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Original Article

Rhinosporidiosis – A Clinical Survey

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Abstract

Background: Rhinosporidiosis is a chronic inflammatory granulomatous disease caused by the organism *Rhinosporidium seeberi*. This causal organism was once believed to be a sporozoan, but is now considered to be a fungus. The disease is present all over the world except in Australia. However, it is endemic only in India and Sri Lanka; more than 95% of reported cases are from these two countries. The most common site of manifestation of rhinosporidiosis in man is the nose accounting for about 70% of cases. Surgical excision remains the mainstay of treatment today even though dapsone and ketoconazole have been tried to some extent in preventing recurrence after surgery.

Aim of the Study: The aim of the study was to study the prevalence, distribution, clinical behavior, results of various forms of treatment and to provide a baseline clinical data and to supplement information for ongoing studies in the field of rhinosporidiosis.

Materials and Methods: A total of 20 patients diagnosed as rhinosporidiosis, who attended the ENT Outpatient Department of Medical College Hospital, Calicut, during the period from December 1998 to November 1999. Detailed history was recorded and patients were subjected to thorough otolaryngological examination. Special attention was given to the site of lesions and type of attachment. Details were also collected with particular reference to bathing habits, occupation, contact with animals, and occurrence of similar illness in the family or in the neighborhood. Investigations included regular blood and urine and blood grouping. All the patients underwent surgical excision of the lesions. The diagnosis was confirmed by histopathological examination of specimen obtained postoperatively. 100 mg of dapsone was administered daily (50 mg daily in children), 6 days a week, for a period of 6 months. All patients were reviewed for follow-up at the end of 1 month, 2, 4, and 6 and 9 months and on completion of a year after surgery.

Observations and Results: In this study, the average age of patients suffering from rhinosporidiosis was 30.6 ± 2.80 years and the age varied between 8 and 52 years. The sex incidence was as follows: Males 17 (85%), females 3 (15%). Male predominance was seen in this series and the male to female ratio was 5.66:1. Most of the subjects suffering from rhinosporidiosis were manual laborers 7 (35%) out of 20, of which 2 (10%) were agricultural workers. The other major group was students accounting for 5 (25%) out of 20 cases. The external appearance of the nose was normal in all patients. Partial nasal obstruction was seen in 13 cases (65%), on the left six, on the right five, and bilateral two cases. The total obstruction was seen in 5 cases (25%) – left two, right two, and bilateral one. Both nasal cavities were patent in only two cases. The vestibule showed the presence of mass in four cases (20%).

Conclusions: Rhinosporidiosis is not an uncommon disease encountered in day-to-day ENT practice. The occurrence of the disease does not bear any relation to the occupation of the patient. The maximum incidence of rhinosporidiosis is seen in the age group of 21–30 years and males predominate. Rhinosporidiosis is more common in the rural population. There is a significant association between dip baths in ponds and the occurrence of disease.

Key words: Rhinosporidiosis, Spores, Nasal polyp, Dapsone

INTRODUCTION

In 1896, Guillermo Seeber in Buenos Aires examined a nasal polyp removed from an agricultural worker, a native of Italy, 19 years of age, but resident for 18 years in Argentina. O'Kinealy (1903) presented a paper on rhinosporidiosis.[1] Minchin and Fantham (1905) from O'Kinealys mounted sections gave a summary of the development sequence of the organism, which they named as Rhinosporidium Kinealy.[2] Castellani and Chalmer (1913) reported the first rhinosporidial infection from Ceylon.[3] Tirumurthi (1916) published a summary of 15 cases from Madras.[4] Ashworth (1922)[5] presented a paper on rhinosporidiosis from the material received Logan Turner, a nasal polyp removed from an Indian who

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hailed from Kerala, a student of Medicine at Edinburgh. He demonstrated that it was a fungus and not protozoa and gave an account of its life history. He also discussed and established its proper name as *Rhinosporidium Seeberi*. Karunaratne,[6] in 1934, worked out the detailed histology of the infected tissue and mentioned one case where carcinoma supervened. Cherian and Satyanarayana,[7] in 1949, published the results of surgical treatment in 72 cases. Mahadevan,[7] in 1952, reported a case of parotid salivary cyst due to rhinosporidiosis; and Kannan-Kutty and Teh[8] have shown that the organism produces hyaluronidase, the substance which helps in the spread of spores submucosally. Nair[9] from Kerala reported the efficiency of dapsone in the treatment of rhinosporidiosis. David[10] described the predisposing factors of rhinosporidiosis as: (1) Irritation of mucous membrane (by chemicals, gases, smoke, etc.), (2) trauma, (3) impairment of ciliary action, and (4) deviated nasal septum and spurs. Over 90% of patients in endemic areas give a positive history of dip baths in stagnant waters such as ponds.[7,11-13] The present study was conducted in the present scenario to study the prevalence, distribution, clinical behavior, results of various forms of treatment and to provide baseline clinical data and to supplement information for ongoing studies in the field of rhinosporidiosis.

Type of Study

This was a prospective, cross-sectional analytical study.

Institute of Study

This study was conducted at the Department of ENT, Government Medical College, Kozhikode, Kerala.

Period of Study

This study was from December 1998 to November 1999.

MATERIALS AND METHODS

The materials for this study were collected from the patients who attended the ENT Outpatient Department of Medical College Hospital, Calicut, during the period from December 1998 to November 1999. An ethical committee clearance was obtained before starting the study. AN ethical committee cleared consent form was used for this study. Twenty patients who were clinically diagnosed to be suffering from rhinosporidiosis were included and evaluated for the study.

Inclusion Criteria

1. Patients of all age groups with the diagnosis of rhinosporidiosis were included in the study
2. Patients with the previous history and treatment for rhinosporidiosis were included in the study.

Exclusion Criteria

Patients without bacteriological evidence of rhinosporidiosis were excluded from the study.

Methods

Detailed history was recorded and patients were subjected to thorough otolaryngological examination. Special attention was given to the site of lesions and type of attachment. A careful systemic examination was carried out to detect the presence of extra nasal rhinosporidiosis as well as to rule out any associated diseases. Details were also collected with particular reference to bathing habits, occupation, contact with animals, and occurrence of similar illness in the family or in the neighborhood. Investigations included regular blood and urine and blood grouping.

Treatment

All patients underwent surgical excision of the lesions. The diagnosis was confirmed by histopathological examination of specimen obtained postoperatively. 100 mg of dapsone was administered daily (50 mg daily in children), 6 days a week, for a period of 6 months.

Follow-up

All patients were reviewed for follow-up at the end of 1 month, 2, 4, and 6 and 9 months and on completion of an year after surgery. Enquiries were made regarding post-operative habits such as bathing in ponds and return to old occupation (If it is water related). Regularity of dapsone intake was confirmed and any untoward effects of it were looked for. Detailed clinical examination to detect residual or recurrent lesions was carried out.

Evaluation of Results

The evaluation of results was made keeping in mind the aims of study. Occurrence of rhinosporidiosis in relation to age, sex, occupation, and income of patients was studied. Efficacy of surgical and medical treatment was also evaluated. All the data were analyzed using standard statistical methods.

OBSERVATIONS AND RESULTS

A clinical survey study of rhinosporidiosis was undertaken. Observations were made regarding age and sex predilection, clinical presentation, and management. Age and sex distribution of patients is given in Table 1.

In this study, the average age of patients suffering from rhinosporidiosis was 30.6 ± 2.80 years and the age varied between 8 and 52 years. The sex incidence was as follows: Males 17 (85%), and females 3 (15%). Male predominance was seen in this series and the male to female ratio was 5.66:1.

Occupation

Most of the people suffering from rhinosporidiosis were manual laborers 7 (35%) out of 20, of which 2 (10%) were agricultural workers. The other major group was students accounting for 5 (25%) out of 20 cases. Some cases were also found to occur in other groups such as businessmen, semiskilled workers, fishermen, tailor, cook, and driver. Two (10%) patients in the group were unemployed. The occupation of patients is given in Table 2.

Native place of the patients was as follows: Kozhikode District 12 cases 60%, Malappuram district 8 cases 40%, 14 patients (70%) came from rural areas, and 6 (30%) from urban areas. Religion of the 20 patients was as follows:

	n (%)
Hindus	09 (45)
Muslims	11 (55)

Educational Status

None of the patients in this study were illiterate. Many of the patients were students.

Socio-Economic Status of Patients

The majority of the patients 16 out of 20 (80%) belonged to the lower socio-economic class. The remaining four patients (20%) belonged to the middle class. It is seen that all patients had nasal obstruction as the chief complaint. It was unilateral in 14 (70%) cases. The right side was affected in 6 (30%) cases and left side in 8 (40%) cases. Six cases (30%) complained of obstruction on both sides. The next common symptom was nasal mass – in 19 cases (95%). Fourteen cases (70%) complained of unilateral nasal mass; right side in 6 (30%) cases left side in 8 (40%) cases. Four cases (20%) complained of bilateral nasal masses and 1 (05%) of only post-nasal mass. In order of frequency, the next symptom was epistaxis. Eighteen cases (90%) complained of epistaxis. The details are summarized in Table 3.

Bleeding was mild to moderate in severity. No patient complained of severe bleeding. It was spontaneous in 8 (40%) of cases and traumatic in 10 (50%) of cases. Thirteen cases (65%) suffered from mouth breathing and 11 cases (55%) complained of snoring and 11 patients (55%) complained of nasal discharge. Ten patients (50%) complained of change in voice. Eight patients (40%) complained of anosmia and seven patients (35%) gave a history of headache. Epiphora was complained of by 5 (25%) of patients and it was on the side of nasal mass. No patient complained of skin swellings or ulcerations [Table 4].

Past History

Among these 20 patients, only 1 (05%) had a history of trauma to nose. Out of 20 patients, 10 cases (50%) were reported to have recurrences. They had undergone surgical procedures in the past, the number of times varying from 1 to 6. 5 out of these all were treated with dapsone but only three patients took dapsone regularly. One (05%) patient gave a history of treatment for pulmonary tuberculosis. There was no significant illness in the remaining patients. Nine (45%) patients were smokers and three patients (15%) consumed alcohol regularly. One patient (05%) was addicted to pan chewing.

Table 1: The age and sex sdistribution of patients with rhinosporidiosis (*n*=20)

Age in years	Male	Female	Total	Percentage
1–10	1	0	1	5
11–20	4	1	5	25
21–30	6	1	7	35
31–40	3	1	4	20
41–50	2	0	2	10
51–60	1	0	1	5
	17	3	20	100

Table 2: The incidence of various occupations of the subjects in the study (*n*=20)

Occupation	*n* (%)
Manual laborer	7 (Agricultural workers-2) (35)
Students	5 (25)
Others	6 (30)
Unemployed	2 (10)

Table 3: The analysis of chief symptoms in the study (*n*=20)

Symptoms	Number of cases	%
Nasal obstruction	20	100
Nasal mass	19	95
Epistaxis	18	90
Mouth breathing	13	65
Snoring	11	55
Nasal discharge	11	55
Change in voice	10	50
Anosmia	8	40
Headache	7	35
Epiphora	5	25
Dysphagia	2	10
Ear discharge	1	5
Ocular mass	0	0
Skin nodule	0	0

Table 4: The incidence of complaints in the study group (*n*=20)

Epistaxis	Number of cases	%
Anterior nasal bleeding	12	60
Post-nasal bleeding	2	10
Both anterior and postnasal	4	20
Unilateral	15	75
Bilateral	3	15

Epidemiological Data

All patients gave a history of daily bathing. Nineteen patients (95%) gave a history of dip bath in ponds. The duration of exposure varied from a few weeks to regular bathing for 26 years. In the case of 8 patients (40%), animals were bathed in the ponds in which they took bath. Three patients (15%) gave a history of similar illness in their family, six patients (30%) also gave a history of similar illness in their family, and nine patients (45%) also gave a history of similar illness in the neighborhood. All these people were sharing the same pond as that used by the patients. History of contact with domestic animals was stained only in three patients (15%).

Clinical Examination Findings

The external appearance of the nose was normal in all patients. The cold spatula test showed partial obstruction is 13 cases (65%) left six, right five, and bilateral two cases. The total obstruction was seen in five cases (25%) – left two, right two, and bilateral one. Both nasal cavities were patent in only two cases. The vestibule showed the presence of mass in 4 cases (20%) [Figure 1a-c] and was normal in the remaining cases. The nasal septum was central in 11 (55%) cases. It was deviated to the right in seven cases (35%) and to the left in two cases (10%).

Nasal Mass

The details of nasal rhinosporidial mass are given in Table 5. Out of the above masses, the sessile ones and those having multiple attachments were seen in recurrent cases.

Nasal Discharge

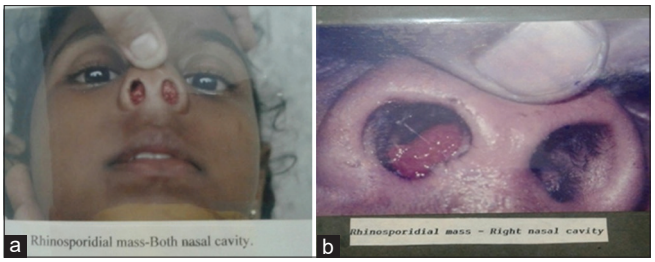
The nasal discharge was present in 11 patients (55%). Nasopharyngeal and Oropharyngeal masses: Nasopharyngeal masses were seen in 9 cases (45%). They can be divided into three types: (1) Extending from the nasal cavity without attachment to nasopharynx 5 cases (25%), (2) attached to nasopharynx three cases (15%), and (3) attached both to nose and nasopharynx one case (5%).

Oropharyngeal Masses

Oropharyngeal masses were seen in three cases (15%). They were of two types: (1) Extending from nasal cavity vianasopharynx2 cases (10%) and (2) attached to oropharynx tonsillar pillars one case (5%). Paranasal sinus tenderness is seen in two cases (16%). Two patients had cervical node enlargement 10%; others did not show any lymph node involvement.

Blood Group

The majority of patients belonged to O group eight (40%); four belonged to A+ (20%), three belonged to B+ (15%), two belonged to AB+ (10%), three belonged to A-ve (15%). Thirteen patients (65%) were operated under general anesthesia (65%) and seven under local anesthesia (35%).



Figures 1: (a and b) The rhinosporidiosis mass lesion seen through the nose

Table 5: The incidence of different signs in the study group (*n*=20)

Nasal mass	*n* (19)	%
Side		
Unilateral	14	70
Left	8	40
Right	6	30
Bilateral	4	20
Site of attachment		
Inferior meatus	9	45
Septum	7	35
Inferior turbinate	1	5
Multiple sites	2	10
Mass		
Single	14	70
Multiple	5	25
Type of attachment		
Pedunculated	16	80
Sessile	3	15

There were no significant post-operative complications. All patients were given dapsone 100 mg daily, 6 days a week for 6 months postoperatively; in children 50 mg daily.

Follow-up

Three patients were lost from follow-up. The rest of the patients attended the outpatient department regularly for follow-up. They were taking dapsone regularly for 6 months until this paper was reported. Two (10%) patients showed residual lesions from 1st month onward. Three patients (15%) developed recurrence, of which two (10%) were detected after 6 months and at the end of 9 months. All the patients who were found to have residual masses were recurrence cases having masses with multiple attachments. Four patients (20%) developed synechiae formation in the nasal cavity postoperatively.

DISCUSSION

Rhinosporidiosis is one of the common otolaryngological diseases in this part of the world. Although the disease is thought to be waterborne, nobody has succeeded in isolating the causative organism or any intermediate host from water. Moreover, no definite associated factors

have been identified. Attempts at culture studies and animal inoculation have not met with success. Only when the causative organism is isolated from water and its mode of transmission proved, we can hope to control rhinosporidiosis. Incidence of rhinosporidiosis in relation to age, sex, occupation, and locality was analyzed and tabulated. The comparison of age and sex incidence of rhinosporidiosis in various studies is as follows [Table 6].

The male predominance as seen in other series observed in this study also. Like most other studies, the most common age group affected was 20–30 years. Rajam *et al.*[11] were of the opinion that rhinosporidiosis was common in agricultural workers. Satyanarayana[14] also had a similar opinion. Jain and Sahai (1967)[15] studied 26 patients and they varied in occupation from agricultural laborer to gold smith and shopkeeper. In the series of Das[16] farmers were in the majority followed by students and housewives. David[10] reported that the highest incidence was in agricultural laborers followed by unemployed people and others. In this study, most of the patients were manual laborers – seven patients (35%) and out of these two (10%) were agricultural by workers. The other major group was constituted of students – five cases (25%). Five cases (25%) were also found to occur in others such as fisherman, cooks, and drivers. The predominance of the disease in agricultural workers as mentioned in the above studies was not seen in this study. Kameswaran[17] has also opined that rhinosporidiosis has not significant relationship with agricultural work. Rajam *et al.*[11] were of the opinion that rhinosporidiosis was predominantly a disease of persons living in rural areas. Jain and Sahai (1967),[15] David,[10] Das (1967),[16] and Iqbal and Dani[12] were also having similar opinion. In this study, 14 cases (70%) were from rural areas and six (30%) from urban areas. This higher incidence may be due to easy accessibility to ponds in rural areas. Kurup (1931)[18] suggested that Muslims are more prone to the disease. Das[16] has reported 31 cases and all of them were Hindus. In this study, 11 cases (55%) were Muslims and the remaining nine (45%) were Hindus. A comparison was made in regard with the symptomatology of rhinosporidiosis of this study with other studies. The comparison of symptoms in various studies is given in Table 7. In this study, nasal obstruction, nasal masses, and epistaxis were found to be the most common symptoms as seen in other studies also. Satyanarayana[14] has opined that the rhinosporidial masses bleed profusely. Das[16] has noted that 6.5% of his cases presented with epistaxis and were admitted as urgent cases. In all patients, in this study who complained of epistaxis, its severity was mild to moderate. The duration of symptoms is indefinite, varying from 4 weeks to 30 years. In the series of Satyanarayana[14] and David[10] observed that the duration of disease ranged from 1 month to 6 years. According to the study of Das[16] duration varied from 15 days to 2 years, the average being from 3 to 5 months. In this study, the duration of symptoms varied from 1 month to 11 years

Table 6: The comparative study of age and sex incidence of rhinosporidiosis

Author	Youngest patient's age (years)	Oldest patient's age	Most common age group (years)	Male: female ratio
Satyanarayana (255 cases)[14]	4	61	21–30	4:1
Jain and Sahai (1967) (26 cases)[15]	24	45	31–40	All males
Das (31 cases)[16]	5	75	11–20	6.75:1
David (100 cases)[10]	6	61	11–20	3:1
Iqbal and Dani (110 cases)[12]	3	60	11–20	5.8:1
Present study (20 cases)	8	52	20–30	5.7:1

Table 7: The symptomatology in the case study (*n*= 20)

Jain and Sahai (1967) (26 cases)[15]	Das (31 cases)[16]	David (100 cases)[10]	Iqbal and Dani (110 cases)[12]	Present study (20 cases)
Nasal discharge (Blood stained) (100%)	Nasal obstruction (74%)	Epistaxis	Nasal obstruction (48%)	Nasal obstruction (100%)
Nasal obstruction (4%)	Epistaxis (58%)	Nasal obstruction	Nasal mass (32%)	Nasal mass (95%)
	Nasal discharge (32%)	Dysphagia (If growth in oropharynx)	Mass in oral cavity (5.5%)	Epistaxis (90%)
	Headache (9.6%)		Swelling naso-optic sulcus (3.6%)	Mouth breathing (65%)
			Dysphagia (3.6%)	Snoring (65%)
			Epistaxis (2.7%)	Nasal discharge (55%)
				Change in voice (50%)
				Anosmia (40%)
				Headache (35%)
				Epiphora (20%)

Table 8: The comparison of sites of attachment of nasal masses in different studies (*n*=20)

Jain and Sahai (1967) (26 cases)[15]	Das (31 cases)[16]	David (100 cases)[10]	Iqbal and Dani (110 cases)[12]	Present study (20 cases)
Middle turbinate (92%)	Floor of lateral wall (41.9%)	Septum (31.8%)	Septum (52.8%)	Inferior meatus (45%)
Floor (4%)	Septum (29%)	Inferior turbinate (27.5%)	Floor	Septum (35%)
Inferior turbinate (4%)	Middle turbinate and meatus (12%)	Nasal floor (23.28%)	Inferior turbinate	Inferior turbinate (5%)
	Inferior turbinate (9%)	Inferior meatus (6.8%)	Multiple attachment (9.6%)	Multiple attachment (15%)

with an arithmetic mean of 2.5 ± 1.45 years. Thus, we may infer that duration of the disease varies greatly from patient to patient. Trauma to the nose as a predisposing factor for infection by *Rhinosporidium Seeberi* was suggested by Satyanarayana[14] and David.[10] However, Kameswaran[17] was of the opinion that trauma as necessary prerequisite cannot be established beyond doubt. In this study, only one patient gave a history of major accidental trauma to the nose. This shows that trauma as predisposing factor for the development of rhinosporidiosis does not have much significance. According to David,[10] 15% of cases were recurrent. One of his patients complained that they underwent operation 7 times previously for the removal of his nasal growth and another mentioned that his nasal disease recurred after a symptom free period of 9 years. In this study, ten patients (50%) gave a history of operation for rhinosporidiosis. The high rate of recurrence cases in this study may be due to the resumption of bathing in ponds following completion of treatment [Table 7].

Satyanarayana[14] reported that 92% of his patients had nasal mass. Karunaratne (1964)[6] stated that 70% of his cases exhibited nasal rhinosporidiosis. Jain and Sahai (1967)[15] noted that in all of his cases, the nose was affected. Kameswaran[17] was of the opinion that nasal lesions account for 78% of the cases of rhinosporidiosis. Iqbal and Dani[12] found that 85% of the cases had nasal involvement. The sites of attachment of nasal masses of rhinosporidiosis in various studies are compared in Table 8. Contrary to the findings obtained by other studies, this study shows that the most common site of attachment of nasal mass is the inferior meatus. The reason for this may be the fact that the inferior meatus most frequently comes into contact with pond water during dip baths. Another possibility is the organism first entering the eyes and then reaching the inferior meatus through a patent nasolacrimal duct. The type of attachment of masses from David's[10] study shows that it was pedunculated in 87% (101/116) and sessile in 13% cases (15/116). Das[16] found that the lesions appeared polypoidal or pedunculated in 18 cases out of 31 (58%) and sessile in 13 cases (42%). The findings in this study also agree with the above finding in that pedunculated lesions are much more common as compared to sessile lesions [Table 8].

Satyanarayana[14] found that after the nose, nasopharynx was the most common site of involvement (12%).

Out of these, 6% were associated with nasal rhinosporidiosis and the remaining 6% were nasopharyngeal lesions alone. Karunaratne (1964)[6] was of the opinion that eye came second to nose in the frequency of involvement. Kameswaran[17] found out nasopharyngeal involvement in 16% cases. In the study, Das[16] lesions were seen in the nasopharynx only in two cases (6%). Mohammed lqbal *et al.* (1993),[12] in his series, found that nasopharyngeal mass occurred in 6/110 cases (5.4%). In this study, the nasopharyngeal mass was present in nine patients 45% and out of these, the mass was extending from nasal cavity to nasopharynx in 5 (25%), [Figure 1a and b], three patients (15%) had masses attached to the nasopharyngeal wall. Three patients had only nasopharyngeal masses. In the series reported by Satyanarayana, oropharyngeal involvement was noted in 2.4% of cases. Similarly, Kameswaran (1974)[17] also noted a 3% incidence of oropharyngeal rhinosporidiosis. Iqbal and Dani[12] found that oropharynx was involved in 4.5% cases. In this study, three patients (15%) showed masses in the oropharynx out of which two (10%) were extending from the nasal cavity through nasopharynx. Only one patient had an oropharyngeal mass attached to the tonsillar pillar. Kameswaran (1974)[17] noted that the highest incidence of rhinosporidiosis was seen in individuals belonging to the O+ve blood group. He also found that the next highest incidence is seen in the blood Group AB+. David[10] noted a predominance of B group (46%) and O group (33%). Blood Groups A and AB groups accounted for 10% of patients each. As observed by Kameswaran,[17] the most common blood group of patients in this study also is O+ (40%), followed by A+ve (20%). Satyanarayana[14] found that 10.5% of cases developed recurrence of infection after surgical removal. Of these, 6.2% were single recurrences and 4.3% were multiple recurrences. Das[16] found that recurrence of growth after excision occurred in 9.6% cases. In this study, three patients developed recurrence after surgical excision of mass and administration of dapsone postoperatively. Two patients (10%) showed residual lesions. They were all old rhinosporidiosis patients with masses having multiple attachments. The cause for the incomplete removal could be the multiplicity of attachments and the poor

visualization due to hemorrhage during surgery. Out of the patients who developed recurrence, 77% were those who had been operated in the past and had masses with multiple attachments. This may indicate that prognosis is poor following surgery on such patients as compared to those who have a mass with a single pedunculated attachment. This may be because, in such cases, the pedicle can be visualized, the mass removed in entirety and then the pedicle cauterized. Nair[9] reported the results of dapsone therapy on operated cases of rhinosporidiosis. He found out that the recurrence rate in these cases was 29.6%, of which 10.7% developed recurrence in 6 months and the rest at the end of 1 year. In those patients who underwent surgery but were not treated with Dapsone, the recurrence rate was 65.5% at the end of the year. Out of these 35.5% developed recurrence in the first 6 months. None of the patients on dapsone needed operation later. In this series, three patients (15%) developed recurrence. In two patients, (10%) it was detected in 6 months and in one after 9 months, even though they are taking dapsone. Considering these factors, it may be fair to assume that dapsone is not fully effective in checking the recurrences of rhinosporidiosis. Iqbal and Dani (1933) have expressed a similar opinion regarding the inefficacy of dapsone.

CONCLUSION

Rhinosporidiosis is not an uncommon disease encountered in day-to-day ENT practice. The occurrence of the disease does not bear any relation to the occupation of the patient. The maximum incidence of rhinosporidiosis is seen in the age group of 21–30 years and males predominate. Rhinosporidiosis is more common in the rural population. There is a significant association between dip baths in ponds and the occurrence of disease. The major symptoms are nasal obstruction, nasal mass, and epistaxis and the duration of symptoms varies widely. The most common site of attachment of nasal mass in rhinosporidiosis is the inferior meatus. Surgical management carries a good prognosis in pedunculated masses which can be removed with the pedicle. Prognosis is poor in masses with multiple attachments. Dapsone chemotherapy is not fully effective in preventing recurrences.

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Original Article

Effect of CO_2 Insufflation on Corrected QT Interval Prolongation during Laparoscopic Surgeries: A Prospective Observational Study

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Abstract

Introduction: Laparoscopic surgeries in various surgical specialties are most routinely performed with general anesthesia. The physiological effects of intra-abdominal CO_2 insufflation combined with the variations in patient positioning can have a major impact on cardiorespiratory function. Prolongation of corrected QT interval (QTc) has been known to predispose torsades de pointes, a potentially fatal ventricular arrhythmia may occur during CO_2 insufflation. Our aim is to evaluate the effect of insufflation of CO_2 on QT interval and QTc during prolonged laparoscopic surgeries.

Methodology: Fifty patients of American Society of Anesthesiologists physical status 1 and 2, of either sex, between the ages of 25 and 65 years posted for laparoscopic surgeries included in the study. After general anesthesia, we measured mean arterial pressure, heart rate, SpO_2 and $ETCO_2$ before anesthesia induction, before CO_2 insufflation, 30, 60, 120, and 150 min after CO_2 insufflation, 5 min after CO_2 deflation, and at the end of surgery. We observed statistically significant increase of QTc interval around 120 min after CO_2 insufflation.

Conclusion: The cause of this QTc interval prolongation is multifactorial and clinical significance of producing life-threatening cardiac arrhythmias has to be determined.

Key words: Cardiac arrhythmias, CO_2 insufflation, Laparoscopic surgeries, Corrected QT interval

INTRODUCTION

Laparoscopic surgery is a principle technique for minimally invasive surgery of the abdomen, and it has been employed in procedures ranging across multiple surgical disciplines.[1] Laparoscopic surgeries in various surgical specialties are most routinely performed with general anesthesia. It is, furthermore, facilitated by proper decompression of the gastrointestinal tract and by the establishment of adequate muscle relaxation, pneumoperitoneum, and various patient positions. The physiological effects of intra-abdominal CO_2 insufflation combined with the variations in patient positioning can have a major impact on cardiorespiratory function. A complete understanding of these hemodynamic changes is essential for optimal anesthetic care. One indicator of these changes is corrected QT interval (QTc), an index of myocardial function. Prolongation of QTc has been known to predispose torsades de pointes, a potentially fatal ventricular arrhythmia may occur during CO_2 insufflation.[2] The purpose of this study is to evaluate the effect of insufflation of CO_2 on QT interval and QTc during prolonged laparoscopic surgeries.

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METHODOLOGY

This prospective observational study conducted in our tertiary care hospital. After obtaining the Institutional Ethical Committee approval and informed consent, 50 patients of American Society of Anesthesiologists physical status 1 and 2, of either sex, between the ages of 25 and 65 years posted for laparoscopic surgeries included in the study. Patients with cardiovascular, respiratory, or cerebrovascular diseases were excluded from the study.

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All patients received injection glycopyrrolate 0.2 mg intramuscular as premedication. At operation theater, all anesthesia equipment and anesthesia drugs were checked and kept ready as per institutional protocol. On arrival of the patient at operation theater standard, 12-lead electrocardiogram (ECG), non-invasive blood pressure, and pulse oximetry were attached to all patients. After preoxygenation, anesthesia induced with injection propofol 2 mg/kg and injection fentanyl 150 μg. Tracheal intubation done with appropriate size endotracheal tube and injection vecuronium 0.1 mg/kg. Once airway secured $ETCO_2$ monitoring device attached to endotracheal tube. Anesthesia was maintained with nitrous oxide and oxygen 2:1 supplemented with 1–2% of sevoflurane and titrated dose of injection vecuronium. The anesthesia ventilator setting adjusted to tidal volume of 9 ml/kg of patient weight and respiratory rate of 10–12/min. The $PETCO_2$ was maintained between 35 and 45 mmHg by adjusting the respiratory rate during intraperitoneal CO_2 insufflation. All patients received continuous infusion of crystalloid solution 5 ml/kg intraoperatively.

Intraoperatively, pneumoperitoneum was created by insufflation CO_2 through Veress needle and CO_2 insufflator. Intra-abdominal pressure was maintained between 10 and 12 mmHg throughout the procedure. The patient was positioned according to the type of laparoscopic surgery.

We measured mean arterial pressure, heart rate, SpO_2 and $ETCO_2$ before anesthesia induction, before CO_2 insufflation, 30, 60, 120, and 150 min after CO_2 insufflation, 5 min after CO_2 deflation, and at the end of surgery. Intraoperatively, measurement of the RR interval, QT interval, and QTc interval according to the Bazett's formula was performed before anesthesia induction, before CO_2 insufflation, 30, 60, 120, and 150 min after CO_2 insufflation, 5 min after CO_2 deflation, and at the end of surgery. Statistical analysis for continuous variables such as mean arterial pressure, heart rate, and SpO_2, QT interval, and QTc interval is presented as mean ± standard deviation (SD). *P* value was determined and $P < 0.05$ was taken as statistically significant.

RESULTS

A total of 50 cases were enrolled in this study. The demographic details of the patients such as age, gender, duration of surgery, and duration of anesthesia were recorded [Table 1]. The pre-operative and intraoperative mean arterial pressure, heart rate, SpO_2, $ETCO_2$, QT interval, QTc interval before CO_2 insufflation, 30, 60, 120, and 150 min after CO_2 insufflation, and 5 min after CO_2 deflation were recorded. We observed that the mean arterial pressure was increased from 86.36 ± 5.76 mmHg before insufflation of CO_2 to 88.04 ± 5.92 mmHg at 120 min after insufflation [Figure 1]. The rise in mean arterial pressure was not statistically significant ($P > 0.15$). We noticed that the heart rate was increased from 84.18 ± 5.36 per minute before insufflation of CO_2 to 82.34 ± 5.72 per minute at 120 min after insufflation [Figure 1] and it was statistically insignificant ($P > 0.15$) [Figure 1].

Table 1: Demographic details

Parameters	Mean±SD
Age (years)	40.94±16.0
Duration of surgery (minutes)	140.98±12.97
Duration of anesthesia (minutes)	154.12±11.59
Gender (M/F)	27/23

SD: Standard deviation

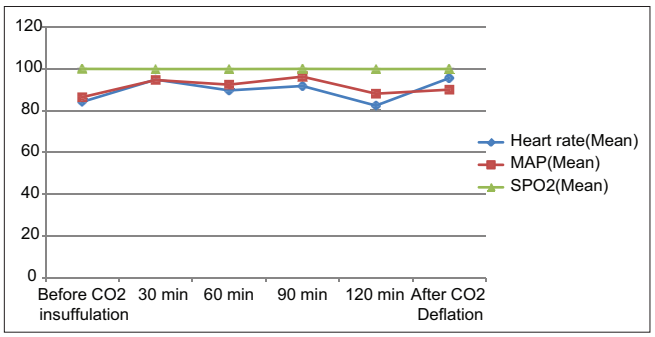

Figure 1: Changes in heart rate, mean arterial pressure, and SpO_2

We observed statistically significant increase ($P < 0.0001$) of QTc interval from 361.7 ± 11.76 ms before insufflation of CO_2 to 461.10 ± 17.2 ms at 120 min after insufflation [Table 2] [Figure 2]. We also observed statistically significant increase ($P < 0.008$) in $ETCO_2$ from 34.78 ± 3.14 mmHg before insufflation of CO_2 to 42.10 ± 3.54 mmHg at 120 min after insufflation [Figure 3].

DISCUSSION

The QT interval recorded on the surface ECG reflects the time required for ventricular depolarization and repolarization. The normal range of heart rate QTc varies with age and sex. Typically, QTc interval <440 ms is considered to be normal. Abnormal cardiac repolarization which can be identified by prolongation of QT interval and QTc interval on ECG is a well-known cause for developing life-threatening tachyarrhythmias like torsade des pointes, characterized by "twisting" of QRS axis around the isoelectric line.

The QTc interval prolongation may be due to either inherited like long QT syndrome or acquired causes. Large numbers of medications have potential to prolong QTc interval. Some of the drug classes that are implicated in QTc prolongation are antiarrhythmic agents, antihistaminic

Table 2: Mean and SD of all measured variables

Parameters	Before CO_2 insufflation Mean±SD	120 min after CO_2 insufflation Mean±SD	*P* value*
Heart rate (per minute)	84.18±5.36	82.34±5.72	>0.10
Mean arterial pressure (mmHg)	86.36±5.76	88.04±5.92	>0.15
$ETCO_2$ (mmHg)	34.78±3.14	42.10±3.54	<0.008
Corrected QT interval (ms)	361.7±11.76	461.10±17	<0.0001

**P*<0.05 is significant SD: Standard deviation

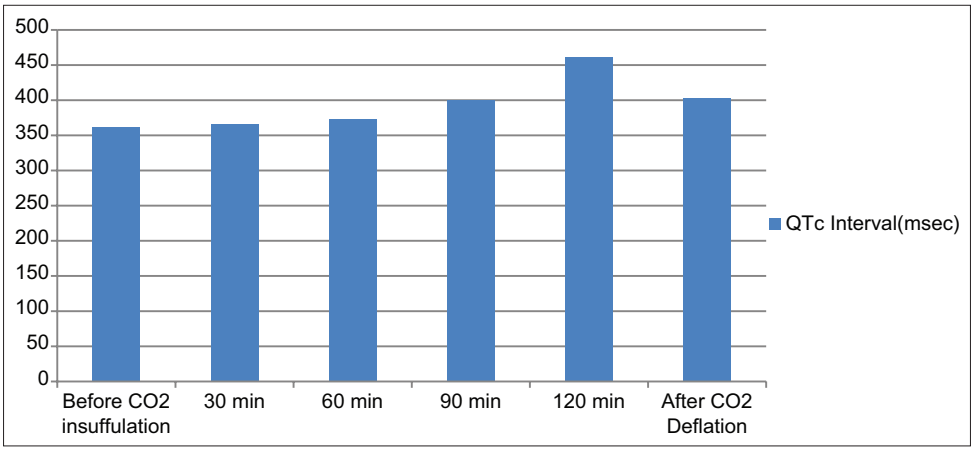

Figure 2: Corrected QT interval in ms

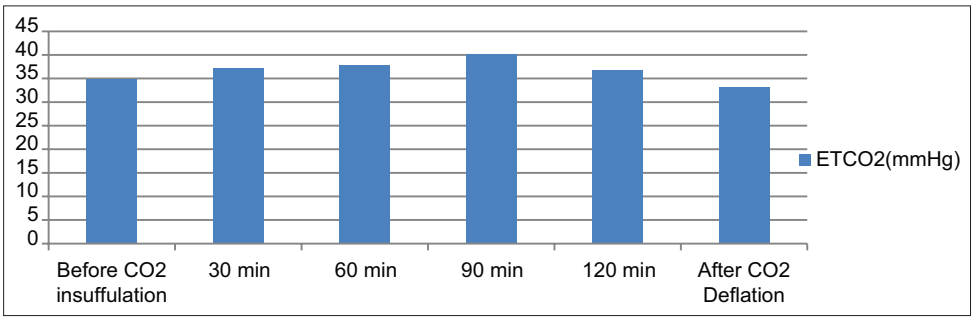

Figure 3: $ETCO_2$ in mmHg

agents, antimicrobials, promotility drugs, and antineoplastic agents. Non-pharmacologic factors which cause QTc prolongation include electrolyte disturbances such as hypokalemia, hypomagnesemia, and hypocalcemia.

In the present study, QTc interval of all the patients before start of laparoscopy was within normal limits. After about 120 min from the start of insufflation of CO_2, we noted QTc prolongation in all patients with mean ± SD of 461.10 ± 17.2 ms. The cause of this prolongation cannot identify but hypothesized to the following reasons such as intraoperative electrolyte disturbance, hypercapnia due to CO_2 insufflation during laparoscopy, and anesthetic drugs such as sevoflurane and surgical stress.

Hypercapnia which may be a result of insufflation of CO_2 during laparoscopic surgeries has been incriminated to produce QTc interval prolongation, which was confirmed by Ciftci *et al.*[3] in their study. In our study, $ETCO_2$ monitored during laparoscopic surgeries and there was no hypercapnia noted during the procedure.

Surgical stress may cause QTc interval prolongation but as mentioned in Egawa *et al.*[4] The laparoscopic procedures are minimally invasive procedures and surgical invasion may have had minimal effect on changes in QT interval and QTc interval.

The effects of commonly used general anesthetic drugs and inhalational agents on QTc interval have been studied in healthy adults and children. A recent study found that the mean QTc interval prolongation of 46 ms in patients anesthetized with inhalational agents.[2] The effect of sevoflurane on QTc interval is controversial. Some studies have shown a prolongation of QTc interval, but others failed to show the QTc interval prolongation.[5]

QTc interval prolongation has been shown to predispose to ventricular arrhythmias. It is exhibited in patients with myocardial infarction, subarachnoid hemorrhage, and diabetes mellitus.[6] In the present study, however, no arrhythmic events were observed during laparoscopic cholecystectomy in both elderly and younger patients. This may be due to the fact that patients with cardiac diseases were not included in this study.

CONCLUSION

CO_2 insufflation in laparoscopic surgeries is associated with prolongation of QTc interval. The cause of this QTc interval prolongation is multifactorial and clinical significance of producing life-threatening cardiac arrhythmias has to be determined.

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Original Article

Clinicoepidemiological Study of Traumatic Chest Injuries in a Tertiary Care Center

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Abstract

Introduction: Chest trauma is one of the most serious injuries of the chest and also a common cause of significant disability and mortality. Chest trauma is the leading cause of death from physical trauma after head and spinal cord injury. Thoracic injuries are primary or a contributing cause of about one-fourth of all trauma-related deaths. Traumatic chest injuries are on the rise mainly due to increased frequency of road traffic accidents (RTAs) and rise in community disharmony. Chest injuries are one of the common causes of major mortality and morbidity. The management of traumatic chest injuries depends on the severity of injury, patient accessibility to nearby hospital, and availability of resources at tertiary care center.

Materials and Methods: It is a prospective study of a total of 134 patients presenting to the emergency department with chest injuries of varying severity in Sanjay Gandhi Memorial Hospital from 1 June 2018, to 31 May 2019 had been carried out. Data collected regarding common injury modes, age and gender distribution, pre-hospitalization practices, clinical presentations, associated injuries, severity of injuries, and management options from the hospital record section and these data were analyzed with descriptive statistics.

Results: Chest trauma is most common in males in their thirties with mean age of presentation 33.47 years. The most common mode of injury was RTA 69.4%, followed by fall from height 14.9% and assault 11.1%. Pain in chest (53%) was the most common symptom of blunt trauma chest in the patients of our study sample followed by dyspnea (31%) and asymptomatic (9%). Clinical sign was tenderness over chest. About 61.2% of patients found with collection in pleural cavity, in which hemothorax (23.9%) was the most common collection followed by pneumothorax (22.4%) and hemopneumothorax (15.7%).

Conclusions: Chest injury is seen commonly in RTA patients. Most of the patients of chest injury had soft tissue trauma over chest in the form of abrasions and majority of these patients can be managed by symptomatic care and simple life-saving intervention, i.e. intercostal drainage. With increased RTAs, it is needed to have public awareness regarding road safety measures and educating them about the first aid measures for trauma patients.

Key words: Chest injury, Tertiary care, Trauma

INTRODUCTION

Blunt trauma is physical trauma by a non-penetrating impact through a blunt object or surface to a body part. Blunt trauma is the primary trauma, from which develops more specific types such as contusions, abrasions, lacerations, and/or fractures. Traumatic injury is the leading cause of death under the age of 45 worldwide. Approximately 5.8 million people die each year as a result of injuries. This accounts for 10% of the world's deaths, more than the number of fatalities from malaria, tuberculosis, and HIV/AIDS combined. In India, every 1.9 min, trauma-related death occurs. Approximately 1 million people die and 20 million are hospitalized every year due to injuries.[1]

Chest trauma is one of the most serious injuries of the chest and also a common cause of significant disability and mortality. Chest trauma is the leading cause of death from physical trauma after head and spinal cord injury. Thoracic injuries are primary or a contributing cause of about one-fourth of all trauma-related deaths. The mortality rate in these cases is about 10%. Thoracic injuries account approximately 20–25% of deaths due to trauma. 16,000 deaths occur per year in India alone as a result of chest

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trauma. Blunt trauma chest contributes to major accidental injuries in India due to increased incidence of road traffic accidents (RTAs) (6% of global vehicular accidents) due to increased road traffic, availability of new high-speed vehicles and less awareness regarding traffic rules. A very few studies had been conducted to analyze its magnitude and management in the Indian scenario.[2]

This study is carried out to determine the epidemiology and mechanism of chest trauma along with analyzing the management scheme and to note the prognosis and improvement of the management of chest injuries.

Chest radiograph is obtained for every blunt trauma chest patient after stabilization of the patient. The diagnosis is generally obvious with standard chest radiography but more subtle sign requires careful analysis with computed tomography (CT)-chest. High-resolution CT (HRCT) is the most important imaging method in this field. Its advantages occur especially due to high speed and high geometric resolution in any plane. Due to its advantages, HRCT has become the first choice method in high-energy trauma. Diagnostic imaging with HRCT plays a key role in the management of high-energy chest trauma. HRCT is the most important imaging method in this kind of injury, as detailed information can be acquired in a short time.

MATERIALS AND METHODS

A study of cases of chest trauma admitted in Sanjay Gandhi Memorial Hospital from 1 June 2018, to 31 May 2019 had been carried out. The study was pertaining to blunt chest trauma. Information was obtained directly from the patient whenever possible and from other witness of accident if available.

Number of Patients

134.

Inclusion Criteria

- All patients with blunt trauma chest were included in the study.

Exclusion Criteria

The following criteria were excluded from the study.

- Penetrating chest injury
- Patients who absconded or left against medical advice.

Methodology

The study was conducted over the patients admitted from casualty, outpatient department and those who transferred from other wards. After eliciting the proper history and mode of trauma, vitals were regarded and initial airway, breathing, circulation, and deformities were assessed without any delay. After stabilizing vitals, the patients who were diagnosed as blunt trauma chest were assessed properly and sent for lab investigations and X-ray done. Those who were in need of inter costal drain (ICD) such as tension pneumothorax, hemothorax, and flail chest were undergone for procedure after proper written consent. The patients were then shifted to ward and sent for CT chest. The reports of X-ray chest and CT chest were analyzed and recorded in pro forma. Those patients who were diagnosed with associated injuries such as head injury, blunt trauma abdomen, and long bone fracture were also included for the study, but after stabilizing from these associated injuries if needed CT chest was done but X-ray chest was done to them as a bedside investigation. Those patients who undergone for ICD insertion were followed up properly by doing repeat X-ray immediately after ICD insertion and on the 3rd day or as when needed and after removal of ICD once patient condition improved. The patients were advised for vigorous chest physiotherapy and their improvement was recorded properly. All these data were recorded meticulously in pro forma and master chart after that systematic tabulation, observation, and analysis done. Summary and conclusion were drawn after discussion with review of literature.

OBSERVATIONS AND RESULTS

All trauma patients with blunt trauma chest fulfilling the inclusion criteria, irrespective of age, sex, and mode of trauma were included in the study.

On admission, patients were briefly interrogated, clinically examined, and resuscitation started according to priority, i.e., patency of airway, breathing, and circulation were restored. Bleeding surface wounds (chest or any other body part) were stitched in time and fracture site if any splinted.

After clinical stabilization of the patients, his/her particulars, i.e., name, age, sex, occupation, residence, etc., were noted. Detailed history regarding the circumstances and mode of sustaining injury was obtained. Thorough clinical examination was conducted to evaluate the nature and severity of injury. All efforts were made to diagnose other associated injuries.

The patients were investigated and treated according to the pre-decided protocol of the study. The data were collected and recorded on predesigned pro forma by principal investigator. The following observations were made and analyzed using necessary statistical tools.

It is evident from Table 1 that majority of the patients 31.3% of the blunt trauma chest belonged to 21–30 years

of age group. A total of 22.4% of patients belonged to 31–40 years of the age group which was also the second most common age group presented with chest injury. Minimum age was 2 years while maximum was 90 years. The mean age was 33.47 years, with standard deviation 16.24.

It is evident from Table 2 that RTA (69.4%) was the most common cause of blunt trauma chest in the patients of our study sample followed by fall from height (14.9%) and assault (11.1%).

It is evident from Table 3 that pain in chest (53%) was the most common symptom of blunt trauma chest in the patients of our study sample followed by dyspnea (31%) and asymptomatic (9%).

It is evident from Table 4 that head injury (18.6%) was the most common associated injury with blunt trauma chest in the patients of our study sample, followed by spinal injury, blunt trauma abdomen, long bone fracture, and other injuries.

It is evident from Table 5 that tenderness (84.3%) was the most common clinical finding of blunt trauma chest in the patients of our study sample followed by bruise (79.8%) and bony crepitus (73.9%).

It is evident from Graph 1 that ribs fracture was the most common pattern of thoracic injuries in blunt trauma chest patients of our study sample, followed by clavicle fracture, hemothorax, and pneumothorax.

It is evident from Table 6 that a total of 61.2% of patients found with collection in pleural cavity, in which hemothorax (23.9%) was the most common collection followed by pneumothorax (22.4%) and hemopneumothorax (15.7%).

It is evident from Table 7 that of 134 blunt trauma chest patients, X-ray chest film shows 2 or <2 ribs fracture

Table 1: Age and sex-wise incidence of the patient

S. no.	Age group (years)	Total	Male		Female	
			No.	%	No.	%
1.	<10	4	3	75	1	25
2.	11–20	22	20	91	2	9
3.	21–30	42	32	76	10	24
4.	31–40	30	27	90	3	10
5.	41–50	22	19	87	3	13
6.	51–60	4	3	75	1	25
7.	61–70	7	5	72	2	28
8.	>70	3	2	67	1	33
Total		134	111	82.8	23	17.2

Table 2: Distribution of patients according to mode of trauma

S. no.	Mode of trauma	No. of patient				
		Total	Male		Female	
			No.	%	No.	%
1.	Road traffic accident	93	77	83	16	17
2.	Fall from height	20	17	85	3	15
3.	Assault	15	12	80	3	20
4.	Others	6	5	83	1	17
Total		134	82.8	86	23	17.2

Table 3: Distribution of patients according to mode of presentation

S. no.	Symptoms	No. of patients				
		Total	Male		Female	
			No.	%	No.	%
1.	Pain in chest	71	57	80	14	20
2.	Dyspnea	42	36	86	6	14
3.	Asymptomatic	12	11	92	1	8
4.	Unconsciousness	3	2	67	1	33
5.	External wound	6	5	83	1	17
Total		134	111	82.8	23	17.2

Table 4: Incidence and sex-wise distribution of associated injuries with blunt trauma chest in the study sample

S. no.	Associated injury	Total	Male		Female	
			No.	%	No.	%
1.	Head injury	25	18	72	7	28
2.	Blunt trauma face	2	2	100	0	0
3.	Blunt trauma abdomen	8	6	75	2	25
4.	Spinal injury	10	8	80	2	20
5.	Long bone fracture	7	7	100	0	0
6.	Scapula fracture	8	5	63	3	37
7.	Pelvis fracture	4	3	75	1	25
8.	Diaphragmatic injury	7	4	57	3	43
Total		71	53	74.6	18	25.4

Table 5: Distribution of patients according to clinical finding

S. no.	Finding	Total patients	
		No.	%
1.	Tenderness	113	84.3
2.	Bruise	107	79.8
3.	Bony crepitus	99	73.9
4.	Lacerated wound	70	52.2
5.	Abrasion	57	42.5
6.	Subcutaneous emphysema	40	29.8

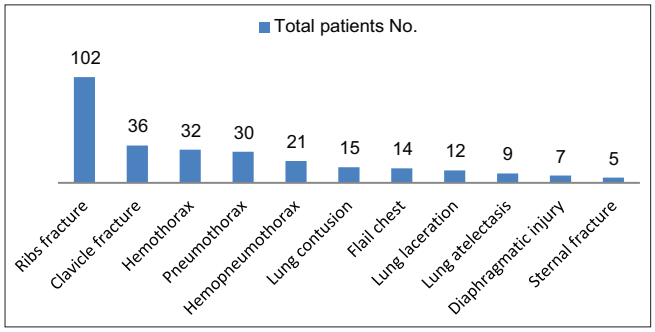
Table 6: Type of collection in pleural cavity

S. no.	Type of collection	Total no. of patients	No. of patients (%)
1.	Hemothorax	32	23.9
2.	Pneumothorax	30	22.4
3.	Hemopneumothorax	21	15.7
Total		82	61.2

present in 61 patients, in which 56 patients recovered and 5 patients expired; hence, mortality is 8.2%, and more than two ribs fracture present in 32 patients, in which 27 patients recovered and five expired and so mortality is 15.6%. It shows no. of ribs fracture directly proportional to mortality.

It is evident from Table 8 that of 134 blunt trauma chest patients, 14 patients present with flail chest in which 3 are expired, so mortality in flail chest was 21.4% in the present study which was very high compare to other patients which is 9.7%.

