the ureter, while IVU readily demonstrates hydroureteronephrosis with upward curving and abrupt termination of the ureter and non-visualization of the middle and distal thirds of the ureter. Spiral CT is considered the investigation of choice compared to IVU because it can delineate both the ureter and IVC [Table 1]. Magnetic resonance imaging may be better than the CT as it can delineate the course of the entire ureter and is not associated with exposure to radiation as compared to IVU or CT.^[16] The diagnosis of retrocaval ureter can be confirmed pre-operatively with antegrade or retrograde pyelography. Diuretic

renography with diethylenetriaminepentaacetic acid or mercaptoacetyltriglycine can assess the level of obstruction and determine the best therapeutic modality [Table 1].^[13]

Asymptomatic patients and those with mild hydronephrosis and infection can be managed non-operatively and followed up subsequently, while surgical treatment is required in symptomatic patients or those with severe hydronephrosis. Treatment can be by open or laparoscopic approach. [17] The first successful surgical correction was reported by Kimbrough in 1935. [18] The procedure essentially involves division of the ureter with or without excision of the narrowed or aperistaltic segment, anteriorization, ureteroureterostomy, or dismembered pyeloplasty over a stent. Laparoscopic/robotic approach through transperitoneal or retroperitoneal route^[19] is less invasive and associated with less morbidity, less post-operative pain, early recovery, short hospital stay, and cosmetically acceptable scar [Table 1]. [19]

CONCLUSIONS

Retrocaval ureter is a congenital anomaly presenting clinically late, in the 3rd and 4th decades of life, and it is rarely noticed and presented in pediatric age groups (1st and 2nd decades of life). So treating clinician also keep suspicious of retrocaval ureter as differential diagnosis in child presented with flank pain with proximal hydroureteronephrosis. Imaging studies are sufficient for making an accurate diagnosis of a retrocaval ureter. Treatment is surgical, which allows for correction of the anomaly, with resolution of symptoms. Although retrocaval ureter can manage by minimally invasive surgery but it is emerging.

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