It is evident from Table 9 that of 134 patients, intercostal drain placement done for 64 patients, of 64 patients, 23 right sided and 26 left sided and 15 bilateral drain placement done, exploratory laparotomy done for 11 patients, craniotomy done for 4 patients, and rest 55 patients of the study sample not required any surgical intervention and managed conservatively.



Graph 1: Pattern of thoracic injuries in blunt trauma chest

Table 7: Ribs fracture present in X-ray associated with death

Ribs fracture (no.)	≤2	>2
Recovered	56	27
Death	05	05
Total	61	32

Table 8: Flail chest incidence and mortality

Flail chest	No. of patients	No. of death	%
Present	14	3	21.4
Absent	120	10	8.3
Total	134	13	9.7

Table 9: Surgical management of blunt trauma chest with associated injuries

Management	Intercostal drain			Exploratory laparotomy/ Diaphragmatic repair	Craniotomy
	Right sided	Left sided	Bilateral		
No. of patients	23	26	15	11	4
% of patients	17.2	19.4	11.2	8.2	3.0

It is evident from Table 10 that mortality high when chest trauma associated with other injuries as compared to isolated chest trauma.

It is evident from Table 11 that maximum number of patients (33.6%) had hospitalization for 11–15 days followed by 6–10 days. Average duration of hospitalization was 8.23 days in our study with standard deviation of 4.31 days.

DISCUSSION

Chest injury is one of the leading causes of mortality and morbidity. This prospective study of 1-year duration included 134 patients with traumatic chest injuries, which included only the admitted cases. In the study, chest injuries were predominantly seen in male sex as they are more involved in public activity and vehicle driving. Chest injury was seen to be more in the 3rd decade of life as it is the more active and adventuress period of life. Mean age of presentation was 33.47 years of age. In another study by Sharma *et al.*[3] of a total of 730 patients, the maximum of 452 was in the age group of 21–30 years and the next common decade was found to be in 4th decade, i.e., 31–40 years, with 98 patients. As with other studies, in our study also RTA was the most common mode of injury. More of industrialisation and urbanisation with non strict laws has lead to increase in RTAs and associated chest injuries. Next common mode was fall from height followed by assault. This suggests that the government has to come

Table 10: Distribution of patients according to cause of death

S. no.	Type of injury	Total no. of patient	Death	
			No.	%
1.	Chest trauma with head injury	25	3	12.0
2.	Chest trauma with abdominal trauma	8	1	12.5
3.	Chest trauma with spinal injury	10	1	10.0
4.	Chest trauma with pelvis injury	4	1	25
5.	Isolated chest trauma	87	7	8.04

Table 11: Duration of hospital stay

S. no.	Duration of hospital stay (days)	Total patients	
		No.	%
1.	1–5	41	30.6
2.	6–10	43	32.1
3.	11–15	45	33.6
4.	16–20	5	3.7
Total		134	100

up with more safety measures for construction workers. In the emergency department, chest pain was the most common presentation in chest injury patients followed by some form of external injury on the chest; most of the patients it was abrasion over the chest. These suggest that patients with chest pain should be given importance even if there is no external injury or breathlessness. Most of the patients had multiple findings, but on consideration, individual tenderness presents over chest (84.3%) and was the most common clinical finding of blunt trauma chest in the patients of our study sample followed by bruise (79.8%) and bony crepitus (73.9%). In another study, Choudhary *et al.*[4] done a study and all injury type data were collected and it includes small chest abrasion to complex chest injuries. In the present study, totally 61.2% of patients developed some type of pleural collection. Most commonly, patients had hemothorax 23.9% followed by pneumothorax 22.4% and hemopneumothorax 15.7%. Most of these cases were managed with intercostal drainage tube. Another study Kumar *et al.*[5] hemothorax was found in 38.3% and pneumothorax 20.7% of cases. In other studies also find similar result, Lin *et al.*[6] found 31.8% traumatic hemothorax, 15.6% pneumothorax, and 9.6% hemopneumothorax. Most of these patients were treated with standard intercostal drainage procedure. Most of the patients were polytrauma cases and were associated with other body injuries, most common being head injury, followed by abdominal, spinal, and long bone injuries with equal incidence each and least was pelvic bone fractures. In the present study, of 134 blunt trauma chest patients X-ray chest film shows 2 or <2 ribs fracture present in 61 patients in which 5 patients expired, so mortality was 8.2%, and more than two ribs fracture present in 32 patients in which 5 patients expired, so mortality was 15.6%. It shows a number of ribs fracture directly proportional to mortality. Also found that ribs fracture is the most common skeletal injury following blunt chest trauma. In the present study, of 134 patients, 39 requiring intubation with ventilator support in intensive care unit (ICU) care mostly had polytrauma in which injury severity score was more than 15. Intercostal drain required for 64 patients, of 64 patients, 26 ICD placement done left side, 23 right side, and 15 bilateral; intercostals drain placement done for flail chest patients, most of hemothorax, pneumothorax, and hemopneumothorax patients. Patients had small collection in there pleural cavity and vitally stable are managed conservatively. Exploratory laparotomy done for 11 patients, of 11 patients, 6 had diaphragmatic injury in which diaphragm repair done, 1 had diaphragmatic injury with splenic rupture so splenectomy with diaphragmatic repair done, and 4 laparotomy more done, in which 2 had ileal perforation and other 2 had jejunal perforation so primary closure of ileal and jejunal perforation done. Craniotomy done for 4 patients, of 3 extradural hemorrhage occurs in 3 patients and 1 had hemorrhagic contusion. Moreover, rest 55 patients of study sample not required any intervention and managed conservatively.

In the present study, of 134 blunt trauma chest patients, ICD placement done in 64 patients in which 59 (92.2%) was recovered and 5 (7.8%) was expired. Conservative management done in 70 patients in which 62 (88.6%) was recovered and 5 (11.4%) was expired. ICD placement shows better result for the management of blunt trauma chest.

Of 134 patients, 87 patients had isolated chest trauma in which 80 (91.96%) recovered and 7 (8.04%) expired and 47 patients had associated head, abdominal, spinal, pelvis, and other injuries in which 42 (89.4%) recovered and 5 (10.6%) expired. Mortality was higher in patients had associated injury with blunt trauma chest.

CONCLUSIONS

This study shows blunt trauma chest most commonly occurs in young adult male mostly in 3rd decade of life due to RTA. Patients presented mostly with complaints of chest pain and most common clinical finding was tenderness over thorax region. Ribs fracture was seen in most of patients. Hemothorax, pneumothorax, flail chest, or lung injuries were also seen in some patients. X-ray chest was found to be very useful and a cost-effective initial diagnostic modality for blunt trauma chest. In majority of the patients, ribs fracture and pleural cavity collection were present in X-ray, while in those patients with inconclusive X-rays, HRCT chest was found to be useful in detecting parenchymal lung injuries, occult collection, or ribs fracture. In the diagnosis of blunt trauma chest, HRCT chest was found to be more sensitive and specific in comparison to X-ray chest. In polytrauma patients, head injury is most commonly associated with blunt trauma chest. Other injuries such as abdominal trauma, spinal injuries, and long bone fractures were also seen. Most of the polytrauma patients with injury severity score of more than 15 needed ICU care with or without intubation or ventilatory support. Approximately half of the patients needed intercostals drain insertion. Clinical outcome in this study was found to be dependent on nature of injury, number of ribs fracture, associated injuries and injury severity score. Mortality was higher when chest trauma was associated with other injuries of head, abdominal, or other organs as compared to isolated chest trauma.

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Original Article

Evaluation of 0.1% Olopatadine Hydrochloride versus 0.5% Ketorolac Tromethamine Solution in the Management of Allergic Conjunctivitis

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Abstract

Introduction: The term "allergic conjunctivitis" refers to a group of hypersensitivity disorders of eye. This is a common ocular condition which presents with itching, redness, tearing, swelling, burning, fullness in the eye, leading to rubbing of the eye, and blurred vision. Histamine, prostaglandins, and mast cell degranulation are important mediators responsible for the signs and symptoms of seasonal and perennial allergic conjunctivitis. Olopatadine is a novel drug with dual action of mast cell stabilizer with blocking of histamine H1 receptors. Ketorolac tromethamine 0.5% ophthalmic solution is a very potent nonsteroidal anti-inflammatory drug (NSAID) that inhibits the enzyme cyclooxygenase and decreases the synthesis of prostaglandins.

Objectives: The objectives of the study were to compare the clinical efficacy and therapeutic effects of 0.1% olopatadine hydrochloride to that of 0.5% ketorolac tromethamine ophthalmic solution with different pharmacological mechanisms in the management of seasonal allergic conjunctivitis.

Materials and Methods: This was a comparative study that was conducted on patients with allergic conjunctivitis attending ophthalmology outpatient department in a tertiary health-care center during the study period of 1 year. A total of 100 patients were chosen by purposive sampling method and randomized into two groups. Group A patients were treated with olopatadine and Group B patients were treated with ketorolac and the drugs were instilled twice daily. Patients were evaluated for clinical signs and symptoms at baseline and at 30 min, 2 days, 7 days, and 14 days of application of eye drops.

Results: The mean age in our study was 27.81 years and had male predominance. There was a significant reduction in the frequency of all ocular signs and symptoms of hyperemia and itching following initiation of medication. The percentage of non-responders was comparable between both the groups. Three patients showed increase in hyperemia signs at 30 min post-application of ketorolac. Adverse reaction was observed in three patients in the ketorolac group.

Conclusion: The topical dual-action drug-olopatadine and NSAID-ketorolac both have an attenuating and equivocal effect on the clinical signs and symptoms of allergic conjunctivitis.

Key words: Allergic conjunctivitis, Antihistamines, Hyperemia, Itching, Nonsteroidal anti-inflammatory drug

INTRODUCTION

Allergic conjunctivitis is a group of inflammatory disorders which is the only ocular phenomenon that can be completely explained by an immunoglobulin E (IgE)-dependent mechanism, including late-phase reactions.[1]

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The allergic reaction is the body's response to the environmental allergen exposure, binding an IgE on the surface of conjunctival mast cells, and causing an immediate release of histamine, which triggers the inflammatory cascade with a release of inflammatory mediators such as tryptase, prostaglandins, and leukotrienes.

The clinical presentation of ocular allergy can be seen in isolation or more commonly associated with rhinitis, asthma,

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atopic dermatitis, or angioedema. The severity of disease ranges from mild to severe. Ocular manifestations include itching, redness, tearing, pain, burning sensation, and foreign body sensation, with itching and hyperemia as the cardinal features.

The signs and symptoms of allergic conjunctivitis can be inhibited by modulating the allergic process at various levels ranging from tear dilution, to local vascular constriction, to inhibition of mediator activity after release, and, ultimately, inhibiting the mast cell from reacting in the presence of a sensitizing agent.[2]

Olopatadine is a novel drug which has been shown clinically to have therapeutic value in the treatment of allergic conjunctivitis.[3-6] It has a dual action of mast cell mediator release with blocking of histamine H1 receptors.[3,5,6]

Ketorolac tromethamine 0.5% ophthalmic solution is a very potent nonsteroidal anti-inflammatory drug (NSAID) that inhibits the enzyme cyclooxygenase and decreases the synthesis of prostaglandins.[7]

MATERIALS AND METHODS

This was a prospective, comparative study that was conducted on outpatients attending the Outpatient Department in Rajarajeswari Medical College and Hospital, Bengaluru. The study was conducted on 100 patients chosen by purposive sampling method who came with signs and symptoms of allergic conjunctivitis and met the predefined criteria of the same. The patients were randomized into two groups, Group A consisted of 50 patients who received treatment with 0.1% olopatadine hydrochloride and Group B consisted of the other 50 patients who received treatment with 0.5% ketorolac tromethamine [Figure 1].

Data were collected over a period of 12 months, from November 2018 to October 2019, and each patient's follow-up was done for a minimum time duration of 15 days. All patients above 18 years of age with ocular itching, hyperemia, and mucus discharge and clinically proven allergic conjunctivitis were included in the study. Patients with infective cause of conjunctivitis, other ocular pathologies, pregnant and lactating mothers, and immune-compromised patients were excluded from the study. Patients with systemic manifestations of allergy and on systemic therapy with antihistamines, NSAIDs, steroids, and other medications were also excluded from the study.

The study was initiated after obtaining the Institutional Ethical Committee clearance.

Thorough ocular examination was performed starting from visual acuity, slit-lamp biomicroscopy to evaluate conjunctival and corneal involvement if any. Intraocular pressure was measured using non-contact tonometer. Fundus examination using indirect ophthalmoscopy was performed in all the patients.

After establishing the diagnosis, the patients were graded for clinical signs and symptoms. Each subject graded ocular itching using a scale ranging from 0 (none) to 4 (an incapacitating itch which requires significant eye rubbing).[8] as in Table 1. Ocular hyperemia was assessed in three-vessel beds: Conjunctival, ciliary, and episcleral. Each vessel bed was graded for hyperemia using a scale ranging from 0 (none) to 4 (extremely severe) as described in Table 2. These scorings were taken as the baseline score of clinical findings.

The patient's clinical signs and symptoms were recorded, and then, the starting point of treatment was considered as the first application of either of the drug during patients 1st visit. Clinical responses were recorded in the next

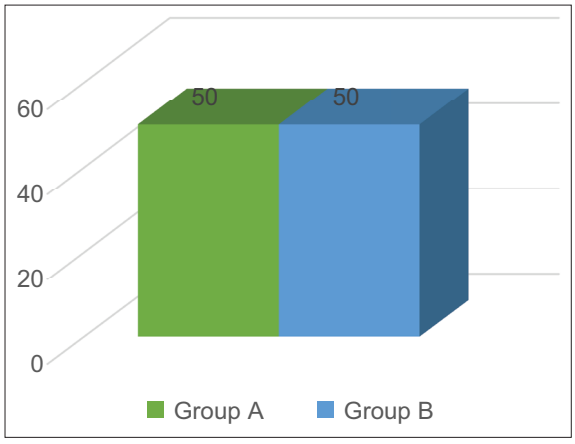

Figure 1: Frequency distribution of patients in Group A and Group B

Table 1: Grading of itching symptoms

Score	Itching symptoms
0	None
1	Intermittent tickling sensation, involving more than corner of eye
2	Mild, continuous itch without desire to rub
3	Severe itch with desire to rub

Table 2: Grading of hyperemia signs

Score	Hyperemia signs
0	None
1	Mild, slightly dilated blood vessels, pink in color, may be quadrantal
2	Moderate, more apparent vessel dilatation, vessel color is more intense, involves most of vessel bed
3	Severe, numerous, and obvious dilated blood vessels, color deep red, not quadrantic

30 min, 2 days, 7 days, and 14 days. The patients were advised to instill the drops twice daily.

Response in treatment was evaluated based on whether the patient showed any improvement in the clinical signs and symptoms. Ocular scorings were again recorded at 30 min, at 2nd, 7th, and 14th days. The final point of evaluation will be the time when the patient reaches a score 0.[9] Patients reported any kind of adverse reaction or intolerance that appeared after the application of the drug. The evaluation of adverse effects was as follows: 0 – absent, 1 – mild, 2 – moderate, and 3 – severe as shown in Table 3.[9]

After the data collection, the data were analyzed using descriptive and inferential statistics. The software used for analysis was MS Excel and SPSS statistics software version 20.0. To find the significance in categorical data, Chi-square test was used. In the above statistical tool, $P < 0.05$ was considered as statistically significant.

No adverse reaction was observed in patients treated with olopatadine. Stinging sensation was observed in three patients who were treated with ketorolac. Mild stinging sensation was reported in all the three patients hence had an adverse reaction score 1.

There was an increase in hyperemia signs in three patients of the ketorolac group at the 1st visit. These observations were made only at 30 min of application and not on any other follow-up visits.

DISCUSSION

Allergic conjunctivitis is a bilateral and self-limiting inflammatory process.[10] It is an immunopathological disease[9] and the inflammation is fundamentally caused by an IgE-mediated immune mechanism or immediate hypersensitivity mechanism resulting from direct contact of the allergen with the conjunctival surface in sensitized patients – triggering mast cell activation and the release of different mediators.[10] Mast cells play an important role in the pathophysiology and mediate the inflammatory reaction.

Table 3: Grading of adverse reactions to medications

Score	Adverse reactions
0	Absent
1	Mild: Mild stinging or foreign body sensation at instillation
2	Moderate: Mild stinging or foreign body sensation at instillation which persists
3	Severe: Important stinging or foreign body sensation at instillation and persisting to the point that treatment has to be discontinued

In our study, all the 100 patients completed the study, with 100% compliance to topical drop application to both olopatadine group and ketorolac group. The mean age of subject in Group A was 27.9 years and in Group B was 27.72 years. The mean age of the subjects in total was 27.81 year with a standard deviation of 5.22 years. The study group ranged from 18 to 38 years inclusive of both Group A and Group B [Figure 2].

We observed male predominance in both the groups; 26 males and 24 females in Group A and 28 males and 22 females in Group B [Figure 3]. Similar observation was made in the studies.

In this study, 54% of patients showed improvement in itching symptoms from baseline to 30 min of instillation of olopatadine eye drops. On day 2, 68% of patients improved from baseline symptoms, and on days 7 and 14, all the patients had symptomatic improvement from what was assessed at baseline. About 34% of patients had improvement in itching symptoms from baseline to 30 min of instillation of ketorolac, and on day 2, improvement was 56% from baseline. On days 7 and 14, all the patients showed a significant improvement in symptoms in comparison to the baseline [Figure 4]. Likewise, 50% and 66% of patients had improved in hyperemia symptoms at 30 min and at 2 days, respectively, with reference to baseline with olopatadine. On the other hand, patients

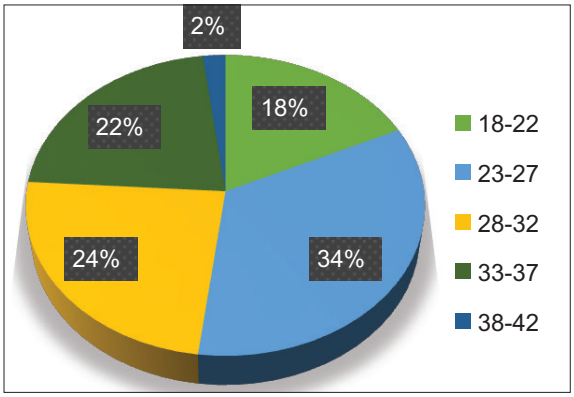

Figure 2: Age distribution of patients

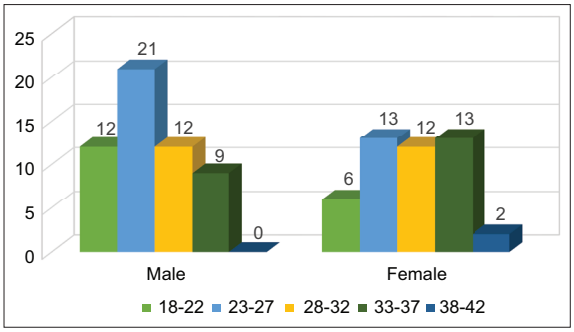

Figure 3: Gender distribution

treated with ketorolac showed 32% and 56% improvement in hyperemic symptoms at 30 min and 2 days with reference to pre-treatment analysis. There was 100% improvement in symptoms from baseline on day 7 and day 14 in both Group A and Group B [Figure 5].

It was observed that the mean score for itching in olopatadine group was 1.94 at 30 min, 1.14 at 2 days, 0.12 at 7 days, and 0.02 at 14 days. The mean score for itching in ketorolac group was 1.64 at 30 min, 1.4 at 2 days, 0.14 at 7 days, and 0.04 at 14 days. Comparing the effectiveness between Group A and Group B, *P*-value was significant (significance level: 0.045) at 30 min in controlling itching. When the mean scores of olopatadine-treated eyes were compared to the mean scores of ketorolac-treated eyes, the scores of itching were found to be lower in the olopatadine group, indicating better therapeutic effectiveness, although the difference did not reach statistical significance, as *P*-value at 2 days was 0.2187. It was also observed that, on day 7 and day 14, there was 100% improvement in itching symptoms from the baseline in both the groups. In Yaylali *et al.*[11] study, the itching scores were found to be significantly lower in the olopatadine group at 2, 7, and 15 days ($P = 0.339$, 0.446, 0.018, 0.007, and 0.036, for baseline, 30 min, 2, 7, and 15 days, respectively). The mean scores for itching were found to be lower in the olopatadine and ketorolac group than in the ketorolac group in Meena *et al.*[12] study. At day 15, 95% of patients had no complain of itching in Group 2 (ketorolac and olopatadine combination) with $P < 0.0001$, indicating that olopatadine and ketorolac in combination were superior to ketorolac in inhibiting ocular pruritus.

It was observed that the mean score for hyperemia in olopatadine group was 1.44 at 30 min, 0.98 at 2 days, 0.14

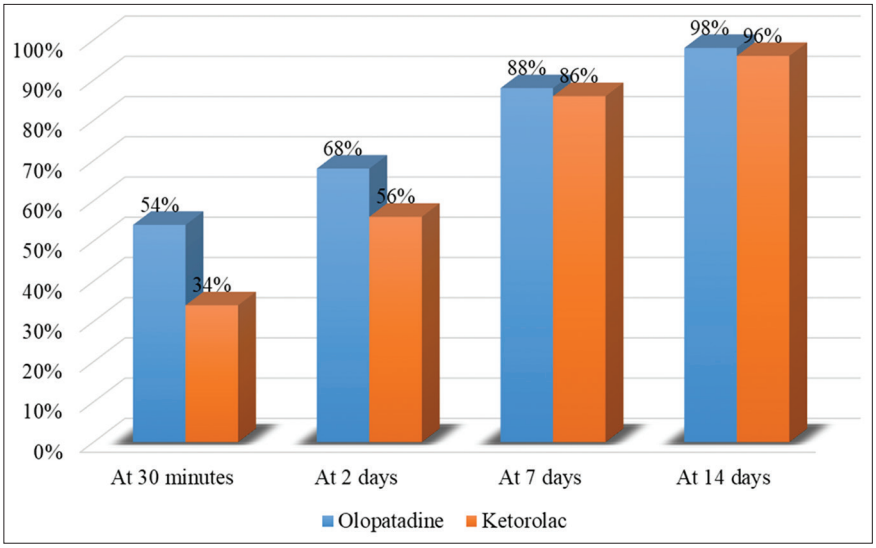

Figure 4: Rate of improvement in itching

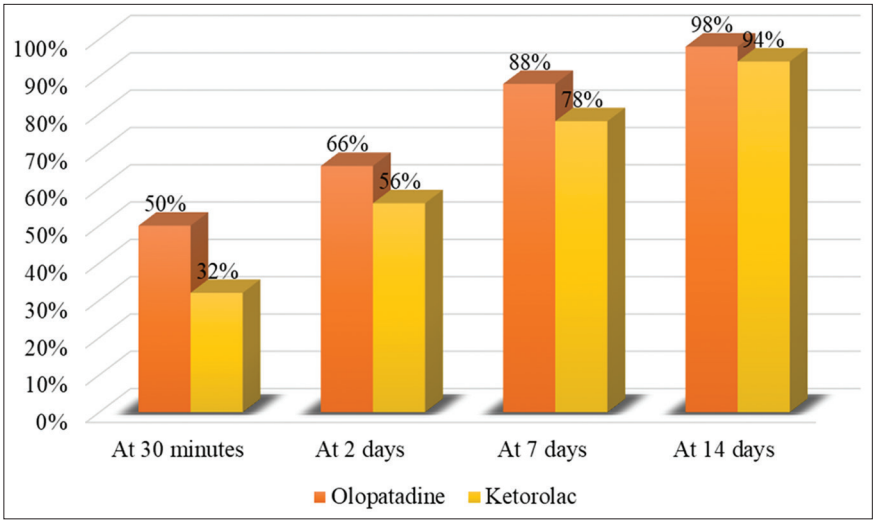

Figure 5: Rate of improvement in hyperemia

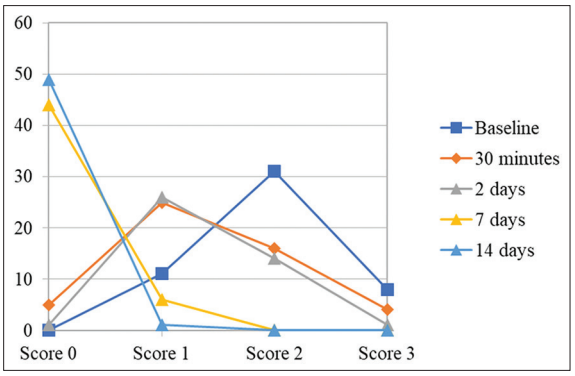

Figure 6: Comparison of the rate of improvement in itching symptoms in Group A

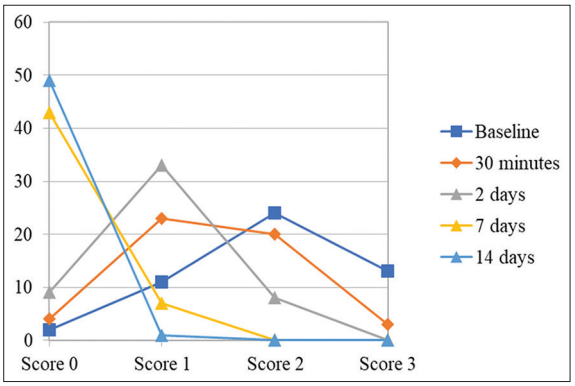

Figure 7: Comparison of the rate of improvement in itching symptoms in Group B

at 7 days, and 0.02 at 14 days. The mean score for itching in ketorolac group was 1.7 at 30 min, 1.32 at 2 days, 0.22 at 7 days, and 0.06 at 14 days. On comparing the mean scores of olopatadine to the ketorolac-treated eyes, it was seen that the scores of hyperemia were found to be lower in the olopatadine group, indicating better therapeutic effectiveness. It was observed that $P = 0.0687$ and 0.3077 at 30 min and 2 days ($P > 0.05$), respectively on comparing the mean scores of olopatadine treated eyes, hence there was no statistical significance between Group A and Group B at 30 min and 2-day interval. It was also observed that, on day 7 and day 14, there was 100% improvement in itching symptoms from the baseline in both the groups. In Yaylali *et al.*,[11] the mean scores of olopatadine-treated eyes were compared to the scores of ketorolac-treated eyes, the mean scores of hyperemia were found to be lower in the olopatadine group, indicating better therapeutic effectiveness, although the difference did not reach statistical significance ($P = 0.154$, 0.9, 0.65, 0.79, and 0.79, for baseline, 30 min, 2, 7, and 15 days score, respectively). In Figures 6 and 7 we can see the comparison of the rate of improvement in itching symptoms in Group A and Group B respectively. Likewise, in Figures 8 and 9 we can see the comparison of rate of improvement in hyperemia signs in Group A and Group B respectively.

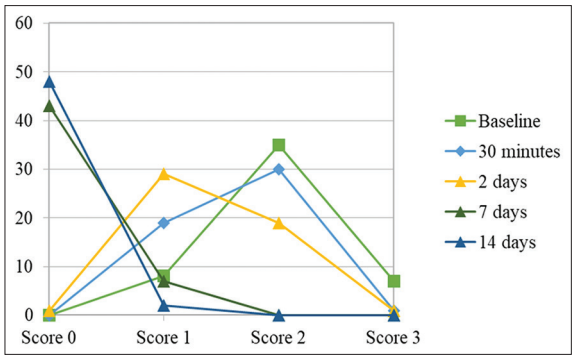

Figure 8: Comparison of the rate of improvement in hyperemia signs in Group A

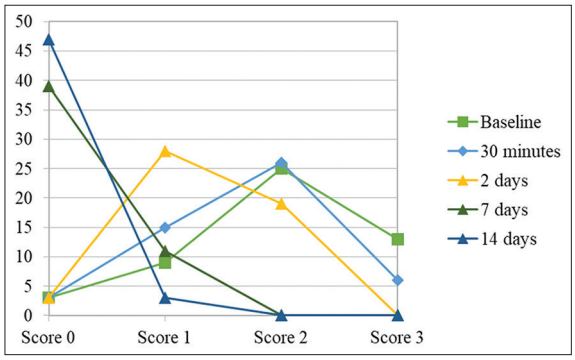

Figure 9: Comparison of the rate of improvement in hyperemia signs in Group B

Three patients apart from this had reported of stinging sensation on application of the ketorolac drops. Hence, it was observed that olopatadine eye drops were considerably superior to ketorolac eye drops in reducing the hyperemia symptoms at all-time intervals and the patients did not have any adverse effects with its application as well. In Discepola *et al.*[13] study, emedastine eye drops significantly reduced hyperemia as assessed at 3, 10, and 20 min after antigen challenge. This reduction was observed in the mean total redness scores as well as in the three-vessel beds evaluated. On the contrary, ketorolac treatment failed to inhibit redness. Compared to placebo, ketorolac actually resulted in significant ($P < 0.05$) increase of 13%, 11%, and 11% in the total redness scores at three assessment points.

CONCLUSION

All the patients showed improvement in itching and hyperemic symptoms by the 7th and 14th days. Percentage of responders included those who had an itching or hyperemia score of 0 at the time assessment after drug application. The percentage of non-responders was comparable between both the groups.

This study showed the efficacy and potency of drugs having dual action and NSAIDs such as olopatadine and ketorolac,

respectively. Similar results were obtained between both the drugs in attenuating the cardinal signs and symptoms of allergic conjunctivitis. Minor side effects caused by ketorolac should be kept in mind. The treatment preference for allergic conjunctivitis should give due consideration to patient compliance, cost, and side effects.

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Original Article

Pattern of Mortality in Pediatric Intensive Care Unit from a Tertiary Care Hospital in South India

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Abstract

Background: Management of critically ill children poses a great challenge to the treating physician. With the advances in the management of critically ill children, there is an increased survival of critically ill children. Profile of mortality in the pediatric intensive care unit (PICU) varies between different age groups and between different studies. Childhood mortality is an important indicator of health status of a country.

Objective: The objective of the study was to study the pattern of mortality in a PICU.

Materials and Methods: It is a retrospective study done at a tertiary care hospital. PICU records of all deaths were analyzed from January 2018 to December 2018.

Results: Of 1993 admissions, there were 209 deaths. The mortality rate was 10.52%. One-hundred and nine children died due to infections and 100 children died due to non-infectious causes.

Conclusion: Overall infections were the major cause of death in children which are higher than the developed countries. Infections were the major cause of death in children under 5 years of age. In children older than 5 years, non-infectious causes were the major cause of death. Mortality can be further reduced by improving infrastructure.

Key words: Children, Infections, Mortality, Non-infectious causes

INTRODUCTION

Pediatric critical care remains one of the challenging aspects in the field of pediatrics. The pediatric intensive care unit (PICU), where critically ill pediatric patients who require advanced airway, respiratory, and hemodynamic supports are usually admitted with the aim of achieving a better outcome. With the advancement in intensive care facilities, there is a dramatic increase in survival of critically ill children. Childhood mortality is one of the good indicators of a country's health status of the population. The infant mortality rate in our country is 37/1000 live births and maximum being reported from Madhya Pradesh.[1] Under-five mortality according to data provided by UNICEF is 39.4 deaths/1000 live births in 2018.[2] Diarrheal diseases, pneumonia, and other infectious diseases are leading causes of death among the children below 5 years of age in developing countries like India.[3,4] However, little is known about the causes of death in children after 5 years of age. Profile of mortality in PICU varies between different age groups. Evaluation of the mortality pattern can help in better decision-making, improving quality of care, and modifying future management.

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Aim of the Study

The aim of the study was to find the mortality pattern in PICU of a tertiary care hospital.

MATERIALS AND METHODS

Study Center

This study was conducted at PICU of a tertiary care hospital in South Tamil Nadu.

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Sampling

It is a retrospective analytical study which analyzed records from PICU of a tertiary referral center, from January 2018 to December 2018. This hospital has a well-equipped 8-bedded PICU with 16-bedded step down with eight high-end ventilators. We admit pediatric patients 1 month–12 years of age. Patients who are critically ill and those who require airway/respiratory support and hemodynamic support were admitted. PICU records of all the death cases were analyzed. The data collected on patients included age, gender, diagnosis, any comorbid conditions, and duration of unit stay. All patients were treated according to standard protocol. Relevant investigations, including hemoglobin, total and differential blood counts, blood glucose, urea, creatinine, electrolytes, blood culture, and arterial blood gas, were done whenever required. Other relevant investigations such as computed tomography and magnetic resonance imaging were done to arrive at the diagnosis. Expert opinion obtained whenever required.

RESULTS

During the study, there were 1993 admissions in PICU, of which 1157 were boys and 836 girls. There were 209 deaths (mortality rate 10.52%). Of 209 deaths, 120 (57.4%) were boys and 89 (42.6%) were girls. Table 1 shows the distribution of death among different age groups. A number of deaths were maximum in 1–12 months age group (n = 84; 40.2%).

Of 209 deaths, approximately one-third of the death (n = 58; 27.8%) occurred within 24 h of admission. Eighty-seven (41.6%) died within 5 days and the remaining 64 (30.6%) died after 5 days of admission [Table 2].

One-hundred and nine (52.1%) cases succumbed to infections and 100 (47.8%) deaths were due to non-infectious causes [Figure 1]. Among the infections, sepsis (n = 39; 18.7%) and pneumonia (n = 37; 17.7%) were the leading cause of death [Table 3].Comorbid conditions were found in 14% of children and malnutrition was the most common comorbidity. In non-infectious causes, neurological diseases (n = 18; 8.1%) were the major cause of death followed by cardiovascular diseases (n = 15; 7.2%). Other causes include accidental injuries and surgical causes [Table 4]. In children under 5 years of age, infections were responsible for 89 (58.9%) deaths and 62 (41%) children died of non-infectious causes. In children more than 5 years of age, 20 (34.5%) died due to infections and the remaining 38 (65.5%) died of non-infectious causes. [Figure 2].

Table 1: Age and sex distribution

Age group	Male	Female	Percentage
1 month–1 year	49	35	40.2
1–5 years	39	28	32.0
5–12 years	32	26	27.8

Table 2: Duration of PICU stay

Duration	Number of cases	Percentage
<1 day	58	27.8
1–5 days	87	41.6
>5 days	64	30.6

PICU: Pediatric intensive care unit

DISCUSSION

During the study, 1993 children were admitted to PICU. Majority were male children. Haque *et al.* also found that in their study, majority (60.9%) of patients were male.[5] Two-hundred and nine patients died during the study. The mortality rate was 10.52% which is comparable to the study conducted by Rashma *et al.* which was 10.56%.[6] The lower mortality rate was reported by Shah *et al.* (2.1%) and Choi *et al.* with the mortality rate (2.6%) from a general hospital in Hong Kong.[7,8] In our study, there was higher mortality among male children (57.4%) which is similar to the results of Siddiqui *et al.* and the male-to-female ratio was 1.3:1.[9] In the present study, we observed that most of the deaths (40%) were below 1 year of age which is comparable to other studies by Shashikala *et al.* and Ramnarayan *et al.* (51%,

Table 3: Spectrum of infectious diseases

Causes	Number of cases (%)
Sepsis	39 (18.7)
Pneumonia	37 (17.7)
Meningitis/encephalitis	17 (8.1)
Acute hepatitis	4 (1.9)
Tuberculosis	3 (1.4)
Other infections	9 (4.3)

Table 4: Spectrum of non-infectious causes

System involved/causes	Total number of cases (%)
Neurologic illness	17 (8.1)
Congenital heart diseases	11 (05.3)
Leukemia	10 (4.8)
Liver diseases	9 (4.3)
Poisoning/envenomation	9 (4.3)
Late HDN	8 (3.8)
Kidney diseases	6 (2.9)
Chronic lung diseases	4 (1.9)
Hematological diseases	4 (1.9)
Endocrine/metabolic	4 (1.9)
Acquired heart diseases	4 (1.9)
SLE	4 (1.9)
Solid tumors	3 (1.4)
Drowning	3 (1.4)
Others	4 (1.9)

HDN: Hemorrhagic disease of the newborn, SLE: Systemic lupus erythematosus

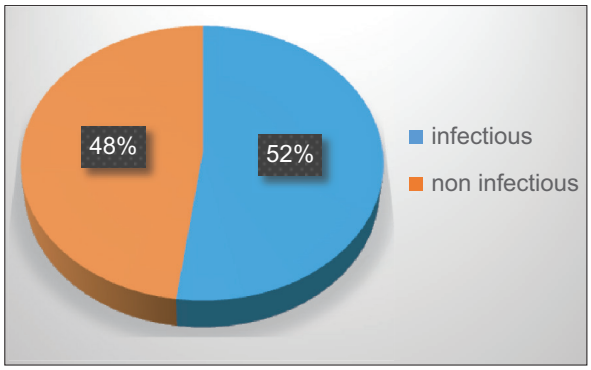

Figure 1: Distribution of death

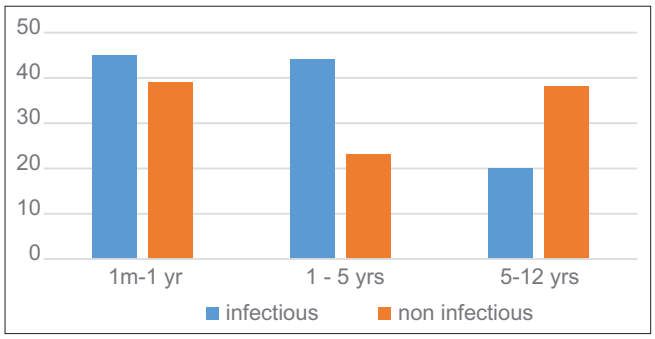

Figure 2: Distribution of death among the different age groups

57.7%), respectively.[10,11] Of 209 patients, 58 (27.8%) patients died within 24 h of admission. Shashikala *et al.* reported 16% of deaths occurring within 24 h of admission.[10] It may be due to delayed referral from peripheral health centers and lack of awareness regarding danger signs. Among the infections, sepsis (18.7%) and pneumonia (17.7%) were the leading causes of death, which are comparable to the study by Kapil and Bagga.[12] They reported that septicemia (18.6%) was the most common cause of death followed by congenital heart disease (10.6%). Shah *et al.* in their study reported that pneumonia (23.4%) was the most common cause of death.[7] In children below 5 years of age, infections were responsible for 58.9% of deaths which are similar to other studies.[13,14] In our observation, 65.5% of death in above 5 years of children is due to non-infectious causes. This is contrary to the study done by Morris *et al.* which showed about 60% of death due to infectious causes.[15] This is probably due to the fact that our center is a tertiary referral hospital, where the profile of referred children is different from the community. There are some limitations in our study. Since it is a retrospective study, it may have some recall and interpretation bias that could lead to incomplete data. Second, this study does not include the children who got discharged against medical advice then died later at home.

CONCLUSION

Our center showed a mortality rate of 10.5% which is higher than in developed countries. Mortality can be further reduced by strengthening of infrastructure and workforce. Infections were the leading cause of death which can be prevented by improving the socioeconomic status of the population and strengthening immunization coverage. Approximately one-third of children died within 24 h of admission which can be avoided by early referral and educating the community regarding danger signs. Majority of children with >5 years of age died due to non-infectious causes. Further studies are needed to confirm these observations.

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Original Article

Comparative Study of Bacteriological Profile of Cellulitis in Diabetic versus Non-Diabetic Patient

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Abstract

Introduction: Comparative study of bacteriological profile of cellulitis - in diabetic versus non diabetic patient.

Materials and Methods: During a period of June 2018–May 2019 in Sanjay Gandhi Memorial Hospital surgical wards, approximately 100 cases including both diabetic and non-diabetic getting admitted through surgery out patient department, casualty, or transferred from other departments diagnosed as cellulitis based on clinical suspicion. Samples were collected from the deeper portion of the ulcers, among these samples, one swab was used for Gram staining and the other was used for culture. A direct Gram stained smear of the specimen was examined. The organisms were identified on the basis of their Gram staining properties, their biochemical reactions, and the culture identified.

Results: According to pus culture sensitivity is was found that among Gram-negative isolates, *Pseudomonas aeruginosa* (25.19% in D and 28.06 in ND) is most common in both diabetic and non-diabetic followed by *Escherichia coli* (16.12% in D and 17.39% in ND) and *Klebsiella pneumoniae* (12.9% in D and 8.6% in ND). Among Gram-positive isolates, *Staphylococcus aureus* is most commonly isolated followed by *Enterococcus* in diabetics, as in non-diabetics, *S. aureus* (32. 25% in D and 30.43% in ND) is most commonly isolated followed by *Enterococcus* (9.6% in D and 4.3% in ND) and methicillin-sensitive *S. aureus* (1.6% in D and 2.17% in ND) (D – diabetics and ND – non-diabetics).

Conclusion: Microbiological evaluation of the ulcers revealed that the prevalence of Gram-negative organisms 47 (57.75%) was found to be more than Gram-positive organisms 14 (17.5%), *Candida albicans* 3 (3.75%), and polymicrobial species 17 (21.25%). Among Gram-negative isolates, *P. aeruginosa* is most common in both diabetic and non-diabetic followed by *E. coli* and *K. pneumoniae*. Among Gram-positive isolates, *S. aureus* is most commonly isolated followed by *Enterococcus* in diabetics, as in non-diabetics, *S. aureus* is most commonly isolated followed by *Enterococcus* and methicillin-sensitive *S. aureus*.

Key words: Cellulitis, Comparative study, Culture study of pus discharge from cellulitic ulcer, Diabetic versus non-diabetics

INTRODUCTION

Cellulitis is a bacterial infection involving the inner layers of the skin. It specifically affects the dermis and subcutaneous fat. It affects patients of all age groups. The presence and the stability of comorbid conditions like diabetes that may complicate or delay the resolution of the infection influence the clinical management of the disease.

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Numerous microorganisms can cause cellulitis. The most commonly isolated organisms are Gram-positive beta-hemolytic streptococci and *Staphylococcus aureus*. Unusual organisms like clostridium may cause infections in circumstances such as in animal bites, fresh/saltwater exposure, and certain occupational exposures.

Diabetes is a prevalent disease worldwide and wound infection is a major complication in diabetic patients. Patients with diabetes having impaired wound healing associated with multitude of factors, including neuropathy, vascular disease, and foot deformities, Gadepalli *et al.*[1] Metabolic abnormalities of diabetes lead to impaired leukocyte function, inadequate migration of neutrophils, and macrophages to the wound, along with reduced chemotaxis, predispose individuals to an increased risk of wound infection.

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Studies have revealed that diabetic wounds showed significantly higher bacterial counts compared with non-diabetic wounds. Natural skin flora itself induced sustained bacterial infections in the wound tissue in diabetic wounds, whereas non-diabetic organisms were able to cope with endogenous bacterial contamination.[2] It is a fact that diabetic patients are not only more susceptible to infection but also when infection occurs they are more severe as the diabetic is a compromised host while certain types of infection do have predilection for the diabetic.

The predominantly isolated organisms are *S. aureus*, Gram-negative Bacilli such as Pseudomonas aeruginosa, Escherichia coli, Klebsiella species, Proteus species, and anaerobic organisms. The remainders are due to Streptococcus species, Candida, etc. The infection may be polymicrobial also and mixed organisms are frequently encountered.[3]

However, the spectrum of microorganisms depends mainly on microbial flora of particular area, metabolic factors, hygiene, and the use of antibiotics. Management of these infections requires isolation and identification of the microbial flora, appropriate antibiotic therapy according to the sensitivity patterns.[4] Emergence of resistance among organisms against the commonly used antibiotics has been clearly outlined in various studies as being largely due to their indiscriminate use.

Early diagnosis of microbial infections is aimed to institute the appropriate antibacterial therapy and to avoid further complications in view of the above facts, a cross-sectional study was done to compare the microbial profile of diabetic wound infections with non-diabetic wound infections, to assess their *in vitro* susceptibility to antibiotics and detection of methicillin-resistant *S. aureus* and extended-spectrum beta-lactamase producers in Gram-negative *Bacilli*.

Aims and Objectives

The study entitled "*Comparative study of bacteriological profile of cellulitis – in Diabetic versus Non-Diabetic patient*" will be carried out on patients admitted in surgical wards of Sanjay Gandhi Memorial Hospital (SGMH) associated with Shyam Shah Medical College, Rewa (Madhya Pradesh), during the period of June 1, 2018,–May 31, 2019, with following aims and objectives:

1. To study the incidence of cellulitis in surgical wards SGMH
2. To study the pattern of bacterial profile in wounds in case of cellulitis
3. To compare the bacteriological profile.

Inclusion Criteria

The following criteria were included in the study:

1. All cases of cellulitis
2. Age group of 10–60 years.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patient already on antibiotic therapy
2. Patient on immunosuppressant drugs
3. Patient having chronic disease such as tuberculosis and cancer.

MATERIALS AND METHODS

During a period of June 2018–May 2019 in SGMH surgical wards, approximately 100 cases including both diabetic and non-diabetic getting admitted through SOPD, casualty, or transferred from other departments diagnosed as cellulitis based on clinical suspicion, during the period of study will be included in the study.

Samples were collected from the deeper portion of the ulcers using two sterile swabs which were dipped in sterile glucose broth. The samples were collected by making a firm, rotatory movement with the swabs. One swab was used for Gram staining and the other was used for culture. A direct Gram-stained smear of the specimen was examined. The specimens were inoculated onto blood agar, chocolate agar, MacConkey's agar, and thioglycolate medium.

The inoculated plates were incubated at 370°C overnight and the plates were examined for growth, the next day. The further processing was done according to the nature of the isolate, as was determined by Gram staining and the colony morphology. The organisms were identified on the basis of their Gram staining properties and their biochemical reactions.

OBSERVATION AND RESULTS

Distribution of Bacteria Isolated from Study Population

Rani and Nithyalakshmi[6] microbiological evaluation of the ulcers revealed that the prevalence of Gram-negative organisms 47 (57.75%) was found to be more than Gram-positive organisms 14 (17.5%), *Candida albicans* 3 (3.75%), and polymicrobial species 17 (21.25%).

Among the organisms isolated, *P. aeruginosa* was the most frequent pathogen isolated from 19 (23.75%) subjects followed by *E. coli* isolated from 12 (15%) subjects. Different types of Gram-negative and Gram-positive bacteria isolated from ulcers are summarized in Tables 1-3.

Table 1: Proportion of bacteria isolates in specific age groups

Age (in years)	Total number of cellulitis patient both diabetic and non-diabetic	Proportion of bacteria isolated in specific age groups							
		Staphylococcus aureus	*Pseudomonas aeruginosa*	*Escherichia coli*	*Klebsiella pneumoniae*	E	Methicillin-sensitive *S. aureus*	Beta-hemolytic streptococci	A.s
1–10	7	3	2	1	-	-	-	2	-
10–20	4	1	1	2	1	-	-	-	-
20–30	7	4	1		1	1	-	-	-
30–40	25	8	7	3	4	2	1	1	-
40–50	25	10	7	4	2	2	1	1	-
50–60	21	6	7	5	4	1	-	-	1
60–70	11	2	3	3	-	2	1	-	-
70 and above	-	-	-	-	-	-	-	-	-

Table 2: Number of patients based on Gram-negative culture isolates

Gram-negative isolates	Cellulitis	
	Diabetic (%)	Non-diabetic (%)
Pseudomonas aeruginosa	15 (24.19)	13 (28.06)
Escherichia coli	10 (16.25)	8 (17.39)
Klebsiella pneumoniae	8 (12.09)	4 (8.6)
Proteus mirabilis	-	-
Proteus vulgaris	-	-
Citrobacter species	-	-
Acinetobacter species	1 (1.6)	-

Table 3: Number of patients based on Gram-positive isolates

Gram-positive isolates	Cellulitis	
	Diabetic (%)	Non-diabetic (%)
Staphylococcus aureus	20 (32.25)	14 (30.43)
Enterococcus species	6 (9.6)	2 (4.3)
Methicillin-sensitive *Staphylococcus aureus*	1 (1.6)	2 (4.3)
Beta-hemolytic streptococci	1 (1.6)	1 (2.1)

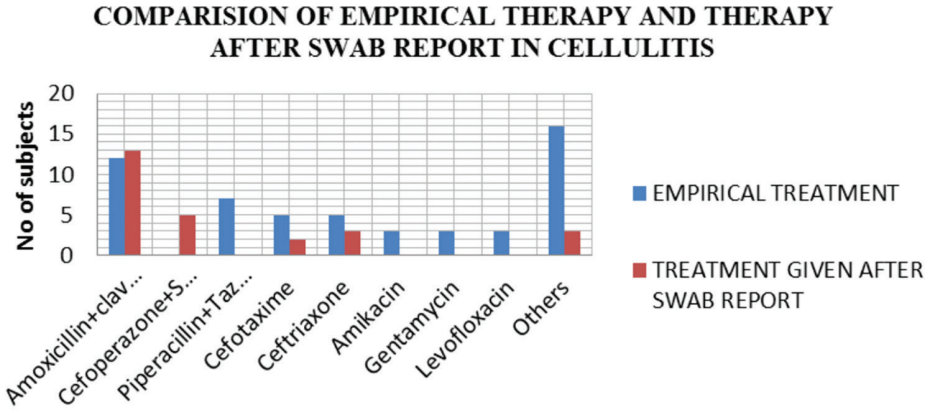
Comparison of Empirical Therapy and Therapy Given After Swab Report in Cellulitis Subjects

Considering antibiotic prescribing patterns in the cellulitis subjects, penicillin combinations 23 (28.75%) in normal patients followed by clindamycin 7 (8.13%) and amikacin 8 (9.30%) in intensive care patients were preferred as an empirical therapy in foot ulcer subjects.

In cellulitis subjects, penicillin 12 (22.22%) (Amoxicillin +Clavulanic acid) and cephalosporin's 10 (12.5%) are mostly prescribed drugs as empirical treatment. Amoxicillin + Clavulanic acid (U; 25 [33.78%] and C; 13 [33.33%]) is mostly prescribed drug after swab report due to its sensitivity against Gram-positive and Gram-negative activity in cellulitis subjects.

DISCUSSION

The present study observed types of microbial infections and patterns of antibiotics prescribed to subjects diagnosed with foot cellulitis. In the present study, male predominance was noted over females. This may be due to the fact that males tend to be more active in the outdoor activities, leading to injuries and prone to the development of ulcers. In the current study, we found that patients with an age range of 30–50 years constituted the majority with cellulitis. The mean age of patients in the present study is 38.78 ± 10.09 years which is on the line of study by Sundresh *et al.*[7] In our study, among social habits, both smoking and alcohol were important risk factors for the



development of diabetic and non-diabetic cellulitis. Multiple wounds were the most common symptom identified among diabetic and non-diabetic cellulitis. Swelling with skin color change was most predominant symptom identified among diabetic and non-diabetic cellulitis, during the study period. These findings are consistent with the earlier published literature, Tiwari *et al*.[8]

Microbiological evaluation of diabetic cellulitis showed that the prevalence of Gram-negative organisms was found to be more than Gram-positive organisms, Rani and Nithyalakshmi.[6] *P. aeruginosa* was the most frequent followed by *E. coli*. These findings correlated well with those of studies carried out in India which showed that Gram-negative *Bacilli* as the most common organism and pseudomonas being the predominant pathogen, Manisha *et al*.[9]

The present study also adds to the literature by providing a detailed comparison of antibiotic utilization patterns among diabetics and non-diabetics. We demonstrated that diabetics were more likely to have significant exposure to antibiotics with broad Gram-negative activity, particularly antipseudomonal agents (the broad-spectrum antibiotics). Since the initiation of broad Gram-negative therapy in the emergency department or urgent care was not more common among diabetics, the increased use of these agents among diabetics appeared to be driven by inpatient providers. It is also notable that of patients who received any antibiotic with broad Gram-negative activity, these agents accounted for similar proportions of the total days of therapy in both diabetics and non-diabetics. In aggregate, our findings demonstrate that diabetics are more likely to be started on antibiotics with broad Gram-negative activity by inpatient providers, diabetics are not necessarily continued on longer durations of broad Gram-negative therapy once started, and the total amount of exposure to broad Gram-negative agents is substantial.

Overall, our findings suggest that inpatient providers perceive diabetics with cellulitis or abscess to be at increased risk for Gram-negative pathogens. This perhaps reflects an extrapolation of recommendations to use broad-spectrum empiric therapy in diabetics with certain complicated skin infections. However, for patients with cellulitis or cutaneous abscess, IDSA guidelines recommend antibiotic therapy targeted toward *S. aureus* and streptococcal species; there is no suggestion to use a broad spectrum of therapy in diabetics, Stevens *et al*.[10]

Our findings, therefore, highlight an important opportunity to improve antibiotic selection for all patients hospitalized with cellulitis, but particularly diabetics. It is also noteworthy that by linear regression, diabetes mellitus was independently associated with longer treatment durations. Although the average increase in treatment duration was small (1 day), this finding adds to the evidence that the presence of diabetes mellitus alters providers' treatment approach to cellulitis.

We found that despite more frequent treatment with broad Gram-negative therapy, diabetics were more likely than non-diabetics to be classified as clinical failure. It is important to point out that diabetics were also more likely than non-diabetics to have post-discharge outpatient follow-up visits raising the possibility of biased ascertainment of clinical failure events in this group. However, we also demonstrated that diabetics with cellulitis were more likely to be rehospitalized than non-diabetics. One could hypothesize that the increased frequency of clinical failure events among diabetics was due to their older age, hyperglycemia, or vascular insufficiency; however, other factors may have contributed.

Amoxicillin+Clavulanic acid along with metronidazole is commonly prescribed drugs irrespective of diabetes mellitus in this study, Dong *et al*.[11] These findings support current ISDA guidelines that recommend antibiotic therapy targeted toward Gram-negative isolates irrespective of diabetes mellitus.

Our results shown that relaxing incision followed by debridement was the most common surgical procedure among diabetic and non-diabetic ulcer which was significant to Tian *et al*.[12] study.

The present study demonstrates that a variety of organisms can be isolated from these ulcers. Knowledge of the microbes that cause infection and their susceptibility toward the antibiotics will allow physicians to make best out their choice. Considering the nature of the organism and the type of isolate, appropriate empirical antibiotic therapy should be initiated, especially for the patients who are at risk categories. Once the nature of the organism and the probable pathogens are isolated, de-escalation of empiric therapy with a single drug or combination therapy can be guided by relevant culture results.

CONCLUSION

The present study entitled "*Comparative study of bacteriological profile of cellulitis – in Diabetic versus Non-Diabetic patient*" was carried out on 100 patients admitted in surgical wards of Sanjay Gandhi Hospital associated with Shyam Shah Medical College, Rewa (M.P), during the period of June 1, 2018,–May 31, 2019.

According to pus culture sensitivity is was found that among Gram-negative isolates, *Pseudomonas aeruginosa* (25.19% in D and 28.06 in ND) is most common in both diabetic and non-diabetic followed by *E. coli* (16.12% in D and 17.39% in ND) and *Klebsiella pneumoniae* (12.9% in D and 8.6% in ND). Among Gram-positive isolates, *S. aureus* is most commonly isolated followed by *Enterococcus* in diabetics, as in non-diabetics, *S. aureus* (32. 25% in D and 30.43% in ND) is most commonly isolated followed by *Enterococcus* (9.6% in D and 4.3% in ND) and methicillin-sensitive *S. aureus* (1.6% in D and 2.17% in ND) (D – diabetics and ND – non-diabetics).

Amoxicillin+Clavulanic acid is mostly prescribed drug after swab report due to its sensitivity against Gram-positive and Gram-negative activity in both cellulitis subjects.

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Original Article

An Analysis of Role of Computed Tomography Scan Abdomen in Differentiating Perforated from Non-perforated Appendicitis Accurately and Comparing with Histopathology Reports

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Abstract

Background: Acute appendicitis is one of the most common abdominal surgical emergencies requiring accurate diagnosis. It is characterized by obstruction of its lumen, leading to inflammation and finally perforation. To define its prognosis, choose an appropriate surgical procedure and to decide non-surgical treatment, the pre-operative diagnosis of perforated or non-perforated appendicitis is very important.

Aim of the Study: This study aims to analyze the diagnostic accuracy of computed tomography (CT) scan abdomen in differentiating perforated from non-perforated appendicitis using histopathology as the final diagnosis.

Materials and Methods: A prospective, cross-sectional analytical study, wherein 85 patients diagnosed with acute appendicitis referred to the radiological department for CT scan abdomen were included in the study. Patients aged between 15 and 70 years were included in the study. CT scan abdomen with and without contrast was performed on a Toshiba 64 Multislice CT scanner (Toshiba Medical Systems Corp., Tokyo, Japan) which was used for all the patients. All the CT scans were interpreted by the same consultant radiologists with a minimum of 5 years of experience. The radiological features for the diagnosis of non-perforated acute appendicitis by CT were based on swollen appendix, thickened enhancing wall, and smudging of surrounding fat planes, whereas the radiological features for perforated appendicitis used were, with abscess formation, phlegmon, extraluminal air, extraluminal appendicolith, and focal defect in the appendicular wall. Histopathology of the specimen collected following surgery was undertaken by the hospital consultant pathologist of more than 5-year experience.

Observations and Results: Among the 85 patients included in this study for the analysis of CT scan abdomen features, there were 57 (67.05%) males and 28 (32.94%) females with a male-to-female ratio of 2.03:1. The mean age of the patients was 38.90 ± 6.70 years. The incidence of non-perforated appendicitis was 66/85 (77.64%) including males 44/85 (51.76%) and females 22/85 (25.88%). The incidence of perforated appendicitis was 19/85 (22.35%) and males were 12/85 (14.11%) and 7/85 (8.23%) were female. Patients aged 15–45 years of both genders constituted to 63/85 (74.11%) of the total patients. Among these patients, presenting with non-perforated appendicitis was 51/85 (60%) and perforated appendicitis was 12/85 (14.11%).

Conclusions: Multislice CT scan abdomen was considered as the modality of choice for acute appendicitis not only to confirm the diagnosis but also it plays an important role in assessment of appendicular complication, particularly in the detection of perforated appendix. Using one or more of the five radiological signs of CT scan abdomen to identify appendicular perforation raised the sensitivity significantly reaching 94.12%.

Key words: Abscess formation, Appendix, Extraluminal air and phlegmon, Multislice computed tomography scan, Perforated appendix

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INTRODUCTION

Appendicitis being the most common abdominal surgical emergency with an incidence 7–12% of the general population demands accurate diagnosis which is essential for taking a surgical decision in its management. The management may be either medical or surgical in

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nature.[1] Usually, appendicitis starts with block in the lumen or its opening followed by accumulation of fluid within its lumen.[2,3] As the disease process continues, the appendix becomes swollen and the inflammatory process involves its wall and progresses into the periappendicular fat planes.[4] The most common complications are appendicular perforation, abscess formation, peritonitis, and bowel obstruction.[5] The characteristic clinical features of appendicitis are pain in the right lower quadrant of abdomen fever, vomiting, and rebound tenderness.[6,7] Laboratory finding of increased white blood cell count has a low predictive value for the diagnosis of appendicitis.[8] Even though clinical and laboratory findings are helpful in the diagnosis of acute appendicitis, about 30% of patients have atypical presentation that can be misleading.[9] In such critical times, computed tomography (CT) scan is the modality of choice to diagnose the acute appendicitis and differentiate it from the other causes of acute abdomen. The progressive use of CT scan in such situations has resulted in significant reduction in the negative appendectomy rates from 30% to 2%.[10] The differentiation between the non-perforated and perforated appendicitis is important because the perforation of appendix is associated with higher mortality rate.[11] The incidence rate of post-operative complications in patients with perforated appendectomy is high compared to non-perforated appendectomy (28.4% vs. 4.7%).[12] In one study, the mean length of hospital stay in the perforated group was 6.3 days while it was 2.9 days in the non-perforated group.[13] The advantages of CT scan of abdomen are that it is non-operator dependent, widespread non-invasive technique, and easy detection of the diseased or non-diseased appendix even in its different positions.[11] Ultrasound sound abdomen appears less sensitive and less accurate in diagnosing in acute appendicitis when compared to the CT scan,[12,13] especially in those patients with severe pain, marked gaseous distension, and in obese patients. The progress in CT scanners is allowing shortening of the scan time and multiplanar reformatted images with high spatial resolution.[14] The radiological features for diagnosis of non-perforated acute appendicitis by CT are based on swollen appendix, thickened enhancing wall, and smudging of surrounding fat planes,[12,14] whereas the diagnosis of perforated appendicitis was suggested with abscess formation, phlegmon, extraluminal air, extraluminal appendicolith, and focal defect in the appendicular wall.[15] In one study, the sensitivity and specificity of CT to diagnose perforated appendicitis was 69% and 97%, respectively.[16] In the present context, this study was conducted to analyze the diagnostic accuracy of CT scan abdomen in differentiating perforated from non-perforated appendicitis using histopathology as the final diagnosis.

Type of Study

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

Duration of Study

This study was from October 2015 to October 2018.

Institute of Study

This study was conducted at Al Azhar Medical College and Super Specialty Hospital, Thodupuzha, Kerala.

MATERIALS AND METHODS

A prospective, cross-sectional analytical study was conducted at a tertiary teaching hospital of Kerala, wherein 85 patients diagnosed with acute appendicitis referred to the radiological department for CT scan abdomen were included in the study. An ethical committee clearance was obtained before the commencement of the study. An ethical committee accepted pro forma was used for this study.

Inclusion Criteria

1. Patients aged between 15 and 70 years were included in the study
2. Patients with symptoms of pain in the abdomen, fever, and vomiting were included in the study
3. Patients with rebound tenderness in the right lower quadrant of the abdomen were included in the study
4. Patients of both the genders were included in the study.

Exclusion Criteria

1. Patients aged below 15 and above 70 years were excluded from the study.
2. Those patients who were refused surgery in this same hospital and referred to other hospitals or with deranged renal function were excluded from the study.

CT scan abdomen was performed on a Toshiba 64 Multislice CT scanner (Toshiba Medical Systems Corp., Tokyo, Japan) which was used for all the patients. The scanning protocol included the acquisition of axial helical CT sections before and after the administration of intravenous contrast, extending from the xiphoid process of the sternum to the pubic symphysis pubis at 120 kVp and 210 mA. At the time of scanning, intravenous contrast was administered using a power injector at a rate of 5 mL/s followed by the acquisition of axial cuts at 4-mm slice thickness in the portal venous phase (60–70 s after injection of bolus contrast). Sagittal and coronal multiplanar reconstruction was also performed. All the CT scans were interpreted by the same consultant radiologists with a minimum of 5 years of experience. The radiological features for the diagnosis of non-perforated acute appendicitis by CT were based on swollen appendix, thickened enhancing wall, and smudging of surrounding fat planes, whereas the radiological features for perforated appendicitis used were, with abscess formation, phlegmon,

extraluminal air, extraluminal appendicolith, and focal defect in the appendicular wall. Histopathology of the specimen collected following surgery was undertaken by the hospital consultant pathologist of more than 5-year experience. All the data were analyzed using descriptive statistics, frequency, and percentage which were computed for gender, CT scan findings, and histopathology findings. Mean ± standard deviation for age was calculated. Sensitivity, specificity, positive and negative predictive values, and diagnostic accuracy of perforated appendicitis on CT scan were calculated using histopathology as the final diagnosis. The accuracy through Chi-square test, $P < 0.05$ was considered statistically significant.

OBSERVATION AND RESULTS

Among the 85 patients included in this study for the analysis of CT scan abdomen features, there were 57 (67.05%) males and 28 (32.94%) females with a male-to-female ratio of 2.03:1. The youngest patient was aged 16 years and the eldest patient was aged 70 years with a mean age of 38.90 ± 6.70 years. The incidence of non-perforated appendicitis was 66/85 (77.64%) observed in this study. Among the 66/85 non-perforated appendicitis, males were 44/85 (51.76%) and 22/85 (25.88%) were female. The incidence of perforated appendicitis was 19/85 (22.35%) and among them, males were 12/85 (14.11%) and 7/85 (8.23%) were female. Patients aged 15–45 years of both genders constituted to 63/85 (74.11%) of the total patients. Among these patients, presenting with non-perforated appendicitis was 51/85 (60%) and perforated appendicitis was 12/85 (14.11%), [Table 1].

CT scan abdomen features suggestive of non-perforated appendicitis includes enlarged appendicular diameter (>6 mm) with an occluded lumen was observed in 27/85 (40.90%), appendicular wall thickening (>2 mm) in 14/85 (21.21%), periappendicular fat stranding in 12/85 (18.18%), appendicular wall enhancement in 9/85 (13.63%), and appendicolith in 4/85 (6.06%) was observed [Table 2].

Specific signs for perforated appendicitis on CT scan abdomen included a defect in enhancing the appendicular wall was observed in 7/85 (36.84%), focal area of non-enhancement with enhancing of the remaining appendicular wall was observed in 5/85 (26.31%), extraluminal air in 3/85 (15.78%), extraluminal appendicolith in 2/85 (10.52%), and abscess formation in 2/85 (10.52%) patients [Table 3].

CT scan abdomen reports in this study showed that there were 19/85 (22.35%) patients that had perforated and 66/85 (77.64%) had non-perforated appendicitis while histopathology reported 14/85 (16.47%) with perforated appendicitis and 53/85 (83.52%) with non-perforated appendicitis. That leaves us with 5/85 (5.88%) false-positive cases among the perforated appendicitis cases and 13/85 (15.29%) false-positive cases among the non-perforated appendicitis. Hence, in the present study, the sensitivity of CT scan abdomen in the diagnosis of perforated appendicitis was 94.12% and sensitivity ion the diagnosis of non-perforated appendicitis was 84.71%. Positive predictive value of non-perforated appendicitis was 62.35% and positive predictive value of perforated appendicitis was 73.68%. The accuracy of CT in the detection of perforated appendicitis was 85.4% in male cases and 92.2% in female cases.

DISCUSSION

In addition to rapid and accurate diagnosis of acute appendicitis, the surgeon needs to know accurately whether any associated complication is associated with it, especially whether it is perforated or non-perforated. This information would be of great value to the operating surgeon so that he could be sure of the prognosis. Localization of the inflamed appendix can be determined by the radiologist in most of the cases before surgical interference. High sensitivity and specificity in detection of acute appendicitis ranging between 94 and 98% were reported by many authors with the help of CT scan abdomen increasing its diagnostic value.[17] Even though surgical treatment

Table 1: Incidence of types of appendicitis in different age groups (*n*=85)

Age group	Non-perforated appendicitis – 66 (77.64%)	Perforated appendicitis – 19 (22.35%)	Percentage
15–30 (38)	Total – 31 (24.70) Male – 21, female – 10	Total – 7 (8.23) Male – 4, female – 3	44.70
31–45 (25)	Total – 20 (23.52) Male – 13, female – 7	Total – 5 (5.88) Male – 3, female – 2	29.41
46–60 (11)	Total – 8 (9.41) Male – 5, female – 3	Total – 4 (4.70) Male – 3, female – 1	12.94
61–75 (11)	Total – 7 (8.23) Male – 5, female – 2	Total – 3 (3.52) Male – 2, female – 1	12.94
Total	Total – 66 (51.76) Male – 44, female – 22	Total – 22 (25.88) Male – 12, female – 7	100

Table 2: Incidence computed tomography scan abdomen findings in non-perforated appendicitis (*n*=66)

Radiological features	Number	Percentage
Enlarged appendicular diameter with occluded lumen>6 mm	27	40.90
Appendicular wall thickening (>2 mm)	14	21.21
Periappendicular fat stranding	12	18.18
Appendicular wall enhancement	9	13.63
Appendicolith	4	6.06

Table 3: Incidence computed tomography scan abdomen findings in perforated appendicitis (*n*=19)

Radiological features	Number	Percentage
Enhancing the appendicular wall	7	36.84
Focal area of non-enhancement with enhancing of the remaining appendicular wall	5	26.31
Extraluminal air	3	15.78
Extraluminal appendicolith	2	10.52
Abscess formation	2	10.52

is adopted for uncomplicated acute appendicitis, few surgeons treat non-complicated appendicitis or appendicitis without palpable mass by conservative medical treatment instead of surgical interference. The medical conservative treatment and antibiotic therapy if administrated in the first 12 h are considered effective method for treatment with 68–84% success rate.[18,19] In situations, where a clinical examination reveals complication of acute appendicitis such as perforation choosing a non-surgical management depends on accurate and reliable CT scan abdomen interpretation. Review of current literature reveals that the sensitivities and specificities for CT scan abdomen for the diagnosis of acute appendicitis are around 90%, resulting in significantly reduced negative appendectomy rates from 15–20% to 2–12%.[20,21] In spite of high sensitivity, the differentiation between perforated and non-perforated appendicitis is not as accurate as it should be because differentiating perforated from non-perforated appendicitis is decided on by a wide range of radiological signs of CT scan abdomen. They include the presence of free fluid, phlegmon, abscess, extraluminal air, and bowel wall thickening; each of these characteristics favors perforation.[21,22] In this study, CT scan abdomen features suggestive of non-perforated appendicitis includes enlarged appendicular diameter (>6 mm) with an occluded lumen was observed in 27/85 (40.90%), appendicular wall thickening (>2 mm) in 14/85 (21.21%), periappendicular fat stranding in 12/85 (18.18%), appendicular wall enhancement in 9/85 (13.63%), and appendicolith in 4/85 (6.06%) was observed [Table 2]. Specific signs for perforated appendicitis on CT scan abdomen included a defect in enhancing the appendicular wall was observed in 7/85 (36.84%), focal area of non-enhancement with enhancing of the remaining appendicular wall was observed in 5/85 (26.31%), extraluminal air in 3/85 (15.78%), extraluminal appendicolith in 2/85 (10.52%), and abscess formation in 2/85 (10.52%) patients [Table 3]. In the present study, the sensitivity of CT scan abdomen in the diagnosis of perforated appendicitis was 94.12% and sensitivity ion the diagnosis of non-perforated appendicitis was 84.71%. Positive predictive value of non-perforated appendicitis was 62.35% and positive predictive value of perforated appendicitis was 73.68%. The accuracy of CT in the detection of perforated appendicitis was 85.4% in male cases and 92.2% in female cases. In another study, the sensitivity and specificity of CT to diagnose perforated appendicitis was 69% and 97%, respectively.[13] In the Fraser *et al*. study,[23] CT scan abdomen had a sensitivity of 62% with a specificity of 81% in predicting appendicular perforation.

CONCLUSIONS

Multislice CT scan abdomen was considered as the modality of choice for acute appendicitis not only to confirm the diagnosis but also it plays an important role in assessment of appendicular complication, particularly in detection of perforated appendix. Using one or more of the five radiological signs of CT scan abdomen to identify appendicular perforation raised the sensitivity significantly reaching 94.12%. However, individual CT scan abdomen finding showed relatively low-to-moderate sensitivity in diagnosis of perforated appendicitis.

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Original Article

Pediatric Pneumonia: A Review of Clinical Practice Essentials – A Clinical Study in a Tertiary Hospital

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Abstract

Background: Lower respiratory tract infections are common cause of morbidity in infants and preschool children. Among them, infectious pneumonia is foremost in causing serious illness and creates problems in its diagnosis. Determination of exact etiology of pneumonia is uncertain due to difficulty in obtaining suitable and adequate samples and shortage of accurate diagnostic methods.

Aim of the Study: The aim of the study was to review the clinical diagnosis, investigations, diagnosis, and management of pneumonia in children in the light of the WHO guidelines.

Materials and Methods: A total of 79 children with pneumonia attending a tertiary teaching hospital were included in the study. Children aged between 2 and 59 months were included in the study. Children satisfying WHO criteria for the diagnosis of pneumonia were included from the study. Children with documented evidence of comorbidities were excluded from the study. Demographic data, nutrition history including breastfeeding practices, immunization history, and treatment history, were elicited. Children were divided as Group A: Children with weight for age <3rd percentile, and Group B: Children with weight for age ≥3rd percentile. Investigations included radiological, hematological investigations such as complete blood picture, sputum examination, and nasopharyngeal aspirates analysis for organism and blood cultures were done. All the children were treated following the WHO guidelines. The hospital stay was grouped as <1 week group and more than 1 week group.

Observations and Results: Among 79 children there were 43 (54.43%) male children and 36 (45.56%) female children. The youngest child was 2 months old and the eldest child was aged 57 months old with a mean age of 28.4 ± 1.3 months. Children belonging to Group A were 40 (50.63%) and belonging to Group B were 39 (49.36%). Among 79 children, 46/79 (58.22%) were diagnosed as "Pneumonia" and the remaining 33/79 (41.77%) children as severe pneumonia. 62/79 (78.48%) children below 36 months (3 years) were found to have either pneumonia or severe pneumonia. 17/79 (21.51%) children belonged to the age group above 36 months were found to have either pneumonia or severe pneumonia in this study. 39/62 (62.90%) children who had pneumonia were below 36 months and 23/62 (37.09%) children who had severe pneumonia were below 36 months.

Conclusions: Pneumonia is a clinically curable disease when identified and initiated on recommended treatment protocols. Lack of exclusive breastfeeding till 6 months of age, failure of complete immunization coverage, child malnutrition, infancy, and toddler age are the risk factors for both types of the pneumonia but more so with severe pneumonia. There was no statistical significance correlating the X-ray findings and severity of pneumonia was observed.

Key words: Atypical pneumonia, Breastfeeding, Children, Infections, Malnutrition, Pneumonia

INTRODUCTION

Pneumonia is a common pediatric disease with significant mortality. Every year nearly 1.6 million children die from pneumonia.[1] The pneumonia etiology research for child health (PERCH) study is the largest multicenter study of childhood pneumonia in the present times, which helps in defining pneumonia according to their etiology, predisposing factors, investigations, and management.[2] In 2015, the maternal and child epidemiology estimation group of the WHO reported mortality of an estimated 0.9 million children all over the world under-five age group. This observation was made from the WHO global health observatory data and declared that pneumonia continues to be the leading cause of death among children in developing countries.[3] In India 143,286 children aged

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<5 years were reported to have died due to pneumonia in the post-neonatal period during the year 2015 contributing to 28% of post-neonatal deaths.[3] The case fatality rate due to pneumonia among hospitalized children aged 1 month–59 months reported was 8.2%.[4] It was reported that factors such as age of the child, nutrition state, and breastfeeding practices, vaccination status, bacterial profile and associated congenital anomalies determined the severity of pneumonia, and mortality due to pneumonia. The WHO panel of experts redefined the severity of pneumonia as "pneumonia:" Child with fast breathing and/or chest in drawing and "severe pneumonia:" Pneumonia with any general danger signs.[5] The aim was to study the clinical profile, risk factors of pneumonia and to determine the bacterial etiology of pneumonia in children. The clinical conditions enumerated under the definition of pneumonia by WHO includes: Bacterial and viral pneumonia, acute viral bronchiolitis, and bacterial and viral bronchitis which can coexist and duel pathogens are can occur commonly, especially in critically ill children in low-resource settings. In many of pneumonia in children, they start with an acute viral infection followed by mucosal invasion or drip aspiration of nasopharyngeal (NP) bacteria. The NP colonization of bacteria in children varies from 95% in the first 2 months of life to 30% by age 1–5 years; so as the risk of bacterial pneumonia accompanying a viral upper respiratory tract infection also varies greatly.[6-8] In the lancet, the PERCH study group from their study reported that ten pathogens accounted for almost 80% of WHO-defined pneumonia in the cases studied. The top ten list of pathogens varied between sites, but the universal causes included respiratory syncytial virus (RSV), *Streptococcus pneumoniae*, parainfluenza virus, *Haemophilus influenzae*, human metapneumovirus, and *Mycobacterium tuberculosis*. However, the incidence of pneumococcal infections by PERCH was low.[9] Only 31.7% of children in the PERCH study had wheeze on auscultation, 52.5% had no consolidation or opacification on chest X-ray, and 31.1% had RSV, suggesting that many cases had viral bronchiolitis (with or without pneumonia).[10] The International Classification of Diseases (ICD) or the WHO radiographic criteria for pneumonia[9] are different from the WHO clinical criteria.[10] ICD criteria for pneumonia exclude clinical bronchiolitis and, thus, the prevalence is not diluted by all cases with severe acute lower respiratory infections, unlike in the PERCH cohorts. The threshold for pneumonia with positive chest X-ray in the PERCH study was defined as "consolidation, other infiltrate, or both," and viruses (including in viral bronchiolitis) can be associated with infiltrates on chest X-rays.[11,12] The typical predisposing factors in very severe acute lower respiratory infections in low-income countries often includes household overcrowding and possible genetic factors (which lead to dense bacterial colonization of the upper airway), smoke exposure, viral respiratory infections, and insufficient breastfeeding and early solid feeding (leading to breaches in barrier and mucosal immunity and drip aspiration of *S. pneumoniae* and *H. influenzae*).[13] The new WHO recommendations for policy-making and practice of treating pneumonia were called as "Grading of recommendations, assessment, development, and evaluation" with available evidence profiles, and to deliberate the factors that determined the strength of the recommendations. The first consultation for preventing and managing pneumonia in HIV-infected and HIV-exposed infants and children; these were published in 2010.[2] The second consultation for managing pneumonia in non-HIV affected infants and children was published in 2012.[2] The revisions include changing the recommendation for the first-line antibiotic and re-defining the classification of pneumonia severity. In this context, the present study was conducted to review the essential practices of treating pneumonia in children.

MATERIALS AND METHODS

Seventy-nine children diagnosed with pneumonia attending the Department of Pediatrics of a tertiary teaching hospital were included in the present study. An ethical committee clearance was obtained before the commencement of the study. An ethical committee cleared consent form was used for this study. The period of study was from January 2017 to December 2018.

Inclusion Criteria

- Children aged from 2 months to 59 months were included in the study
- Children presenting with complaints of fever, cold, cough, shortness of breath, and increased respiratory rate with chest in drawing satisfying WHO criteria for pneumonia were included in the study.

Exclusion Criteria

- Children below 2 months and above 59 months were excluded from the study
- Children with documented evidence of comorbidities such as suspected or confirmed meningitis, HIV exposure or infection, severe acute malnutrition typically identified by the presence of visible severe wasting or edema, skin changes of kwashiorkor, and mid-upper-arm circumference <11.5 cm (from WHO reference charts), and chronic cardiorespiratory illnesses were excluded from the study
- Children with complications of pneumonia were excluded from the study.

Demographic data of all the children were recorded. Detailed clinical history was taken. Nutrition history including breastfeeding practices, immunization history,

and treatment history was taken. Children were divided into two groups: Group A: Consisted of children with weight for age <3rd percentile and Group B: Children with those with weight for age ≥3rd percentile. Age-wise categories were made from 0 to 12 months, 13 to 24 months, 25 to 36 months, 37 to 48 months, and 49 to 59 months. Investigations included radiological imaging with plain X-ray and ultrasonography wherever necessary. Hematological investigations such as complete blood picture, sputum examination, NP aspirates analysis for the organism, and blood cultures were done. The etiology was determined by microbiological, serological, and molecular tests. All the children were treated following the WHO guidelines: Recommendation 1: Children with fast breathing pneumonia with no chest in drawing or general danger sign were treated with oral amoxicillin: At least 40 mg/kg/dose twice daily (80 mg/kg/day) for 5 days. Children with fast breathing pneumonia who fail on first-line treatment with amoxicillin were treated with parenteral ampicillin (or penicillin) and gentamicin. Recommendation 2: Children age of 2–59 months with the chest in drawing pneumonia was treated with oral amoxicillin: At least 40 mg/kg/dose twice daily for 5 days. Recommendation 3: Children aged 2–59 months with severe pneumonia were treated with parenteral ampicillin (or penicillin) and gentamicin as a first-line treatment; ampicillin; 50 mg/kg, or benzylpenicillin: 50,000 units/kg IM/IV every 6 h for at least 5 days; gentamicin: 7.5 mg/kg IM/IV once a day for at least 5 days. Ceftriaxone was used as a second-line treatment in children with severe pneumonia having failed on the first-line treatment. The hospital stay was grouped as two; <1 week group and more than 1 week group; all the data collected were analyzed using standard statistical methods.

OBSERVATIONS AND RESULTS

Seventy-nine children diagnosed with symptoms of pneumonia attending the Department of Pediatrics, Viswabharathi Medical College Hospital, R T Nagar, Kurnool, were included in this study. There were 43 (54.43%) male children and 36 (45.56%) female children. The youngest child was 4 months old and the eldest child was aged 57 months old with a mean age of 28.4 ± 1.3 months. Children belonging to Group A were 40 (50.63%) and belonging to Group B were 39 (49.36%). The distribution of Group A and Group B patients in different age intervals is tabulated in Table 1. 62/79 (78.48%) of the children were aged from 0 to 36 months, which included both Groups A and B [Table 1].

Demographic data and nutrition history, including breastfeeding practices, immunization history, and treatment history, are tabulated in Table 2.

Among 79 children of this study 46/79 (58.22%) were diagnosed as "Pneumonia" of WHO typing (children with cold, cough, shortness of breath, and increased respiratory rate without chest in drawing) and the remaining 33/79 (41.77%) children as severe pneumonia (children with cold, cough, shortness of breath, and increased respiratory rate with chest in drawing). 62/79 (78.48%) children below 36 months (3 years) were found to have either pneumonia or severe pneumonia. 17/79 (21.51%) children belonged to the age group above 36 months were found to have either pneumonia or severe pneumonia in this study. 39/62 (62.90%) children who had pneumonia were below 36 months and 23/62 (37.9%) children who had severe pneumonia were below 36 months [Table 3]. It was observed that there was statistical difference in demographic observations such as gender, socio-economic status, breastfeeding, and immunization, among the two types of pneumonia in this study [Table 3], ($P < 0.05$; with $P < 0.05$). There was no statistical difference in demographic observations such as treatment before admission and a previous history of pneumonia ($P > 0.05$), [Table 4].

The incidence of two types of pneumonia among Groups A and B patients was observed and found that there was a statistically significant higher incidence of severe pneumonia in Group A patients than in Group B patients ($P < 0.05$), [Table 4].

The findings of radiological imaging, hematological investigations such as complete blood picture, sputum examination, NP aspirates analysis for the organism, and blood cultures are tabulated in Table 5. Out of 46 pneumonia cases, 16/46 (34.78%) children had bilateral infiltrates, 11/46 (23.91%) had unilateral infiltrates, 13/46 (28.26%) had lobar consolidation, and 6/40 (13.04%) had syn-pneumonic effusion [Table 5 and Figure 1]. Among the severe pneumonia children, 10/33 (30.30%) children had bilateral infiltrates, 11/33 (33.33%) had unilateral infiltrates, 10/33 (30.30%) had lobar consolidation, and 3/33 (9.095%) had syn-pneumonic effusion [Table 5]. In the pneumonia group, *Staphylococcus aureus* was isolated in 11/46 (23.91%) children, acinetobacter in 4/46 (8.69%) children, methicillin-resistant *S. aureus* (MRSA) in

Table 1: The incidence of weight for age among the children of the study (*n*-79)

Age in months (%)	Group A-40 (%)	Group B-39 (%)
0–12–21 (42.5)	11 (11.39)	10 (10.12)
13–24–23 (50)	12 (13.92)	11 (11.39)
25–36–18 (42.5)	9 (8.86)	9 (12.65)
37–48–9 (42.5)	3 (7.59)	6 (6.32)
49–59–8 (35)	5 (8.86)	3 (8.86)

Table 2: The demographic data of the study group (*n*-79)

Observations	0–12 months (21)	13–24 months (23)	25–36 months (18)	37–48 months (9)	49–59 months (8)
Socio-economic status					
Low–32	9	6	10	4	3
Middle–23	5	6	6	3	3
High–24	7	11	2	2	2
Breastfeeding history					
Present–69	20	20	17	7	5
Absent–10	1	3	1	2	3
Immunization					
Completed–62	17	21	16	5	3
Irregular–9	1	1	1	3	3
Absent–8	3	1	1	1	2
Treatment before admission					
Oral antibiotics–18	3	5	4	4	2
Parenteral antibiotics–20	3	5	6	3	3
No treatment–16	2	6	5	1	2
Symptomatic treatment–25	13	7	3	1	1
Previous history of pneumonia					
Present–10	2	3	3	1	1
Absent–69	19	20	15	7	8

Table 3: The demographic data in both pneumonia and severe pneumonia children in the study (*n*-79)

Observations	Pneumonia – 46 (58.22%)	Severe pneumonia – 33 (41.77%)
Age		
0–12–21	14	7
13–24–23	12	11
25–36–18	13	5
37–48–9	4	5
49–59–8	3	5
Gender		
Male–49	29	20
Female–30	17	13
Socio-economic status		
Low–37	22	15
Middle–21	12	9
High–21	12	9
Breastfeeding history		
Present–63	42	21
Absent–16	4	12
Immunization		
Completed–64	44	20
Irregular–9	1	8
Absent–6	1	5
Treatment before admission		
Oral antibiotics–15	9	6
Parenteral antibiotic–16	12	4
No treatment–24	13	11
Symptomatic treatment–24	12	12
Previous history of pneumonia		
Present–10	4	6
Absent–69	45	34

Table 4: The incidence of pneumonia according to age for weight percentile (*n*-79)

Age for weight of the children (%)	Pneumonia – 46 (%)	Severe pneumonia – 33 (%)
Group A–40 (50.63)	15 – (37.50)	25 – (62.5)
Group B–39 (49.36)	31 – (79.48)	8 – (20.51)

10/46 (21.73%) children, Coagulase-negative staphylococci in 12/46 children, and *Klebsiella* ion 9/46 (19.56%) children [Table 5]. In severe pneumonia group, *S. aureus* was isolated in 9/33 (27.27%) children, acinetobacter in 3/33 (9.09%) children, MRSA in 6/33 (18.18%) children, Coagulase-negative staphylococci in 8/33 (24.24%) children, and *Klebsiella* ion 7/33 (21.21%) children [Table 5].

Pneumonia group children (40), all age groups with fast breathing with no chest in drawing or general danger sign were treated with oral amoxicillin: 40 mg/kg/dose twice daily (80 mg/kg/day) for 5 days. When these children failed to this treatment with amoxicillin were treated with parenteral ampicillin (or penicillin) and gentamicin as a first-line treatment; ampicillin: 50 mg/kg, or benzylpenicillin: 50,000 units/kg IM/IV every 6 h for at least 5 days or gentamicin: 7.5 mg/kg IM/IV once a day for at least 5 days. In severe pneumonia children (39), of all age groups, parenteral antibiotics were started on the day of admission: Ampicillin: 50 mg/kg or benzylpenicillin: 50,000 units/kg IM/IV every 6 h for at least 5 days or gentamicin: 7.5 mg/kg IM/IV once a day for at least 5 days. Ceftriaxone was used as a second-line treatment in children with severe pneumonia having failed on the first-line treatment.

DISCUSSION

Pneumonia is an acute illness of lung in which the alveolar air spaces become inflamed and filled with fluid and white blood cells, giving rise to the appearance of consolidation on the chest radiograph. It can be caused by bacterial, viral, or parasitic infection, as well as by noninfectious agents. Most severe cases of pneumonia are caused by bacteria, of which the most important are S. pneumoniae

Table 5: The laboratory investigations in the study group (*n*-79)

Investigations	Pneumonia – 46 (58.22%)	Severe pneumonia – 33 (41.77%)
X-ray findings		
Bilateral infiltrates	16	10
Unilateral infiltrates	11	11
Lobar consolidation	13	9
Syn-pneumonic effusion	6	3
Hematological tests		
Neutrophilia	36	30
Lymphocytosis	10	3
Nasopharyngeal aspirate culture		
Positive	34	23
Negative	12	10
Bacteriological study		
Staphylococcus aureus	11	9
Acinetobacter	4	3
Methicillin-resistant *Staphylococcus aureus*	10	6
Coagulase-negative *Staphylococci*	12	8
Klebsiella	9	7
Sputum examination		
AFB positive	5	3
AFB negative	41	30

AFB: Acid-fast bacilli

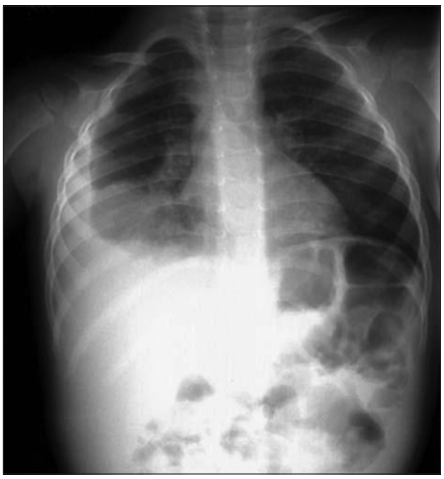

Figure 1: The right basal pneumonia

(Pneumococcus) and H. influenzae. According to the WHO, definition pneumonia is an acute illness with cough or difficulty breathing associated with an increased respiratory rate.[14] The incidence in children is more frequent than in adults. Deaths from pneumonia have been reduced by improving the living conditions, air quality, and nutrition in developed countries. However, in countries like India pneumonia are common causes of deaths in children due to multiple factors. Every year 1.9 million children under 5 years of age die from pneumonia.[15] On average, 2–3% of children in India each year have pneumonia severe enough to require hospitalization.[16] In this study, among 21/79 (26.58%) infants (0–12 months), 14/79 (17.72%) had pneumonia and 7 (8.86%) had severe pneumonia. Among the 23/79 (29.11%) children between 12 and 24 months age (Toddlers), 12/79 (15.18%) had pneumonia and 11/79 (13.92%) had severe pneumonia. Among the 18 children aged between 25 and 36 months, 13/79 had pneumonia and 5/79 (6.32%) had severe pneumonia. Totally, 62/79 (78.48%) children under the age of 3 years were with pneumonia. There was no significant difference in the incidence of severe pneumonia in infants and toddlers. However, when compared with 17/79 (21.51%) preschool children (37–59 months), the proportion of pneumonia was higher in children <3 years group. Therefore, infancy and toddler age formed a risk factor for the incidence of pneumonia with $P < 0.05$ and it was significant. However, the incidence of severe pneumonia was 23/62 (37.09%) in children under 3 years of age and 10/62 (16.12%) in preschool children [Table 6]. There are three challenges in formulating empirical treatment protocol in pneumonia of children according to the etiological agents. (1) Difficulty in obtaining specimens in lower respiratory tract infections in children as they cannot bring out sputum. Moreover, lung aspirations being an invasive procedure are not accepted by the parents and are done in small numbers.[16] However, because lung aspirates are invasive, they are only conducted at a small number of research centers in developing countries.[17,18] (2) The pathogens of pneumonia are fastidious and require sophisticated laboratory culture systems for growth or replication. (3) Existing tests for most pathogens that cause pneumonia are imperfect and there is, therefore, no gold standard against which to test new diagnostics. Isolation of organisms on the blood culture of patients with severe pneumonia is highly specific for bacterial pneumonia, but it has a sensitivity of <15%.[19] Multiplex polymerase chain reaction (PCR),[20,21] for example, the respiratory multi Code–PLx Assay (RMA; Era Gen Biosciences) integrates multiplex PCR with microsphere flow cytometry to allow simultaneous identification of eight groups of respiratory virus (RSV; parainfluenza virus; influenza A and influenza B; human rhinovirus; enteroviruses; metapneumovirus; adenovirus B, adenovirus C, and adenovirus E; and coronaviruses). Compared with conventional diagnostic methods, this technique increases the number of pathogen-positive samples roughly three-fold.[20] Detecting bacterial polysaccharides in urine with a simple immuno-chromatographic strip tests helps as a rapid diagnostic test for respiratory pathogens in adults, but in children this test lacks specificity as 60% of children are have meningococcal organisms as commensals in the nasopharynx.[22,23] In the present study, X-ray examination, sputum culture, blood examination, and NP aspirate studies are undertaken in confirming the diagnosis and the etiological agents which lack specificity. It was observed that there was statistical difference in demographic observations such as gender,

Table 6: The analysis of pneumonia and severe pneumonia groups versus predisposing factors (*n*-79)

Observation	Pneumonia group – 46	Severe pneumonia group – 33	Total	*P* value
Age				0.024
<3 years	39	23	62	
3 years	7	10	17	
Gender				0.091
Male	29	20	49	
Female	17	13	30	
Weight for age percentile				0.14
Weight for age <3 percentile	15	25	40	
Weight >3 percentile	31	8	39	
Breast feeding				0.043
Breastfed	42	21	63	
Not breastfed	4	12	16	
Vaccination				0.021
Vaccinated	45	28	73	
Not vaccinated	1	5	6	
Duration of hospital				0.12
Stay<1 week	20	18	38	
Stay>1 week	26	15	41	

socio-economic status, breastfeeding, and immunization, among the two types of pneumonia in this study [Table 3], ($P < 0.05$; with $P < 0.05$). Out of 46 pneumonia cases, 16/46 (34.78%) children had bilateral infiltrates, 11/46 (23.91%) had unilateral infiltrates, 13/46 (28.26%) had lobar consolidation, and 6/40 (13.04%) had Syn-pneumonic effusion [Table 5]. Among the severe pneumonia children, 10/33 (30.30%) children had bilateral infiltrates, 11/33 (33.33%) had unilateral infiltrates, 10/33 (30.30%) had lobar consolidation, and 3/33 (9.095%) had Syn-pneumonic effusion [Table 5]. Whereas the study done by Bharti *et al.* published in Indian pediatrics in 2008, out of 83 X-rays taken in severe pneumonia cases, lobar consolidation (n = 43, 51.8%) was the most common radiological abnormality, 26 (31.3%) had interstitial abnormalities, and 14 (16.9%) had normal chest radiographs.[24] In this study, bacterial culture was done in blood and either sputum or NP aspirate. In the pneumonia group, *S. aureus* was isolated in 11/46 (23.91%) children, acinetobacter in 4/46 (8.69%) children, MRSA in 10/46 (21.73%) children, coagulase-negative staphylococci in 12/46 children, and *Klebsiella* in 9/46 (19.56%) children [Table 5]. In severe pneumonia group, *S. aureus* was isolated in 9/33 (27.27%) children, acinetobacter in 3/33 (9.09%) children, MRSA in 6/33 (18.18%) children, coagulase-negative staphylococci in 8/33 (24.24%) children, and *Klebsiella* in 7/33 (21.21%) children [Table 5]. In a similar study by Karambelkar *et al.,* in West India reported that methicillin-sensitive *S. aureus*, *S. pneumoniae,* and *Klebsiella* species were the most common organisms isolated.[25] The other pathogens identified were MRSA, and *Pseudomonas* species. Blood culture was positive in 26 (23.63%) of cases whereas NP aspirates yielded organisms in 34 (31%) samples in the present study. Aroma and Aggarwal reported blood culture positivity in 21.9% cases of severe pneumonia.[26] In this study, it was positive in 15/79 children (18.98%) only. In this study, oral amoxicillin administered at hospital for the first 48 h was effective in treating WHO defined severe pneumonia in 38/79 (48.18%) children who were otherwise clinically stable and did not have comorbid conditions. The remaining patients required recommendations 2 and 3 of the WHO protocol. Hospital stay for <1 week was seen in 38 (48.18%) of children and more than 1 week in 41 (51.89%) children.

CONCLUSIONS

Pneumonia is a clinically curable disease when identified and initiated on recommended treatment protocols. Lack of exclusive breastfeeding till 6 months of age, failure of complete immunization coverage, child malnutrition, infancy, and toddler age are the risk factors for both types of the pneumonia but more so with severe pneumonia. There was no statistical significance correlating the X-ray findings and severity of pneumonia was observed. Bacterial cultures of blood and NP/induced sputum have grown predominantly *Staphylococcus* and *Klebsiella pneumoniae* in this study. Amoxicillin oral route to start with and parenteral route when not responding to the oral route remains the drug of choice. The second-line antibiotic of choice was ceftriaxone sodium parenterally. The hospital stay was minimized with good supportive therapy.

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Original Article

Histopathological Changes in Stomach Wall at Sites Other than the Ulcer Site in Peptic Ulcer Disease and its Association with *Helicobacter pylori*

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Abstract

Introduction: A peptic ulcer (PU) is a break in the lining of the gastrointestinal tract, extending through to the muscular layer (muscularis mucosae) of the bowel wall. It is an endoscopic diagnosis. While they may technically appear anywhere in the gastrointestinal tract, they are most often located on the lesser curvature of the proximal stomach or the first part of the duodenum.

Aim: This study aims to study the changes in stomach wall at sites other than the ulcer site in PU disease and to correlate the association of stomach wall changes with *Helicobacter pylori* infection.

Materials and Methods: In this study, patients with duodenal ulcers diagnosed in endoscopy were included in the study. During an endoscopy, the stomach wall is examined and any changes in the stomach wall are noted. Endoscopically and biopsy from two areas in the stomach are taken from antrum and body and sent to histopathological examination. Rapid urease test to confirm the presence of *H. pylori* was done.

Results: Sixty patients were included, 67% of patients were male, 82% of patients were positive in rapid urease test, 84% antrum was affected, and 50% in the body of the stomach was affected. The overall incidence of chronic atrophic gastritis is nearly 84.1% when compared to other types of lesions.

Conclusion: Gastric antrum was the most common site for *H. pylori* than the body of the stomach. The presence of *H. pylori* in the stomach wall is associated with active on chronic gastritis.

Key words: Chronic duodenal ulcer, Endoscopic findings, *Helicobacter pylori*, Histopathological pattern

INTRODUCTION

Peptic ulcer (PU) disease (PUD) is a common ailment in patients suffering from symptoms of dyspepsia. PUs occur in the stomach (gastric) and the first portion of the small intestine (duodenal). Most PUs are associated with abdominal discomfort 45–60 min after meals or during the night described as gnawing, burning, cramp like, aching, or heartburn. Eating or antacids usually give great relief. In the elderly, the presentation may be subtle and atypical compared with younger patients, leading to a delay in diagnosis.[1-4] Duodenal ulcers nearly constitute one-third of all cases of PUD. It is characterized by a defined defect in the mucosa which extends into muscular propria as well. Duodenal ulcers occur most often in the first part of the duodenum or in the pre-pyloric region of the stomach (antrum). Gastric ulcers are most frequently seen on the lesser curve of the stomach at the junction of the body and antrum (angularis). Acute stress ulcers involve the body of the stomach and are often multifocal and transient. Histologically, the ulcer is a break in the mucosa with loss of epithelial cells, exposure of the basement membrane, and involvement of the muscularis mucosae.[5-7] Ulcers develop due to an imbalance between the normal protective attributes to the stomach and the potentially damaging secretions in the lumen of the stomach. This imbalance may be caused by a number of factors, the principal one being colonization by *Helicobacter pylori*. *H. pylori* infection and hyperchlorhydria can induce stomach and duodenum. It has

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to be documented whether *H. pylori* produces any change in the stomach wall other than the ulcer site. Infection by *H. pylori* can occur in the gastric mucosal surface as well as mucosa in the proximal duodenum. Recent studies plan to eradicate *H. pylori* in an attempt to heal PUD have given promising results and prove a clear correlation between *H. pylori* infection and PUDs.[8,9]

Aim

This study aims to study the changes in stomach wall at sites other than the ulcer site in PUD and to correlate the association of stomach wall changes with *H. pylori* infection.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of General Surgery at Government Stanley Medical College and Hospital at Chennai. The study involves the patients who present to the department of general surgery with symptoms of dyspepsia subjecting to endoscopy. Among these patients who are subjected to endoscopy, those who are having duodenal ulcers are taken into study. Exclusion criteria: Patients with carcinoma stomach, gastric polyps, and alcoholic gastritis were excluded from the study. After documentation of history, clinical examination involves general physical examination is done. During an endoscopy, the stomach wall is examined and any changes in the stomach wall are noted. Endoscopically and biopsy from two areas in the stomach are taken from antrum and body and sent to histopathological examination. During the histopathological examination, the specimen is subjected to rapid urease test to confirm the presence of *H. pylori*. The histopathological changes are noted and the lesions are recorded. Based on this study, we analyze the incidence of different types of lesions such as chronic atrophic gastritis and superficial pangastritis in these patients other than the site of PUD and their association with *H. pylori*.

RESULTS

Of the 60 patients under study 67% were male, 49 patients were found to be positive for *H. pylori* using rapid urease test positive in the antral biopsy [Figures 1 and 2]. Twenty patients were found to have been *H. pylori* positive in the specimen with a biopsy from the body of the stomach. The histopathological findings on these were usually atrophic gastritis, superficial pangastritis, and intestinal metaplasia. About 84% antrum was affected and 50% in the body of the stomach was affected [Figure 3]. In antrum, the most common histopathological change was chronic atrophic gastritis nearly 80% and the remaining showed that 18.5% of patients have superficial gastritis including the mucosa and submucosa. Nearly 1.5% of patients showed the features of intestinal metaplasia. Moreover, patients were mainly males nearly 80% and females were 20% affected due to *H. pylori*. The old individuals are mostly affected than the younger population. The prevalence rate of *H. pylori* infection in the colonization of the stomach wall in the antrum was nearly 92% and the body showed colonization in 46% of cases. The histological findings in that

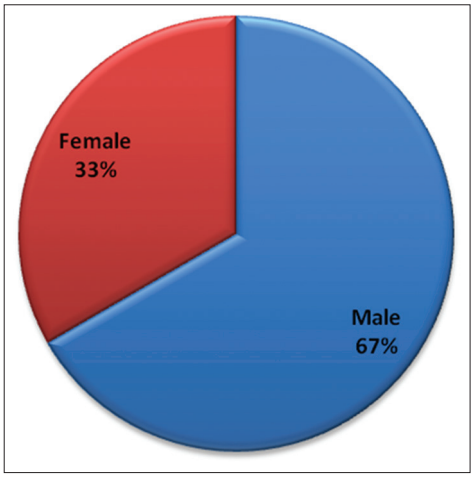

Figure 1: Distribution of gender

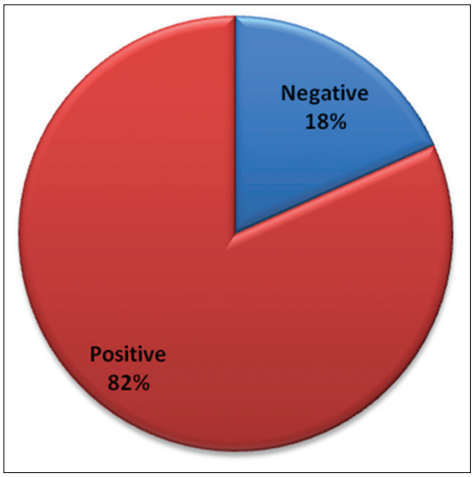

Figure 2: Distribution of rapid urease result

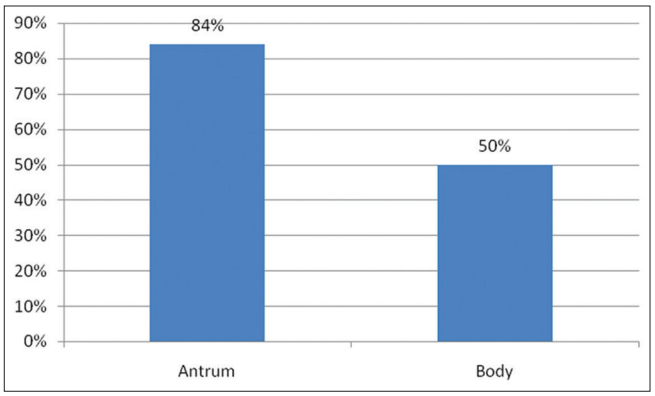

Figure 3: Distribution of the most common area to be affected

study were, chronic gastritis of antrum was 93% and fundus was affected in 66% of cases. The overall incidence percentage of chronic atrophic gastritis in that study was 82% and the percentage of cases in our study is 84%.

DISCUSSION

PUD is a source of significant morbidity and mortality worldwide. Sequelae may range from abdominal pain and gastrointestinal bleeding to gastric outlet obstruction and perforation. Higher PUD incidence has been found to be associated with male sex, smoking, and chronic medical conditions.[10,7] PUD has also been found to be associated with increasing age.[11] The majority of PUD cases are now known to be associated with *H. pylori* infection or the use of nonsteroidal anti-inflammatory drugs (NSAIDs) or both.[12] *H. pylori* is a Gram-negative bacterium that colonizes the gastric mucosa, progressing to gastritis and potentially PUD and gastric cancer.[8,13] *H. pylori* affect a large segment of the population; however, only a small subset will develop clinical disease.[13] NSAID use, including aspirin, is common and leads to an increased risk of gastrointestinal adverse events, including PUD. The relative risk of developing a symptomatic ulcer is 4.0 for non-aspirin NSAID users and 2.9 for patients taking aspirin.[14]

Collins *et al.* (Belfast, Northern Ireland-1988) studied the mucosal changes and their relationship to H. pylori infection in gastric antral and body biopsies in 20 patients with duodenal ulcer (DU; n=20). According to him, the prevalence rates for H. pylori were 94% for antral and 8% for body biopsies. In the antrum and body, the mononuclear cell count was significantly higher in lamina propria in H. pylori-positive cases showing active inflammation.[15]

CONCLUSION

The prevalence of *H. pylori* infection is more common in the antrum than the body of the stomach. The most common histopathological change in the stomach wall produced by *H. pylori* is chronic gastritis which is of atrophic type. Men are usually affected than women by *H. pylori* and the elder population has a higher incidence than the younger population.

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Original Article

A Prospective Study of the Demographic Pattern and Site of Perforation of Non-traumatic Hollow Viscus Perforation Peritonitis in Vindhya Region

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Abstract

Background: Perforation peritonitis is a commonly encountered surgical emergency and it is defined as inflammation of the serosal membrane that lines the abdominal cavity and the visceral organs. The aim of this study is to analyze the demographic pattern and site of perforation of non-traumatic hollow viscus perforation peritonitis in Vindhya region.

Materials and Methods: A total of 209 cases were studied with hollow viscus perforation peritonitis admitted in the surgical wards in Sanjay Gandhi Memorial Hospital associated with Shyam Shah Medical College, Rewa (MP), India, in the period from June 1, 2018, to May 31, 2019. All necessary investigations were carried out. X-ray, Ultrasonography abdomen, and blood investigations were done. The patient underwent emergency exploratory laparotomy and a careful record of pre-operative and post-operative findings was made and was carefully filled in the pro forma. All the patients were advised to attend the surgical outpatient department for follow-up.

Results: Of 10,887 patients admitted to Sanjay Gandhi Memorial Hospital associated with Shyam Shah Medical College, Rewa (MP), India, from June 1, 2018, to May 31, 2019, in which non-traumatic hollow viscus perforation peritonitis was diagnosed in 209 patients (1.9%), among which most of the patients were male (177) and rest were female (32). Most of the patients belonged to the low-socio-economic status of 21–40 years of the age group. From this study, the duodenum was found to be the most common site of perforation, followed by stomach.

Conclusion: Patients were admitted in the Department of Surgery, Shyam Shah Medical College and Sanjay Gandhi Hospital Rewa, the Vindhya region in the Madhya Pradesh, patients diagnosed as a case of non-traumatic hollow viscus perforation peritonitis were included in the study. The majority of the patients of the perforation peritonitis belonged to 21–40 years of age group. 41–60 years of age group was the second most common age group of patients who presented with perforation peritonitis with a male-to-female ratio of 5.5:1. The most common site of perforation was duodenum followed by gastric and appendicular and the least common site of perforation was colon.

Key words: Demographic pattern, Non-traumatic hollow viscus perforation, Perforation site

INTRODUCTION

Gastrointestinal perforation is a common abdominal emergency faced by general surgeon. A high index of suspicion is essential to diagnose visceral perforation early, as significant morbidity and mortality results from the diagnostic delay.[1] Several studies have shown that morbidity and mortality of perforation peritonitis can effectively be reduced by early diagnosis and timely intervention. Peritonitis is defined as an inflammation of the serosal membrane that lines the abdominal cavity and the organs contained therein. The peritoneum, which is an otherwise sterile environment, reacts to various pathologic stimuli with a fairly uniform inflammatory response. Depending on the underlying pathology, the resultant peritonitis may be infectious or sterile. Intra-abdominal sepsis is an inflammation of the peritoneum caused by pathogenic microorganisms and their products. Intra-

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abdominal sepsis from a perforated viscus (i.e., secondary peritonitis or suppurative peritonitis) results from direct spillage of luminal contents into the peritoneum (e.g., perforated peptic ulcer, diverticulitis, appendicitis, and traumatic perforation). With the spillage of the contents, Gram-negative and anaerobic bacteria, including common gut flora, such as *Escherichia coli* and *Klebsiella pneumoniae*, enter the peritoneal cavity. Endotoxins produced by Gram-negative bacteria lead to the release of cytokines that induce cellular and humoral cascades, resulting in cellular damage, septic shock, and multiple organ dysfunction syndromes.

Aim and Objectives

A prospective study to know the demographic pattern and site of perforation of non-traumatic hollow viscus perforation peritonitis in Vindhya region.

MATERIALS AND METHODS

The proposed study entitled "a clinical study on post-operative outcome in perforation peritonitis patients with reference to a history of nonsteroidal anti-inflammatory drugs (NSAIDs) use" was carried out on 209 patients admitted in surgical wards in the Department of Surgery, Shyam Shah Medical College and Associated Sanjay Gandhi Memorial Hospital, Rewa, form June 1, 2018, to May 31, 2019.

Inclusion Criteria

All cases of perforation peritonitis admitted in the Surgery Department of Shyam Shah Medical College and Associated Sanjay Gandhi Memorial Hospital, Rewa, and have consented for participation in the study.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patients left hospital during the course of treatment
2. Patients operated outside the institution
3. Patients with traumatic perforation peritonitis
4. Patients under 13 years of age due to different physiological status
5. Post-operative peritonitis
6. All pregnant females.

Sample Size

The sample size was 209 non-traumatic perforation peritonitis patients.

Methodology

All patients who were admitted in the surgical ward of Sanjay Gandhi Memorial Hospital, Rewa, for treatment of abdominal pain due to perforation peritonitis from June 1, 2018, to May 31, 2019. Brief history was recorded such as duration of abdominal pain, nature of pain, relieved by medication or by change in any posture, whether associated with fever or not, associated with any comorbid conditions, any drug abuse, use of alcohol or tobacco, and corticosteroids or immunosuppressants for long time, and a detailed history regarding the use of NSAIDs was recorded. After confirming the diagnosis of perforation peritonitis, patients were resuscitated and underwent exploratory laparotomy and the results were concluded. Clinical examination included the complete general examination of the patient along with per abdomen examination. The general examination was usually performed in the supine position in adequate light and with proper exposure of the patient. Per abdomen, examination was done in the supine position with knee flexed in adequate light and proper exposure of the patient. Most of the patients of perforation peritonitis had abdominal pain which was constant and severe. On general examination, most of the patients were having tachycardia, hypotension, tachypnea, inability to pass flatus, and feces. On per abdomen examination, most of the patients had distended abdomen with diffuse tenderness along with diffuse guarding and board-like rigidity. On percussion, the obliteration of liver dullness was found in most of the patients. On auscultation of the abdomen, bowel sounds were often found sluggish or absent. Tenderness was present per rectal examination. The presence of free gas under the diaphragm in X-ray abdomen in standing position was mainstay for the diagnosis of perforation peritonitis. For the diagnosis of perforation peritonitis, X-ray abdomen has a sensitivity of 84.62% and specificity of 97.30%. Abdominal ultrasonography (USG) although is not a primary modality for evaluating pneumoperitoneum, free gas can be detected on ultrasound when gas shadowing is present along the peritoneum. USG has a sensitivity of 76.92% and specificity of 97.30% for the diagnosis of perforation peritonitis. Computed tomography became an important tool in the detection and characterization of acute abdominal involvement in perforation peritonitis. Computed tomography imaging is often the initial modality in the acute abdomen in a significant proportion of patients, and radiologists should have a high level of suspicion in the detection and interpretation of peritoneal abnormalities. Contrast-enhanced computed tomography has 100% of specificity and sensitivity for the diagnosis of perforation peritonitis. Laboratory investigations were carried out as per clinical relevance, including complete blood count, random blood sugar, serum electrolytes, renal function tests, liver function tests, blood grouping and typing, and Widal test. Thus, we observe the per abdomen clinical findings and presence of free gas under the diaphragm in X-ray abdomen in standing position and the results were calculated and tabulated, accordingly.

OBSERVATIONS AND RESULTS

It is evident from Table 1 that there were 10,887 patients admitted in the surgical wards of Sanjay Gandhi Hospital,

Rewa, from June 1, 2018, to May 31, 2019, in which non-traumatic hollow viscus perforation peritonitis was diagnosed in 209 patients (1.9%).

It is evident from Table 2 that the majority of the patients (45.9%) of the perforation peritonitis belonged to 21–40 years of age group. A total of 30.6% of patients belonged to 41–60 years of age group which was the second most common age group of patients who presented with perforation peritonitis [Table 2 and Graph 1]. The minimum age of the patients was 14 years, the maximum was 90 years, and the mean age noted was 37.5 years.

It is evident from Table 3 that the majority of the patients of perforation peritonitis were male (84.6%) with a male-to-female ratio of 5.5:1 [Table 3 and Graph 2].

It is evident from Table 4 that most of the patients of perforation peritonitis (88.5) belong to low-socio-economic status [Table 4 and Graph 3].

It is evident from Table 5 that most common site of perforation was duodenal (36.3%) followed by gastric (22.9%) and appendicular (15.3%) and the least common site of perforation was colon (5.7%) [Table 5 and Graph 4].

Table 1: Incidence of non-traumatic hollow viscus perforation peritonitis

S. No.	Total admissions in surgical ward	Number of non-traumatic hollow viscus perforation (*n*)	In %
1.	10,887	209	1.9

Table 2: Age-wise incidence of the patients

S. No.	Age (in years)	Total (*n*)	Males		Females	
			n	In %	*n*	In %
1.	14–20	30	27	90	3	10
2.	21–40	96	81	84.3	15	15.7
3.	41–60	64	52	81.2	12	18.8
4.	61–0	15	13	86.7	2	13.3
5.	>80	4	4	100	0	0
Total		209	177	84.6	32	15.4

Table 3: Sex-wise incidence of the patients

S. No.	Sex	Number of cases
1.	Males	177
2.	Females	32
Total		209

Table 4: Socio-economic status of patients of perforation peritonitis

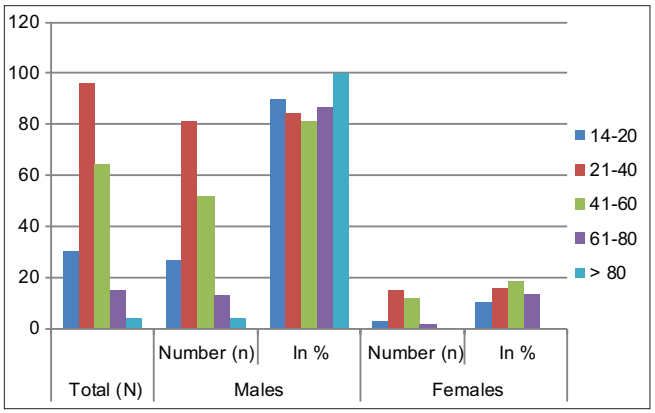
Socioeconomic status	Low		Middle	
	Number of cases	In %	Number of cases	In %
Socioeconomic status	185	88.5	24	11.5
Total		209		

Table 5: Site of perforation

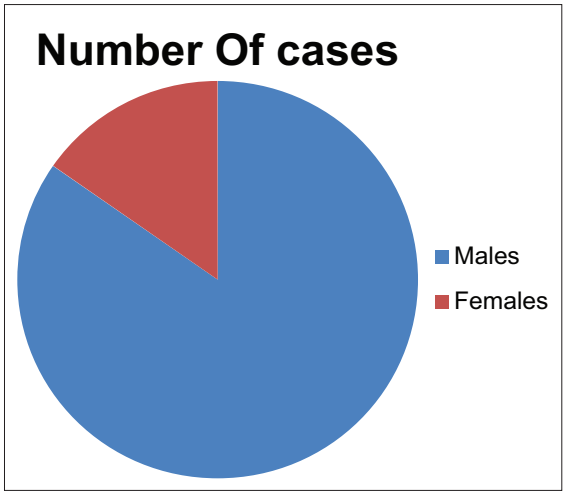
S. No.	Site of perforation	Number of cases
1.	Duodenum	76
2.	Gastric	48
3.	Ileum	41
4.	Appendix	32
5.	colon	12
Total		209

DISCUSSION

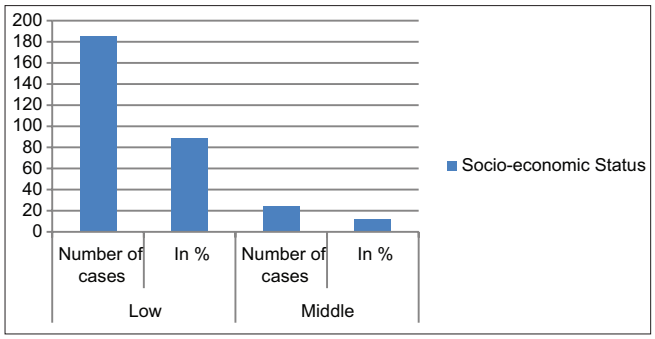
Non-traumatic hollow viscus perforation peritonitis is the source of major suffering and very huge cost for both the patient and the health-care system. Perforation peritonitis needs intensive care as it can be complicated by septic shock,



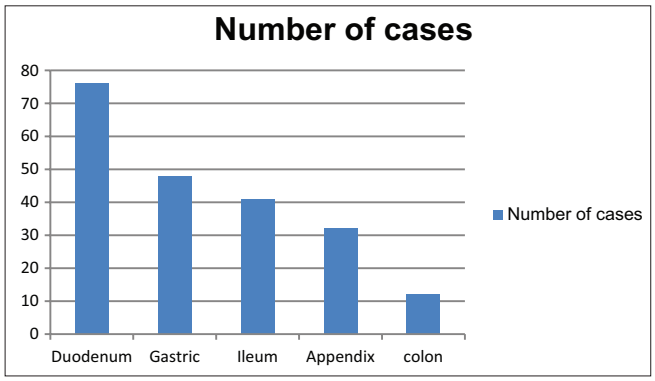
Graph 1: Age-wise incidence of the patients



Graph 2: Sex-wise incidence of the patients



Graph 3: Socio-economic status of patients of perforation peritonitis



Graph 4: Site of perforation

hypovolemic shock, and comorbidities. As reviewed in the literature, the non-traumatic perforation peritonitis cases are a major cause of morbidity and burden on health-care system.

In this study, the most common age group affected was 21–40 years and 45.9% of patients who were affected, belonged to this group. A significant number of patients (30.6%) were in the age group of 41–60 years. The mean age was 37.5 years. This is due to the fact that most of the persons who are addicted to alcohol and tobacco belong to 21–60 years of age. A similar study conducted by Chowdri *et al.* in 2006[2] on perforation peritonitis and concluded that most common age group affected was 30–40 years, while in another study conducted by Rao *et al.* in 2015[3] found 21–35 years as the most common affected age group. Perforation peritonitis was found in 84.6% in males and 15.4% in females. The male-to-female ratio of the study was observed to be (5.5:1), this result is comparable to the study conducted by Mewara *et al.* in 2017,[4] in which 89% of patients were male, while rest was female. In most of the studies, it was seen that in most of the patients of perforation peritonitis, the duodenum was the most common site of perforation, followed by stomach and then ileum. Similar results were obtained by Abdulhameed *et al.*, in 2017,[5] in which duodenum was found to be the most common site of perforation, followed by the stomach.

CONCLUSION

A total of 10,887 patients were admitted in the Department of Surgery, Shyam Shah Medical College and Sanjay Gandhi Hospital Rewa, the Vindhya region in the Madhya Pradesh, in which 209 (1.9%) were diagnosed as a case of non-traumatic hollow viscus perforation peritonitis. The educational status of this territory is below average, and the peoples are very unaware of their health. Most of the people do hard work for their wages and for their tiredness, they are abusing the painkillers with their empty stomach. The majority of the patients (45.9%) of the perforation peritonitis belonged to 21–40 years of age group. A total of 30.6% of patients belonged to 41–60 years of age group which was the second most common age group of patients who presented with perforation peritonitis with a male-to-female ratio of 5.5:1. The most common site of perforation was duodenum (36.3%) followed by gastric (22.9%) and appendicular (15.3%) and the least common site of perforation was colon (5.7%).

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ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Original Article

Benefits of Video Laryngoscopy in Patients Undergoing Elective Cholecystectomies: A Comparative Study

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Abstract

Background: Several methods have been used to blunt the cardiovascular response associated with laryngoscopy and tracheal intubation in susceptible patients to prevent myocardial ischemia and cerebrovascular events. For almost 75 years measures are taken to prevent such responses with more focus on pharmacological methods as compared to non-pharmacological methods. Our study has focused on non-pharmacological methods in the form of using different kind of laryngoscopes in the American Society of Anesthesiologists (ASA) Group I and II patients to compare hemodynamic responses and electrocardiographic changes in three groups, namely, Macintosh, McCoy, and Video laryngoscope (primary aim) and also to assess the intubation time, number of attempts and complications (bleeding, laceration, dental injury, and sore throat) if any (secondary aim).

Materials and Methods: This study was conducted on 90 patients of the ASA Grade I and II posted for elective open cholecystectomy surgeries under general anesthesia. Patients were allotted into three groups: Group A (Macintosh), Group B (McCoy), and Group C (Video) and they were intubated with their respective laryngoscopes and hemodynamic parameters at 0, 1, 3, 5, 7, and 10 min after laryngoscopy were recorded along with time of intubation and any complications associated with the procedure.

Results: The time of intubation was shortest with Group C (Video) when compared with Group A (Macintosh) and Group B (McCoy). Hemodynamic changes of patients were lowest in Group C (Video) than Group B (McCoy) and highest with Group A (Macintosh). Furthermore, number of attempts at intubation was higher with Macintosh and McCoy as compared to with Video laryngoscope group. Likewise, more complications such as dental injury and injury to oral mucosa were seen with Macintosh laryngoscope than McCoy and least with Video laryngoscope. The results were compiled and analyzed using software IBM SPSS 26 to draw relevant conclusions.

Conclusion: Thus, we can see that with the use of Video laryngoscope, lesser alterations in hemodynamics are produced which can reduce the incidences of myocardial ischemia and cerebrovascular accidents in susceptible patients. Furthermore, lesser time taken by Video laryngoscope in intubation again reduces the stress response to laryngoscopy in susceptible patients. Laryngoscopy by Video laryngoscope is comparatively easy when compared with Macintosh and McCoy laryngoscopes as number of attempts and complication rate was lesser with Video laryngoscope.

Key words: Backward upward rightward pressure, Diastolic blood pressure, Heart rate, Ischemic heart disease, Mean arterial pressure, Optimal laryngeal external manipulation, Saturation, Seconds, Systolic blood pressure

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INTRODUCTION

Laryngoscopy and endotracheal intubation are the essential maneuvers in general anesthesia and in emergency situations where maintaining a patent airway is a prime responsibility of an anesthesiologist. Laryngoscopy and tracheal intubation lead to stimulation of pharyngeal, laryngeal, and tracheal

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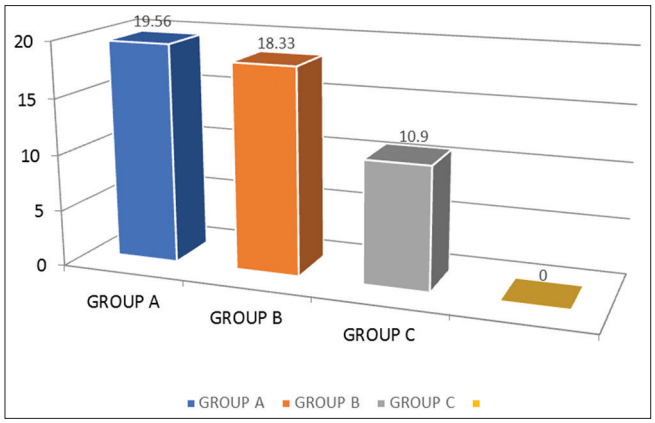

Figure 1: Time of intubation

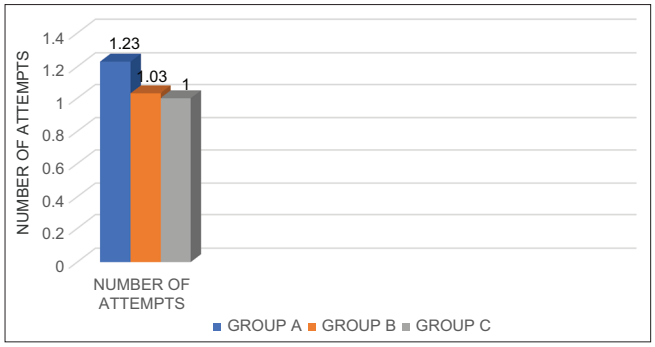

Figure 2 : Number of intubation attempts

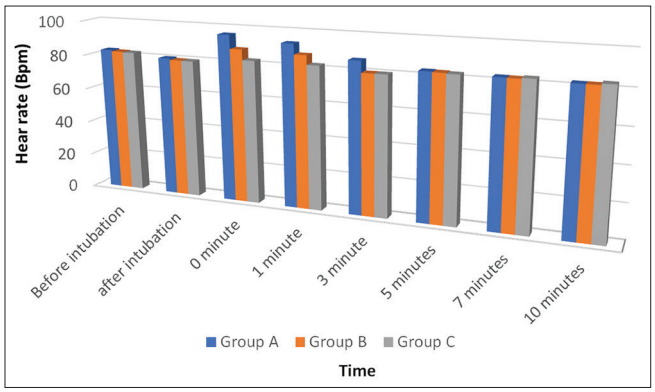

Figure 3: Heart rate changes

nociceptive receptors through vagal and glossopharyngeal afferents and reflex hemodynamic stress response commonly manifested as tachycardia, hypertension, or arrhythmia in adults and adolescents. The response is transient occurring within 30 s after intubation and lasting for <10 min. These can be potentially hazardous in patients with hypertension, coronary artery disease, and cerebrovascular disease.[1]

The magnitude of hemodynamic stress response is related to amount of force applied to expose the glottis and degree of airway manipulation done during endotracheal intubation. During laryngoscopy with Macintosh laryngoscope, a relatively high forward and upward force is applied (approximately 4–5 kg) on laryngoscope handle to visualize glottis by aligning oral, pharyngeal, and laryngeal axis. The magnitude of hemodynamic response correlates with force of laryngoscopy.[2]

McCoy laryngoscope uses a levering mechanism which reduces the force required to align all the three axes to view the glottis.[3] The McCoy laryngoscope with hinged tip has been shown to provide improved view of glottis and lesser hemodynamic response to intubation as compared to Macintosh laryngoscope.[4] Video laryngoscopes do not require alignment of oral, pharyngeal, and laryngeal axes for the visualization of glottis and the force needed to align these three axes is greatly reduced (approximately 1.5 kg). Video laryngoscopes provide a wider viewing angle, making alignment of oral, pharyngeal, and tracheal axis less mandatory.[5]

The first Video laryngoscope named Glidescope was invented in 1999 which is a reusable biomedical device and incorporated a high-resolution digital camera, connected by a video cable to a high-resolution LCD monitor.[6]

Likewise, more hemodynamic instability will occur if intubation time is prolonged. Hence, the laryngoscope which requires less time to intubate will result in lesser hemodynamic fluctuations as compared to laryngoscope which requires more time for intubation.

The primary outcome of our study was to lessen the hemodynamic changes associated with laryngoscopy and intubation with use of Video laryngoscope.

MATERIALS AND METHODS

After obtaining approval from the institutional thesis and ethics committee, the study was conducted on 90 patients of the American society of anesthesiologists (ASA) Grade I and II posted for elective open cholecystectomy surgeries under general anesthesia. The study was registered in the Clinical Trial Registry of India (CTRI/2018/04/019581). The patients were allotted into three groups: Group A (Macintosh laryngoscope), Group B (McCoy laryngoscope), and Group C (Video laryngoscope) of 30 patients each who were intubated using their respective laryngoscopes.

A detailed history and thorough general examination before the surgery were done. All patients included in the study were kept nil orally for 8 h preoperatively. On arrival to operation theatre, baseline vital parameters such as heart rate, systolic blood pressure (SBP), diastolic BP, mean arterial BP, and SpO_2 were recorded. An intravenous line

Table 1: Heart rate changes

Time	Group A			Group B			Group C			*P* value		
	Mean	SD	% age change from baseline	Mean	SD	% age change from baseline	Mean	SD	% age change from baseline	A/B	B/C	A/C
Before induction	83	3.81		82.43	3.73		82.2	5.31		0.56	0.97	0.55
After induction	80.4	3.80	−3.05	79.7	4.13	−3.21	79.63	4.61	−3.29	0.49	0.95	0.48
0 min	96.1	4.55	16.01	88.3	4.34	7.33	82.4	4.03	0.02	0.00	0.00	0.00
1 min	93.40	3.44	12.79	87.53	0.77	6.40	82.26	5.06	0.04	0.00	0.00	0.00
3 min	86.57	2.93	5.9	80.07	2.01	4.66	82.93	3.50	0.64	0.00	0.96	0.49
5 min	83.27	2.49	0.55	83.07	2.11	0.97	82.77	2.87	0.68	0.73	0.64	0.47
7 min	82.83	2.42	0.02	82.73	3.05	0.52	82.23	3.36	0.02	0.88	0.54	0.43
10 min	82.33	2.59	1.84	82.37	2.98	−0.18	83.20	3.04	1.21	0.96	0.28	0.24

SD: Standard deviation

Table 2: Systolic blood pressure changes

Time	Group A			Group B			Group C			*P* value		
	Mean	SD	% age change from baseline	Mean	SD	% age change from baseline	Mean	SD	% age change from baseline	A/B	B/C	A/C
Before induction	121.7	4.85		121.9	5.13		129.5	5.41		0.87	0.88	0.88
After induction	106.43	4.52	−12.44	105.9	5.34	−12.95	105.9	4.11	−12.62	0.71	0.06	0.67
0 min	142.06	2.83	16.95	134.5	3.76	10.53	127.8	5.95	5.33	0.00	0.00	0.00
1 min	140.8	1.58	16.68	132.53	1.38	8.91	122	7.5	0.64	0.00	0.00	0.00
3 min	137.63	5.19	13.27	130.40	3.33	7.15	119.3	8.32	−1.6	0.00	0.00	0.00
5 min	132.53	4.91	9.03	126.17	7.34	3.71	118.37	4.93	−2.3	0.00	0.00	0.00
7 min	120.87	5.37	1.09	124.07	5.39	2.05	119.63	4.72	−1.3	0.39	0.24	0.01
10 min	123.4	5.04	1.6	123.73	4.44	1.71	120.77	3.69	−0.4	0.78	0..80	0.02

SD: Standard deviation

Table 3: Diastolic blood pressure changes

Time	Group A			Group B			Group C			*P* value		
	Mean	SD	% age change from baseline	Mean	SD	% age change from baseline	Mean	SD	% age change from baseline	A/B	B/C	A/C
Before induction	80.96	7.50		80.0	6.75		79.9	5.47		0.95	0.91	0.53
After induction	71.83	6.91	−10.5	74.06	8.11	−7.16	72.1	7.95	−9.27	0.005	0.34	0.89
0 min	89.46	8.13	10.49	84.26	10.48	5.32	83.26	5.91	4.63	0.03	0.18	0.02
1 min	85.13	7.41	5.76	83.36	7.08	5.17	81.1	5.88	1.96	0.34	0.12	0.02
3 min	83.37	6.22	3.81	81.53	6.45	2.69	81.33	5.92	2.23	0.26	0.9	0.2
5 min	79.53	7.17	−0.93	82.63	9.46	3.68	77.47	6.21	−2.7	0.15	0.01	0.23
7 min	77.83	7.41	−2.96	80.67	7.49	1.52	79.9	6.9	0.40	0.14	0.68	0.26
10 min	78.27	6.86	−2.4	79.43	7.07	0.09	79.53	7.06	−1.11	0.51	−0.5	0.48

SD: Standard deviation

Table 4: Mean arterial pressure changes

Time	Group A	SD	% age change from baseline	Group B	SD	% age change from baseline	Group C	SD	% age change from baseline	*P*-value		
										A/B	B/C	A/C
Before induction	91.06	6.84		90.96	6.77		90.26	6.52		0.95	0.68	0.64
After induction	81.5	5.85	−9.97	82.36	6.63	−9.18	81.5	5.85	−8.12	0.59	0.96	0.54
0 min	104.6	4.85	14.9	98	4.32	7.73	95.03	6.23	5.28	0.03	4.27	0.00
1 min	99.63	5.26	9.88	83.36	7.08	6.47	92.46	6.55	2.95	0.04	3.05	0.00
3 min	99.63	5.75	10.04	95.37	6.09	5.37	92.2	5.79	2.67	0.04	2.66	0.00
5 min	95.3	6.79	−0.93	93.53	8.46	3.71	86.8	6.18	−2.39	0.00	1.36	0.00
7 min	88.67	7.88	−2.15	92.3	7.59	2.20	91.1	7.05	1.52	0.52	0.94	0.21
10 min	88.87	7.28	−1.83	90.07	6.88	−0.28	90.17	6.74	0.51	0.95	1.48	0.47

SD: Standard deviation

was secured with 20G cannula and 10 ml/kg/h ringer lactate infusion was started. Pre-medication (injection midazolam 0.02 mg/kg, injection ondansetron 4 mg, and injection butorphanol 1 mg) was given. Injection glycopyrrolate was not given as it can produce tachycardia and could have interfered with the results. Baseline hemodynamic parameters were recorded. Pre-oxygenation with 100% oxygen was done for 3 min. After that, patients were induced with propofol 2.5 mg/kg until the eyelash reflex and spontaneous respiration were abolished followed by injection succinylcholine 2 mg/kg and intubation with respective laryngoscopes in all the three groups.

After that, anesthesia was maintained with isoflurane, injection vecuronium bromide, nitrous oxide, and oxygen.

After laryngoscopy, hemodynamic parameters in the form of SBP, diastolic BP, mean arterial pressure (MAP), heart rate, and electrocardiographic changes at various intervals: Before induction, after induction/before laryngoscopy, and after laryngoscopy and intubation at 0 min, at 1, 3, 5, 7, and 10 min after intubation, then at the interval of every 5 min until the end of the surgery, were recorded. Furthermore, time of intubation, any complication during laryngoscopy and any sore throat after surgery were recorded.

Statistical Analysis

The data from the present study was systematically collected, compiled, and statistically analyzed using software IBM SPSS 26 to draw relevant conclusions. Data were expressed as mean, standard deviation, number, and percentages. The patient characteristics (nonparametric data) were analyzed using the "Chi-square tests" and the intergroup comparison of the parametric data was done using the unpaired "*t*" test and ANOVA test. "*P*" value was determined to finally evaluate the levels of significance. $P < 0.05$ was considered as statistically significant. The power achieved was well above 90%. The results were then analyzed and compared to previous studies.

RESULTS

Hemodynamic variables showed minimal changes in patients of group Video laryngoscope, moderate changes in group McCoy, and maximum changes in group Macintosh laryngoscope after laryngoscopy at 0 min.

Intubation time was seen longest in Group A, then Group B, and shortest in Group C. Maximum number of intubation attempts was required in Group A, then Group B, and least with Group C.

The heart rate, SBP, diastolic BP, and the mean arterial BP measured at every 2 min during laryngoscopy and after, until 10 min after intubation showed minimum changes in the patients of Group C that settled after 3 min of intubation. Maximum hemodynamic changes were seen in Group A which settled after 5–7 min of intubation.

Arterial oxygen saturation was well maintained in all the groups and was statistically non-significant. Furthermore, complications such as dental injury and bleeding from oral cavity were seen maximally in Group A, then after that in Group B, and minimally in Group C. Sore throat incidences were seen in maximum number of patients in Group A, then Group B, and least with Group C.

DISCUSSION

Laryngoscopy and intubation can elicit a sympathoadrenal response leading to hypertension, tachycardia, and arrhythmia which can be deleterious in patients with ischemic heart disease (IHD) and low cardiac reserve. This response is caused by stretching of the oropharyngeal tissue in an effort to align the oropharyngeal-laryngeal axis for intubation.

Over the years, many researchers have adopted various methods for attenuating the pressor response caused by laryngoscopy and tracheal intubation using various inhalational and other pharmacological agents such as beta-blockers, calcium channel blockers, lignocaine, gabapentin,[7] nitroglycerin,[8] clonidine,[9] and dexmedetomidine.[10] Earlier methods have been used to blunt the cardiovascular response with the help of pharmacological methods more as compared to non-pharmacological methods. There is limited literature available regarding the influence of the type of laryngoscope blade on the hemodynamic response to laryngoscopy and intubation. Our study used different types of laryngoscope blades that helped to decrease the pressor responses.

All the groups were comparable in mean age, weight, height, body mass index, ASA grading, and duration of surgery. In our study, intubation time in Group A was 19.56 s, in Group B was 18.33 s, and in Group C was 10.90 s as shown in Figure 1. On comparing groups with each other, $P = 0.00$ was statistically significant. Our results were similar to results concluded by Moningi *et al.* and Zia Arshad (2013).

Our results were comparable with the study conducted by Bhandari *et al.* in 2013 who observed that Airtraq was better than the Macintosh laryngoscope as duration of successful intubation was shorter in Airtraq than the Macintosh laryngoscope.

In our study, intubation attempts in Group A were 1.23, in Group B was 1.03, and in Group C was 1 as shown in

Figure 2. 23 out of 30 patients in Group A were successfully intubated with first attempt whereas remaining patients required more than one intubation attempt. Twenty-nine of 30 patients of Group B were intubated at their first attempt whereas in Group C 30 of 30 patients were intubated with their first attempt. After comparing the three groups, $P = 0.14$ was statistically insignificant. Our results were similar with Maharaj *et al.* study.

In our study, heart rate changes from baseline at 0 min of laryngoscopy were 16.1% increase in Group A, 7.33% increase in Group B, and in 0.02% increase from baseline Group C as shown in Table 1. $P = 0.00$ is statistically significant. Figure 3 shows heart rate changes in the three groups after intubation. Heart rate increase is seen maximum in Group A and least in Group C at 1 mint after laryngoscopy which starts to settle around baseline values after 5 mints of laryngoscopy in all groups. Our results were supported by another study conducted by Haidry and Khan[11] in 2013, where maximum change in heart rate after intubation was 18.7% from baseline in the Macintosh and 7.7% from baseline in the McCoy group. Joseph *et al.* in 2012 and Woo in 2011 showed similar results.

The increase in SBP in Group A at 0 min (during laryngoscopy) was 142.06 mmHg (16.95% increase from baseline) and in Group B was 134.5 mmHg (10.53% increase from baseline) and in Group C was 127.8 mmHg (increased by 5.33% from baseline) as shown in Table 2. $P = 0.00$ was statistically significant. After 5 min, SBP started to normalize toward baseline values in Group A and after 3 min in Group B. These results were supported by another study conducted by Haidry and Khan in 2013 where increase in systolic arterial pressure was 22.9% from baseline in the Macintosh and 10.3% from baseline in the McCoy group. Alexandra Gavrilovska-Brzanov *et al.* in 2015 also showed similar results for Macintosh and Video laryngoscope groups.

In our study, diastolic BP after intubation at 0 min in Group A was 89.46 mmHg (increased by 10.49% from baseline), in Group B was 84.26 mmHg (increased by 5.32% from baseline), and in Group C was 83.26 mmHg (4.63% from baseline) as shown in Table 3. $P = 0.03$ was statistically significant. Another study conducted by Haidry and Khan in 2013 also showed that rise in diastolic BP from baseline was 27% in Macintosh group and 15% in McCoy group. Furthermore, a study conducted by Gavrilovska-Brzanova *et al.* (2015) showed that diastolic BP after intubation was found to be 89.85 ± 11.7 mmHg in group Macintosh and 76.00 ± 11.3 mmHg in group Airtraq.

MAP in our study, in Group A was 104.6 mmHg (18.6%), in Group B was 98 mmHg (7.73%), and in Group C was 95.03 mmHg as shown in Table 4. Arora *et al.* showed MAP in group Macintosh was 28.08% and in group McCoy was 15.25% ($P = 0.0001$). Our results were comparable with results of Moningi *et al.* as MAP was higher in group McCoy as compared to group Video laryngoscope after laryngoscopy and in group McCoy it took longer time to normalize to baseline values when compared to Video laryngoscope group. Furthermore, a study conducted by Gavrilovska-Brzanov *et al.* (2015) showed that the mean BP was 114.92 ± 13.7 mmHg in group Macintosh and 98.80 ± 12.1 mmHg in group Airtraq.

In our study, saturation changes in Group A, Group B, and Group C were comparable ($P > 0.05$). Arora *et al.* in 2016 also showed comparable SpO_2 changes in both groups. This was attributed to the fact that Mallampati Grade 1 and 2 were chosen as the inclusion criteria and no difficult airway were included in the study; therefore, no patient desaturated due to prolonged intubation time.

No arrhythmias were seen in either of the group in our study as myocardial stressors like tachycardia and hypertension were reduced with the use of video laryngoscopy. Also the choice of patients were from ASA grade I and II, thus reducing the the risk of arrythmias in all groups. Our results were supported by study conducted by Haidry and Khan.

In our study, complication rate was highest in Macintosh group (10%), McCoy (3.3%), and Video (0.0%). Complications included dental injuries and bleeding from oral cavity. Hossali in 2017 also showed that maximum complications occurred with Macintosh and least with Airtraq Video laryngoscope.

Limitations

One limitation of our study was the noninvasive measurement of BP, but it was not justified to use invasive blood monitoring technique in the relatively healthy ASA 1 and 2 patients. We also did not measure the muscle relaxation and the degree of relaxation at the time of tracheal intubation which may affect the response. The study could not be blinded because anesthesiologist could not have been blinded to the type of laryngoscope he is using and the BP and heart rate recordings displayed on the monitor.

CONCLUSION

In our study, we conclude that Video laryngoscope is better to maintain the hemodynamics of the patient during laryngoscopy as it exerts less force and less time to intubate. While doing laryngoscopy with Video laryngoscope, one can get immediate help of the accompanied person by directly looking at the monitor and doing whatsoever

is necessary in aiding the intubation (optimal laryngeal external manipulation, backward upward rightward pressure, or handling airway adjuncts such as stylet or bougie). Thus, expert help is provided to the novice laryngoscopist in no time in times of difficult intubations. Hemodynamic alterations produced by laryngoscopy with Macintosh and McCoy can be disastrous in susceptible patients leading to morbidities and mortalities due to myocardial ischemia and cerebrovascular accidents in IHD patients and neurological disease patients. Thus, benefits of Video laryngoscope in providing better hemodynamics and lesser complications produced by it make it a better laryngoscopic technique when compared to conventional Macintosh and McCoy laryngoscopes.

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Original Article

A Prospective Study of Common Surgical Problems in Geriatric Patient with Special Reference to Gastrointestinal Tract Diseases in Vindhya Region

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Abstract

Background: Aging is a continuous process which begins with conception and ends with death. It is said that nobody grows old merely by living a certain number of years, while aging merely stands for growing. The health problems to be considered should include – physical, mental, emotional, and socioeconomical. Old age is not a disease but the aged people are often vulnerable to long-term diseases such as cardiovascular, cerebrovascular, respiratory, gastrointestinal, cancers, mental derangement, hearing and visual loss, and conditions affecting the locomotor system. Aim of this study is to analyze the common surgical problems in geriatric patient with special reference to gastrointestinal tract (GIT) diseases in Vindhya region.

Materials and Methods: A total of 1585 cases were studied with common surgical geriatrics problems admitted in the surgical wards in Sanjay Gandhi Memorial Hospital associated with Shyam Shah Medical College, Rewa (MP), India, in the period from 1 June 2018 to 31 May 2019. The proposed study includes patients with age 60 years and above who will be admitted through surgical outpatient department, casualty and/or will be transferred from other departments. After admission of patients, particular will be recorded and they will be also inquired for chief complaints with duration, history, drug history, personal history, and family history. Their findings will be recorded in a pro forma.

Results: Of 10,887 patients admitted in Sanjay Gandhi Memorial Hospital associated with Shyam Shah Medical College, Rewa (MP), India, during the period of 1 June 2018–31 May 2019, in which common surgical problems were diagnosed in 1585 patients (14.55%), among which most of the patients were males (1137) and rest were females (448). Most of the patients belonged to 60–64 years of age group. From this study, intestinal obstruction among GIT diseases was found to be the most common surgical problem.

Conclusion: Majority of elderly patients admitted with GIT disorders were having intestinal obstruction (22.17%), followed by PUD (21.47%), peritonitis (17.09%), malignant lesions and hemorrhoids (9.23%), and colitis (6.92%). Of sex-wise total admission. The incidence of intestinal obstruction (26.11% vs. 20.40%) and colitis (14.92% vs. 3.34%) was more common in female than male. Whereas PUD (23.41% vs. 17.16%) and perforation peritonitis (19.06% vs.12.68%), hemorrhoids were more common in male than female.

Key words: Diseases, Geriatric, Patient

INTRODUCTION

Aging is a continuous process which begins with conception and ends with death. No one knows when old age begins "The biological age" of a person is not identical with his "chronological age." The health problems to be considered should include – physical, mental, emotional, and socioeconomical. Old age is not a disease but the aged people are often vulnerable to long-term diseases such as cardiovascular, cerebrovascular, respiratory, gastrointestinal, cancers, mental derangement, hearing and visual loss, and conditions affecting the locomotor system. These diseases produce disabilities. However, these disabilities can be minimized by early detection and proper treatment.

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Today surgery is being frequently performed in the elderly not only to the life-threatening emergency but also as an elective procedure to treat symptomatic states, which trends to disturb an otherwise peaceful retired life of the individual. Discoveries in medical science and improved socioeconomic conditions during the past few decades have increased the life span of people. In India, approximately two-thirds of the elderly live in the rural areas and more than half of the population is on the margin of poverty and poor health.

The effects of aging include poor wound healing manifesting as wound dehiscence and anastomotic leaks of bowel, delayed callus formation, disordered coagulation, and reduced enzyme synthesis decreased oxidative metabolism of drugs by the liver and immunological depression with increased susceptibility to infection. Decreased tolerance to radiotherapy and cytotoxic chemotherapy, all with the severe mental apathy and physical exhaustion of the elderly.

The prime aim of the surgeon is to prolong useful and good quality of life after surgery.

Aim and Objectives

This was a prospective study of common surgical problems in geriatric patient with special reference to gastrointestinal tract (GIT) diseases in Vindhya region.

MATERIALS AND METHODS

Number of Patients

1585.

Inclusion Criteria

Patient of age 60 years and above in both sexes was included in the study.

Exclusion Criteria

The following criteria were excluded from the study:

1. Patient left hospital during course of treatment
2. Patient operated outside the institute
3. Patient below age 60 years.

The proposed study includes patients with age 60 years and above who will be admitted through surgical outpatient department (OPD), casualty and/or will be transferred from other departments.

After admission of patients, particular will be recorded and they will be also inquired for chief complaints with duration, history, drug history, personal history, and family history. Their findings will be recorded in a pro forma.

Patients will then thoroughly examined with details of general, systemic, and local examination and a provisional diagnosis will be made on clinical grounds of the underlying surgical problems and associated systemic disorders with medical problems such as hypertension, diabetes mellitus, nephropathy, and mental illnesses. Patients admitted in emergency will be resuscitated and subjected to relevant investigations for primary pathology and associated systematic disorders. Routine investigations will be carried out in every patient and specialized investigation as an when required.

Patients will be treated accordingly either conservatively or by surgical intervention which will be done according to indication. After assessment of patients, they will be subjected to various surgical procedures if required and full details of anesthesia and operative procedures will be recorded.

Patients who underwent various surgical procedures will be discharged postoperatively patients will receive treatment as per plan and complications will be recorded. Patients who will be treated conservatively will be discharged on relieve of their symptoms and with regression after removal of their stitches and will be followed up in surgical outpatients department.

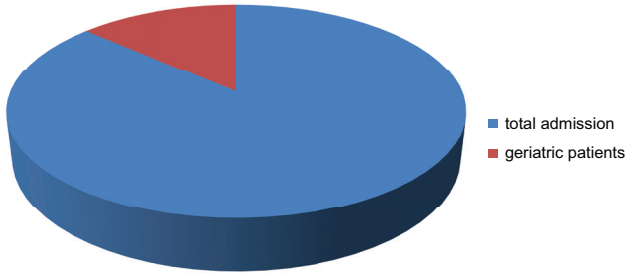
OBSERVATIONS AND RESULTS

In the present study, the incidence of geriatric surgical problems in total admission was found to be 14.55% [Table 1].

As evident from Table 2, the majority of patients were male (70.71%) with male:female ratio of 2.4:1. Majority of patients were in age group 60–64 years (29.90%). Number of patients in age group 80 years and above was also significant (14.51%). The eldest patient was a 100-year-old male.

Table 1: Incidence of surgical problems in geriatric patients

Total admission	Geriatric patients admitted	Incidence
10887	1585	14.55%



It is evident from Table 3 that the majority of elderly patients admitted with GIT disorders were having intestinal obstruction, followed by peptic ulcer disease (PUD) (21.47%), peritonitis (17.09%), malignant lesions and hemorrhoids each (9.23%), and colitis (6.92%).

Of sex-wise total admission, the incidence of intestinal obstruction (26.11% vs. 20.40%) and colitis (14.92% vs. 3.34%) was more common in female than male.

DISCUSSION

In the present study, geriatric patients having surgical problems were 14.55% of total admissions. In a similar study by Sandeep *et al.* (2010),[1] total geriatric patients admitted were 15.39% of total admissions in surgical ward. It is evident that geriatric patients with surgical problems were a major group that requires special care and it is increasing in number with time due to increase longevity of life.

Age Distribution

The present study shows the maximum number of patients (29.90%) were present in 60–64 years of age group followed by 22.20% in 65–69 years of age group and 22.20% in 70–74 years of age group. High incidence of the patient in 60–64 years of age group may be due to the higher number of geriatric population in this age group.

In a similar study by Kumar and Khan (2012)[2] on 380 geriatrics patients, majority of patients were from the 60–70 years age group (82.00% [*n*=200] among the males and 82.22% among the females).

In a similar study by Pasari (1990),[3] majority of patients (45%) were having surgical problems from age group 60–64 years, admitted in surgical ward.

Sex Distribution

In the present series, number of males exceeded females with proportion of 2.4:1. The higher number of male patients was due to the higher number of cases of benign prostatic hyperplasia, PUD, hernia, and skin and soft tissue infection in male than female. A higher number of male patients due to lifestyle factor of male or it may be males are more health-conscious as compared to females and this awareness toward health brought them to the hospital or it may be due to financial dependency of female or it may be [Table 4].

Distribution According to System Involvement

The present study shows that majority of surgical patients was involved gastrointestinal system (27.31%), next common being genitourinary system (25.17%), skin and soft tissue lesions (21.51%), and hepatobiliary system (12.87%). A study by Sandeep *et al.*[1] (2009) shows 31.07% geriatric patients suffering from GIT disorder.

Gastrointestinal System

The most common lesion in GIT disordered patients was intestinal obstruction (22.17%), next common PUD (21.47%), perforation peritonitis/peritonitis (17.09%) and malignant lesions, and hemorrhoids (9.23%) each. It is evident that >50% of GIT disorder burden due to intestinal obstruction, PUD, and perforation peritonitis/peritonitis. The cause behind high incidence

Table 2: Distribution of patients according to age and sex

S. No.	Age group (in years)	Total		Male		Female	
		No.	%	No.	%	No.	%
1.	60–64	474	29.90	319	28.05	155	34.59
2.	65–69	352	22.20	251	22.07	101	22.54
3.	70–74	352	22.20	260	22.86	92	20.53
4.	75–79	177	11.16	130	11.43	47	10.49
5.	80 and above	230	14.51	177	15.56	53	11.83
Total		1585	100	1137	100	448	100

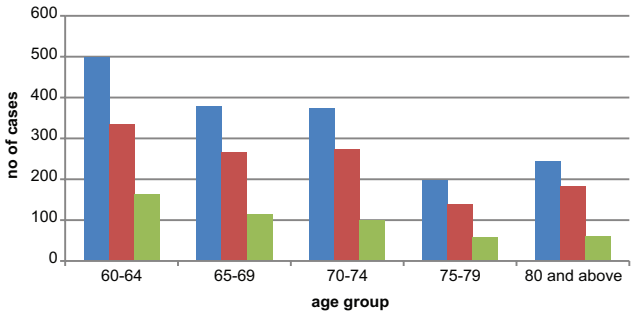


Table 3: Distribution of patients according to gastrointestinal system involvement (*n*-433)

S. No.	Type of lesion	Total		Male		Female	
		No.	%	No.	%	No.	%
1.	Intestinal obstruction	96	22.17	61	20.40	35	26.11
2.	Peptic ulcer disease	93	21.47	70	23.41	23	17.16
3.	Perforation peritonitis/ peritonitis	74	17.09	57	19.06	17	12.68
4.	Malignant lesions	40	9.23	35	11.70	5	3.73
5.	Hemorrhoids	40	9.23	30	10.03	10	7.46
6.	Colitis	30	6.92	10	3.34	20	14.92
7.	Acute appendicitis/ appendicular lump	30	6.92	22	7.35	8	5.97
8.	Ileostomy/colostomy	6	1.38	3	1.00	3	2.23
9.	Pancreatitis	6	1.38	2	0.66	4	2.98
10.	Prolapse rectum	10	2.30	3	1.00	7	5.22
11.	Fistula in ano	5	1.15	4	1.33	1	0.74
12.	Gastric outlet obstruction	2	0.46	1	0.33	1	0.74
13.	Splenic abscess	1	0.23	1	0.33	00	00
Total		433	100	299	100	134	100

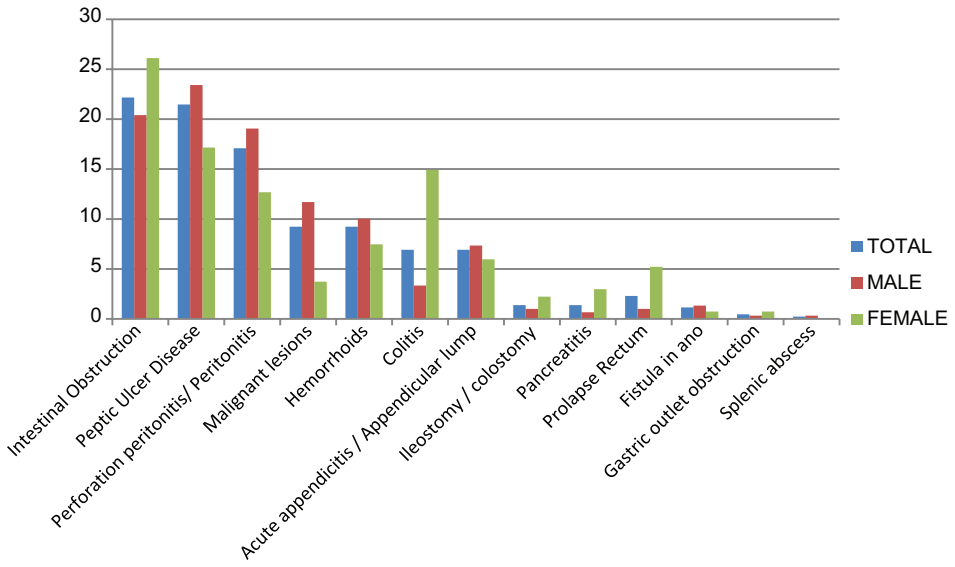


Table 4: Comparative study of sex-wise distribution of geriatric patients

S. No.	Workers	Year	Male	Female	Total
1.	Cogbill	1967	522	3	525
2.	Gurjar	2000	146	54	200
3.	Sabnis Sandeep	2010	765	252	1017
4.	Ahirwar Sandeep	2014	1224	516	1740
5.	Present series	2019	1137	448	1585

of gastrointestinal disorder in geriatrics may be due to reductions in esophageal peristalsis and lower esophageal sphincter pressures are also more common in the aged and may cause gastroesophageal reflux, delayed small bowel motility, and gastric emptying also common elderly subjects. Aging affects all function of the gastrointestinal system, motility, enzyme and hormone secretion, and digestion and absorption.

A study by Dumic *et al.*[4] shows that incidence and mortality from PUD are in elderly remains very high.

CONCLUSION

The present study "study of common surgical problems in geriatric patients" was carried out in 1585 patients with age group of 60 years and above, who were admitted in surgical wards of Sanjay Gandhi Memorial Hospital and associated Shyam Shah Medical College, Rewa (MP), during from 1 June 2018 to 31 May 2019. Patients were admitted through surgical OPD, casualty and/or were transferred from other departments. Detailed history was recorded, thorough clinical examination done, provisional diagnosis was made, and relevant investigations were carried out.

Patients were treated according to merits of their diagnosis either conservatively or by surgical intervention which was done according to indication. After stabilization of condition of patients, they were subjected to various surgical procedures and full details of anesthesia and operative procedures were recorded.

Postoperatively patients received treatment as per plan and complications were recorded. Patients treated conservatively were discharged on relive of their symptoms and with regression of their signs. Patients who underwent various surgical procedures were discharged after removal of their stitches and were followed up in surgical OPD.

All the observations made, were critically analyzed and following conclusions were drawn:

1. The incidence of geriatric patients with surgical problems was 14.55% of total admission in the year from 1 June 2018 to 31 May 2019
2. Majority of patients were male (71.73%) with male:female ratio of 2.4:1. Majority of patients were in the age group 60–64 years (29.90%)
3. Majority of elderly patients admitted with GIT disorders were having intestinal obstruction (22.17%), followed by PUD (21.47%), peritonitis (17.09%), malignant lesions and hemorrhoids (9.23%), and colitis (6.92%). Of sex-wise total admission. The incidence of intestinal obstruction (26.11% vs. 20.40%) and colitis (14.92% vs. 3.34%) was more common in female than male. Whereas PUD (23.41% vs. 17.16%) and perforation peritonitis (19.06% vs.12.68%), hemorrhoids were more common in male than female.

ACKNOWLEDGMENTS

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ETHICAL APPROVAL

The study was approved by the Institutional Ethics Committee.

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Original Article

A Study on Secondary Neck Nodes from Squamous Cell Carcinoma

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Abstract

Introduction: Head and neck squamous cell carcinoma also carries a high rate of occult nodal metastasis. It is important to detect lymph node development in its early stages for improving the prognosis. The mechanisms by which malignant tumors, invade lymphatics, and metastasize to regional lymph nodes are complex and interrelated, the exact mechanisms have only recently been the subject of intense interest and sophisticated experimentation.

Aim: The aim of the study was to correlate the incidence of cervical node metastases by the site of primary in squamous cell carcinoma of the head and neck region and to correlate individually the size of the tumor and its degree of histopathological differentiation.

Materials and Methods: The present prospective study of 60 patients with proven squamous cell carcinoma at various sites of head and neck was undertaken to study the possible tumor factors which influence the incidence and the pattern of regional nodal metastases.

Results: A progressive increase in the incidence of node metastases was observed with increasing tumor size 55.55% for lesions smaller than 2 cm, 75% for lesions between 2 and 4 cm, and 100% for lesions larger than 4 cm. A progressive increase in the incidence of node metastasis was observed with increasing histological undifferentiation of the tumor (4.3% for well-differentiated primaries and 75% for moderately differentiated primaries).

Conclusion: Large primaries (more than 4 cm) and those with higher histologic grade (moderate to poorly differentiated) especially when situated in the oropharynx or the oral tongue, have a greater propensity for developing regional nodal metastasis compared to the rest.

Key words: Cervical node metastases, Head and neck, Squamous cell carcinoma

INTRODUCTION

Squamous cell carcinoma of the head and neck, especially those arising in the oral cavity and oropharynx accounts for more than 50% of all cancers in India compared to 2–3% in the U.K. and U.S.A. More than 30% of these patients have clinical evidence of cervical node metastases when the first seen.[1]

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The presence of an enlarged node proven histological positive for metastases is an ominous sign and as a general rule decreases the 5-year survival rate by at least 50%. When the nodal involvement becomes multiple and extends low in the neck, few patients get cured regardless of the treatment given.[2]

No definite conclusions about the efficacy of treatment of the neck in the absence of palpable nodal disease can be drawn from studies from the literature. However, many indicate improved survival for those undergoing therapeutic neck treatment for occult disease versus those undergoing therapeutic neck treatment for clinically positive nodes. Spiro and strong reported significantly better survival for patients undergoing elective neck treatment for oral and oropharyngeal cancers who had clinically negative

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but histologically positive nodes, compared to patients undergoing therapeutic neck dissection for clinically positive nodes.[3]

Since there is currently no way to identify occult disease in the cervical nodes other than removing and examining them histopathologically, various features of the primary tumor (namely, site, size, gross appearance thickness, and differentiation) have been correlated with the incidence of nodal disease in the neck by different workers.[4]

In the present study, an attempt has been made to determine the tumor factors increase the propensity for regional metastases in squamous cell carcinoma of the head and neck, so as to help, identify the cluster of high-risk patients who are likely to harbor occult nodal disease in the absence of clinically negative nodes and for whom elective neck treatment may prove beneficial.

Nine areas of the head and neck including five primary sites in the oral cavity, three in the oropharynx, and the maxillary antrum have been considered under the preview of this study, as these were the sites involved in the patients presenting with squamous cell carcinoma of the head and neck in the surgical department of our hospital.

Aim

The aim of the study was to correlate the incidence of cervical node metastases by the site of primary in squamous cell carcinoma of the head and neck region and to correlate individually the size of the tumor and its degree of histopathological differentiation.

MATERIALS AND METHODS

This prospective study was conducted in patients with carcinoma arising in the oral cavity, oropharynx, or maxillary antrum in the surgical units of Kilpauk Medical College and Hospital and Government Royapettah Hospital, Chennai. A total of 60 patients were ultimately included in the study and all had histologically proven squamous cell carcinoma of varying degrees of differentiation. The patients who were not included in this study were seven for want of one reason or other, for example, biopsy report one case reported as pseudoepitheliomatous hyperplasia without any evidence of malignancy, one case reported as adenocarcinoma arising from ulcer in the lower lip, and another case involving the buccal mucosa were adenoid cystic carcinoma.

A detailed history was obtained regarding the nature and duration of presenting complaints as well as of all other associated complaints particular attention being paid to factors increasing the likelihood of malignancy, for example, white or red patch in the oral cavity, non-healing ulcer, throat pain more than 3 weeks duration, non-tender enlarging neck mass, pressure symptoms or obstructive symptoms, or addiction to tobacco, alcohol, betel leave chewing, snuff dipping, irradiation to head and neck in the past, and past treatment of other head and neck carcinomas.

Complete physical examination including an indirect laryngoscopy in selected cases was done to note characteristics of the primary in terms of site, extent, size (in cm), macroscopic appearance (exophytic, endophytic, or mixed), degree of local infiltration, presence of other synchronous lesions, and T stage of the tumor.

Attention was then paid to the neck to detect any palpable nodes. The criterion for "a clinically positive node" as defined by Lindberg was used to differentiate metastatic from nonmetastatic nodes throughout the study. Any palpable node more than 1 cm in size, spherical rather than ovoid in shape, hard in consistency, and situated in the drainage area of a histologically proven primary was considered as metastases.

The note was made of the side and triangle of the neck involved, the total number of palpable nodes, the groups involved, size (in cm), consistency, presence of tenderness, fixity to the skin as well as node, and N stage of the nodes.

When nodes belonging to deep cervical chain were enlarged, they were included in the anterior cervical triangle with regard to their position, as the classical description of the cervical triangle excludes the nodes deep to sternocleidomastoid muscles from either of two major triangles. Midline nodes were considered as homolateral nodes. In evaluating the size of the nodal mass, allowances made for the intervening soft tissue.

Biopsy from the primary site was obtained in all the cases included in the study to obtain histological proof regarding its nature as well as to note its degree of differentiation. The latter was expressed in terms of three grades, well differentiated, moderately differentiated, and poorly differentiated.

RESULTS

Of 60 patients with histologically proven squamous cell carcinoma arising from various primary sites in the head and neck who were ultimately included in the study. Thirty-five (58%) were males and 25 (42%) were females. Palpable neck nodes were detected on admission in 30 males (68%) and 14 females (32%). The overall incidence of patients with head and neck squamous cell carcinoma (HNSCC) was in the age group of 30–70 years [Figure 1]. Incidence

of cervical node metastases on clinical examination was 73%. [Figure 2].

The most frequent site of the primary in the present series was the buccal mucosa (18 patients) which accounted for 30% of the head and neck cancers [Table 1]. Next in frequency was the anterior 2/3rd of the tongue 11 patients (18.3%) and alveolus 7 patients (11.6%). Posteriorly situated cancers arising in the oropharynx showed a comparatively lower frequency with the base of tongue having the highest 7 patients (11.6%). Overall the least frequent site was maxillary antrum 3 patients (5%). Irrespective of sex, patients had clinical evidence of cervical node metastases on admission. Bilateral nodes were present in 2 patients. Sixteen were negative for adenopathy.

Among the primaries, tonsils accounted for the higher incidence of node metastases. All 4 patients with tonsillar carcinoma had palpable nodes on admission, accounting for 100% nodal involvement. Other posteriorly situated cancers also showed a similar pattern of behavior as compared to the anteriorly situated cancers with the base of the tongue and soft palate having 85.71% and 50%,

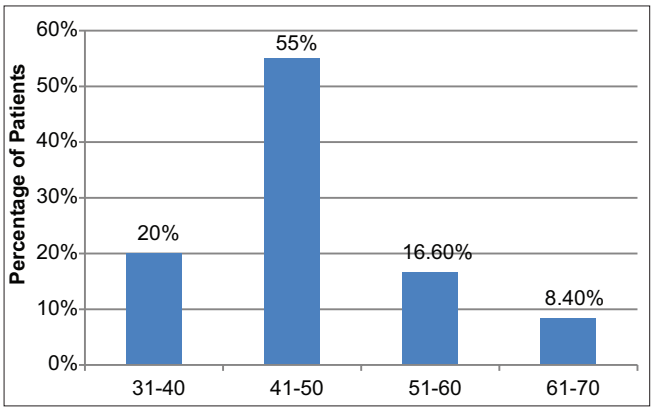

Figure 1: Age of incidence of primary

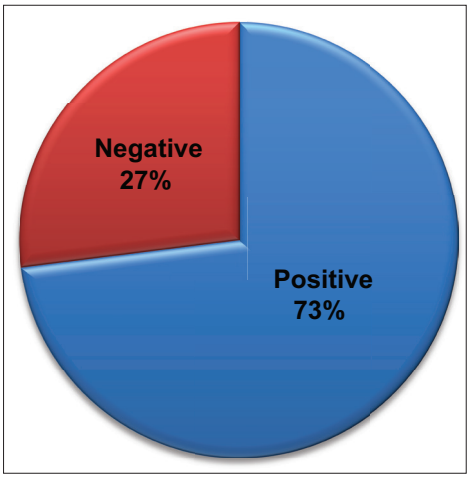

Figure 2: Incidence of cervical node metastases

respectively. The least incidence of nodal metastases was from lesions of the hard palate and maxillary antrum.

Carcinoma of the buccal mucosa predominantly metastasized to the submandibular nodes. Only when very advanced (T4 with retromolar extension), they involve the upper deep cervical nodes. Submental node involvement was totally absent. Carcinoma of the alveolus predominantly metastasized to submandibular nodes. Submental node involvement was infrequent.

Carcinoma of hard palate infrequently metastasized. The only one patient, in whom this happened, had involvement of the ipsilateral submandibular node. The lower incidence of cervical metastases in patients with cancer of the hard palate has been ascribed in the literature to a less extensive lymphatic network in the immobile palate mucosa. Although the number of patients with hard palate cancer was small in the present series, our findings appeared to confirm with this explanation.

Carcinoma of the anterior two-thirds of the tongue most commonly involved the upper deep cervical group followed by the submandibular group of nodes. In only one instance, the middle deep cervical nodes involved. The involvement of nodal groups at a lower level in the neck was not seen. As none of the primaries involved the tip of the tongue, predictably submental node involvement was absent. Bilateral nodal involvement was present in one instance with the involvement of the contralateral submandibular nodes.

Carcinoma of the floor of the mouth predominantly metastasized to the ipsilateral submandibular nodes, in spite of the anterior location of the tumors and their proximity to the midline, submental node involvement was infrequent and contralateral nodes were uninvolved at all.

Carcinoma of the soft palate commonly metastasized to upper deep cervical nodes. Although it is a midline structure, the incidence of the bilateral nodal involvement was nil, possibly of the small numbers of patients involved in the present study [Tables 2 and 3].

Going by individual sites all the patients who had tumors larger than 4 cm in diameter with primaries situated in the buccal mucosa, alveolus, and anterior two-third of the tongue and the maxillary antrum had clinically palpable nodes on admission. Conversely, the majority of patients having tumors smaller than 2 cm with primaries in the same sites had a clinically negative node on admission [Figure 3].

The degree of differentiation of the primary varied according to the tumor site. The majority of the

Table 1: Incidence of cervical node metastases by site of primary

Primary	No. of patients	%	No. palpable nodes (N0) on admission	Palpable nodes (N+) on admission	% of (N+) patients
Buccal mucosa	18	30	3	15	83.33
Alveolus	7	11.60	3	4	57.14
Hard palate	3	5	2	1	33
Floor of mouth	4	6.60	1	3	75
Soft palate	3	5	1	2	66
Tongue ant 2/3rd	11	18.30	3	8	72.72
Tongue post 1/3rd	7	11.60	1	6	85.71
Tonsil	4	6.60	0	4	100
Max. antrum	3	5	2	1	33

Table 2: Topographical distribution of cervical nodal metastases from ipsilateral nodes only

Ipsilateral nodes only	N0	N1	N2a	N2b	N2c
Buccal mucosa – submandibular node (main)	3	9	4	2	-
Alveolus (submandibular node)	3	2	1	1	-
Hard palate (submandibular node)	3	1	-	-	-
Floor of mouth – submandibular (main)	1	2	1	-	-
Soft palate (upper and middle cervical nodes)	1	2	-	-	-
Tonsils (jugulodigastric nodes)	0	2	1	1	-

Table 3: Topographical distribution of cervical nodal metastases from ipsilateral nodes and contralateral nodes

Ipsilateral nodes and contralateral nodes	N0	N1	N2a	N2b	N2c	N3
Tongue anterior 2/3rd (upper deep cervical nodes)	3	4	2	1	-	1
Tongue posterior 1/3rd (upper deep cervical nodes)	1	2	1	1	-	2
Maxillary antrum (submandibular node)	2	-	1	-	-	-

anteriorly situated tumors, i.e., those arising in the oral cavity, were well or moderately differentiated (55.55 and 26.66%, respectively), whereas the bulk of those situated posteriorly, i.e., in the oropharynx was moderately or poorly differentiated (26.66 and 53.33%, respectively) [Table 4].

The degree of differentiation, in turn, was found to influence the incidence of regional nodal metastases. Overall tumor differentiation showed an inverse relationship with the incidence of nodal metastases. Decreasing tumor differentiation was associated with increasing nodal spread (64.29%, 75%, and 87.5% in cases of well, moderately, and poorly differentiated tumors, respectively). Conversely, the number of patients who had a clinically negative neck on admission showed a decline with increasing tumor grade 35.7%, 25%, and 12.5% with well, moderately, and poorly differentiated, respectively [Table 5].

When both tumor differentiation and its site were considered together in relation to the incidence of node metastases, it was observed that the majority of

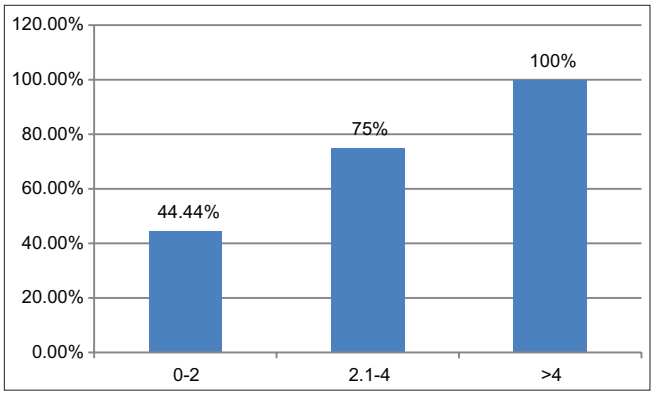

Figure 3: Correlation between tumor size and cervical nodal metastases

the anteriorly situated tumors were histologically well differentiated, and 33–83% of these tumors produced regional metastases. This was in contrast to the posteriorly situated tumors, the majority of which were histologically moderate to poorly differentiate and gave rise to a high regional metastatic rate of 66–100%.

DISCUSSION

Squamous cell cancer of the head and neck is one of the most common cancers worldwide, with incidences of more than 30/100,000 population in India (oral cancer) and in France and Hong Kong (nasopharyngeal cancer). It constitutes about 4% of all cancers in the United States and 5% in the United Kingdom. A total of 2940 new cases of lip, mouth, and pharyngeal cancer in men were reported in the United Kingdom in 1996: An incidence of 10.2/100,000 population.[5] People in their 40s and 50s are most susceptible. The 3:1 ratio of prevalence in men to women is decreasing: In the past 10 years, the incidence in Scotland has risen by 19.4% in men and 28.7% in women. In the United Kingdom, incidence and mortality are greater in deprived populations, most notable in carcinoma of the tongue.[6]

Depending on the site of the primary, 73% of these patients already have palpable nodes in the neck when first seen. A significant percentage, in addition (20% according

Table 4: Tumor site and its histologic differentiation

Site	Total number	Well-differentiated (%)	Moderately differentiated (%)	Poorly differentiated (%)
Anteriorly situated tumors (buccal mucosa, alveolus, hard palate, tongue ant 2/3rd, floor of mouth	45	25 (55.55)	12 (26.66)	8 (17.77)
Posteriorly situated tumors (soft palate, tonsils, tongue post 1/3rd, maxillary antrum	15	3 (20)	4 (26.66)	8 (53.33)

Table 5: Correlation between tumor differentiation and cervical nodal metastases

Degree of differentiation	No. of patients	Total N0 (%)	Total N+ (%)	N1 (%)	N2 (%)	N3 (%)
Well	28	10 (35)	18 (64.29)	16 (57.15)	2 (7.14)	-
Moderately	16	4 (25)	12 (75)	4 (25)	6 (37.5)	29 (12.5)
Poorly	16	2 (12.5)	14 (87.5)	4 (25)	9 (56.25)	1 (6.25)

to one estimate), harbor occult nodal disease which manifests clinically at a later date often after the primary has been treated adequately.

The presence of the palpable regional lymph nodes markedly alters the prognosis of patients with HNSCC by reducing the 5-year survival rate to less than half. Therefore, treatments of the neck before regional nodes become clinically palpable may help to improve the local-regional control rate and the overall survival in these patients.

However, in view of the morbidity imposed by any form of additional treatment to the neck at the time treating the primary, especially when surgery is chosen as the modality. Its blanket use in all patients with head and neck primary has not been considered justifiable.

Kuperman *et al*. revealed the relationship between the risk of distant metastasis and tumor site, size, and nodal status.[7] The size of the cervical lymph node remains an important factor in the interpretation of a clinically suspicious lymph node metastasis; however, it remains controversial regarding the significance of the size of the cervical node.

The accuracy of staging depends on the status of the cervical node. Many methods have attempted to detect the node status but no gold standard exists, except the histopathologic examination. Some studies have reported that the size of the cervical node was an inaccurate predictor of nodal metastasis and could not be regarded as an accurate means of staging in patients with clinically negative nodes.[8,9] Neck dissection is both a therapeutic and staging procedure and has evolved to include various types with standardized level designations (I–VI) for lymph node groups. Neck dissection is still a challenging treatment among patients with clinically negative nodes.

Ozer *et al*. suggested therapeutic neck dissection among patients with clinically negative nodes because pathologically positive nodes might be found in some patients.[10] Some reports have shown pathologically identified neck node metastasis occurred 34–51% in prophylactic neck dissections.[11,12]

Di *et al*. reported the significance of the size of the lymph node and recurrence. The size of the cervical node metastasis is the key risk factor in determining the development of cervical recurrence. Patients presenting extracapsular nodal spread and invasion of non-lymphatic structures have a high risk of developing cervical recurrence.[13]

CONCLUSIONS

Squamous cell carcinoma at various sites of head and neck was undertaken to study the possible tumor factors which influence the incidence and the pattern of regional nodal metastases. That large primaries (more than 4 cm) and those with higher histologic grade (moderate to poorly differentiated), especially when situated in the oropharynx or the oral tongue, have a greater propensity for developing regional nodal metastasis compared to the rest. These data could help to define the group of patients who are likely to harbor occult disease in their neck in the absence of clinically detectable nodes and for whom elective treatment of neck at the treatment of the primary may prove to be beneficial.

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Original Article

A Clinical Study of Effect of Centchroman on Fibroadenoma

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Abstract

Background: Centchroman has been studied earlier and literature mentions it to be a novel non-steroidal, selective estrogen receptor modulator, antiestrogen, and mild anti-inflammatory drug with a significant decrease in size of fibroadenoma. Our study aims to check the reduction in the size of fibroadenoma in response to centchroman.

Materials and Methods: A prospective observational study was carried out in patients of fibroadenoma attending surgery outpatient department and wards of Sanjay Gandhi Memorial Hospital associated with Shyam Shah Medical College, Rewa (Madhya Pradesh) from August 2015 to July 2016. Patients were included in the study after obtaining an informed consent. Patients were followed up for 12 weeks.

Results: In our study, the maximum number of fibroadenomas was found in the left upper outer quadrant; of 102 patients, total lesions (fibroadenoma) were 130. Of 102 patients studied for the effect of centchroman on fibroadenoma, there was a response in 36 patients, which accounted for 35.29%. In 66 (64.8%) patients, there was no response after the treatment with centchroman and they were subjected to excision and biopsy. The mean difference in volumes of fibroadenoma was statistically insignificant. However, there was a reduction in size of mean volume of fibroadenoma which was 4.085 at the presentation and which was 3.24 at the end of the 12th week.

Conclusion: Fibroadenoma was common in the age group of 21–30 years. The left breast was more involved in fibroadenomas. The most common site for fibroadenoma was the left upper outer quadrant. The effect of centchroman on decrease in volume of fibroadenoma was seen in 35.29% of patients. Reduction in volume of fibroadenoma was statistically insignificant. More than 50% reduction in volume of fibroadenoma was seen only in 3 patients (2.94%). Surgical excision and biopsy were the preferred modality of treatment for fibroadenomas in patients where the drug centchroman showed no response in regression in volume (64.8%).

Key words: Centchroman, Fibroadenoma, Reduction in size

INTRODUCTION

During the process of evolution, a group of animals of phylum vertebrae developed special glands to feed their newborn called mammary glands and the class was called Mammalia. This species homoserine is the zenith of mammalian hierarchy. However, in our body, besides parental care, the mammary gland or breast plays an important role as accessory reproductive organ with an equally cosmetic value.

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The term benign breast disease encompasses a heterogeneous group of lesions, including developmental abnormalities, inflammatory lesions, epithelial and stromal proliferations, and neoplasm. It may present a wide range of symptoms which may be breast pain, nodularity, discrete breast lump nipple discharge, and nipple inversion. The aberration of normal development and involution (ANDI)[1] classification provides an overall framework of benign conditions.

Benign breast disease is the most common cause of breast problems. Up to 30% of women will suffer from a benign

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breast disorder requiring treatment at some time or other in their lives. The aim of treatment is to exclude cancer and to treat the patients for their presenting symptoms and signs.

Sir Cooper[2] gave the name chronic mammary tumor to well defined, mobile tumor of breast in the early 19th century. The World Health Organization has defined fibroadenoma as "a discrete benign tumor showing evidence of connective tissue and epithelial proliferation."[3] This tumor is relatively frequent in young women and felt as rubbery, firm, smooth, and very mobile mass with well-defined margins.

Discrete, firm, and mobile lump in the breast are usually fibroadenoma, which is a benign ANDI without any risk for malignancy.[4] This tumor is relatively frequent in young women and felt as rubbery, firm, smooth, and very mobile mass with well-defined margins.

In women between adolescence and the mid-20s, the lobules and stroma in the breast may respond to hormonal stimuli in an exaggerated fashion with the development of single and multiple palpable fibroadenomas. Post-menopausal women on hormone replacement therapy (HRT) have a high incidence of fibroadenoma as compared to women not receiving HRT.[5] These presumably begin with lobular hyperplasia of breast tissue which progressively increases in size to 3–5 cm. Multiple fibroadenomas can occur in same breast or in bilateral breast and can be present varying in number up to 4–5 lesions. They are surrounded by a well-marked capsule. Of these fibroadenomas, 10–15% regresses spontaneously in the period of 6–60 months.[6] For evaluation of fibroadenoma, clinical assessment and ultrasonography (USG)[1] are the main tool.

Surgical excision is the usual plan of management for fibroadenomas at most of the centers. As hyperresponsiveness to oestrogen, is the underlying cause of fibroadenoma 'antiestrogenic drugs have been tried for managent. Other medical managements have been tried with tamoxifen and danazol.

As a novel approach in medical management, a newer drug, centchroman, or ormeloxifene is tried. It is a novel nonsteroidal oral contraceptive pill, being a selective estrogen receptor modulator (SERM) weak agonist and strong antagonist of estrogen.[7] Centchroman is devoid of steroidal and androgenic side effects. Centchroman is native to India developed by Central Drug Research Institute, Lucknow, and marketed in the name of Saheli.

MATERIALS AND METHODS

A prospective observational study was carried out in patients of fibroadenoma attending surgery outpatient department and wards of Sanjay Gandhi Memorial Hospital associated with Shyam Shah Medical College, Rewa (Madhya Pradesh) from August 2015 to July 2016.

All the patients of discrete breast lump (clinically fibroadenoma) until the age of 40 years were included in the study. The exclusion criteria comprised the patients with history of breast carcinoma or family history of breast carcinoma, patients with polycystic ovarian diseases and uterine cervical hyperplasia, pregnancy, first 6 months of lactation and all male patients.

A well-informed written consent was taken and patients presenting with the discrete breast lumps (clinically fibroadenoma) were included in the study after triple assessment (clinical, fine-needle aspiration cytology, and USG breast). The included patients were well explained about the nature of the disease and pros and cons of centchroman use.

Patients were given tablet centchroman 30 mg on biweekly basis for 12 weeks and serial clinical assessments were done to note any difference in size of fibroadenoma. USG breast was done at the start of the study for the diagnosis as a part of the triple assessment and at the follow-up at the 12th week in the selected patients in whom clinical response was seen for the confirmation of the change in size of the fibroadenoma. The patients were evaluated at the 1st week to assess about the side effects of the drug they experienced during the treatment. Further, follow-ups were done at 2 weeks, 4 weeks, 8 weeks, 12 weeks, and 16 weeks. Clinical examination was the basis of assessment.

While doing clinical examination and ultrasound for fibroadenoma two dimension length and breadth were noted (a and b) in cm. Later on, the volume of fibroadenoma in cm^3 was calculated using simplified formula for an ellipsoid.

$$\text{Third dimension } (cm^3) = \text{average of } a + b$$

$$\text{Volume of fibroadenoma} = a \times b \times c \times 0.52$$

50% reduction in symptoms and signs was regarded as efficacy of the drug.

The data were collected and put to statistical analysis and results were obtained.

Observations

From August 1, 2015, to July 31, 2016, 102 cases of fibroadenoma were studied and data were analyzed.

Fibroadenoma was found to be most common in the age group of 20–30 years (66.66%). The next common age

group was <20 years (23.52%). The least common age group was more than 30 years (9.83%) [Graph 1].

For the study of fibroadenoma, each fibroadenoma was taken as a unit. A total of 102 patients were studied in which 130 fibroadenomas were there. Of the 102 patients studied, 41 patients (40.19%) were having fibroadenoma right side, 50 patients have fibroadenomas (49.06%) on the left side, and 11 patients had bilateral fibroadenoma [Table 1].

The maximum number of fibroadenomas was found in the left upper outer quadrant; of 102 patients, total lesions (fibroadenoma) were 130.

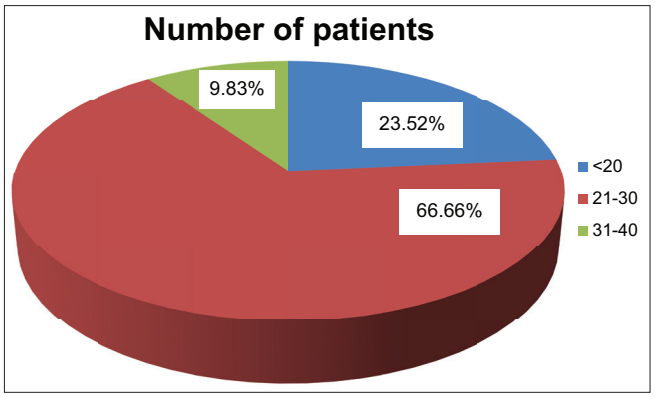
Of 102 patients studied for the effect of centchroman on fibroadenoma, there was a response in 36 patients which accounted for 35.29%. In 66 (64.8%) patients, there was no response after the treatment with centchroman and they were subjected to excision and biopsy [Graph 2].

A total of 36 patients who had 39 fibroadenomas detected clinically had a response of centchroman 30 mg given twice a week. Clinical assessment was the main basis of assessment at the presentation and in subsequent follow-ups. Patients were subjected to USG of the bilateral breast and axilla at the presentation. Of 36 responders, 54 fibroadenomas were detected by USG. Patients were assessed by clinical examination at each follow-up that is at 1st week, 2nd week, 4th week, 8th week, and 12th week [Graphs 3-5]. In case the change in the size of the fibroadenoma was felt clinically then the patient was subjected to USG for the confirmation. There was no change in size of fibroadenoma at the 1st and 2nd week and in subsequent follow-ups, there was a reduction in size of fibroadenomas [Table 2].

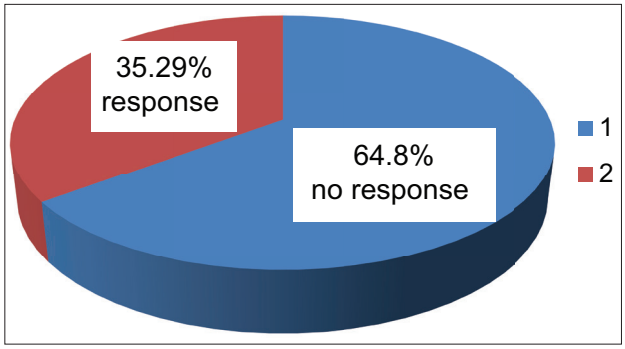
From the tables, it is clear that at the 8th week, eight fibroadenomas had a reduction of <10% in the volume. Twenty-two fibroadenomas had a reduction of 10–20%, three fibroadenomas had reduction of 20–30%, four fibroadenomas had a reduction of 30–40% and one fibroadenomas each had a reduction of 40–50% and >50% [Table 3].

At the 12th week, there were 12 fibroadenomas had a reduction of 30–40% in volume of their fibroadenomas and three fibroadenomas had a reduction of >50%. At the end of the 12th week, the results obtained clinically were confirmed by USG. By USG 36 patients had 54 fibroadenomas [Table 3 and Graph 6].

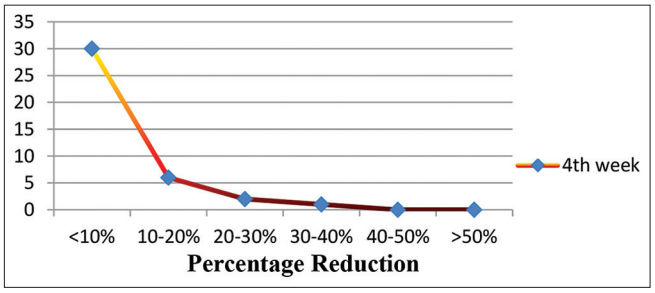
There was only one patient (one fibroadenoma) which regressed completely with the treatment.



Graph 1: Age-wise distribution of fibroadenoma



Graph 2: Effect of centchroman on fibroadenoma

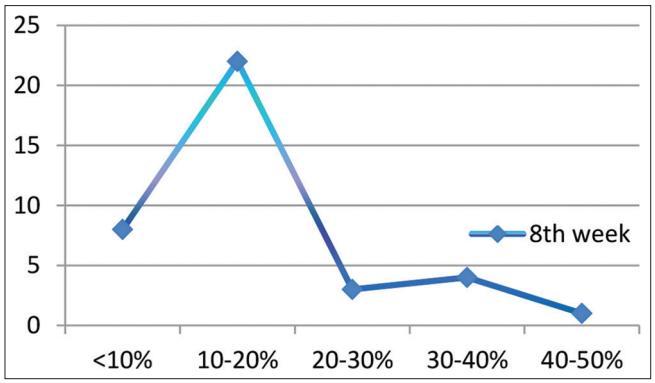


Graph 3: Response in 4th week

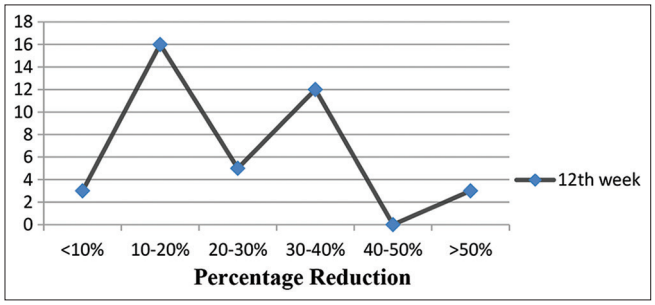
Table 1: Distribution of fibroadenoma in each breast *n*=130

Quadrant	Right breast (%)	Left breast (%)	Total (%)
Upper outer	30 (23.07)	44 (33.84)	74 (56.92)
Upper inner	6 (4.61)	6 (4.61)	12 (9.23)
Lower outer	6 (4.61)	7 (5.38)	13 (10.0)
Lower inner	3 (2.3)	3 (2.3)	6 (4.6)
Central	12 (9.23)	13 (10.0)	25 (19.25)
Total	57 (43.84)	73 (56.15)	130 (100)

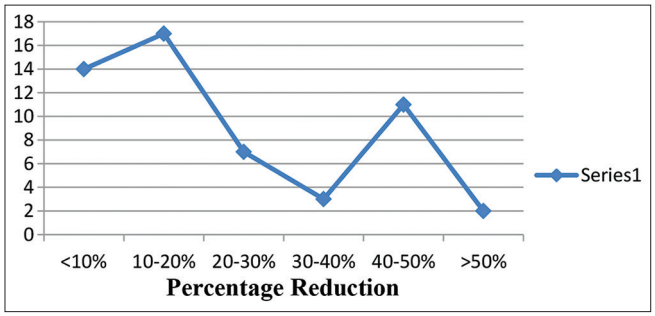
Overall mean volume of fibroadenoma detected clinically is 6.99 with a standard deviation of 6.66 (6.99 ± 6.66). Mean volume of fibroadenoma in patients who responded clinically to the treatment was 4.08 with a standard deviation of 7.42 [Table 4].



Graph 4: Response in 8th week



Graph 5: Response in 12th week



Graph 6: Distribution of fibroadenomas as per the percentage decrease in size (ultrasonography volume)

For assessing the result of centchroman in the reduction of the volume of the fibroadenoma comparison within the group was done.

The mean difference in volumes of fibroadenoma was statistically insignificant. However, there was a reduction in size of mean volume of fibroadenoma which was 4.085 at the presentation and which was 3.24 at the end of the 12th week [Table 5].

DISCUSSION

The ever-increasing incidence of malignancy in general and of breast, in particular, is associated with increased consciousness among females for any abnormal feel in the breast. In recent years, female breast has achieved an enhancement of clinical and scientific interest in the complex endocrinology background of mammary growth. This is an organ which has commanded the interest of surgeons, since the birth of surgical art and practice, from Celsius of the date of the present study. Considering fibroadenoma to be at one end of the spectrum of normal breast tissue rather than as a disease entity gives encouragement to a policy of nonsurgical management.

A study done by Carty *et al.*, at breast unit, Royal South Hants Hospital, Southampton, Department of Surgery, University College, London, reports the mean age of

Table 2: Distribution of fibroadenomas as per the percentage decrease in size (Clinical Volume): *n*=39 patients

Visits	Percentage reduction					
	<10%	10–20%	20–30%	30–40%	40–50%	>50%
4th week	30	6	2	1	0	0
8th week	8	22	3	4	1	1
12th week	3	16	5	12	-	3

Table 3: Distribution of fibroadenomas as per the percentage decrease in size (ultrasonography Volume): *n*=54 patients (at 12th week)

S. No.	No. of fibroadenomas	Percentage
1	14	<10
2	17	10–20
3	7	20–30
4	3	30–40
5	11	40–50
6	2	>50

Table 4: Effect of centchroman on mean volume of fibroadenomas (clinically)

No. of visit	Mean volume
0 week	4.08±7.42
1 week	4.08±7.42
2 weeks	4.08±7.42
4 weeks	3.76±6.61
8 weeks	3.50±6.61
12 weeks	3.24±5.98
16 weeks	3.24±5.98

Table 5: Within-group comparison of clinical volume of fibroadenoma (regression in volume of fibroadenoma after centchroman) *n*=39

Time in weeks	Mean difference	*P* value
0–4 weeks	−0.3867	0.981
0–8 weeks	−0.4433	0.9791
0–12 weeks	−0.733	0.4656

Significant value of $P \leq 0.05$

patients presenting with fibroadenoma as 28 years (range 15–48 years) (July 1986–December 1988).[8]

Gaharwar (1987) reported incidence of benign breast lesion, 41.5% in the age group <30 years.[9]

The fibroadenoma was common in the age group of 21–30 years in the study done at the Department of General Surgery, Apollo Hospital, Chennai (1990–2000). The other studies which reported the similar studies are Kaur *et al.* and Khanna *et al.*[10,11] In our study also the fibroadenoma was common in the age group of 21–30 years. Moreover, the mean age was 22.83 years.

Fibroadenomas are described to be more in the left breast. In our study also of the 102 patients studied, 41 patients (40.19%) were having fibroadenoma right side, 50 patients have fibroadenomas (49.06%) on the left side, and 11 patients had bilateral fibroadenoma. In our study, fibroadenomas were more common in the upper outer quadrant, followed by central fibroadenoma then lower outer quadrant, upper inner quadrant, and lower inner quadrant serially.

A pilot study conducted at All India Institute of Medical Sciences, New Delhi by Dhar and Srivastava from August 2003 to September 2004 has included 18 patients of fibroadenoma. In the study, centchroman 30 mg was given on alternate days for a period of 12 weeks and effect was observed at 12 weeks and at 24 weeks. The study reveals disappearance of 40% of fibroadenomas, partial regression in 20% and no change in remaining 40%.[12]

SUMMARY AND CONCLUSION

1. Fibroadenoma was common in the age group of 21–30 years
2. The left breast was more involved in fibroadenomas
3. The most common site for fibroadenoma was left upper outer quadrant
4. Effect of centchroman on decrease in volume of fibroadenoma was seen in 35.29% of patients
5. Reduction in volume of fibroadenoma was statistically insignificant
6. More than 50% reduction in volume of fibroadenoma was seen only in 3 patients (2.94%)
7. Surgical excision and biopsy were the preferred modality of treatment for fibroadenomas in patients where the drug centchroman showed no response in regression in volume (64.8%).

In patients of benign breast diseases, it is of prime most importance is to rule out malignancy and to assure the patients, and convince her about its absolutely benign nature. The aim of the study was to find out the efficacy of the drug, centchroman, which can be used as a boon for the patients of benign but troublesome disorder of normal development of the breast. Using the centchroman as conservative line of management in fibroadenoma can improve the quality of life of the patient, cosmetic appeal, and reduction in morbidity associated with the surgical modality of treatment.

Centchroman has been studied earlier and literature mentions it to be a novel nonsteroidal, SERM, antiestrogen, and mild anti-inflammatory drug with a significant decrease in size of fibroadenoma. Our study showed that there was no significant response in patients of fibroadenoma.

The effect of centchroman in fibroadenoma is mentioned with promising results in a few trials and has equivocal responses in others. Further randomized long-term trials are required to establish its role.

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Original Article

A Study of Abdominal Wall Hernias and Its Management

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Abstract

Introduction: Hernia is defined as the gap in the continuity of the fascia. The most common types of hernia are inguinal (inner groin), incisional (resulting from an incision), femoral (outer groin), umbilical (belly button), and hiatal (upper stomach).

Aim: The aim of the study was to study the various risk factors and complications of different types of hernias, clinical presentations, and their management.

Materials and Methods: All cases of abdominal wall hernias presenting above 12 years of age were included in the study. Patients were assigned to undergo suture repair or mesh repair at the operating surgeon's discretion. All patient-related data were collected for analysis.

Results: Among the 185 cases studied, 86 were incisional hernia (46.4%), 75 were umbilical hernia (40.5%), and 21 were epigastric (11.3%), one Spigelian, and two lumbar hernia. Female preponderance was seen in incisional hernias with male to female ratio of 1:6.7. The swelling was the most common complaint in 55% followed by pain 31.6. Previous surgery or trauma was the single most important cause for ventral (Incisional) hernias. Simple suture repair and or Mayo's repair was the choice of repair in emergencies in all age groups.

Conclusion: Size of the defect and presence of complications are the guiding factors for choosing the type of repair. Laparoscopic approach for ventral hernia repair is definitely a method of choice with the advantages of good operative field visibility, lessened duration of hospital stay, and minimal post-operative scar.

Key words: Hernioplasty, Incidence, Incisional hernia, Mesh repair

INTRODUCTION

Abdominal wall hernias are familiar with surgical problems. Abdominal wall hernias are those that appear through the layers of abdominal walls at sites of weakness. They occur both due to congenital and acquired defects. Hernias commonly cause pain and are esthetically distressing to patients. This coupled with the risk of incarceration, is the most common reason patient seeks surgical repair of hernias. Advances in the basic and clinical sciences have allowed a better understanding of the pathophysiology of hernia formation. The field of hernia repair has evolved as a result of surgical innovation and has benefited significantly from technological improvements.[1]

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Tension-free repair is one of the key concepts that have revolutionized hernia surgery. The use of mesh prosthesis to approximate the fascial defect has resulted in a decrease in recurrence rates for inguinal and incisional hernias. More recently, laparoscopic approaches to the inguinal and incisional hernia have extended the options and approaches for repairing the fascial defect. However, large abdominal incisions and wide tissue dissection with the creation of large flaps often lead to a high incidence of post-operative morbidity and wound complications. Nowadays, open ventral herniorrhaphy has been challenged by reports of the successful implementation of minimally invasive techniques. The benefits of laparoscopic ventral hernia repair include a faster convalescence, fewer complications, and, most important, a low recurrence rate.[2-4]

The Stoppa repair used a large mesh in the preperitoneal space to support the fascial defect, which is the concept

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upon which the laparoscopic inguinal hernia repair is based. Contemporary repair of abdominal wall hernias is supported by strong evidence and calls for a tension-free repair with placement of mesh in the majority of cases. Laparoscopic repair demands significant expertise to achieve outcomes comparable with those of open repair. In ventral incisional hernias, placement of the mesh in a sublay position has been found to be effective and to have a low recurrence rate, although randomized trials have not been performed.[4]

An incisional hernia, a late complication of laparotomy, still lacks an evidence-based prophylactic approach. Postoperatively, incisional hernias occur due to multiple factors. Pre-operative comorbidities belong to these risk factors. There is a range of studies comparing the techniques of surgical wound closure, suture materials differences, and newer techniques of repair.[5,6]

Aim

The aim of the study was to study the various risk factors and complications of different types of hernias, clinical presentations, and their management.

MATERIALS AND METHODS

This prospective observational study was conducted in the Department of Surgery, Tirunelveli Medical College and Hospital. This study was based on the analysis of cases of abdominal wall hernias observed from January 2011 to September 2012. The study accounts for all the cases of abdominal wall hernias that were diagnosed and treated both electively and emergency. Ethical committee clearance obtained. Consent was obtained from all patients. A simple random sampling was done for selecting the patients.

Inclusion Criteria

All cases of abdominal wall hernias presenting above 12 years of age were included in the study.

Exclusion Criteria

Age <12 years, patients with inguinal and femoral hernias were excluded from the study.

The patient's related factors, namely age, sex, multiparity, obesity, cough/chronic obstructive pulmonary disease, constipation, prostatism, diabetes mellitus, hypertension, steroid therapy, consumption of tobacco and alcohol, past surgical history were recorded. A master chart has been made recording relevant history and findings of personally studied 185 cases of ventral hernia. Routine investigations, namely, hematology, urine examination, chest X-ray, electrocardiography, ultrasound abdomen, and pelvis for all patients and other special investigations were done for associated diseases wherever required.

As clinical diagnosis was made, patients with medical illnesses were appropriately treated to attain near-normal parameters before surgery. At the induction of anesthesia, the prophylactic dose of antibiotic (1st generation cephalosporin) was given. Patients were assigned to undergo suture repair or mesh repair at the operating surgeon's discretion.

In suture repair, continuous stitches with stitch width and interval approximately 1 cm were put using polypropylene (Prolene no. 1-0). In mesh repair, Prolene mesh was used with at least 4 cm of mesh overlapping the approximated edges of the fascial defect and secured with no. 1 Prolene interrupted stitches over the fascia. A suction drain was used for all patients with incisional hernia and drain removed 48–72 h interval or when drain decreased. Sutures were removed on 8 post-operation day.

Particular attention was given to study various aspects of ventral hernias such as:

- Distribution of ventral hernias with respect to age and sex of the patient
- Types of hernia
- The period between the previous surgery and the development of incisional hernia
- Etiological/predisposing factors for the development of ventral hernias
- Common presentations
- Exact location and size of the defect
- Various surgical options for the management of ventral hernias
- Complications in the perioperative period
- Follow up done at 1, 6, 12, and 18 months of the interval following surgery.

RESULTS

Among the 185 cases studied, 86 were incisional hernia (46.4%), 75 were umbilical hernia (40.5%), and 21 were epigastric (11.3%), one Spigelian, and two lumbar hernia.

Incisional Hernia

In 86 incisional hernia cases, 50% were home workers, 36% moderate workers, and 14% heavy workers. The incisional hernia was common in third to the fifth decade, 11 were males and 75 were female. Of the 86 cases, 46 cases were with <25 body mass index (BMI), this shows, obesity does not influence incision hernia occurrence. Almost all cases had swelling to present with, but presentation as the swelling was in 51 cases, pain in 25 cases, both in 10 cases. Of the 86 cases, 25 were cesarean section (29%), 14 were lap sterilization (16.3%), 8 were puerperal sterilization (9.3%), 8 were hysterectomy (9.3%) 20 were

laparotomies (23.2%), 4 were appendicectomy (4.6%), 2 were cholecystectomy (2.3%), 1 was bone graft from iliac crest (1.2%), 1 was at Rt lumbar drain site (1.2%), and 3 were recurrent incisional hernia (3.4%).

In gynec surgeries, lower midline incision was predominantly used (23.2%) followed by Pfanensteil incision (15%) and lower transverse incision.

Of 86 cases, 42 cases had onset after 5 years of surgery (48.8%), 21 it between 2 and 5 years (24.4%), and 23 cases developed within 2 years of surgery. In 86 cases, 22 cases had large defects of over 6 cm diameter (26%), 24 had small defect of <3 cm (28%), and 40 cases had average defect of 3–6 cm (46%). These 2 cases of wound infections and 3 cases of recurrence noted postoperatively.

Epigastric Hernia

Of the 21 cases, 17 were male (81%) and 4 were female (19%); 8 cases, 38% were BMI <25%; and, 13 cases, 62% were BMI >25%. All the cases had swelling but the presenting symptom was found only in 6 cases (34%). The major presentation was a pain in the epigastric region 14 cases (66%). Most of the cases were electively treated but for one case that was taken up for irreducibility as an emergency. Most epigastric hernias are found to have multiple defects along the linea alba 15 cases (71.4%), only 6 cases had a single defect. Most of the cases were with defect 3–6 cm (57%), >6 cm (5%), and <3 cm (4%). Of the 21 cases, 5 cases were anatomically repaired (23.8%), others were repaired by meshplasty.

Umbilical Hernias

Of the 75 cases, pure umbilical swelling was present in 36 cases (48), more common in female 33 cases (44%), males 42 (56%), 55 cases, 72% were BMI <25%, and 20 cases 28% BMI >25%. Mostly presented for elective surgical repair, of the 75 cases, 7 cases were taken up for emergency surgery (5 – irreducible and 2 – obstruction). All patients had swelling of which only 45 cases had it as a presenting complaint (66%), the pain was the next presenting complaint in 25 cases (33.3%), 5 other patients came for cosmetic surgery. There were defects of 3–6 cm size in most patients 42 cases, <3 cm in 25 cases, and >6 cm in 8 cases. Of the 75 cases, 13 cases were given anatomical repair (17.3%), Mayo's repair was done in 12 cases (16%), rest were given mesh repair.

Spigelian hernia

One case of 35-year female presented with pain abdomen 1 year duration, swelling for 1 week, diagnosed clinically as Spigelian hernia. Ultrasonography showed a defect in the left side of umbilicus of 5 cm × 3 cm. Treated by mesh repair.

Lumbar hernia

Two cases – males of age 35, 46 presented with the swelling lumbar area in the superior triangle treated by mesh repair.

DISCUSSION

Ventral hernias: Incidence is second only to inguinal hernias, accounting for 25–35% of all hernias. Ventral hernias include incisional and primary defects in the abdominal fascia, which can cause umbilical, epigastric, or Spigelian hernias. Incisional hernias account for 80% or more of ventral hernias that surgeons repair. The prevalence of incisional hernias after laparotomy is 2–11% and increases substantially when certain risk factors for post-operative incisional hernia, such as a wound infection or obesity, in our study, incisional hernias accounted for 46.4% of ventral hernias. About 40.5% were umbilical hernia, 11.4% were epigastric hernias.[7]

Toms *et al.*[8] says midline incision through the relatively avascular linea alba contributes more than transverse incision, especially where muscle splitting approaches are been used. Carlson found a 10.5% ventral hernia rate in 4129 midline incisions compared with a 7.5% rate for transverse incision and a 2.5% rate of paramedian incision.[9]

Korenkov *et al.* says that incisional hernia can occur after all types of abdominal surgery and the risk lies between 11 and 15% after midline laparotomy and 0.2–1.2% after laparoscopy.[10]

Incisions	Present study		Bose *et al.*[11]		Ríos *et al.*[12]	Balén *et al.*[13]
	n	%	*n*	%	%	%
Vertical	40	46.5	91	82.72	-	-
IU	20	23.2	35	38.46	36	9.1
SU	20	23.2	0	0	16	20.6
Transverse	14	16.27	0	0	-	6.89
McBurney	3	3.4	19	10.86	-	2.29
Subcostal	2	2.3	0	0	6	2.29
Pfanensteil	13	15	-	-	-	2.29

Cassar and Munro observed incisional hernia as a bulge visible and palpable swelling when the patient is standing and often requiring support or repair.[6] Toms *et al.* said that abdominal wall hernias may be asymptomatic or present with a life-threatening emergency.[8]

Incisional hernia presents with pain, complications such as incarceration (6–15%) or strangulation of the bowel (2%) (van't Riet *et al.* 2002).[14] Usually, an asymptomatic bulge noticed by the patient or a bulge directly over the incision

or in an adjacent area locally related to the incision is the presentation (Millikan, 2003).[15]

The major cause of post-operative herniation is wound infection as leads to fascial necrosis with resultant loss of integrity of the closure (Bucknal *et al.* 1982).[16]

In Balén *et al.* study, 4% seroma, 4% ileus, and 2% fistula.[13] In a review of 3107 incisional hernia repairs, Heydorn and Velanovich reported that the mortality rate was appreciably higher in patients undergoing repair of complicated hernias (1.1%) than in those individuals undergoing elective repair (0.3%).[17]

S. No.	Reference year	Type of repair	No of pt.	Recurrence%	Follow-up in months
1	Liakakos *et al*. 1994[18]	Suture	53	25	90
		Mesh	49	8	90
2.	Schumpelick *et al*. 1996[19]	Suture	190	33	64
		Mesh	7	7	64
3.	Clark 2001[20]	Suture	13	38	25
		Mesh	8	25	13
4.	Luijendijk *et al*. 2000[21]	Suture	97	46	26
		Mesh	84	23	26
5.	Korenkov *et al*. 2002[22]	Suture	33	12.12	16
		Mesh	39	7.69	16
6.	Our study	Suture	24	0.01	6–18
		Mesh	62	0.01	6–18

CONCLUSION

Ventral hernias were common surgical problems second only to groin hernias. Most of the incisional hernias developed >5 years of previous surgery. Swelling, pain, and complications along with esthetic concerns are the causes for seeking a surgical solution. Most of the ventral hernias were uncomplicated at the time of presentation, remaining presented with either obstruction or strangulation necessitating emergency repair. Incidence of incisional hernias was more in females with male to female ratio of 6.7:1, while epigastric and umbilical hernias were more common in males with a male to female ratio of 4:1 and 1.2:1, respectively. Size of the defect and presence of complications are the guiding factors for choosing the type of repair. Laparoscopic approach for ventral hernia repair is definitely a method of choice with the advantages of good operative field visibility, lessened duration of hospital stay, and minimal post-operative scar.

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Original Article

Level 3 Axillary Nodal Status in the Absence of Metastatic Disease in Level 1 and 2 Axillary Node in Carcinoma Breast – A Retrospective Analysis

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Abstract

Introduction: The intention of axillary lymph node dissection (ALND) is to stage the axilla precisely for prognostic information. This study is to assess the possibility of skip lesion in Level 3 in the absence of disease in Level 1 and 2 which may help in undertaking randomized controlled study to avoid Level 3 nodal dissection in our patients.

Materials and Methods: Retrospective analysis of 60 patients who underwent surgery for invasive breast cancer from October 2013 to October 2019 in the Department of Surgical Oncology, Government Thoothukudi Medical College Hospital, Thoothukudi, was performed.

Results: About 33.3% of patients (20) were disease free in the axilla and the remaining 66.7% (40) had nodal involvement. Of those 39 patients who had nodal involvement in Level 1 and 2, 15 were found to have the disease in 4 or more nodes, 24 had the disease in <4 nodes. Totally 16 patients had metastases in Level 3 nodes. There is a 60% chance of involvement of Level 3 when there is 4 or more nodal positivity in Level 1 and 2 and it drops to 25% if the involved nodal count becomes <4. One patient had skip lesion in Level 3 (4.8%) without disease in Level 1 and 2.

Conclusion: Since there has been a dearth of randomized studies about levels of nodes to be addressed in ALND and studies about skip lesion in Level 3 from our country, we urge the need for more studies probably multicentric, regarding the extent of ALND. Until then, it may be fruitful to do complete ALND up to Level 3 for the better staging of the axilla.

Key words: Axillary lymph node dissection, Carcinoma of breast, Level 3 nodes

INTRODUCTION

Breast cancer tops the list of cancers affecting women in many parts of India.[1] It tends to affect the younger age group also.[2] Surgery is a critical part in the management of breast cancer. Even though breast surgery has undergone a paradigm shift from the Halstedian era of radicalism to Fisher's concept of breast cancer being a systemic disease from the beginning, the foundation of locoregional therapy still relies on the complete eradication of the disease from breast and axilla.

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Axillary nodal involvement is the most important prognostic factor in cancer breast. Axillary lymph node dissection (ALND) has long been considered as the gold standard treatment in node-positive patients. The principle behind complete ALND is to stage the axilla for accurate prognostic information, to maintain adequate local control, to provide a rational basis for decisions regarding adjuvant therapy, and possibly to maximize survival. Even in clinicoradiological node-negative axilla, there lies the possibility of occult metastasis in 30–40% of patients.[3] Hence, axilla has to be addressed in all cases. Anatomically axillary space is divided into three levels by the pectoralis minor muscle. The assumption was that metastases from primary usually would first involve Level 1, then Level 2, and only later Level 3.[4]

The dissection of Level 3 nodes located between the costoclavicular ligament and medial border of pectoralis minor muscle needs experience and may require slightly

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longer surgical time. Since there is no international consensus regarding the levels of nodes to be removed and paucity of specific studies to find out skip lesions in apical nodes (Level 3), our policy is to do complete ALND up to Level 3 as followed in many dedicated cancer centers in India.[5,6]

Aim

The aim of the study was to assess the status of Level 3 node in the absence of disease in Level 1 and 2. This may lay the foundation for further studies to assess the feasibility of skipping Level 3 dissection without compromising oncological safety in our population.

MATERIALS AND METHODS

A retrospective analysis of data of patients who underwent modified radical mastectomy (MRM) for invasive breast cancer between the periods, October 2013–October 2019 in the Department of Surgical Oncology, Government Thoothukudi Medical College Hospital was carried out. All patients were treated with curative intent after getting informed consent and are being followed up regularly. The Institutional Ethical Committee of our hospital has given approval for this study. Until date, sentinel lymph node biopsy (SLNB) was not performed in our department due to a lack of technical expertise.

Only the data of those 60 patients whose Level 3 nodal status was known is taken for analysis. All surgeries were done by a single qualified surgical oncologist. The grossing of the specimen and histopathological reporting was done by multiple pathologists over the above period. In all patients, ALND was done up to Level 3. Level 1 and 2 axillary nodes were removed *en bloc* with mastectomy, and Level 3 nodes were removed separately by interpectoral approach.

We follow the stepwise approach identifying all structures carefully while doing mastectomy and ALND.[6-8] In almost all cases, pectoralis minor muscle was preserved. We use diathermy for raising the flaps. A suction drain was used in all cases. Level 3 area was reached by the interpectoral approach retracting the pectoralis minor muscle laterally, retracting pectoralis major muscle above and medially. Complete clearance was done up to costoclavicular ligament. Specimens (breast with Level 1 and 2 nodes, Level 3 nodal tissue) were sent in separate containers.

All patients were given proper adjuvant therapy depending on our institutional protocol. Patients were being followed up monthly in the 1st year, 2 monthly in the 2nd year, 3 monthly in the 3rd year, 6 monthly for 4th, and 5th years and yearly thereafter as per our department protocol. Follow-up included clinical examination at each visit, yearly chest X-ray and ultrasonography abdomen with the pelvis and other investigations as indicated. We routinely teach shoulder mobilization exercises for the patients and encourage them to follow it regularly.

RESULTS

In this study, 60 patients who underwent MRM, whose Level 3 nodal status in their post-operative histopathology report is known, were included in the study. The median age of the study patients was 52.5 years in range 30–90 years [Table 1]. Twenty-one patients were below 50 years of age. The average node count retrieved in Level 1 and 2 is 10.7 which meets the optimum requirement suggested by international guidelines. The average node count retrieved in Level 3 is 2.6. The average node count retrieved in complete ALND is 12.8.

Of those 60 patients, 28 received pre-operative chemotherapy and 32 underwent upfront surgery. Thirty-seven patients had a tumor on the right breast and 23 were left sided. A total of 33.3% of the patients were disease-free in the axilla and the remaining 66.7% had nodal involvement. Of those 39 patients who had the disease in Level 1 and 2, 24 were found to have the disease in <4 nodes and 15 were found to have the disease in 4 or more nodes. A total of 26.7% of the patients had the disease in Level 3 (16 patients) [Figure 1]. One patient had skip lesion in Level 3 in the absence of nodal positivity in Level 1 and 2 (4.8%). This patient underwent surgery after neoadjuvant chemotherapy.

Table 1: Clinicopathological details

Clinicopathological characteristics		Measure
Age	Median (range)	52.5 (30–90)
Side of lesion	Right	37
	Left	23
Status of ALND	Uninvolved patients	20
	Involved patients	40
Status of involved nodal level	Level 1 and 2 (more than 4 nodes)	15
	Level 1 and 2 (<4 nodes)	24

ALND: Axillary lymph node dissection

Table 2: Percentage of skip lesion in Level 3 in various studies

Studies	Year of study	Sample size	% of skip lesion in Level 3 axillary node
Aslan[20]	2007	87	1.14
Khafagy *et al*.[21]	2011	59	1.70
Joshi *et al*.[5]	2019	1591	0.70
Our study	2020	60	4.80

Of those 15 patients who had 4 or more nodal positivity in Level 1 and 2, 9 had the disease in Level 3 (60%). Of those 24 patients who had <4 nodal involvements in Level 1 and 2, 6 had the disease in Level 3 (25%) [Figure 2]. The nodal burden in Level 3 increases with the number of nodes involved in Level 1 and 2.

DISCUSSION

In this era of organ conservation, the radicalism of surgery is gradually losing its shine. For breast cancer, surgery for the primary as well as axilla is moving from radicalism toward conservation.[9,10] SLNB is the current strategy in clinically node-negative axilla in many centers.[11] In some centers, low axillary sampling is considered as an alternative to SLNB.[12]

SLND for clinically node-negative axilla gained popularity following the advent of the landmark NSABP-32 trial.[11] If the sentinel node is negative, ALND is avoided which may help to avoid the potential complications of ALND. When the sentinel node is positive, the patient will be subjected to complete ALND. Further advancement in SLNB was obtained with the advent of the landmark trial ACOSOGZ0011.[13] On the other hand, ALND is still the gold standard procedure for the management of axilla in many parts of the world where these technological advances are not available. There is no international consensus regarding the levels to be removed in ALND. NCCN guidelines recommend dissection of Level 1 and 2 with the advice that, Level 3 to be removed when there is gross disease in Level 1 and 2.[14] In fact, there are questions whether the evidence from early screen-detected cancers in the western population can be blindly followed in our population with a possibly different tumor biology and presentation as locally advanced disease.

In general, Level 1 nodes are commonly involved in breast cancer.[15] Involvement of Level 2 or Level 3 lymph nodes without the involvement of the Level 1 is uncommon. The involvement of Level 3 lymph nodes with negative Levels 1 and 2 lymph nodes is rare, occurring in <3% of all patients with positive nodes.[16,17] The risk of involvement of the higher lymph-node levels increases substantially with increasing numbers of involved nodes or when lower levels are involved.

In a study by Gaglia *et al.*, 9% of patients with 1–3 positive lymph nodes and 47% of those with 4 and more positive lymph nodes had involvement of Level 3 lymph nodes.[18] In the study by Boova *et al.*, Level 1 lymph nodes were found to be positive, the Level 2 lymph nodes were involved in 41% of patients, and Level 3 lymph nodes were involved in 21%. When Level 2 lymph nodes were involved, 31% of patients also had metastases to Level 3.[15] Similar trend had been reported by Chevinsky *et al.*[16] Moreover, a higher incidence of Level 3 involvement has been noted when lymph nodes in lower levels were grossly involved by tumor (41%) compared with when they were only involved microscopically (15%).[17]

In a study by Fan *et al.*, there is a 9% chance of residual positive nodes in Level 3 after neoadjuvant chemotherapy. They found that tumor size, non-responsiveness of the primary tumor to neoadjuvant chemotherapy were independent predictors for Level 3 nodal positivity. Disease-free survival (DFS) was found to be lower for Level 3 positive group.[19]

Joshi *et al.* in a prospective single-institution study from a reputed cancer center in India have found that 9.4% had the disease in Level 3 when 1–3 positive nodes were present

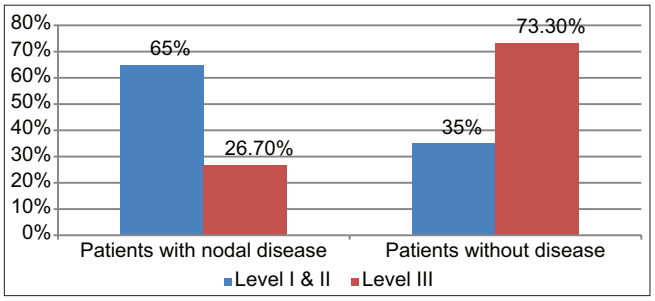

Figure 1: Status of axillary lymph node dissection

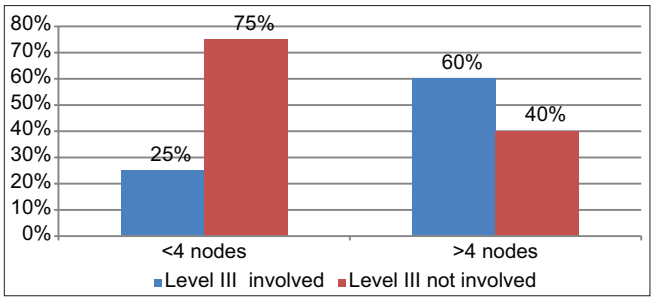

Figure 2: Status of Level 3 nodes in the presence of disease in Level 1 and 2

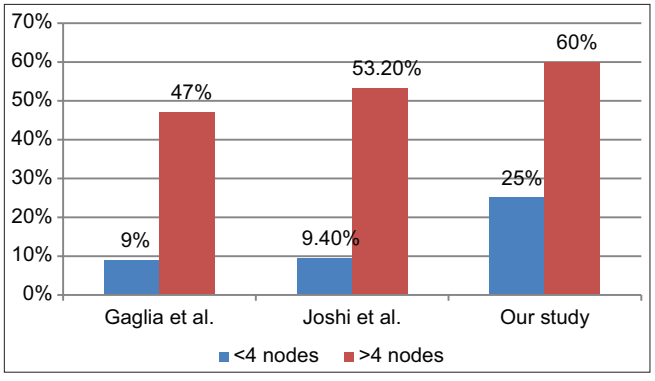

Figure 3: Involvement of Level 3 depending on diseased nodal count in Level 1 and 2

in Level 1 and 2 and it increased to 53.2% if 4 or more nodes are positive in Level 1 and 2 [Figure 3]. In their study, 0.7% had skip lesion in Level 3 in the absence of nodes in Level 1 and 2. DFS was significantly worse for Level 3 ALN metastases on univariate analysis.[5]

In our study, 25% had the disease in Level 3 when 1–3 positive nodes were present in Level 1 and 2 and it increased to 60% if 4 or more nodes are positive in Level 1 and 2 [Figure 2]. In our study, 4.8% had skip lesion in Level 3 in the absence of nodes in Level 1 and 2 [Table 2]. In a study by Boova *et al.*, 3.5% manifested skip lesions in Level 2 and 3 without the involvement of Level 1.[15]

With the available data, as the positive nodal count in Level 1 and 2 is 4 or more, there is a high chance of involvement of Level 3 (60%) which is statistically significant (P = 0.029). If a partial (Levels 1 and 2) ALND is done as per current recommendation, one of two patients with 4 or more positive nodes in Level 1 and 2 may have residual disease in Level 3. Since the axillary nodal burden is higher in developing countries like India, many surgeons feel that leaving behind Level 3 nodes may amount to inadequacy of dissection defeating the therapeutic intention of ALND. The morbidity of doing Level 3 dissection is very minimal in the hands of experienced surgeons who know the finer aspects of oncological clearance. Hence, complete ALND may be the highly rewarding procedure in the accurate staging of axilla in our population.

CONCLUSION

In carcinoma breast, individualized treatment based on disease burden and availability of technical expertise along with multidisciplinary cooperation is considered as the best option. Since there has been a dearth of randomized studies about levels of nodes to be addressed in ALND and studies about skip lesion in Level 3 in our country, we urge the need for more studies probably multicentric, regarding the extent of ALND. Until then, it may be fruitful to do complete ALND up to Level 3 for the better staging of axilla.

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Original Article

Comparison of Baska Laryngeal Mask Airway and Endotracheal Tube in Adult Patients Undergoing Surgery under General Anesthesia: A Prospective Randomized Study

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Abstract

Background: Airway management is considered as an integral part of general anesthesia. Use of Baska mask, since a supraglottic airway device, could result in the low incidence of hemodynamic alterations and post-operative pharyngolaryngeal complications. We conducted this study to compare the hemodynamic parameters, i.e., systolic blood pressure (SBP), diastolic blood pressure, mean arterial pressure (MAP), heart rate (HR), ease of insertion, time of insertion, and post-operative pharyngolaryngeal complications during Baska mask and endotracheal tube (ETT) insertion.

Materials and Methods: It was a prospective randomized study which was conducted on 80 adult patients admitted for elective surgery under general anesthesia (GA) of 60–90 min duration. A total of 80 patients were randomly allocated into two groups, i.e., Group B and Group E of 40 each. Group B patients underwent Baska mask insertion and Group E patients underwent ETT insertion. The statistical analysis was done by Student's *t*-test and Chi-square test. $P < 0.05$ was considered statistically significant.

Results: There was a statistically significant rise in SBP, diastolic blood pressure, MAP, and HR during ETT insertion as compared to Baska mask insertion. The mean time of insertion of Baska mask was 12.8 ± 1.36 s and of ETT was 15.93 ± 1.51 s. Insertion of Baska mask was easy in 85% whereas insertion of ETT was easy in 65%.

Conclusion: Baska mask can be used as an alternative to ETT in adult patients undergoing surgeries under GA of 60–90 min duration with minimal hemodynamic alterations and post-operative pharyngolaryngeal complications.

Key words: Baska, Insertion, Intubation, Post-operative, Sore throat

INTRODUCTION

Airway management is an integral part of general anesthesia (GA). Endotracheal intubation has been considered as a conventional gold standard method for securing the airway during GA. The disadvantages of tracheal intubation are concomitant hemodynamic responses such as tachycardia, hypertension, and arrhythmias which can lead to myocardial ischemia; damage to oropharyngeal structures during insertion of endotracheal tube (ETT) itself or during laryngoscopy and post-operative sore throat. Baska mask is the latest third generation supraglottic airway device[1] designed by Australian anesthesiologists Kanag and Meena Baska with gastric sump channels that offer protection against aspiration.[2] As we do not require laryngoscopy during Baska mask insertion leading to a lower incidence of post-operative pharyngolaryngeal complications.

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MATERIALS AND METHODS

Ethics

After approval from the Institutional Ethics Committee, Government Medical College, Amritsar, and after taking written informed consent, the prospective randomized study was conducted on 80 healthy patients. The patients

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were of either sex belonging to the American Society of Anesthesiologists Grades I or II, aged 20–50 years and bodyweight 40–76 kg undergone surgeries of 1–1.5 h duration under GA. Patients with inadequate mouth opening, body mass index >26 kg/m^2, anticipated difficult airway, the patient having increased risk of aspiration, oropharyngeal pathology, and severe respiratory disease were excluded from the study.

Patients were randomized for airway management with Baska mask and ETT by opening an opaque envelope inside the operation theatre containing the computer generated random assignment into two groups of 40 each.

- Group B – Undergone Baska mask insertion
- Group E - Undergone endotracheal intubation.

Each patient was examined in the preanesthesia room and was explained about the questionnaire related to sore throat and hoarseness of voice. The sore throat was defined as constant pain or discomfort in the throat independent of swallowing.

The severity of post-operative sore throat was graded as:

- Grade 0 – No sore throat at any time since the operation
- Grade 1 – Patient answered in the affirmative when asked about sore throat (minimal)
- Grade 2 – Patient complained of sore throat on his/her own (moderate)
- Grade 3 – Patient is in obvious distress (severe).

Hoarseness is defined as an abnormal change in voice and often experienced in conjunction with a dry or scratchy throat.

The patient was kept nil per orally after 12 midnight and tablet alprazolam (Alprax) 0.5 mg was given at 6 am in the morning before surgery with a sip of water which acts as anxiolytics. In the operation theatre, standard monitors were attached and baseline parameters were recorded. The monitoring equipment and anesthetic drugs used during general anesthesia were kept on the work station on the head side of the operating table.

After removal from its sterile packet, the integrity and function of the Baska mask were checked by occluding the airway opening of the proximal connector end with one thumb, holding the mask head with the other hand and placing the other thumb over the airway opening of the mask to seal. The pressure was applied for 5 s using a reservoir bag squeeze to confirm the absence of leak in the device. The entire body of the mask was then lubricated with a water-based lidocaine (lignocaine) gel.

The insertion time of Baska mask was measured in seconds as the time between picking up of the Baska mask to the appearance of the first capnograph trace. However, in the case of ETT, insertion time was measured from the direct laryngoscopy to the appearance of the first capnograph trace.

After attaining the intravenous access, injections of midazolam 0.02 mg/kg, glycopyrrolate 0.005 mg/kg, and butorphanol 1–2 mcg/kg were given. General anesthesia was induced by injection propofol 1.5–2.5 mg/kg. Neuromuscular blockade to facilitate placement of device was achieved by injection vecuronium 0.08–0.1 mg/kg. Following induction and adequate paralysis, the corresponding airway was inserted in each group. In Group B, size 3 Baska mask was used for females and size 4 Baska mask was used for males according to their weight. In Group E, endotracheal intubation (7–7.5 females and 8–8.5 in males) was performed in a standard manner. After Baska mask insertion and intubation in the respective group of patients, the anesthesia was maintained with oxygen, nitrous oxide, isoflurane, and vecuronium. The seal pressure was calculated as the plateau pressure with fresh gas flow at 6 liters by closing the adjustable pressure limiting valve at 70 cm H_2O and was measured in cm of H_2O at 10 min post placement of Baska mask. The cuff pressure of ETT was measured 10 min of post-intubation using an aneroid manometer. The aneroid manometer was connected to the pilot balloon of the ETT cuff through a three-way stopcock and ETT cuff pressure was measured and recorded. The correct placement of the devices was confirmed by adequate chest movement on manual ventilation, auscultation, square wave capnography, expired tidal volume of more than 8 ml/kg, and no audible leak.

Hemodynamic responses include mean arterial pressure (MAP), SpO_2, electrocardiogram (heart rate [HR]), and $ETCO_2$. All these parameters were recorded before induction; after induction/before laryngoscopy; after laryngoscopy; during intubation/Baska mask insertion; at 1, 3, 5, 10, and 15 min after insertion of device, then every 10 min until the end of surgery; and even after removal of the airway devices. Ease of insertion was also noted during insertion of Baska mask and ETT. Insertion of baska mask is categorised as - Insertion at first attempt with no resistance (easy); difficult insertion or at second attempt or insertion with manipulation of tab (fair); failed insertion or insertion not possible (difficult).

At the end of surgery, injection Myo Pyrrolate (neostigmine + glycopyrrolate) 0.04–0.06 mg/kg was given as reversal. When the patient was awake and following commands, Baska mask and ETT were removed. Parameters such as the presence of bloodstain on the cuff, incidence of bronchospasm, laryngospasm, regurgitation, and aspiration were noted. The patient was then shifted to the post-

anesthesia care unit. After surgery, pharyngolaryngeal complications, consisting of a sore throat, coughing, and hoarseness of voice, were assessed at 1, 2, 4, 8, 12, and 24 h postoperatively. The predetermined definitions of pharyngolaryngeal complications were used for the assessment.

Statistics

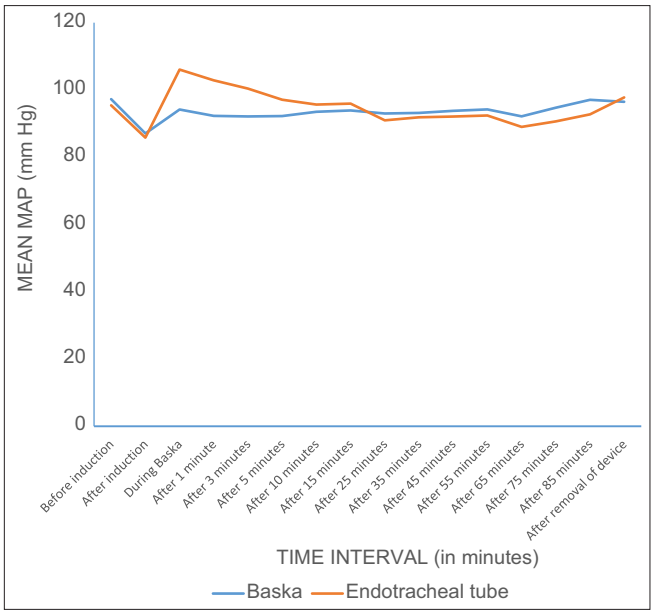
The sample size was calculated keeping in view at most 5% risk, with minimum 85% power and 5% significance level (significant at 95% confidence interval) ($\alpha = 0.5$, $\beta = 0.5$) for comparison of quantitative and continuous data, a minimum of 40 patients in each group with a total minimum of 80 patients either male or female were included in the study. Raw data were recorded in a Microsoft Excel spreadsheet and analyzed using Statistical Package for Social Sciences version 23.00 (IBM Corporation ARMONK, NY, USA). The continuous variables were presented as mean with standard deviation (SD) (mean ± SD). Normally continuous variables were analyzed using Student's *t*-test. The categorical variables were analyzed using Chi-square test. *P*-value of 0.01–0.05 was considered statistically significant and $P < 0.001$ was considered highly statistically significant.

RESULTS

With respect to the demographic parameters, the patients in the two groups were analogous as is evident from Table 1. Themean duration of surgery was 69.02 ± 9.55 min in Group B and 70.35 ± 9.74 min in Group E. The difference was statistically non-significant ($P > 0.05$).

Coming to the hemodynamic parameters, when the MAP was compared during insertion of Baska mask and ETT, statistically highly significant difference was found ($P < 0.001$) with MAP 94.18 ± 5.80 mmHg in Group B and 106.05 ± 4.34 mmHg in Group E. The rise in MAP during insertion of airway device was 8% and 24% in Group B and Group E, respectively, when compared with their post-induction values. Even at 1 min, 3 min, and 5 min post-insertion statistically significant difference was found in mean MAP between Group B and Group E ($P > 0.05$). The MAP was then measured at 10 and 15 min, every 10 min interval until the end of surgery, and even after removal of airway device, statistically insignificant difference was observed between Group B and Group E ($P > 0.05$) [Graph 1 and Table 2].

The mean HR during insertion of Baska mask and ETT shows statistically highly significant difference ($P < 0.001$) with mean HR 102.13 ± 10.67 beats/min (bpm) in Group B and 113.55 ± 9.57 bpm in Group E. The rise in HR was 7% and 16% in Group B and Group E, respectively when compared with their baseline values. Even at 1 min, 3 min, and 5 min of surgery statistically significant difference was found in mean HR between Group B and Group E ($P > 0.05$). When the comparison of HR at 1 min was done with their respective baseline values, 5% and 14% rise was observed in Group B and Group E, respectively. At 10 min, 15 min, and at every 10 min interval until the removal of the airway device, no statistically significant difference was observed in mean HR between the two groups [Graph 2 and Table 3].



Graph 1: Variations in mean arterial pressure at different time interval in both groups

Table 1: Demographic characteristics of patients

Demographic data	Group B (Baska)	Group E (endotracheal tube)	*P*-value
Mean age (in years)	36.12±9.51	38.10±10.36	0.377 (NS)
Mean body weight (in kg)	60.58±8.30	62.90±7.27	0.09 (NS)
Duration of surgery (in minutes)	69.02±9.55	70.35±9.74	0.16 (NS)

NS: Non-significant

The mean $ETCO_2$ and SpO_2 in both Group B and Group E from the pre-induction phase until the removal of the device remained statistically non-significant ($P > 0.05$).

When we compared the ease of insertion of Baska mask with ETT, we observed that the insertion was easy in 85% of patients and fair in 15% of patients whereas insertion of ETT was easy in 65% patients and fair in 35% of patients and the difference came out to be statistically significant ($P < 0.05$). None of the patient in any of the group had difficult insertion of device [Graph 3 and Table 4].

The mean duration of insertion of Baska mask was 12.8 ± 1.36 s and of ETT was 15.93 ± 1.51 s. The difference in

Table 2: Variations in MAP in Group B and Group E

Time interval	Group B		Group E		*t*-value	*P*-value	Statistical significance
	MAP (mmHg)	SD	MAP (mmHg)	SD			
Before induction	97.26	7.24	95.44	7.21	0.91	0.13	NS
After induction	87.08	3.04	85.82	4.84	1.16	0.09	NS
During insertion	94.18	5.80	106.05	4.34	−10.17	0.00	HS
After 1 min	92.29	5.20	102.86	4.63	−7.62	0.02	S
After 3 min	92.13	6.04	100.42	3.57	−6.59	0.03	S
After 5 min	92.23	5.66	97.10	4.52	−3.79	0.04	S
After 10 min	93.52	5.32	95.65	5.23	−1.85	0.06	NS
After 15 min	93.91	4.75	95.94	5.14	−1.67	0.06	NS
After 25 min	93.01	3.90	90.97	5.94	1.51	0.07	NS
After 35 min	93.18	4.11	91.87	5.12	1.22	0.10	NS
After 45 min	93.81	4.59	92.11	5.67	1.45	0.07	NS
After 55 min	94.21	5.79	92.40	4.69	1.32	0.06	NS
After 65 min	92.17	8.70	89.02	11.22	−3.93	0.13	NS
After 75 min	94.73	3.08	90.65	9.98	−5.22	0.19	NS
After 85 min	97.07	4.23	92.75	5.80	−3.52	0.07	NS
After removal of device	96.49	5.20	97.78	8.22	−0.69	0.20	NS

NS: Non-significant; *P*>0.05, HS: Highly significant; *P*<0.001, S: Significant; *P*<0.05. MAP: Mean arterial pressure, SD: Standard deviation

Table 3: Comparison of variation of heart rate (heart rate in beats per minute) in Group B and Group E

Time interval	Group B		Group E		*t*-value	*P*-value	Statistical significance
	Mean	SD	Mean	SD			
Before induction	89.98	14.80	90.63	11.55	−0.20	0.41	NS
After induction	94.70	15.71	97.38	8.56	−0.97	0.17	NS
During insertion	102.13	10.67	113.55	9.57	−4.91	0.00	HS
After 1 min	99.13	18.84	103.18	9.38	−1.99	0.02	S
After 3 min	92.68	11.08	99.80	9.47	−2.59	0.01	S
After 5 min	89.25	10.35	93.73	8.01	−1.96	0.02	S
After 10 min	90.05	10.63	92.43	8.00	−1.18	0.13	NS
After 15 min	87.28	9.95	90.10	8.13	−1.22	0.08	NS
After 25 min	86.18	7.61	86.70	8.30	−0.28	0.38	NS
After 35 min	84.88	6.62	86.23	7.20	−0.74	0.19	NS
After 45 min	85.35	6.25	87.25	5.62	−1.56	0.08	NS
After 55 min	86.23	8.74	86.98	5.04	−0.47	0.32	NS
After 65 min	84.80	7.06	87.36	5.79	−4.73	0.07	NS
After 75 min	86.40	8.17	86.35	7.91	−7.17	0.50	NS
After 85 min	89.40	6.07	85.88	13.11	−3.46	0.29	NS
After removal of device	89.70	10.69	90.80	12.57	1.72	0.34	NS

NS: Non-significant, *P*>0.05, HS: Highly significant, *P*<0.001, S: Significant, *P*<0.05. SD: Standard deviation

the duration of insertion between Group B and Group E was found to be statistically highly significant ($P < 0.05$) [Graph 4 and Table 5].

Post-operative pharyngolaryngeal complications such as sore throat, hoarseness, and coughing were observed. Increase in incidence of post-operative sore throat at 1, 2, 4, 8, 12, and 24 hour of post operative period in Group E as compared to Group B. Patients who underwent Baska mask insertion developed Grade 1 sore throat whereas in patients who underwent endotracheal intubation developed Grade 2 sore throat.

Similarly incidence of post-operative coughing at 1, 2, 4, 8, and 12 h is statistically significant in Group E as compared

Table 4: The ease of insertion

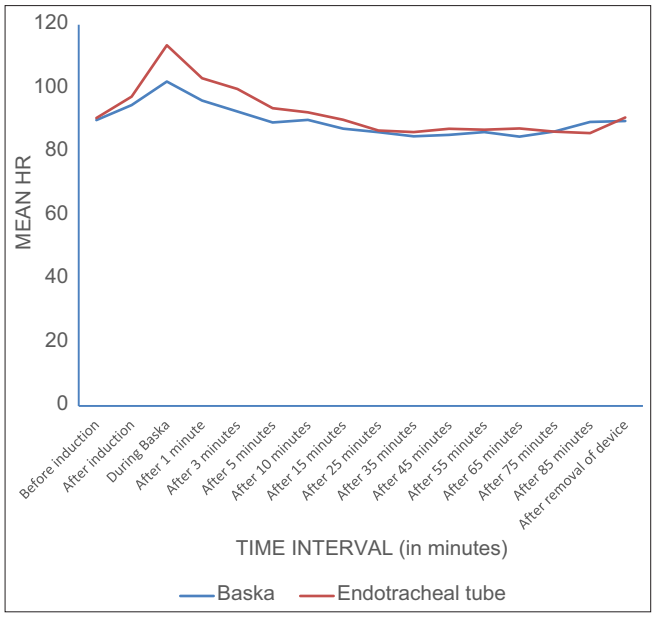
Ease of insertion	Group B		Group E		*P*-value
	Number of patients	Percentage	Number of patients	Percentage	
Easy	34	85.00	26	65.00	0.03 (S)
Fair	6	15.00	14	35.00	0.03 (S)
Difficult	0	0.00	0	0.00	
Total	40	100.00	40	100.00	

S: Significant; *P*<0.05

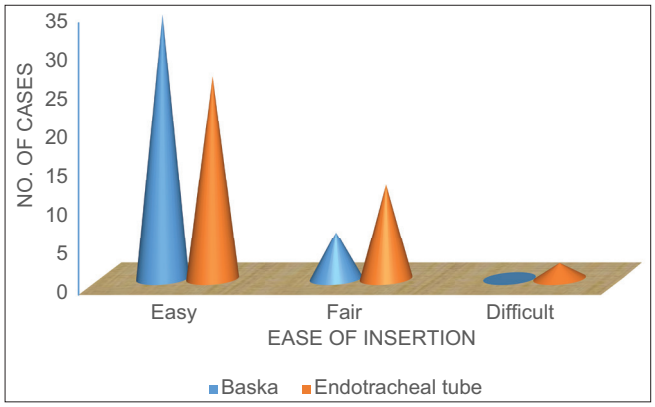
Table 5: Mean duration of insertion (in seconds)

Group	Mean	Standard deviation	*t*-value	*P*-value
B	12.80	1.36	−8.34	0.001 (HS)
E	15.93	1.51		

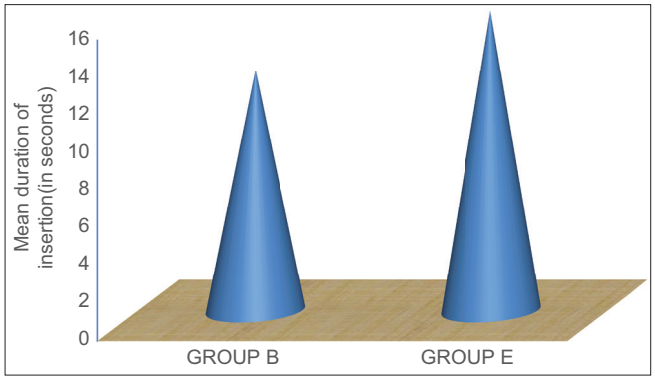
HS: Highly significant, *P*<0.001



Graph 2: Variations in mean heart rate at different time intervals in both groups



Graph 3: Ease of insertion



Graph 4: Mean duration of insertion

to Group B whereas the difference in post-operative cough was statistically insignificant at 24 h. Hoarseness of voice was observed to be more in Group E than Group B at 1, 2, and 4 h of post-operative period.

Regurgitation and aspiration was not observed in any of patient in both groups. Laryngospasm was observed in 1 patient in Group E and managed by switching to 100% oxygen, deepening the plane of anesthesia with intravenous propofol (0.5 mg/kg) and by giving manual positive pressure ventilation.

None of the patient in Group B suffered from trauma to the lip and tongue whereas in Group E, 2 patients (5%) suffered from trauma to lip and tongue during laryngoscopy. In Group B, blood staining of Baska mask during removal was observed in 2 patients (5%) whereas in Group E it was observed in 4 patients (10%).

The mean seal pressure of Baska mask in Group B was found to be 37.03 ± 2.28 cm of H_2O. The cuff pressure of ETT was measured 10 min of post-intubation using an aneroid manometer and was found to be 26.3 ± 8.2 cm of H_2O.

DISCUSSION

The deleterious hemodynamic consequence in the form of an increase in HR and hypertension following laryngoscopy and endotracheal intubation is a matter of concern. The use of laryngeal mask airway (LMA) in place of ETT has been shown to attenuate these hemodynamic responses and provides a promising alternative to ETT.

Baska mask is one of the newly introduced devices to fit in the anatomy of the oropharynx that provides several advantages over the existing supraglottic airway devices. It has non-inflatable self-sealing membranous cuff that facilitates better airway seal, seal increases with intermittent positive pressure ventilation without gastric insufflation. It incorporates a tab to help negotiate the palatopharyngeal curve. It has two large tubes entering the sump area for high suction clearance of the sump.

There was a statistically significant rise in MAP at the time of insertion of ETT and also at 1, 3, and 5 min following the insertion in Group E when compared to Group B ($P < 0.05$). The percentage rise in MAP in Group E was 24% whereas it was only 8% in Group B during the insertion of the device. Similarly, at 10 and 15 min, when MAP was compared between Group B and E , statistically insignificant difference was observed. Thereafter, MAP was monitored at every 10 min interval until the end of surgery and even after removal of the device, no statistically significant difference was observed between two groups ($P > 0.05$).

At the time of insertion of endotracheal intubation requires laryngoscopy that causes an increase in sympathoadrenal

activity. Major sources of the stimuli responsible for the adrenergic response are the distortion of supraglottic structures during laryngoscopy. However, no laryngoscopy is required in insertion of the supraglottic airway devices; thus, they have been shown to have attenuated hemodynamic responses.[3]

There was a statistically significant rise in HR during insertion of device and also at 1, 3, and 5 min following insertion in Group E when compared to Group B. Then, at 10 and 15 min post-insertion, minor variations in HR were observed between Group E and Group B but the difference was statistically insignificant ($P < 0.05$). The HR was then monitored at every 10 min interval until the end of surgery and even after the removal of the device and no statistically significant difference was observed between two groups.

Our study results are consistent with the study conducted by Lamba *et al.*[4] in which they compared Baska mask with ETT and concluded that statistically significant increase in mean blood pressure was seen just after intubation, at 3 and 5 min following intubation when compared to Baska mask insertion.

Similar results were observed by a study conducted by Akhondzade[5] in which the hemodynamic changes after insertion of ETT group, LMA group, and I gel group were assessed and it was concluded that there was significant increase in systolic blood pressure and HR during ETT insertion and at 1, 2, and 5 min after insertion of ETT when compared to other groups. Similar results were also reported by another study conducted by Dadmehr *et al.*[6]

Insertion of Baska mask was found easy in 34 patients (85%) and fair in 6 patients (15%) whereas insertion of ETT was easy in 26 patients (65%) and fair in 14 patients (35%). The major advantage in our study was the 100% success rate of insertion of Baska mask. The physical characteristic that aids in easy insertion of Baska mask is that the extended hand tab that can be attached to the cuff permits the operator to control the degree of flexion of the device, thus, aids in easier insertion.

Concordant results were found by Kumar *et al.*[7] in which they concluded that the insertion of Baska mask was very easy, i.e. no manipulation needed in 88% of cases, easy (hand tab manipulation required) in 10% of cases, difficult in 1% cases (needed jaw thrust for Baska insertion), and very difficult (repositioning of Baska mask needed after insertion) in 1% of the patients.

Almost similar results were reported by Lamba *et al.*,[8] the insertion of Baska mask was easy in 90% of cases whereas in 10% of cases require the second attempt for insertion. However, ETT was placed in the first attempt in 70% of cases and 24% of cases required the second attempt.

Similar results were also obtained by a study conducted by Mahajan[9] in which they evaluated the performance of Baska mask in laparoscopic cholecystectomy. The rate of insertion in the first attempt was 88.23% and the rate of insertion in the second attempt was100%.

The mean duration of the insertion of Baska mask was 12.8 ± 1.36 s and of ETT was 15.93 ± 1.51 s. This difference comes out to be statistically highly significant ($P < 0.001$).

As we know that the insertion of endotracheal intubation requires laryngoscopy and cuff inflation, thus increases the average duration for insertion of ETT. The contributing factors that make the insertion of Baska mask easier are first the membranous cuff of the Baska mask that inflates and deflates with the positive pressure ventilation, and second, the oropharyngeal curve that can be easily negotiated by pulling the tab of the Baska mask and thus aids in easy and insertion.

These results are comparable to the study conducted by Mahajan[9] in which they concluded that the meantime of insertion of Baska mask was 11.02 ± 2.11 s which were almost similar to the results obtained in our study.

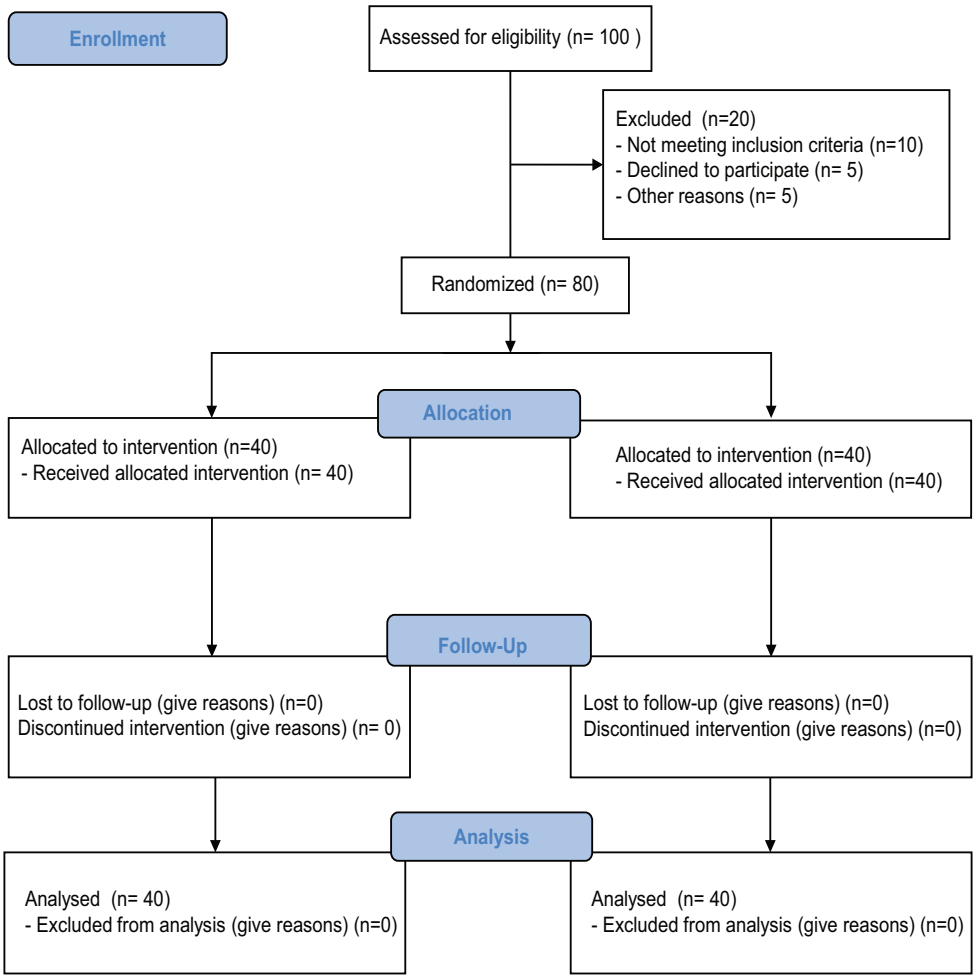
Similar results are obtained by a study conducted by Lamba *et al.*[8] in which the meantime of Baska mask insertion was 10 ± 2 s and of ETT was 16 ± 2 s. Comparable results were found by Sachidananda *et al.*[10] in which the mean insertion time of the Baska mask was 14.9 ± 6.2 s.

The mean seal pressure of Baska mask in Group B was found to be 37.03 ± 2.28 cm of H_2O. It was observed in our study that due to the thermolability of the membranous cuff of the Baska mask it get easily fit over the patient's laryngopharynx and inflated during each breath; thus, there is a gradual improvement in seal of the mask over first 2–3 min.[11]

On measuring the cuff pressure of ETT in Group E, it was found to be 26.3 ± 8.2 cm of H_2O. It came out to be in the safe recommended range, i.e., in between 20 and 30 cm of H_2O which was unlikely to impair tracheal capillary mucosal perfusion.[12]

Our results were also similar to the study conducted by Kumar *et al.*[7] and found that the mean seal pressure of Baska mask was 42.46 ± 19.11 cm of H_2O.

Post-operative sore throat and cough are one of the most common complaints following intubation and LMA



Flow Chart: Consort Flow Diagram

insertion. It usually results from an inflammatory process caused by irritation of the pharyngeal mucosa during laryngoscopy and tracheal mucosa due to ETT cuff. Trauma during laryngoscopy and intubation is another major contributing factor.

In the post-operative period at 1, 2, 4, 8, 12, and 24 h, there was a significantly higher incidence of sore throat and coughing in Group E as compared to Group B. Hoarseness of voice at 1, 2, and 4 h postoperatively was observed more in Group E than in Group B. These observations were comparable with the study conducted by Tosh *et al.*[8]

As in our study, none of the patient developed post-operative aspiration and regurgitation. There was no incidence of laryngospasm in Group B and only in 1 patient in Group E. There were only 2 patients in Group E who developed trauma to the lip and tongue whereas in none of the patient in Group B. Blood staining of the device on removal was observed in 2 patients in Group B and in 4 patients in Group E.

Strengths of Study

The unique distinction of our study is that we have also taken into account the potential known confounders for pharyngolaryngeal complications that are the ease of insertion, number of attempts of insertion, incidence of laryngospasm, and presence of blood staining after removal. Furthermore, the anesthetic technique used for all the cases was similar thus ensuring homogeneity in the procedure. None of the patients were excluded from our study; this also adds an additional advantage to our study.

Limitations of Study

The limitation of our study includes small sample size. As the data had been derived from a single center, thus it may have a referral bias. This study was conducted on healthy, normotensive patients with normal airways. It is, therefore, not known how the changes would have been in hypertensive patients. Baska mask cannot be inserted in patients with body weight <30 kg and in pediatric patients as pediatric size of Baska mask is not available. Another drawback of our study was that all the intubations and Baska mask insertions were not performed by a single anesthesiologist.

CONCLUSION

From our study, we concluded that a significant hemodynamic response consisting of an increase in HR and MAP was seen after the insertion of ETT as compared to Baska mask. The duration of insertion of Baska mask was significantly shorter and insertion of Baska mask was easier. Baska mask provides adequate positive pressure ventilation that is comparable with ETT. Post-operative complications such as sore throat, cough, and hoarseness of voice are significantly less with Baska mask as compared to ETT.

In conclusion, we can say that during routine elective surgeries of 60–90 min duration, the Baska mask provides a satisfactory airway for positive pressure ventilation and therefore is a suitable alternative to endotracheal intubation for adult patients.

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Original Article

Effect of Ondansetron in Prevention of Hypotension in Elective Lower segment Cesarean Section under Spinal Anesthesia: A Randomized, Double-Blind Study

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Abstract

Background: Spinal anesthesia is the preferred modality of anesthesia for lower segment cesarean section, but it is complicated with hypotension and bradycardia, which may be harmful to both parturient and baby. Bezold–Jarisch reflex plays an important role through 5HT3 receptors located in intracardiac vagal nerve endings in causing hypotension and bradycardia. In this study, we evaluated the effect of ondansetron, as a 5HT3 receptor antagonist, on the hemodynamic response following spinal anesthesia in parturients undergoing elective lower segment cesarean section.

Methodology: Sixty parturients who were scheduled for lower segment elective cesarean section were randomly allocated into two groups. Before giving the spinal injection, Group O (n = 30) received intravenous ondansetron 4 mg and Group S (n = 30) received normal saline. Blood pressure, heart rate, and vasopressor requirements were assessed.

Results: Total dose of vasopressor (mephentermine) used in Group "O" was 78 mg (mean±SD = 2.60 ± 4.36) and in Group "S," it was 168 mg (mean ± SD = 5.6 ± 4.43 (P = 0.010). In Group O, the incidence of hypotension was 9 out of 30 patients while in Group S, 21 out of 30 patients developed hypotension at any point of surgery ($\chi 2$=9.6 and P = 0.002).

Conclusion: Ondansetron 4 mg, given intravenously 5 min before spinal anesthesia, causes reduction in hypotension and vasopressor use in parturients undergoing elective lower segment cesarean section.

Key words: Cesarean, Hypotension, Ondansetron, Spinal

INTRODUCTION

Spinal anesthesia is a simple technique, wherein a small quantity of local anesthetic is administered into the spinal canal and a part of the body is anesthetized. This technique has been refined overtime and expanded in its practical applications. Spinal anesthesia has progressed greatly since 1885 and is used successfully in a number of different clinical situations.

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In cafeteria choice of anesthetic modalities, spinal anesthesia has definitive advantage than its counterparts because a rapid profound analgesia can be produced in large part of the body by relatively simple injection of small amount of local anesthetic agent. Due to its simpler technique and less time-consuming procedure and to avoid the undesired consequences of general anesthesia, it has been adopted universally as the most preferred anesthetic technique for obstetric anesthesia. In concern to complications of spinal anesthesia, hypotension is major one of them, frequency of which may be as high as 60%–100% in emergency lower segment cesarean section (LSCS)[1] which is associated with sympathectomy which causes decreased cardiac output and somewhere poses risk to mother and fetus due to compromised uteroplacental flow.[2,3] Recent studies show that prophylactic ondansetron in spinal anesthesia decreases the event of hypotension.

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Ondansetron is 5HT3 antagonist mostly used as antiemetic. Apart from hypotension, nausea and vomiting related events have incidence of around 50%–80% in patients undergoing LSCS without any prophylactic intervention.[4]

Parasympathetic shift of autonomic nervous system after spinal anesthesia causes bradycardia from the left ventricular mechanoreceptors due to sudden decrease in the left ventricular volume, i.e., Bezold–Jarisch reflex. Pharmacological studies reveal that serotonin may be an important factor associated with inducing B-J reflex and can be blocked through ondansetron.[5,6]

Based on these findings, this randomized double-blind study was performed to evaluate the effect of ondansetron in prevention of hypotension in elective LSCS under spinal anesthesia.

METHODOLOGY

After getting approval from the Internal Ethics Committee, the present study was carried out in the Department of Anesthesiology and Critical Care, Netaji Subhash Chandra Bose Medical College and Hospital, Jabalpur, Madhya Pradesh, from a time period of March 2017–August 2018.

Inclusion Criteria

All patients undergoing elective lower segment cesarean section were included in the study.

- Weighing 50–90 kg
- Height 140–180 cm
- Hemodynamically stable.

Exclusion Criteria

The following criteria were excluded from the study:

- Patients with pre-existing cardiac disease
- Patients with liver and renal dysfunctions
- History of hypertension, pre-eclampsia, and convulsions
- Patient with bleeding disorders.

Design of Study

This was a randomized, double-blind, prospective study.

Mode of Selection of Cases

Simple randomization technique was used to divide the study subjects into two groups using table of random number. Subjects who satisfy the criteria would be given consecutive numbers and treatment allocation was be done as per the list prepared prior.

Allocation to Different Groups

Sixty patients will be equally divided into two groups.

Groups	Drugs used	Number of patients
Group O	4 mg of ondansetron	30
Group N	10 ml of normal saline	30

Study Protocol

- In Group O, patient received 4 mg of ondansetron diluted with normal saline up to 10 ml in 1 min, 5 min before spinal
- In Group S, patient was given 10 ml of NS over 1 min, 5 min before spinal anesthesia
- Under all aseptic precautions, spinal anesthesia was given using 23G Quincke needle and 2.2 ml of bupivacaine 0.5% heavy injected in subarachnoid space.

METHODS

After careful pre-anesthetic examination, the patients were included in the study and randomly allocated into the groups by lottery method. Before shifting the patient to the operating table, the table was made horizontal to ground using a fluid-filled leveling device.

After installing all routine monitoring devices such as electrocardiographic leads, non-invasive blood pressure (BP) cuff, pulse oximetry probe, and an intravenous (iv) access were secured using an 18G cannula and the patients were preloaded with 10 ml/kg of Ringer's lactate.

- Group O patient received 4 mg of ondansetron diluted up to 10 ml with NS and injected over 1 min, 5 min before spinal anesthesia
- Group S patient received 10 ml NS over 1 min 5 min before spinal anesthesia
- Patients were positioned on the operating table in the left lateral decubitus position with both lower limbs kept folded to abdomen with back curved and flexed. With all aseptic precautions, the study subjects were painted and draped using sterile solutions who then received a standard lumbar puncture with using 23G Quincke needle at L3-L4 intervertebral space and spinal drug given
- Immediately after injection, the patients were placed in supine position.

Parameters of Comparison

Patients were evaluated for the following parameters from the time of induction to 4 h.

1 The time to onset of sensory block and duration of sensory block from intrathecal administration of drug to regression of S2 segment
2 The time to onset of motor blockade (MODIFIED BROMAGE SCALE) and duration of motor block

from the onset of motor block to achieve Bromage scale 0.

Assessment Scales

- The sensory block was evaluated by HOLLMEN SCALE SCORE which reached up to score IV bilaterally up to T6 level
- Time of intrathecal injection was considered as 0 min. Intraoperative variables mean arterial pressure (MAP), systolic BP (SBP), diastolic blood pressure (DBP), and heart rate (HR) were monitored every 3rd min up to the delivery of fetus and thereafter every 5 min up to the completion of surgery
- Timing and cumulative doses of atropine and mephentermine were recorded
- The motor block was evaluated by MODIFIED BROMAGE SCALE every 5 min till the score reached 3 and postoperatively every 30 min up to a score of 0
- Result was be noted and analyzed.

Adverse Outcomes and Complications

Although rare, the study had some complications related to the procedure done or related to the drug use. These were following

- Hypotension treated when MAP decreased <20% of baseline, SBP <90 mmHg, and DBP < 45 mmHg with mephentermine 6 mg iv
- Bradycardia is considered when HR < 60/min, treated by atropine 0.6 mg iv
- Result was noted and analyzed.

Hollmen Scale Score for Sensory Block

Score	Observation
i.	Normal sensation of pin prick
ii.	Weaker sensation of pin prick
iii.	Pin prick recognized as touch with a blunt object
iv.	No perception of pin prick

Modified Bromage Scale

Score	Observation	Degree of block
0	No motor block	Nil 0%
1	Can flex knee, move foot but cannot raise leg	Partial 33%
2	Can move foot only	Almost complete 66%
3	Unable to move foot or leg	Complete 100%

Data Collection and Methods

The case reports form were numerically coded and validated for illogical, inconsistent entries before data entry. Microsoft Excel 2007 worksheet was used for data entry. Frequency with percentage distribution was used to tabulate the categorical (qualitative) variables and mean with standard deviation was used to summarize the continuous (quantitative) variables. Chi-square test was applied to test the statistical differences between frequency distributions as 2 × 2 contingent table. "Fisher's test" was used if the frequency was <5. "Student's *t*"-test was applied to test the mean differences between two independent groups and "paired *t*"-test was applied to test changes in each parameter over the intraoperative periods. Normality of distribution was checked before applying the parametric statistical methods.

OBSERVATION AND RESULTS

No vasopressor was used in 21 patients in Group O and in 9 patients in Group N. In Group O, 6 mg of vasopressor used once in five patients while it was used in 14 patients in Group S. In Group O, 6 mg vasopressor used twice in four patients while in seven patients of Group S.

Total dose of vasopressor (mephentermine) used in Group "O" was 78 mg (mean ± SD = 2.60 ± 4.36) and in Group "S," it was 168 mg (mean ± SD= 5.6 ± 4.43 (P = 0.010).

In this study, no significant episode of bradycardia was observed in either group. After spinal anesthesia, hypotensive episodes were observed in the form of fall in SBP, DBP, and MAP. Six minutes after spinal anesthesia, significant difference was observed in SBP between two groups with P = 0.0096, whereas at 0 min after giving spinal anesthesia, significant difference was observed in DBP in between two groups with P = 0.0034 [Tables 1-7 and Graphs 1-5].

MAP in both groups when compared had significant difference at 0, 3rd, and 6th min after giving spinal anesthesia with P = 0.0034, 0.026, and 0.0377, respectively.

In Group O, the incidence of hypotension was 9 out of 30 patients while in Group S, 21 out of 30 patients developed hypotension at any point of surgery (χ2=9.6 and P = 0.002).

No significant difference was seen in time to delivery of fetus and total duration of surgery in between two groups.

DISCUSSION

Attempts to find measures for the prevention of hypotension were vividly called by Alison Macarthur "the quest for the holy grail," in obstetric anesthesia.[7] Effect of iv crystalloids, colloids, vasoconstrictors, and various physical methods as limb elevation, bandaging, etc., is studied in the past in various studies.[8]

Unopposed parasympathetic dominance after spinal anesthesia leads to fall in systemic vascular resistance and causes peripheral diversion of circulation. This causes

hypotension. Low volume received in the left ventricle stimulates mechanoreceptors in heart wall triggers the Bezold–Jarisch reflex and this results in reflex bradycardia, vasodilation, and hypotension.[9-11]

Chemoreceptor activation also occurs due to low blood volume mediated through serotonin release from activated thrombocytes.[12,13] Serotonin receptors are G protein-coupled receptors and only 5HT3 is a ligand-gated ion channel. Activation of this causes increased vagal tone and causes bradycardia and hypotension.[14]

In the present study, demographic and preoperative variables were comparable in both groups and had no significant difference [Tables 8 and 9 and Graph 6].

Likewise to our study, other different studies who assessed the effect of ondansetron in attenuation of post-spinal anesthesia hypotension similar doses of hyperbaric bupivacaine for intrathecal injection were used. Sahoo *et al*.[15] and Palmese *et al*.[16] used 10 mg of 0.5% bupivacaine heavy for spinal anesthesia, whereas Marashi *et al*.[17] used 15 mg dose in non-obstetric patients. Trabelsi *et al*.[18] used 10 mg bupivacaine along with 2.5 mcg sufentanyl and Potdar *et al*.[19] used 12 mg hyperbaric bupivacaine with 60 mcg buprenorphine. Intrathecal opioids are used to enhance the quality of block, but we did not use any adjuvant to hyperbaric bupivacaine.

Throughout intraoperative period, non-invasive monitoring was done. For the purpose of analysis, pulse rate (PR), SBP, DBP, MAP, and SpO_2 were recorded every 3rd min up to delivery of fetus and thereafter at every 5th min up to the completion of surgery [Tables 1 and 2 and Graphs 1 and 2].

In our study, the overall incidence of hypotension in Group O was 30% in comparison to 70% in Group N and there was a significant difference between two groups ($P = 0.002$). No incidence of bradycardia was reported in either group.

Similar to our study, Sahoo *et al*.[15] reported less frequent incidence of bradycardia than hypotension, i.e., bradycardia in 2.1–4.9% of patients and hypotension in 36.8–52% of patients.

In concordance to the present study, Owczuk *et al*.[20] showed that iv ondansetron attenuates the arterial BP drop due to spinal anesthesia using 8 mg ondansetron in patients of 20–70 years of age group. Drop in SBP below 90 mmHg in sequential 5 min observations in ondansetron group was 2.8% against the normal saline group, in which SBP <90 mmHg was observed in 20% of patients, which was statistically highly significant.

In our study, hypotension was defined as fall in SBP, DBP, and MAP >20% from its baseline value. Meanwhile, Owczuk *et al*.[20] did not define the hypotension criteria in their study, whereas Sahoo *et al*.[15] defined hypotension as SBP <90 mmHg and DBP <60 mmHg.

Similar to our study, parameters defined in the study of Abbas *et al*.,[21] fall in SBP >20% from baseline value was considered as hypotension. Arivumani *et al*.[22] and Mohamed *et al*.[23] defined hypotension as fall in MAP >20% of its baseline value.

Wang *et al*.[24] used four different doses 2 mg, 4 mg, 6 mg, and 8 mg of ondansetron and concluded that 4 mg of prophylactic i/v ondansetron is an optimal dose to prevent post-spinal hypotension and bradycardia.

Sahoo *et al*.[15] showed the effect of ondansetron in prevention of hypotension on 40 patients of obstetrical entity using 4 mg iv ondansetron before spinal anesthesia. In their study, Group N (normal saline) had significantly lower MAP between 14th and 35th min. Significant differences in MAP in both groups were observed at 5th min (Group O 88 ± 11.7 vs. Group S 82.2 ± 10.5 mmHg) and at 6th min (Group O 87.5±11.3 vs. Group S 80.4±10.8 mmHg).

Similarly, in our study, significant difference was observed of MAP in both groups in initial 6 min after spinal anesthesia. At 0 min, MAP in Group O was 76.16 ± 5.65 mmHg and in Group N was 72.03 ± 4.75 mmHg ($P = 0.0033$). At 3rd min, MAP in Group O was 74.46 ± 5.51 mmHg and in Group N was 71.53±4.34 mmHg ($P = 0.02$). At 6th min, MAP in Group O was 73.43 ± 4.80 mmHg and in Group N was 70.86 ± 4.53 mmHg ($P = 0.037$) [Table 6 and Graph 7].

Our study was in concordance to the study by Marashi *et al*.[17] who used iv 6 mg ondansetron and 12 mg ondansetron against the placebo (normal saline) before spinal anesthesia for the prevention of hypotension where both the doses found to be equipotent for the prevention of hypotension after spinal anesthesia. There was no statistically significant difference observed in MAP and HR in both groups using iv ondansetron 6 mg and 12 mg ($P = 0.06$). In the group using normal saline as placebo, 12 patients (17.14%) had MAP <80 mm in comparison to zero number of patients in the ondansetron groups. There was a significant difference with $P = 0.04$. None experienced significant hypotension or bradycardia that required treatment.

Likewise, the study of Hasanein an El-Sayed[25] was in concordance to our study who demonstrated that hypotensive

bradycardia events reduced in patients from 20.4% using normal saline to 6.1% using 4 mg ondansetron and 6% in group using 8 mg ondansetron. No difference was observed in groups using 4 mg and 8 mg ondansetron. They concluded that 4 mg ondansetron is optimal dose for the prevention of hypotension after spinal anesthesia. Therefore, in our study, iv 4 mg ondansetron before spinal anesthesia was used.

In our study, significant difference in SBP between two groups was observed at 6th min, SBP in Group O mean ± SD was 103.80 ± 8.07 mmHg and in Group N 98.10 ± 8.40 mmHg, $P = 0.009$ [Table 3].

Whereas statistically significant difference in DBP between two groups was observed at 0 minute, DBP in Group O mean ± SD was 61.83 ± 6.60 mmHg and in Group N 57.23 ± 4.86 mmHg, $P = 0.003$ [Table 4].

Similarly, in a study of Potdar *et al*.,[19] SBP (mmHg) at 5th min in 4 mg ondansetron group was 114.71 ± 19.08 and in patients where 8 mg ondansetron group was 109.43 ± 21.44. SBP in placebo group at 5th min was 107.82 ± 15.78. The difference between placebo and 4 mg group was statistically significant, $P = 0.005$. At 10th min, SBP (mmHg) in the placebo group, 4 mg ondansetron group, and 8 mg ondansetron group were 103.64 ± 24.12, 108.45 ± 14.02, and 101.67 ± 37.96, respectively. The difference between placebo and 4 mg group was statistically significant not for 8 mg group ($P = 0.03$) [Table 10 and Grpahs 5 and 6].

In their study, there was a significant difference in DBP (mean ± SD) (mmHg) between the placebo and ondansetron group when compared at 5th min. In group using 4 mg ondansetron, DBP was 66.82 ± 13.22 and in the placebo group 60.92 ± 11.17 ($P = 0.03$) [Table 5 and Graphs 5 and 8].

Our study was in concordance to the study by Potdar *et al*.[19] where there was a significant difference in MAP at 5th and 10th min which was observed between the control group and ondansetron group. MAP (in mmHg) in the ondansetron group at 5th and 10th min was 83.78 ± 17.47 and 80.90 ± 11.09, respectively, whereas it was 79.08 ± 15.31 and 75.51 ± 17.93 in the control group ($P = 0.02$) [Table 7 and Graph 9].

Yet, another variation was observed in different models of studies on ondansetron for the prevention of post-spinal hypotension in their oxytocin infusion protocol after delivery of fetus.

Ortiz-Gómez *et al*.[26] used low doses of oxytocin in the form of IV bolus than continuous infusion at 2.5 U/h, whereas Trabelsi *et al*.[18] used bolus of 5 U oxytocin then 2.5 U/hr. Wang gave 10 U of oxytocin in 250 ml NS slow infusion. Mohamed *et al*.[23] used 5 U of oxytocin bolus just after delivery of fetus followed by 40 U infusion. Here, in the present study, we used 20 U of oxytocin in 500 ml of normal saline infusion at 10 ml/min. This factor needs to be mentioned because it has higher propensity to alter the maternal hemodynamics, but oxytocin infusion post-delivery was equally employed in either group of patients. Bolus doses of oxytocin cause profound hypotension, which are avoided in this study.

In our study, the total average consumption of vasopressor in each patient in Group O was 2.60 ± 4.36 mg, whereas it was 5.6 ± 4.43 mg in Group N patients ($P = 0.0107$) [Table 11 and Graph 10].

Similarly, Hajjan *et al*.[27] showed decreased consumption of vasopressor in the ondansetron group when compared to placebo. The total amount of ephedrine consumption in the ondansetron group was 5.8 mg and 10.7 mg in the placebo group with significant difference in between two groups ($P = 0.009$) [Graph 11].

Observations from the study of Trabelsi *et al*.[18] also support our study where average ephedrine consumption was 5.10 ± 7.78 mg in the ondansetron group in comparison to 12.90 ± 9.24 mg in group using normal saline ($P < 0.001$). There was no incidence of bradycardia reported in either group which requires treatment using i/v atropine.

In our study, neither in Group O nor in Group N, no case of significant bradycardia is reported, but its occurrence is infrequent.

The phenomenon of the incidence of bradycardia due to spinal anesthesia found to be independent from hypotension.

In our study, there was no significant difference in time to delivery of fetus and duration of surgery between two groups (mean ± SD). In Groups O and N, time to delivery

Table 1: Pulse rate (per min) up to delivery of fetus every 3rd min in both groups

Time up to delivery of fetus (min)	Group O		Group N		*P* value
	Mean	±SD	Mean	±SD	
0	79.26	8.29	77.56	6.90	0.39
3	78.06	7.66	76.96	6.31	0.54
6	77.60	8.13	76.43	5.57	0.51
9	76.0	6.72	75.63	5.58	0.81
12	76.83	7.34	74.10	4.48	0.08
15	76.63	6.68	74.44	4.15	0.13
18	75.17	6.77	73.54	4.89	0.31
21	73.83	6.41	72.92	4.83	0.65
24	73.62	7.61	72.87	4.05	0.81
27	76.0	7.07	72.66	3.51	0.62

Table 2: Pulse rate (per min) after delivery of fetus up to the completion of surgery every 5th min

Time after delivery of fetus (min)	Group O		Group N		*P* value
	Mean	±SD	Mean	±SD	
0	76.63	7.08	75.1	5.25	0.34
5	77.16	6.55	75.66	5.51	0.34
10	76.86	5.79	76.66	5.62	0.89
15	76.70	4.61	75.73	4.93	0.43
20	76.43	4.16	75.56	4.72	0.45
25	74.63	3.98	75.73	4.73	0.31
30	73.10	4.19	74.40	4.28	0.24
35	73.30	3.64	74.88	4.16	0.13
40	72.57	3.45	73.83	3.39	0.25
45	72.45	4.34	75.36	1.65	0.11

Table 3: Systolic blood pressure (mmHg) till the delivery of fetus every 3rd min

Time (min) up to del. of fetus	Group O		Group N		*P* value
	Mean	±SD	Mean	±SD	
0	104.90	8.20	101.73	7.19	0.11
3	102.83	8.23	99.30	6.50	0.07
6	103.80	8.07	98.10	8.40	**0.00**
9	102.80	8.04	101.23	6.71	0.41
12	103.36	7.20	103.26	4.15	0.94
15	103.70	5.83	105.37	3.83	0.19
18	105.92	6.02	107.04	3.91	0.42
21	107.83	6.39	100.85	29.24	0.39
24	108.12	6.3	109.25	2.43	0.64
27	108.00	11.31	108.33	1.55	0.97

Significant difference in SBP was noted at 6th min (*P*=0.009). SBP: Systolic blood pressure

Table 4: DBP (mmHg) till delivery of fetus every 3rd min

Time (min) up to del. of fetus	Group O		Group N		*P* value
	Mean	±SD	Mean	±SD	
0	61.83	6.60	57.23	4.86	**0.003**
3	60.23	5.88	57.66	4.58	0.064
6	58.23	5.47	57.26	4.51	0.45
9	58.76	4.43	59.16	4.05	0.71
12	60.23	4.37	60.63	3.50	0.69
15	60.73	4.62	61.24	2.95	0.61
18	62.21	4.39	62.00	2.68	0.83
21	64.05	4.13	62.69	2.35	0.25
24	64.87	4.79	63.37	2.56	0.45
27	65.00	4.24	63.66	1.15	0.72

Significant difference in DBP was present at 0 min just after assumption of supine position after spinal anesthesia (*P*=0.0034). DBP: Diastolic blood pressure

Table 5: Diastolic blood pressure (mmHg) after delivery of fetus up to the completion of surgery every 5th min

Time after delivery of fetus (min)	Group O		Group N		*P* value
	Mean	±SD	Mean	±SD	
0	63.13	4.68	61.76	2.47	0.16
5	64.20	4.03	62.80	2.18	0.10
10	64.20	3.56	62.96	2.09	0.10
15	65.30	3.51	63.90	2.55	0.08
20	64.36	3.32	64.03	2.38	0.63
25	63.06	3.27	64.60	2.81	0.057
30	62.60	3.20	63.63	2.79	0.18
35	63.16	3.38	63.76	2.55	0.45
40	64.42	3.59	63.84	2.11	0.52
45	62.18	4.16	63.81	4.09	0.36

Table 6: Mean arterial pressure (mmHg) till delivery of fetus every 3rd min

Time up to delivery of fetus (min)	Group O		Group N		*P* value
	Mean	±SD	Mean	±SD	
0	76.16	5.65	72.03	4.75	**0.0033**
3	74.46	5.51	71.53	4.34	**0.02**
6	73.43	4.80	70.86	4.53	**0.037**
9	73.54	4.44	73.23	3.95	0.77
12	74.56	3.94	74.80	3.12	0.80
15	75.03	3.98	75.96	2.61	0.29
18	76.67	3.83	77.04	2.25	0.67
21	78.66	3.94	77.92	1.93	0.49
24	79.37	4.24	78.50	2.07	0.61
27	79.50	6.36	78.66	0.57	0.87

Statistically significant differences were observed at 0, 3rd, and 6th min (*P*<0.05)

Table 7: Mean arterial pressure (mmHg) after delivery of fetus up to the completion of surgery every 5th min

Time after del. of fetus (min)	Group O		Group N		*P* value
	Mean	±SD	Mean	±SD	
0	77.30	3.36	76.76	2.48	0.48
5	78.80	2.72	77.86	2.09	0.14
10	78.86	2.60	78.16	1.87	0.23
15	80.06	2.40	78.93	2.13	0.05
20	79.66	2.53	79.03	1.80	0.27
25	78.53	2.09	79.56	2.14	0.06
30	78.30	2.10	78.90	2.24	0.29
35	78.83	2.62	76.11	15.35	0.37
40	79.71	2.70	77.15	8.93	0.24
45	79.81	2.60	80.45	2.25	0.54

of fetus was 18.96 ± 3.05 min and 18.16 ± 3.24 min, respectively ($P = 0.33$). The duration of surgery in Group O was 57.20 ± 4.24 min, while in Group N, it was 55.66 ± 7.18 min, ($P = 0.31$) [Table 12 and Graph 12].

Blauw *et al.* demonstrated the vasodilatory effect of serotonin by injecting serotonin into radial artery of healthy volunteers and this effect was vanished off by administrating 5HT3 antagonist.[28] Serotonin receptors are present peripherally as well in central nervous system (CNS) and serotonergic mechanism of CNS supposed to be a factor involved in cardiovascular collapse after spinal anesthesia.[29] On the contrary, ondansetron shows poor permeability across blood–brain barrier.

Although there is no evidence in favor of direct effect of 5HT3 receptor antagonism on cardiac output, ondansetron is believed to abolish the Bezold–Jarisch reflex and hypotension after spinal anesthesia through blocking the

Table 8: Demographic variables in both groups

Variables	Group O		Group N		*P* value
	Mean	±SD	Mean	±SD	
Age (years)	26.13	3.80	24.73	2.59	0.10
Weight (kg)	59.83	3.40	59.36	4.75	0.66
Height (cm)	151.16	3.34	151.83	2.98	0.41

Table 9: Pre-operative vitals in both groups

Variables	Group O		Group N		*P* value
	Mean	±SD	Mean	±SD	
Pulse rate (per min)	77.5	9.11	76.23	7.71	0.56
Systolic blood pressure (mmHg)	114.36	8.07	114.03	5.24	0.85
Diastolic blood pressure (mmHg)	67.13	5.20	66.36	3.39	0.50
Mean arterial pressure (mmHg)	82.93	3.90	82.23	3.26	0.45
SpO_2	98.76	0.85	98.66	0.75	0.63
RR (per min)	15.73	1.80	15.46	1.88	0.58

Table 10: Systolic blood pressure (mmHg) after delivery of fetus up to the completion of surgery every 5th min

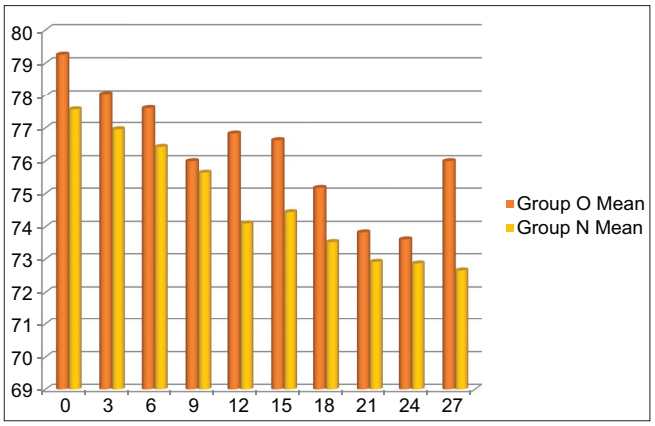
Time after delivery of fetus (min)	Group O		Group N		*P* value
	Mean	±SD	Mean	±SD	
0	105.60	5.36	106.83	3.63	0.30
5	107.13	4.41	108.00	3.42	0.39
10	108.23	4.31	108.60	3.15	0.70
15	109.66	3.92	108.90	2.69	0.38
20	110.23	4.26	108.90	2.23	0.13
25	109.50	3.63	109.20	2.69	0.71
30	109.53	3.43	109.56	2.80	0.96
35	110.16	4.82	109.69	2.51	0.64
40	110.19	4.05	109.66	2.76	0.63
45	111.81	3.02	110.45	3.50	0.34

Table 11: Dose of vasopressor used in both groups

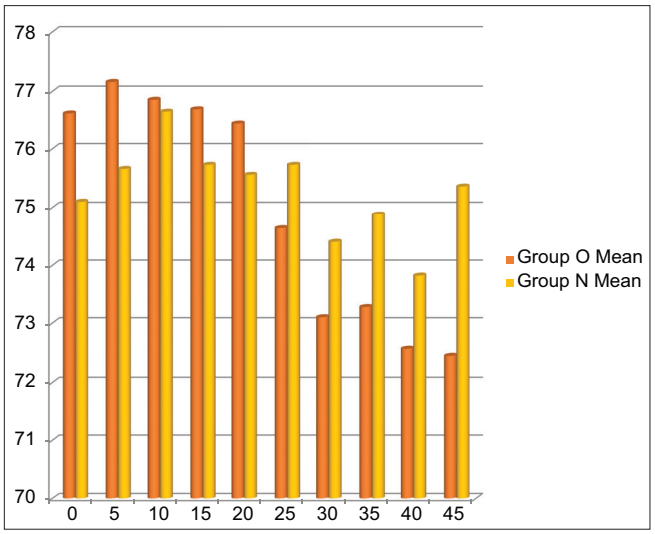
Variables	Group O		Group N		*P* value
	Mean	±SD	Mean	±SD	
Vasopressor (in mg)	2.60	4.36	5.6	4.43	**0.01**

Table 12: Time to delivery of fetus and total duration of surgery in both groups

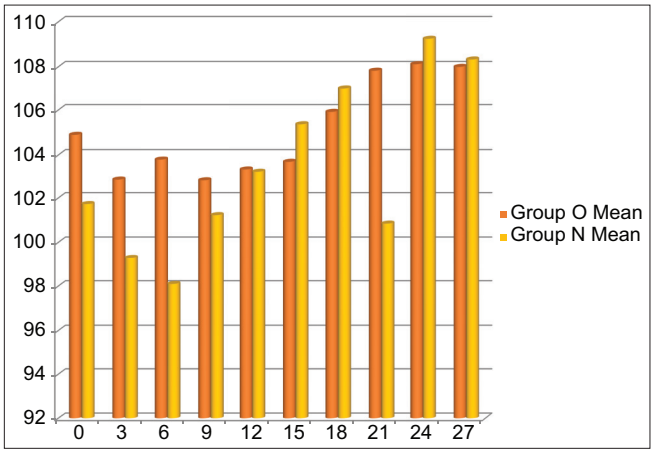
Variables	Group O		Group N		*P* value
	Mean	±SD	Mean	±SD	
Time to del. of fetus (min)	18.96	3.05	18.16	3.24	0.33
Total duration of surgery (min)	57.2	4.24	55.66	7.18	0.31



Graph 1: Pulse rate (per min) up to delivery of fetus every 3rd min in both groups



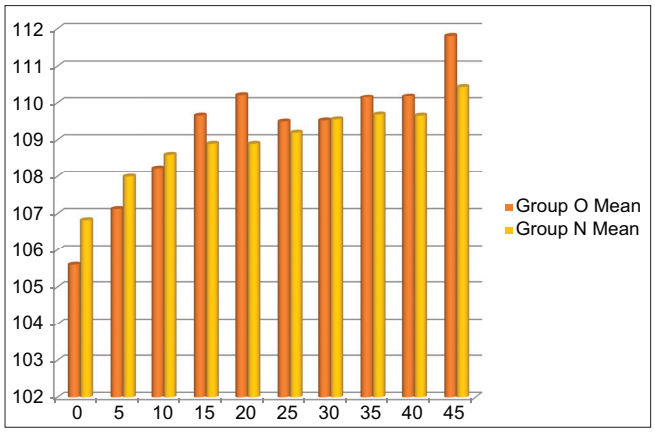
Graph 2: Pulse rate (per min) after delivery of fetus up to the completion of surgery every 5th min



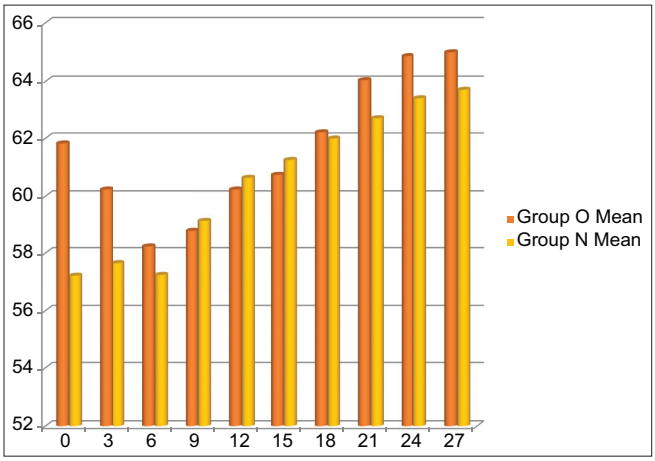
Graph 3: Systolic blood pressure (mmHg) till the delivery of fetus every 3rd min

5HT3 receptor. White *et al.* observed the efficacy of iv 5HT3 blocker granisetron in suppressing hypotension and bradycardia in rabbit model.[15]

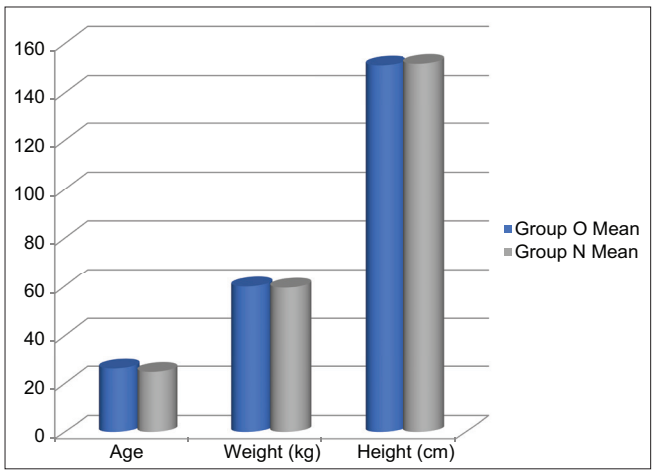
In our study, low incidence of hypotension was observed in Group O than Group N in initial intraoperative period after spinal anesthesia. After the delivery of fetus, no significant difference was observed for hypotension in between two groups. There is a limitation of our study that



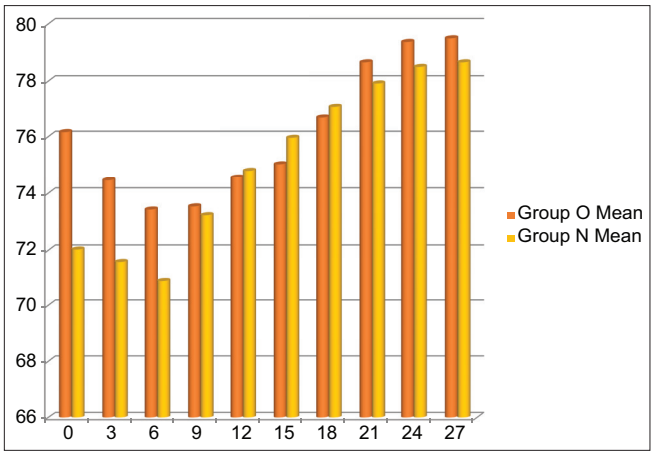
Graph 4: Systolic blood pressure (mmHg) after delivery of fetus up to the completion of surgery every 5th min



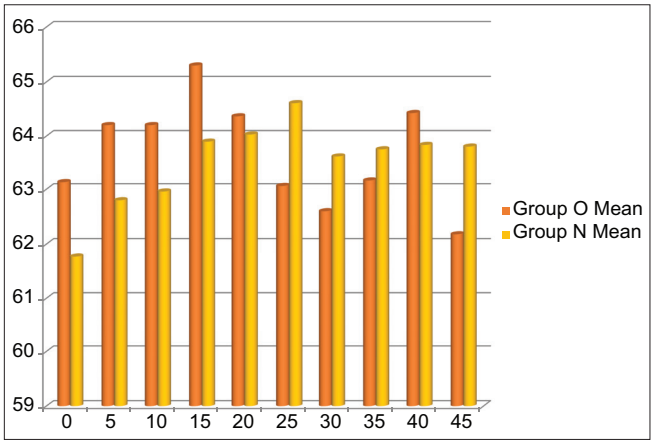
Graph 5: Diastolic blood pressure (mmHg) till delivery of fetus every 3rd min



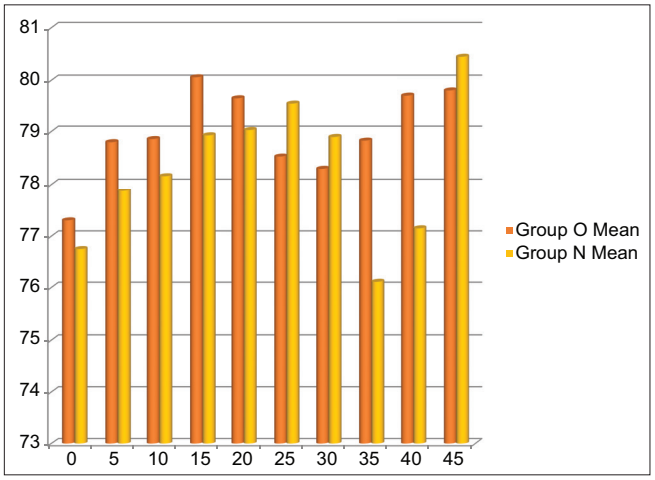
Graph 6: Demographic distribution in both groups



Graph 7: Mean arterial pressure (mmHg) till delivery of fetus every 3rd min

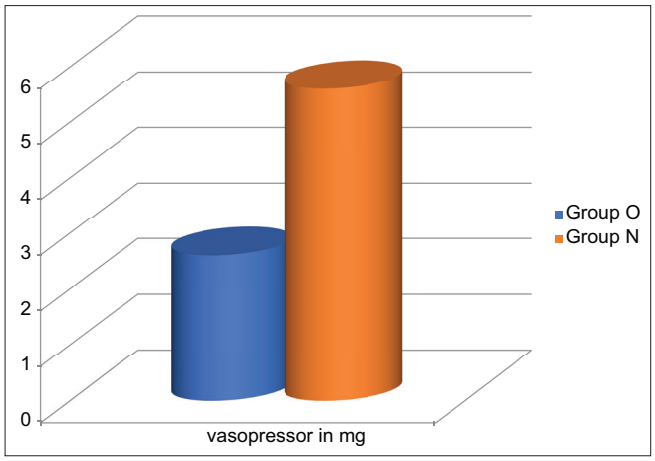


Graph 8: Diastolic blood pressure (mmHg) after delivery of fetus up to the completion of surgery every 5th min

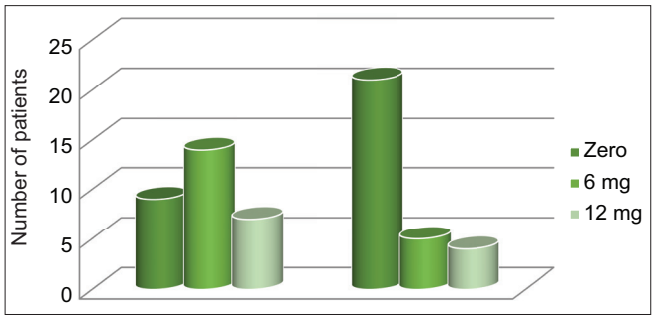


Graph 9: Mean arterial pressure (mmHg) after delivery of fetus up to the completion of surgery every 5th min

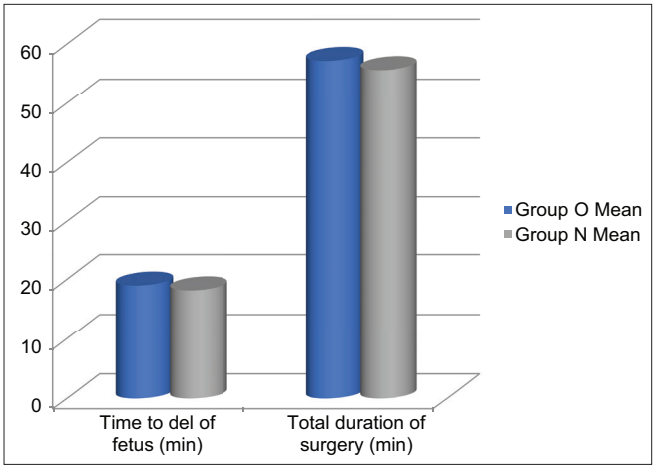
we did not conduct a study on dose-dependent response of ondansetron in prevention of hypotension in that we used only single dose of ondansetron. Due to the limitation of resources, fetal outcome was also not measured using lactate level of cord blood. This is further aspect of the study to be reevaluated that least altered maternal hemodynamics in initial postpartum period have better impact on fetal well-being.



Graph 10: Vasopressor (mephentermine) consumption in both groups



Graph 11: Frequency of vasopressor doses used in both groups



Graph 12: Time to delivery of fetus and total duration of surgery in both groups

In conclusion, our study revealed the similarity in study model from various past studies and all these studies support the concept of our study Ortiz, Sahoo, Owczuk, Potdar etc., gave prophylactically 4 mg iv ondansetron before spinal anesthesia which works on cardiac level by abolishing Bezold–Jarisch reflex and peripherally which causes less fall in SBP, DBP, and MAP and is effective in preventing post-spinal anesthesia-induced hypotension. Rather, this effect was not consistently observed throughout intraoperative period, but lasts only for initial few minutes.

SUMMARY AND CONCLUSION

Out of 60 patients included in our study, 30 patients were randomly allocated into Group O (ondansetron) and another 30 patients were allocated into Group N (normal saline). Group O received 4 mg ondansetron, diluted up to 10 ml with normal saline and Group N received 10 ml of normal saline over 1 min, 5 min before spinal anesthesia.

There was no significant difference in PR in intraoperative period between two groups. There was a significant difference in SBP at 6th min after giving spinal anesthesia. There was a significant difference in DBP at 0 min, assuming supine position just after giving spinal anesthesia. Statistically significant difference was there in MAP in both groups at 0, 3rd, and 6th min after giving spinal anesthesia. No significant difference was observed in PR, SBP, DBP, and MAP in groups after delivery of fetus up to the completion of surgery.

Incidence of hypotension was significantly higher in Group N. Vasopressor (mephentermine) consumption (mean±SD) in each patient in Group O was significantly lesser in comparison to Group N. No incidence of bradycardia was reported in either group. Non-pharmacological measures were taken to prevent shivering, no other side effects were seen in the study.

In our study, considering all these observations, it is concluded that 4 mg iv ondansetron given before spinal anesthesia prevents fall in BP, but its effect exists for initial minutes.

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Original Article

Pectoralis Major Myocutaneous Flap Reconstruction in Head-and-Neck Malignancy – Experience from a Tertiary Care Center

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Abstract

Background: The pectoralis major myocutaneous (PMMC) flap as a pedicle flap is still a reliable option to reconstruct the defects following major oncological resections of head-and-neck cancer. It is the workhorse in centers where the facilities for free tissue transfer are not available. Our aim is to assess the complications of PMMC flap reconstruction.

Materials and Methods: A retrospective analysis of records of 17 patients who underwent reconstruction with PMMC flap as a pedicle flap for head-and-neck malignancies from 2013 to 2019 in the Department of Surgical Oncology, Government Thoothukudi Medical College Hospital, Thoothukudi, was performed.

Results: Records of 17 patients who received PMMC flap were taken for analysis. Of those 17 patients, three were female. Of those 17 patients, 15 had oral cavity malignancy and 2 had malignant parotid tumors. PMMC was used to cover the mucosal defect in eight patients, skin defect in two patients, and both in seven patients as bipaddle flap. None of the patients had a total loss of flap, but one case of marginal necrosis and three cases of partial intraoral flap dehiscence were noted. Oral cavity defect accounts for 15 flaps and the remaining 2 were done to reconstruct the defect following resection of the malignant parotid tumor.

Conclusion: In centers without free tissue transfer facility, PMMC is still the gold standard flap in head-and-neck reconstruction. The morbidity is very minimal in experienced hands.

Key words: Head-and-neck cancer, Pectoralis major myocutaneous flap, Reconstruction

INTRODUCTION

The pectoralis major myocutaneous (PMMC) flap has been considered as the versatile flap to reconstruct the defects following major oncological resections of head-and-neck malignancies since its inception by Ariyan.[1] The advantages of PMMC as a pedicle flap in head-and-neck reconstruction are due to its reliability, good vascularity, ease of harvest, closeness to defect, and bulk to cover exposed vessels in the neck, reduced operating time, and easy learning curve. Compared to free flaps, pedicle flaps significantly reduce the cost and operating time. Hence, pedicle PMMC flap is still shining in the reconstructive armamentarium.

Complications such as seroma, flap dehiscence, and infection occurred in varying degrees in many series, but the total loss of flap is very rare.[2-6] Since these flaps are being used for major oncological resections, non-flap related complications can also occur in the post-operative period. Our aim is to assess the complications of PMMC flap reconstructions.

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MATERIALS AND METHODS

A retrospective analysis of case records of 17 patients who received PMMC flap in the Department of Surgical Oncology, Government Thoothukudi Medical College Hospital from 2013 to 2019 was performed. All surgeries were performed by a team of surgical oncologist and plastic surgeon. All patients were treated with curative intent after getting informed consent and are being followed up

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regularly. The resection for the primary and the type of neck dissection is individualized.

Surgical Technique

All major landmarks such as acromion, xiphoid process, and midclavicular point were marked first. Then, the course of the pedicle to PMMC flap was marked. For skin paddle, our flap design was such that the major part of the paddle will be located inferomedial to the nipple. The nipple will be excluded from the paddle as far as possible. If there was a necessity to extend the skin paddle inferiorly beyond muscle, rectus sheath will be included in the flap to minimize flap necrosis. After marking the skin paddle, the incision was deepened down to the fascia of pectoralis major muscle. Since the skin paddle of PMMC flap is supplied by perforating vessels from the muscle through the intervening fat and breast tissue, we routinely take tacking stitches between skin and muscle to avoid shearing of skin paddle. Then, flap will be elevated in the standard method.

Throughout the procedure, extreme care was taken to avoid injury to the pedicle. Our flap will be designed such that in future, deltopectoral flap (DP flap) can be used at any point of time. In the case of combined PMMC and DP flap, DP flap will be elevated first followed by PMMC flap. After the elevation of PMMC flap, it is generally passed into the neck superficial to the clavicle through a wide subcutaneous tunnel. The tunnel was made large enough to permit easy delivery of the flap into the neck without strangulating the vascular pedicle. The flap inset was done as per requirement. The neck wound was closed primarily and the donor area was either closed primarily or reconstructed with split skin graft (SSG). We always use suction drain after the closure of the neck wound and in the donor area if that donor area was closed primarily. Postoperatively, the positioning of the patient was given due importance in a way that it will not produce tension in the flap. Whenever we do hemimandibulectomy in composite resection, we routinely do tracheostomy after reconstruction.

All patients were given proper adjuvant therapy depending on our institutional protocol. Patients were being followed up monthly in the 1st year, 2 monthly in the 2nd year, 3 monthly in the 3rd year, 6 monthly for the 4th and 5th years, and yearly thereafter as per our department protocol. Follow-up included clinical examination at each visit, yearly chest X-ray, and other investigations as indicated.

RESULTS

Records of 17 patients who received PMMC flap were taken for analysis. Of those 17 patients, 3 were female. Of those 17 patients, 15 had oral cavity malignancy and 2 had malignant parotid tumors. PMMC was used to cover the mucosal defect in eight patients, skin defect in two patients, and both in seven patients as bipaddle flap. None of the patients had a total loss of flap, but one case of marginal necrosis and three cases of partial intraoral flap dehiscence were noted. Oral cavity defect accounts for 15 flaps and the remaining 2 were done to reconstruct the defect following resection of the malignant parotid tumor. Regarding the site, cheek lesion tops the list [Figure 1].

All 15 patients with oral cavity malignancy underwent composite resection. Except for one, hemimandibulectomy was done for the remaining 14 patients. One patient underwent marginal mandibulectomy and was then reconstructed with PMMC as bipaddle flap. Bone reconstruction was not done in our patients. The bulk of the PMMC flap was found to be excellent in filling the defect and covering the exposed neck vessels. Two patients in our series had malignant parotid tumors with significant amount of skin involvement. They required total conservative parotidectomy along with the removal of significant amount of skin. The defect following resection was then reconstructed with PMMC as a single paddle.

Type of flap, either PMMC alone or in combination with other flaps, is decided depending on the defect. In the case of PMMC, it was designed either as a single paddle or bipaddle depending on site and extent of the defect. In our series, PMMC was used as a single paddle in 10 cases, out of which one patient received DP flap in addition to PMMC flap. PMMC was done as bipaddle flap in seven patients. Complications were broken down into flap related and donor site related. We had one patient with marginal necrosis of flap and three patients with partial intraoral flap dehiscence. Intraoral flap dehiscence was noted in two female patients and one male patient. However, none required revision surgery and were managed conservatively. For the donor area, 4 patients received SSG and the remaining 13 patients were managed with primary closure. In the donor site, we had partial graft loss in two cases out of the four patients who received SSG in the donor area. Seroma occurred in one patient and wound infection in one patient [Figure 2].

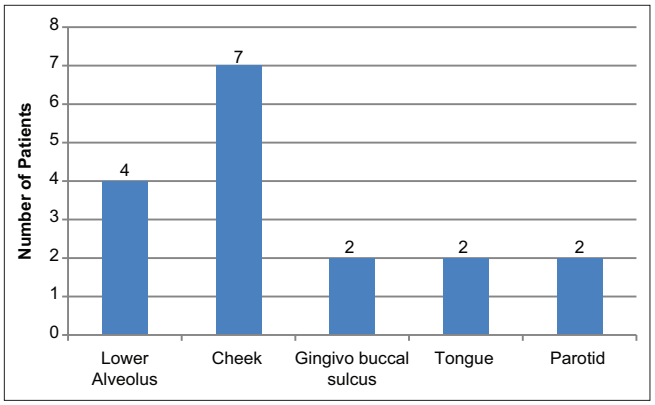

Figure 1: Site of disease reconstructed

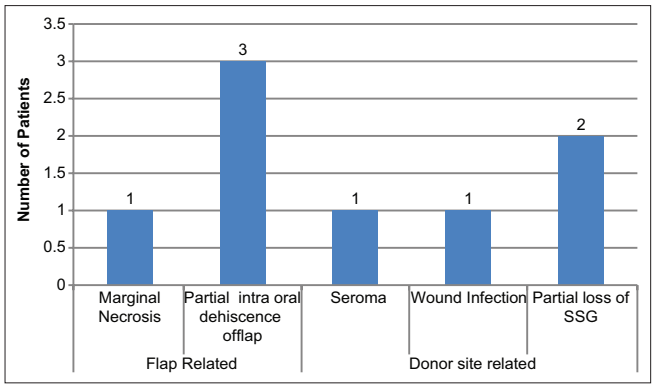

Figure 2: Distribution of complications

DISCUSSION

Reconstruction of post-surgical defects in head-and-neck cancer brings a significant surgical challenge. Microvascular free flaps are considered as the first-line reconstructive option in this current era of technological advancement based on the esthetic advantage. However, the limitations in the free flap technique are increased operating time, high cost, expertise in the field of microvascular reconstruction, and higher anesthetic risk in patients with multiple comorbid conditions. On the other hand, pedicle flap has the advantage of overcoming almost all the limitations mentioned above. PMMC is the gold standard flap in head-and-neck reconstruction in developing countries where microvascular reconstruction facility is not available.

PMMC flap is based on the pectoral branch of the thoracoacromial artery. The disadvantage of using PMMC in the male patient is the hair growth in the oral cavity, but in the long run, this problem will be spontaneously resolved following mucosalization of the flap. In females, due to the bulkiness of flap, there may be a slight increase in complications. In our series, two of the three female patients developed intraoral flap dehiscence, but only one out of 14 male patients had flap dehiscence.

Kroll *et al.* have described in their series that the complication rates after PMMC flap reconstruction in female patients are greater.[7] This may be due to the interposition of breast tissue between the muscle and the skin paddle. However, in a series by Jena *et al.*, they described that complications following PMMC flap in female patients were relatively lower when compared with that reported in other series. Statistical analysis to compare complication rates between men and women was not performed in their series.[8]

Total loss of PMMC flap was not found in many series.[3,4] In our series also, we have not encountered the total loss of flap. In general, the complications of PMMC flap reconstruction are not worrisome.

CONCLUSION

PMMC flap still remains as a valuable reconstructive option in the head-and-neck malignancies. By following proper anatomical landmarks and basic principles of reconstruction, the chance of flap necrosis is negligible. In places, where free tissue transfer facilities are not available, the value of PMMC flap is unquestionable. With reliability, ease of harvest, low morbidity, and reduced operating time, PMMC is still a workhorse.

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Original Article

Methicillin-resistant *Staphylococcus aureus*-prevalence and Antimicrobial Sensitivity Pattern among Burn Patients in a Tertiary Care Hospital in Vindhya Region

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Abstract

Background: Methicillin-resistant *Staphylococcus aureus* (MRSA) is a well-recognized public health problem throughout the world. The evolution of new genetically distinct community-acquired and livestock-acquired MRSA and extended resistance to other non-*β*-lactams including vancomycin has only amplified the crisis. This paper presents data on the prevalence of MRSA and resistance pattern to other antibiotics on the selected specimen from burn patients.

Materials and Methods: This is a prospective study conducted in the burn unit of Shyam Shah Medical College and Sanjay Gandhi Memorial Hospital, Rewa (M.P.), from June 2018 to May 2019, where all patients with flame and scald burns were included in the study who had up to a second degree or partial-thickness burns.

Results: A total of 558 patients were admitted in the burn unit throu`ghout the year, the age ranged from 2 months to 85 years. About 56.10% were females and 43.90% were males. *Pseudomonas aeruginosa* (37.5%) was the most common isolate followed by *S. aureus* (18.75%). The prevalence of MRSA was 57.14% but all the MRSA isolates showed 100% sensitivity to vancomycin and linezolid closely followed by piperacillin and tazobactam combination. The prevalence of methicillin resistance overall among *S. aureus* and *Staphylococcus epidermidis* was found to be 51.72%.

Conclusion: MRSA is prevalent among the burn wounds but is 100% sensitive to vancomycin and linezolid. To ensure early and appropriate therapy, routine microbiological surveillance and a regular update of their antimicrobial susceptibility pattern could help in the prevention of development of multidrug resistance.

Key words: Antimicrobial sensitivity, Burn, Methicillin-resistant *Staphylococcus aureus*

INTRODUCTION

All over the world, it is estimated that approximately 25 lakh people in each continent sustain burns of which 100,000 are hospitalized and there are around 12,000 deaths per year due to thermal injuries. The exact number of burns is difficult to determine in India. Judicious extrapolation suggests that we have 7–8 lakh admissions due to burns and the projected figures suggest an annual mortality rate of 1–1.4 lakhs.

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Burns are the fourth most common and devastating forms of trauma, following traffic accidents, falls. and violence. The extensively burn or severely injured patient is at increased risk of burn infection as well as of injury to other organs as a result of various degrees of impairment of host defense mechanism. The survival rate for burn patients has improved substantially in the past few decades

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due to advances in modern medical care in specialized burn centers. Burn-related deaths depending on the extent of injury have been halved within the past 40 years.

Burn wound surface provides a favorable niche for microbial colonization and proliferation, while the avascularity of the eschar causes impaired migration of host immune cells, restricts delivery of systematically administered antimicrobial agents, and releases toxic substances that impair host immune response. The organisms responsible for infections in patients who suffer from burn injuries may be endogenous or exogenous which can change over time in the individual patient.

The common pathogens isolated from burn wounds are *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Streptococcus pyogenes*, *Acinetobacter baumannii,* and various coliform bacilli. Microorganism is transmitted to the burn wound surfaces of admitted patients by the hands of medical personnel, by fomites, and from patient's skin surface and nose and during intervention.

S. aureus is frequently isolated pathogen in both community and hospital practices. *S. aureus* is normal flora in nasal vestibule and other skin sites, especially anus and armpits of the human population. As burn patients have lost their primary barrier and exposed to microorganism invasion continually and chronically, *S. aureus* becomes one of the greatest causes of nosocomial infection in burn patients.

The cases of antibiotic resistance have increased and resistant species such as methicillin-resistant *S. aureus* (MRSA) provide additional challenges in the form of virulence factors. MRSA has attracted more and more attention in recent years, especially in burn centers. Multimodal infection control concept is required to limit the spread of infection with multidrug-resistant organism including MRSA in a burn unit. Where patients colonized or infected with MRSA appear to be the main reservoir, transfer of these patients to other units or temporary closure of the unit, accompanied by intensive cleaning are very effective measures to stop transmission events.

The presence of drug-resistant bacteria in the hospital environment and in patients is a great threat for public health and because of the ever-increasing number of resistant strains with time, updated information on prevalence of local major pathogens and their sensitivity patterns is very helpful for health personnel responsible in the management of patients and monitoring the emergence of resistant bacteria in any given region.

MATERIALS AND METHODS

This prospective analysis was conducted in the Burn Unit of Shyam Shah Medical College and Sanjay Gandhi Memorial Hospital, Rewa (M.P.). The epidemiological analysis is based on data collected from 558 burn patients hospitalized between June 2018 and May 2019. Data collected included age, sex, percent total body surface area burnt, residence, season of injury, mechanism of injury, and outcome. The clinical samples were taken for microbiological tests from burn wound at different time intervals during the patients' stay in hospital. Culture and sensitivity tests were undertaken at the center's microbiology laboratory.

Microbiological Assessment

Bacterial isolation and identification

For isolation, all the samples were inoculated on a selective and differential medium (mannitol salt agar), enriched medium (blood agar) and incubated at 37°C for 24 h, and colonies of mannitol fermenter and beta-hemolysis of staphylococci were submitted to identification tests according to Bergey's manual of determinative bacteriology.

Antibiotic sensitivity test (Kirby-Bauer method)

Inoculums from the tested bacterium were prepared depending on Kirby-Bauer antibiotic testing. The bacterial suspensions were prepared from fresh single colonies and adjusted by comparison with 2 McFarland turbidity standard (6 × 108 cells/ml) tubes. Sterile cotton swab was dipped into the inoculum and then swabbed evenly across the surface of a Mueller-Hinton agar plate, after that within 15 min of inoculation, the antimicrobial-containing discs are applied to the agar with a forceps pressed firmly to ensure contact with the agar and then plate inverted and incubated at 37°C for 18 h. Inhibition zones were expressed in (mm) as the diameters of clear zones around the discs (CLSI, 2007) [Tables 1 and 2].

Data Entry and Analysis

The quantitative data were analyzed using descriptive statistics summarized and displayed on graphs and charts.

RESULTS

Demographic Profile of Burn Patients

In the study conducted among 558 patients admitted in burns unit, 56.10% patients were female and 43.90% of the affected population was males. The youngest patient in the study was 2 months old and the oldest was 85 years old [Figure 1].

Cause and Source of Burn

The cause of burn in 62.54% (349) patients was flames due to any cause, scalds due to hot liquids in 29.75% (166) and

electric burn in 7.71% (43) patients [Table 3]. In our study group, the majority of patients were afflicted with burns because of scalds due to hot liquids (29.75%) followed by burns due to kerosene oil (24.19%). The least common source was burning due to stove accounting for 6.82% of cases [Figure 2].

Relation of Socioeconomic Status with Infection

It was evident in our study that most of the patients with positive cultures belonged to the lower class (90.48%), indicating the correlation and significance of hygiene with the rate of infection [Figure 3].

Prevalence of MRSA

The wound swabs were taken from 112 patients who satisfied the inclusion criteria, 25% were culture negative. The prevalence for *S. aureus* and coagulase-negative *Staphylococcus* was found to be 18.75% (21) and 6.25% (7), respectively. Among the patients in whom *S. aureus* was isolated, the disc diffusion method using cefoxitin discs was used to detect MRSA. The prevalence of MRSA was found to be 57.14% (12) and prevalence of methicillin resistance was found to be 42.8% (3) in patients with *Staphylococcus epidermidis*. The overall prevalence of methicillin resistance was 51.72% (15) [Table 4].

Antimicrobial Sensitivity of MRSA

All the MRSA isolates showed 100% sensitivity to vancomycin and linezolid closely followed by piperacillin and tazobactam combination with 95.24% and 85.71% sensitivity to *S. aureus* and coagulase-negative *Staphylococcus*, respectively [Table 5].

DISCUSSION

Bacterial infections of the burn wound still remain a major cause of morbidity and mortality in thermally injured patients. The burned patient is prey for a wide variety of microorganisms, as burn presents an extensive surface with a large mass of dead tissue and free exudation of serum which is favorable for bacterial growth. The burn site initially becomes colonized with microorganisms which if uncontrolled progresses to invasion and gives rise to bacteremia and sepsis, which is a major cause of mortality in burn patients. Although the diagnosis of burn wound infections can be made clinically, additional microbiological evidence is needed for instillation of proper therapy.

In studies conducted on burn patients in Rewa, by Lal *et al.* in 2012, Jain *et al.* in 2015, and Singh *et al.* in 2018, the incidence in females was 82.2%, 59.3% and 60%, respectively, which is very well in correlation with our present study.

In contrast, Agnihotri *et al.*, Lari *et al.*, and Ekrami and Kalantar reported that the incidence was higher in males in

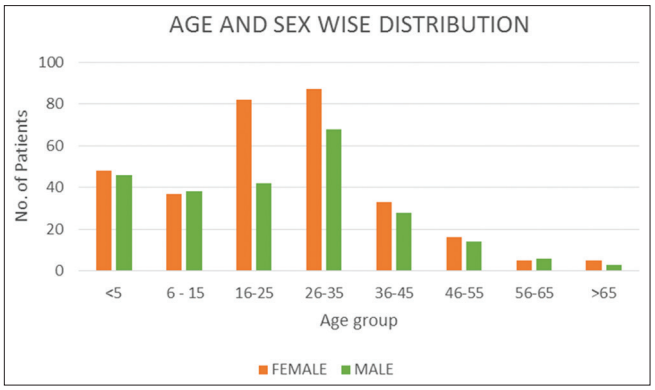

Figure 1: Age and sex wise distribution

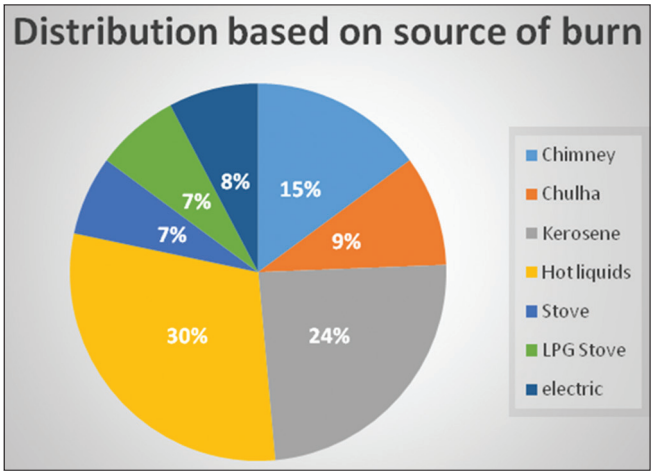

Figure 2: Distribution based on source of burn

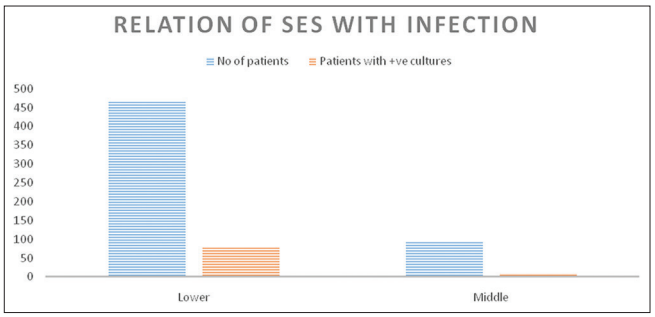

Figure 3: Relation of Socioeconomic status with infection

their studies. High incidence of burns in females is probably due to occupational hazards of working in the kitchen as the kitchen is the most common place to receive a burn. In the Indian rural setting, women are more predisposed especially due to the old methods used such as chulha and chimney which are more susceptible to catch and cause fire. Social evil such as dowry and domestic violence is a major culprit for intentional burn deaths.

According to most studies, flame burns are the most common type of burn injuries. In the present study as well, flame burns were the commonest type of burns

Table 1: Antibiotic discs used for Gram-positive organisms

Antibiotic	Abbreviation	Strength	Antibiotic	Abbreviation	Strength
Penicillin	P	10 units	Gentamycin	GEN	10 µg
Cefoxitin	CX	30 µg	Cotrimoxazole	COT	1.25
Erythromycin	E	15 µg	Amikacin	AK	30 µg
Clindamycin	CD	2 µg	Ciprofloxacin	CIP	5 µg
Linezolid	LZ	30 µg	Piperacillin+Tazobactam	PIT	100/10 µg
Vancomycin	VA	30 µg	Ceftriaxone	CTR	30 µg

Table 2: Antibiotic discs used for Gram-negative organisms

Antibiotic	Abbreviation	Strength	Antibiotic	Abbreviation	Strength
Cefuroxime	CXM	30 µg	Meropenem	MP	10 µg
Amikacin	AK	30 µg	Ceftazidime	CAZ	30 µg
Ceftriaxone	CTR	30 µg			
Cotrimoxazole	COT	1.25			
Gentamicin	GEN	10 µg			
Ciprofloxacin	CIP	5 µg			
Piperacillin+Tazobactam	PIT	30 µg			

Table 3: Cause of burn

S. No.	Cause of burn	Number of patients	Percentage
1	Flame	349	62.54
2	Scald	166	29.75
3	Electric	43	7.71
	Total	558	100

Table 4: Prevalence of methicillin-resistant *Staphylococcus aureus*

S. No.	Organism	Methicillin resistance	Percentage
1	*Staphylococcus aureus* (21)	12	57.14
2	*Staphylococcus epidermidis* (7)	3	42.8

accounting for 62.54% of all the cases. It was followed by burns due to scalds seen in 29.75% of the cases. This is consistent with the study by Delgado *et al.* (2002) in which they reported scalding as the most common cause of burns in children under 5 years. Most of the scalds injuries (47.62%) were seen in children below 12 years of age. Scalds have been unanimously found to be the predominant form of burns among children. As the age increases, frequency of scalds decreases and flame burns increase in number.

In our study, 18.75% of the swabs sent for culture were positive for *S. aureus*. *Staphylococcus* was the predominant cause of burn wound infection in the pre-antibiotic era and remains an important pathogen at present. However, Srinivasan *et al.* stated that the percentage incidence of staphylococci is on the decline from 2002 to 2005.

In our study, coagulase-negative staphylococci (*S. epidermidis*) were recovered at a frequency of 6.25%. This finding is similar to a study by Mama *et al.* (2014) in which they reported a 14.5% coagulase-negative staphylococci isolated from wounds. Coagulase-negative staphylococci being a normal skin flora and common contaminant of wound most often may be isolated (Mama *et al.*, 2014).

Among the patients in whom *S. aureus* was isolated, tests were applied to detect MRSA. The prevalence was found to be 57.14% in patients with *S. aureus* infection and 42.8% in patients with *S. epidermidis*. The overall prevalence of MRSA was 51.72%.

According to an Indian study, the prevalence of infections caused by MRSA has increased from 12% in 1992–80.03% in 1999. The prevalence of MRSA infection in the study by Naqvi *et al.* was 24.6%. It is less than that reported by Mokaddas and Sanyal, 1996, i.e., 74.6% and other studies conducted in Guru Teg Bahadur Hospital in New Delhi, from 1997 to 2002 (Singh *et al.*, 2003). Muscat, Oman, the prevalence of MRSA was about 95% during 1995–1996 (Prasanna and Thomas, 1999). In another study, all isolates of *S. aureus* were resistant to methicillin at Gulhane Military Medical Academy Istanbul Turkey (Oraloncul *et al.*, 2002). The authors of this study suggested many factors that may account for an increased incidence of MRSA colonization and infection. These factors included the use of broad-spectrum antibiotics, average length of hospital stay, and poor hospital infection control practices. A similar picture is also reflected in the present study.

The antimicrobial sensitivity testing was done by Kirby Bauer's disc diffusion method. Methicillin resistance was

Table 5: Antibiotic sensitivity pattern of staphylococci

Organism	P	E	CD	LZ	VA	CIP	PIT	COT	AK	GEN
Staphylococcus aureus										
n (%)	3 (14.29)	13 (61.90)	16 (76.19)	21 (100)	21 (100)	10 (47.62)	20 (95.24)	12 (57.14)	11 (52.38)	NT
Staphylococcus epidermidis										
n (%)	2 (28.57)	3 (42.86)	5 (71.43)	7 (100)	7 (100)	3 (42.86)	6 (85.71)	3 (42.86)	4 (57.14)	NT

GEN: Gentamicin, AK: Amikacin, COT: Cotrimoxazole, PIT: Piperacillin+Tazobactam, CIP: Ciprofloxacin, VA: Vancomycin, LZ: Linezolid, CD: Clindamycin, E: Erythromycin, P: Penicillin

tested using cefoxitin (30 μg) disc and it was found that 57.14% of the *S. aureus* isolates and 42.8% of the coagulase-negative *Staphylococcus* isolates were methicillin-resistant but all the MRSA isolates showed 100% sensitivity to vancomycin and linezolid closely followed by piperacillin and tazobactam combination.

This is in accordance with other studies on MRSA in burn patients by Rajput *et al.* and Oncul *et al.* They both reported a 40% incidence of MRSA. About 33.3% of the CONS isolates were methicillin-resistant. This finding is similar to that by Altoparlak *et al.* who reported 20.9% isolates of CONS to be methicillin-resistant.

The resulting antibiograms give some cause for concern because the predominant bacterial isolates were relatively resistant to the commonly available, more economical antimicrobials.

CONCLUSION

The present study has given us the knowledge regarding incidence of bacterial colonization of burn wounds in our hospital and specifically about the prevalence of MRSA.

In conclusion, to ensure early and appropriate therapy, routine microbiological surveillance and a regular update of their antimicrobial susceptibility pattern could help in the prevention of development of multidrug resistance. Among other precautions, personal hygiene of the patients and handwashing practice among health-care providers is to be emphasized and practiced routinely.

To prevent antibiotic resistance, there should be an Institutional Infection Control Committee that can monitor and provide guidelines for the rational use of antibiotics. Our results may be helpful in providing useful information regarding the pattern of burn wound microbial colonization, the dominant flora and antimicrobial resistance in our burn unit and thus will help in the formulation of effective guidelines for therapy, thus improving overall infection-related morbidity and mortality.

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Original Article

Predictors of Post-operative Pulmonary Complications Following Emergency Laparotomy

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Abstract

Background: Post-operative respiratory complications are a major threat following emergency abdominal surgeries. It significantly increases post-operative morbidity and mortality. The aim of this study was to determine the incidence and factors affecting post-operative pulmonary complications (PPCs).

Materials and Methods: This is a prospective observational study conducted in 270 patients who got admitted through SOPD, casualty or transferred from other department, and undergoing emergency laparotomy over a period of 1 year (June 1, 2018–May 31, 2019). Patients were included in the study irrespective of age, sex, and occupation. Pre- and post-operative data were collected through interview and postoperatively patients were monitored clinically and various investigations were done to record post-operative respiratory complications. Then, their association was analyzed.

Results: Two hundred seventy patients were included in the present study and 55 (20.4%) developed PPCs. Pneumonia (20) was the most common PPC followed by atelectasis (15). Elderly patients had more risk. PPCs were more in current smokers (30.98%), patients with pre-existing respiratory diseases (47.1%), duration of surgery more than 3 h. PPCs significantly increase the duration of hospital stay and mortality.

Conclusion: Pulmonary complications are significant among patients undergoing emergency laparotomy that leads to increased morbidity and mortality. Predictors of PPCs are smoking, pre-existing respiratory diseases, prolonged duration of surgery, and prolonged intubation.

Key words: Emergency laparotomy, Post-operative pulmonary complications, Predictors

INTRODUCTION

Post-operative respiratory complication is a major concern following emergency abdominal surgeries. There is a wide disparity in the incidence of post-operative pulmonary complication (PPC) following abdominal surgery had reported from 5 to 60% by Stein *et al.* (1962), Latmeir *et al.* (1971), Bartlett *et al.* (1973), and Lord (1983). PPC is associated with a 30-day mortality of 18% compared with 2.5% for those without PPCs (Khuri *et al.*, 2005).

PPCs include post-operative hypoxia, atelectasis, bronchospasm, pulmonary infection, pulmonary infiltrate, aspiration pneumonitis, acute respiratory distress syndrome (ARDS), pleural effusions, and pulmonary edema (Arozullah *et al.*, 2000). Depending on the severity, these can be self-limiting, require ward-based interventions, for example, antibiotics or physiotherapy or readmission to critical care, reintubation, and even death.

A number of risk factors for PPCs following elective nonthoracic surgery, derived from clinical history, physical examination, lung function tests, chest x-ray (CXR), and pre- or intra-operative elements, have been described.

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Pre-operative risk factors are a major determinant of post-operative morbidity. Several risk factors, both preoperatively and intraoperatively, have been identified with respiratory impairment after abdominal surgery. Conventionally, factors associated with PPCs are chronic airway disease, advanced age, upper abdominal surgery, intraperitoneal sepsis, and obesity. Other factors affecting PPCs are patient pulmo-operative mobility status, cardiac, respiratory conditions, and malignancies.

Patient-related risk factors that could influence PPCs include age, chronic lung diseases, cigarette use, congestive heart failure, obesity, asthma, obstructive sleep apnea, site and type of surgical incision, duration of surgery, anesthetic technique, and emergency surgery.

The main objectives of our study were clarification of the frequency of PPCs after emergency laparotomy and identify the independent predictors of risk factors for their occurrence.

MATERIALS AND METHODS

The present study was carried out in 270 patients who underwent emergency laparotomy in Sanjay Gandhi Memorial Hospital associated with S.S. Medical College, Rewa (M.P.) during the period of June 1, 2018–May 30, 2019. Patients admitted in surgical wards (irrespective of the age and sex) through SOPD, casualty, or transferred from other departments undergoing emergency laparotomy during the period of study were included in the study. On admission, detailed history and clinical examination were conducted. The data were noted on a predesigned pro forma. Baseline investigations such as complete blood count, urinalysis, serum urea/creatinine, serum electrolytes, CXR, electrocardiograph, HIV, hepatitis B and C profile, blood grouping, and blood sugar (random) were noted. Abdominal radiographs and ultrasonography of abdomen in selected cases were also done to confirm diagnosis where required. After initial conservative management including intravenous fluid resuscitation with Ringer's lactate solution/Foley's catheterization/nasogastric tube insertion, pre-anesthetic assessment was made. After assessment emergency laparotomy was performed.

Patients were observed for any post-operative respiratory complications; morbidity and mortality, predisposing factors, day of appearance of respiratory complication, and post-operative hospital stay were recorded.

Patients having cough, post-operative fever, and chest pain were evaluated further by X-ray chest posteroanterior view, ultrasound chest and high-resolution computed tomography chest (in selected cases), and blood investigations (hemoglobin, T&D, erythrocyte sedimentation rate, and serum electrolytes).

RESULTS

Of 270 patients studied, 55 developed a pulmonary complication. Hence, overall incidence of PPC was 20.4% [Figure 1].

Pneumonia accounted for 36.4% (20 patients) followed by atelectasis in 27.3% (15 patients) of all PPCs. Others were pleural effusion 18.2% (10), ARDS 7.3% (4), acute bronchitis 5.4% (3), and acute exacerbation of respiratory diseases 5.4% (3) [Figure 2].

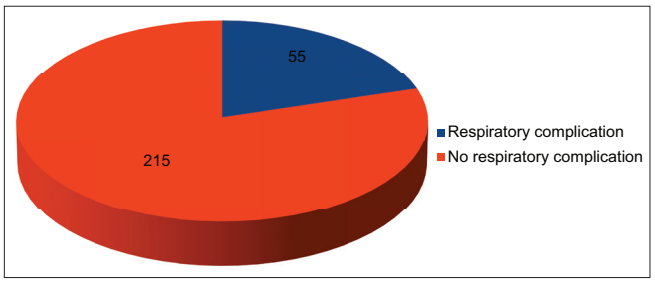

Figure 1: Distribution of cases and respiratory complication

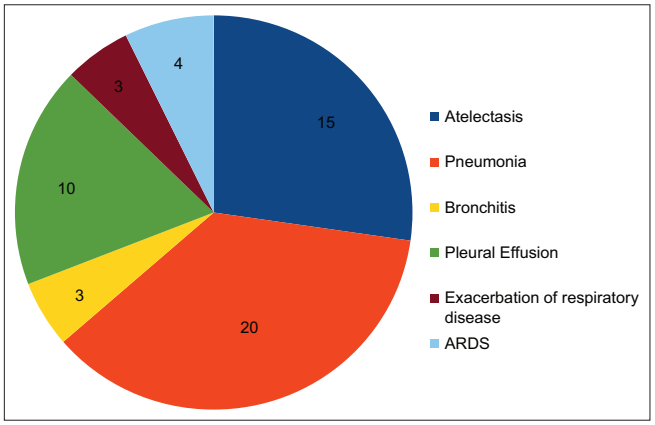

Figure 2: Distribution of various respiratory complications

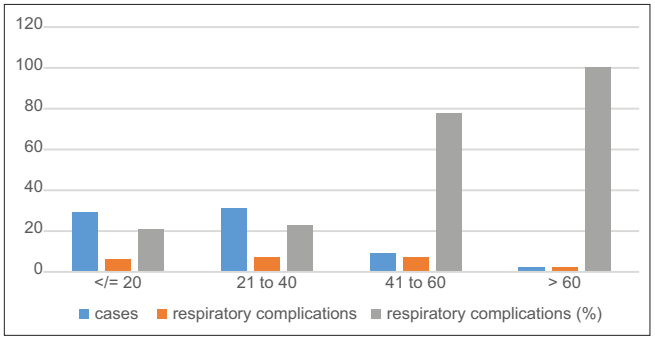

Figure 3: Relationship between smoking in pack years and respiratory complication

Current smokers were more likely to have a PPC compared with ex-smokers, who were in turn more likely than those who had never smoked. The incidence of respiratory complication among smokers was 30.98%, while 16.58% among non-smokers. There is a positive correlation ($P < 0.01$) between smokers and respiratory complication [Table 1]. In active smokers, PPCs incidence increase incrementally with the number of pack-year smoked that is 22.8% (8 of 35 patients). Among patients who smoked <20 pack year, the incidence of PPCs was 70% (7 of 9 patients) among patients who smoked 41–60 pack year, and incidence of PPCs was 100% (2 of 2 patients) among patient who smoked >60 pack year [Figure 3].

In the present study, 17 patients had pre-existing respiratory comorbidities, of which 8 (47.1%) developed respiratory complications [Table 2]. There is a positive correlation between pre-existing respiratory comorbidities and post-operative respiratory complications ($P < 0.01$).

The incidence of respiratory complications among the patients who underwent exploratory laparotomy for more than 3 h was 36.78%.

There is a strong positive correlation between the duration of surgery and post-operative respiratory complication ($P < 0.001$) [Table 3].

DISCUSSION

This is a prospective observational study conducted in 270 patients who underwent emergency abdominal surgeries.

The main objectives of our study were clarification of the frequency of PPCs after emergency laparotomy and identify the independent predictors of risk factors for their occurrence.

There is a wide disparity in the incidence of PPC following abdominal surgery had reported from 5 to 60% by Stein *et al.* (1962), Latmeir *et al.* (1971), Bartlett *et al.* (1973), and Lord (1983).

Authors	Years	Incidence of post-operative pulmonary complications (%)	Types of surgeries
Deodhar *et al.*	1991	54.2	Upper abdominal
Jawai *et al.*	2006	7.0%	Elective and emergency abdominal surgeries
Goreth	2006	28.2	Emergency abdominal
Smith *et al.*	2009	7.0	Laparotomies
Kim *et al.*	2016	16.3	Laparoscopic, emergency and elective laparotomies
Patel and Hadian	2016	11.9	Elective abdominal surgeries
Gangwal and Singh	2016	30.2	Emergency laparotomies
Kumar *et al.*	2018	44.4	Emergency abdominal
		16.0	Elective abdominal
Verma *et al.*	2018	2.9	Emergency abdominal

In our study, the incidence of pulmonary complications was 20.4%, PPCs developed in 55 patients of 270 patients who underwent emergency laparotomy.

Pneumonia is most common PPCs 36.4% (20 patients) followed by atelectasis in 27.3% (15 patients). Others are pleural effusion 18.2% (10), ARDS 7.3% (4), acute bronchitis 5.4% (3), and acute exacerbation of respiratory diseases 5.4% (3).

In various studies (Goreth *et al.*, 2006; Smith *et al.*, 2009; Kim *et al.*, 2016; and Verma *et al.*, 2018), pneumonia is found to be a most common complication.

Smoking is a risk factor for PPC. Morton (1944), Wightman (1968), and Blumen *et al.* in Chest (1998) found that smokers had a significantly higher incidence of PPC, as compared to non-smokers. The incidence of respiratory complications among smokers was 30.98% while 16.58% among non-smokers. There is a positive correlation ($P < 0.01$) between smokers and respiratory complications. In active smokers, PPCs incidence increase incrementally with the number of

Table 1: Relationship between smoking and respiratory complication

Patients	No respiratory complication	Respiratory complication	Percentage
Smokers (*n*=71)	49	22	30.98
Non-smokers (*n*=199)	166	33	16.58
Total (*n*=270)	215	55	

Table 2: Relationship between pre-operative respiratory comorbid diseases with post-operative respiratory complication

Patients	Respiratory complication	Percentage	No. respiratory complication	Percentage
Respiratory comorbid diseases (*n*=17)	8	47.1	9	52.9
No respiratory comorbid diseases (*n*=253)	47	18.6	206	81.4

Table 3: Relationship between duration of surgery and respiratory complication

Duration of surgery	No. respiratory complication	Respiratory complication	Percentage
>3 h (*n*=87)	55	32	36.78
<3 h (*n*=183)	160	23	12.56

pack-year smoked that is 22.8% (8 of 35 patients). Among patients who smoked <20 pack year, the incidence of PPCs was 70% (7 of 9 patients) among patients who smoked 41–60 pack year, and incidence of PPCs was 100% (2 of 2 patients) among patient who smoked >60 pack year.

The pre-existing respiratory disease such as emphysema and bronchiectasis is important factors influencing the PPCs and has been stressed by many authors Mortan (1944), Dripps and Deming (1946), Stein *et al.* (1962), Wightman (1968), Tisi (1979), and Lord (1983). Wightman (1968) has reported that post-operative chest complications occurred 3 times more frequently with pre-existing infections of the respiratory tract. In the study of Deodhar *et al.* (1991), of 67 patients who developed pulmonary complications, 24 cases had pre-existing pulmonary disease and 16 of these had chronic bronchitis due to smoking. Kim *et al.* (2016) have reported that there were no significant differences in PPCs ($P = 0.657$) or requirement for intensive care, including intensive care unit (ICU) care ($P = 0.590$) and mechanical ventilator support ($P = 0.506$), between patients with mild-to-moderate COPD and control subjects. Kumar *et al.* (2018) reported that 67 patients undergoing surgery were identified to have cardiac comorbidity, and 16 (23.9%) among them developed PPCs. Four patients (57.1%) with combined cardiac comorbidity and respiratory comorbidity had significantly increased the risk for the development of PPCs. Patel and Hadian (2016) said that PPCs were more common in patients with a history of chronic obstructive pulmonary disease compared to those with no history (26.7 vs. 10.2%, $P < 0.001$).

In the present study, of 270 patients who underwent exploratory laparotomy, 17 patients had pre-existing respiratory comorbidities, of which 8 (47.1%) developed respiratory complications ($P < 0.01$). We observed that post-operative respiratory complication was much more when patient had a history of respiratory comorbid disease such as COPD, asthma, pulmonary tuberculosis, and interstitial lung disease.

Wong *et al.* (1995) reported that of 105 patients who underwent non-cardiothoracic surgery; 38 of 39 patients (97%) with PPCs had an anesthetic duration >2 h. Brooks-Brunn chest 1997 reported that duration of surgery >4 h was a significant risk factor ($P = 0.0062$) for PPCs. McAlister *et al.* (2005) reported that PPC was affected by the duration of anesthesia (odds ratio 3.3 for operations lasting at least 2.5 h, $P = 0.008$); Kelkar (2015) found that incidence of respiratory complications was decreased in patients, operated for <3 h. Verma *et al.* (2018) reported that surgeries lasting >3 h chances of PPCs increased.

In the present study, of 270 patients who underwent emergency laparotomy, 55 patients were operated for more than 3 h; 32 (36.78%) patients developed PPCs ($P < 0.001$). While of 160 patients who underwent surgery for <3 h, 23 (14.37%) patients developed PPC.

CONCLUSION

The PPCs are higher in smokers, higher in patients with comorbid respiratory diseases, patients with longer duration of surgery, PPCs considerably increase the hospital, and ICU stay and mortality. Pneumonia is the most common respiratory complication observed.

It is concluded from our study that outcomes of laparotomies are multifactorial with high morbidity and mortality, leading to an escalation in hospital costs and prolonged illness. These complications can be avoided if the factors involved are properly addressed.

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Original Article

Antimicrobial Susceptibility Pattern of Bacterial Isolates in Burn Patients in a Tertiary Care Center: A Prospective Study

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Abstract

Background: Burn injuries and deaths pose a major public health concern globally, especially in developing and underdeveloped countries. As burn patients have lost their primary barrier and exposed to microorganism invasion continually and chronically, *Staphylococcus aureus* becomes one of the greatest causes of nosocomial infection in burn patients though it is a normal skin flora. The cases of antibiotic resistance have increased, and resistant species such as methicillin-resistant *S. aureus* (MRSA) provide additional challenges in the form of virulence factors. Multimodal infection control concept is required to limit the spread of infection with multidrug-resistant organism including MRSA in a burn unit. The common pathogens isolated from burn wounds are *S. aureus*, *Pseudomonas aeruginosa*, *Streptococcus pyogenes*, *Acinetobacter baumannii,* and various coliform bacilli. Hence, antimicrobial susceptibility pattern of bacterial isolates in burn patients plays a key role in the management of these patients.

Materials and Methods: This prospective observational study involved the collection of wound swabs from burn patients from June 2018 to May 2019. All patients with burn wounds irrespective of age and sex, admitted through surgery outpatient department or casualty, during the period of study were included in the study.

Results: Maximum prevalence was found for *P. aeruginosa,* i.e., 37.5% followed by *S. aureus,* for which the prevalence was found to be 18.75%. The organism least commonly cultured was *Acinetobacter*; the prevalence of MRSA was found to be 57.14% and the prevalence of methicillin resistance was found to be 42.8% in patients with *Staphylococcus epidermidis*. Overall, the prevalence of methicillin resistance was 51.72%. The drugs most effective against *P. aeruginosa*, the most common isolate, were meropenem (97.62%) and piperacillin/tazobactam (90.48%) followed by gentamicin (64.29%). Meropenem and piperacillin/tazobactam showed 100% efficacy against the other Gram-negative bacilli isolated as well. MRSA isolates showed 100% sensitivity to vancomycin and linezolid closely followed by piperacillin-tazobactam combination. *Klebsiella pneumoniae* showed 100% sensitivity to meropenem and piperacillin/tazobactam.

Conclusions: The overall isolation rate was 75%. Only solitary isolates were studied. Overall, Gram-negative organisms (66.66%) were more common than Gram-positive organisms (33.33%). *P. aeruginosa* (37.5%) was the most common isolate followed by *S. aureus* (18.75%). The prevalence of MRSA was 57.14%, but all the MRSA isolates showed 100% sensitivity to vancomycin and linezolid. On antibiotic sensitivity testing, piperacillin/tazobactam (95.24%) was found to be the most effective drug against all the organisms isolated. Meropenem (99.40%) was the most effective drug against the Gram-negative organisms. Vancomycin (100%) and linezolid (100%) were the most effective drugs for the Gram-positive organisms.

Key words: Antibiotics, Antimicrobial susceptibility, Burn injuries, Gram-negative bacilli, Gram-positive organisms, Methicillin-resistant *Staphylococcus aureus*

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INTRODUCTION

Burn injuries and deaths pose a major public health concern globally, especially in developing and underdeveloped countries. They cause the injury to the largest organ of the body which is responsible for thermoregulation, homeostasis, sensation, immunological defense, and above

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all act as a barrier against infections.[1] The exact number of burns is difficult to determine in India. Judicious extrapolation suggests that we have 7–8 lakh admissions due to burns and the projected figures suggest an annual mortality rate of 1–1.4 lakhs.[2] Burn injuries are the leading cause of disability-adjusted life years in these countries.[3]

Burn wound surface provides a favorable niche for microbial colonization and proliferation, while the avascularity of the eschar causes impaired migration of host immune cells, restricts delivery of systematically administered antimicrobial agents, and releases toxic substances that impair host immune response. The organisms responsible for infections in burn patients may be endogenous or exogenous which can change overtime in the individual patient.

Overcrowding in burn unit is an important cause of cross infection which necessitates regular monitoring of bacterial species and their antibiotic susceptibility for better management. Despite intensive therapy with antibiotics both topically and intravenous, it has been estimated that about 75% of the mortality associated with burn injuries is related to sepsis followed by shock and hypovolemia, especially in developing countries.[4]

Typically, the burn surface is sterile immediately following thermal injury, but after 48 h, the wound is colonized with skin commensals. After 1 week or so, the wounds become colonized with organisms from the host's gastrointestinal or respiratory tracts or from the hospital environment.[4] This colonization, if uncontrolled, may progress to invasion with systemic complications and death.

The common pathogens isolated from burn wounds are *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Streptococcus pyogenes*, *Acinetobacter baumannii,* and various coliform bacilli.

As burn patients have lost their primary barrier and exposed to microorganism invasion continually and chronically, *S. aureus* becomes one of the greatest causes of nosocomial infection in burn patients though it is a normal skin flora.

The cases of antibiotic resistance have increased, and resistant species such as methicillin-resistant *S. aureus* (MRSA) provide additional challenges in the form of virulence factors. Multimodal infection control concept is required to limit the spread of infection with multidrug-resistant organism including MRSA in a burn unit.

Aims and Objectives

The study was carried out at Burn unit of the Department of Surgery, Shyam Shah Medical College and Associated Gandhi Memorial Hospital and Sanjay Gandhi Memorial Hospital, Rewa, Madhya Pradesh, from June 2018 to May 2019 with the following aims and objectives:

1. To estimate the prevalence of different bacteria in wounds of burn patients
2. To study the antibiotic susceptibility pattern of the isolated bacteria including MRSA.

MATERIALS AND METHODS

This prospective observational study involved the collection of wound swabs from burn patients from June 2018 to May 2019. All patients with burn wounds irrespective of age and sex, admitted through surgery outpatient department or casualty, during the period of study were included in the study.

Inclusion Criteria

All burn patients admitted to the burn unit.

Exclusion Criteria

The following criteria were excluded from the study:

- Patients who have received previous antibiotics treatment before hospitalization
- Patients with electric and with chemical burns
- Pregnant females
- Patients who could not survive after 72 h.

Sample Collection

For the purpose of sample collection, the surface of burn wound was cleaned with normal saline to prevent contamination. Each sample was collected with a sterile cotton – tip swab stick, across the entire wound surface and the sample and was transported immediately to the laboratory for culture and sensitivity test.

The samples were processed immediately in the following manner:

a. Direct microscopic examination
b. Inoculation on different culture media
c. Preliminary identification of the growth
d. Biochemical tests
e. Antimicrobial susceptibility.

Standard microbiological techniques were used identification establishing the bacterial isolate.

Antibiotic susceptibility tests

Kirby–Bauer disk diffusion method was employed to determine the susceptibility of the bacteria isolate to antibiotics according to the standard protocols.

Data entry and analysis

The quantitative data were analyzed using descriptive statistics summarized and displayed on graphs and charts.

OBSERVATION AND RESULTS

Total admissions in the burn unit were 558. After the application of exclusion criteria, 112 swabs were obtained. Swabs were taken on days 0, 3, and 7.

Maximum prevalence was found for *P. aeruginosa,* i.e., 37.5% followed by *S. aureus,* for which the prevalence was found to be 18.75%. The organism least commonly cultured was *Acinetobacter*. Swabs were taken on days 0, 3, and 7. *Pseudomonas* was obtained in maximum number throughout, but most of the organisms were cultured maximally on day 7. About 25% of swabs were found to be negative on culture [Table 1 and Graph 1].

Among the patients in whom *S. aureus* was isolated, disk diffusion method using cefoxitin disks was used to detect MRSA. The prevalence of MRSA was found to be 57.14% and prevalence of methicillin resistance was found to be 42.8% in patients with *Staphylococcus epidermidis*. Overall, the prevalence of methicillin resistance was 51.72%.

The outcome of the wound was affected by the invasion of microorganisms. In patients with positive cultures, the complications were high as compared to patients with negative cultures [Table 2].

A total of 84 organisms were isolated and *P. aeruginosa* (42) was the most common isolate followed by *S. aureus* (21). The other isolates included *Klebsiella pneumoniae* (7), *Escherichia coli* (4), and coagulase-negative staphylococci (CoNS) (7). Overall, Gram-negative organisms were predominant accounting for 66.67% of the total isolates.

Table 1: Distribution of isolated organisms from burn wounds

Cultured organism	Day 0	Day 3	Day 7	Total	Percentage
Pseudomonas aeruginosa	5	15	22	42	37.5
Staphylococcus aureus	1	4	16	21	18.75
Staphylococcus epidermidis	-	2	5	7	6.25
Klebsiella pneumoniae	-	2	5	7	6.25
Escherichia coli	1	2	1	4	3.57
Acinetobacter	-	-	3	3	2.68
Culture negative	-	-		28	25
Total				112	100

Table 2: Distribution based on wound outcome in patients with positive cultures

Wound outcome	Culture positive but not MRSA	Percentage	MRSA	Percentage
Granulation	38	55.07	7	46.67
Hypergranulation	6	8.70	3	20
Healing	16	23.19	3	20
Contracture	9	13.04	2	13.33
Total	69	100	15	100

MRSA: Methicillin-resistant *Staphylococcus aureus*

The antimicrobial sensitivity pattern of the organisms to different antimicrobials varied depending on the isolate. The drugs most effective against *P. aeruginosa*, the most common isolate, were meropenem (97.62%) and piperacillin/tazobactam (90.48%) followed by gentamicin (64.29%). The other commonly used drugs that were tested showed moderate sensitivity in the range of 50–60%. The least effective drug was ceftazidime with 30.95% sensitivity [Table 3].

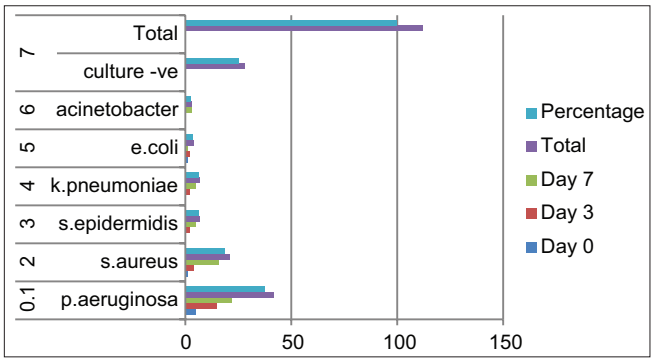
K. pneumoniae showed 100% sensitivity to meropenem and piperacillin/tazobactam. Ceftazidime and ceftriaxone followed with sensitivity of 57.14% and 28.57%, respectively. The other drugs showed high level of resistance [Table 3].

Meropenem and piperacillin/tazobactam showed 100% efficacy against the other Gram-negative bacilli isolated as well. Ceftriaxone, ceftazidime, and amikacin also showed good sensitivity against these isolates [Table 3].

Vancomycin and linezolid remained the most active drug in infections caused by Gram-positive organisms, closely followed by piperacillin/tazobactam with 95.24% sensitivity in *S. aureus* and 85.71% in *S. epidermidis*. The other drugs found to be effective against Gram-positive isolates included clindamycin (73.81%). Penicillin was least effective with a sensitivity rate of 21.43%. Others routinely used antimicrobials such as erythromycin, ciprofloxacin, amikacin, and cotrimoxazole were moderately effective [Table 4].

Methicillin resistance was tested using cefoxitin (30 ug) disk and it was found that 57.14% of *S. aureus* isolates and 42.8% of the CoNS isolates were methicillin resistant, but all the MRSA isolates showed 100% sensitivity to vancomycin and linezolid closely followed by piperacillin-tazobactam combination.

Of the total patients, 67.74% recovered with healthy wounds and were discharged. Death was reported in 29.03% of patients, whereas 3.23% of patients left against medical advice [Table 5 and Graph 2].



Graph 1: Distribution of isolated organisms from burn wounds

Table 3: Antibiotic susceptibility of Gram-negative organisms

Organism	CXM	CTR	COT	CIP	AK	GEN	MP	PIT	CAZ
Pseudomonas aeruginosa (42)									
n	NT	NT	NT	22	25	27	41	38	13
%	-	-	-	52.38	59.52	64.29	97.62	90.48	30.95
Klebsiella pneumoniae (7)									
n	0	2	0	1	0	1	7	7	4
%	0	28.57	0	14.29	0	14.29	100	100	57.14
Escherichia coli (4)									
n	1	3	0	1	2	2	4	4	2
%	25	75	0	25	50	50	100	100	50
Acinetobacter baumannii (3)									
n	NT	NT	0	1	0	1	3	3	1
%	-	-	0	33.33	0	33.33	100	100	33.33

Table 4: Antibiotic susceptibility of Gram-positive organisms

Organism	P	E	CD	LZ	VA	CIP	PIT	COT	AK	GEN
Staphylococcus aureus										
n	3	13	16	21	21	10	20	12	11	NT
%	14.29	61.90	76.19	100	100	47.62	95.24	57.14	52.38	-
Staphylococcus epidermidis										
n	2	3	5	7	7	3	6	3	4	NT
%	28.57	42.86	71.43	100	100	42.86	85.71	42.86	57.14	-

Table 5: Distribution based on patient outcome

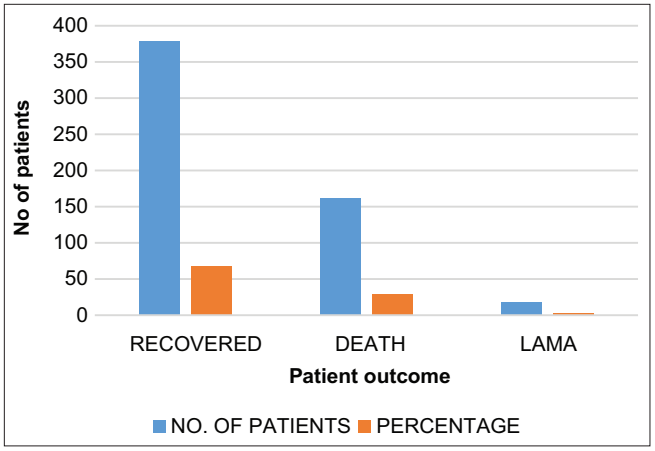
Outcome	Number of patients	Percentage
Recovered	378	67.74
Death	162	29.03
LAMA	18	3.23
Total	558	100

LAMA: Left against medical advice

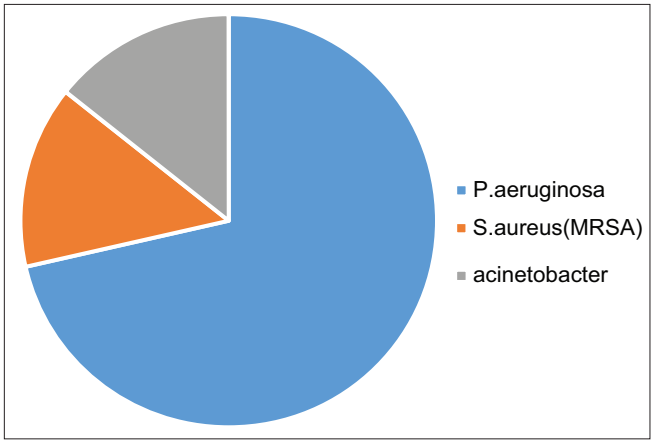
Table 6: Relation of isolated organism and patient outcome

Culture	Death	Percentage
Pseudomonas aeruginosa	5	71.42
Staphylococcus aureus (MRSA)	1	14.29
Acinetobacter	1	14.29
Total	7	100

MRSA: Methicillin-resistant *Staphylococcus aureus*



Graph 2: Patient outcome



Graph 3: Relation of isolated organism with patient outcome

Of the seven deaths reported among the culture-positive patients in this study, when correlated with the cultured organism, *Pseudomonas* was found positive in 71.42% where *S. aureus* and *Acinetobacter* were found positive in 14.29%. Infection with microorganisms was responsible for 7 (4.32%) of the total deaths (162) [Table 6 and Graphs 2 and 3.].

DISCUSSION

Bacterial infections of the burn wound still remains a major cause of morbidity and mortality in thermally injured patients. The burned patient is prey for a wide variety of microorganisms, as burns present an extensive surface

with a large mass of dead tissue and free exudation of serum which is favorable for bacterial growth. The burn site initially becomes colonized with microorganisms which if uncontrolled progresses to invasion and leads to bacteremia and sepsis, leading to mortality. For establishing the microbiological evidence, the swab culture technique was used because it is a simple, convenient, and effective.

In the present study, the overall isolation rate was found to be 75%. This was comparable with the findings of Srinivasan *et al.* (86.3%).[5] Others have reported higher isolation rates such as 95% by Kaur *et al*.[6] and 97.01% by Mehta *et al*.[7]

In our study, only solitary isolates were found. This is comparable to other studies by de Macedo and Santos,[8] Ramakrishnan *et al*., Kaushik *et al*.,[9] and Dhar *et al*.[10] who reported solitary isolation rates of 89.3%, 84%, 78%, and 58.42%, respectively.

Here, *P. aeruginosa* was the most common isolate in burn patients (37.5%). These results were similar to the results from other studies.[11-16] This is consistent with studies by Yousefi-Mashouf and Hashemi (2006). Similar finding was also reported by Dash *et al*.[17] (2013) (49.4%).

Kulkarni *et al*.[18] (2015) reported *Pseudomonas* spp. as the predominant bacteria causing burn wound infection in their study setting at Kalaburagi region in India. Agnihotri *et al*.[19] (2004) reported a high incidence of *Pseudomonas* spp. isolated in their study. *Pseudomonas* spp. (33.6%) was identified as the most common isolate in the study by Lakshmi *et al*.,[20] (2015). Similar findings on *Pseudomonas* spp. as the most common burns isolate have been reported (Ekrami and Kalantar,[21] 2007; Agnihotri *et al*.,[19] 2004).

In contrast, some other reports indicated a decrease in burn wound colonization with *P. aeruginosa*.[22] It has been opined that with the advent of antibiotics against Gram-positive organisms, a significant rise in *Pseudomonas* infection of burned patients had occurred. The prevalence of *Pseudomonas* species in the burn wards may be due to the fact that the organism thrives in a moist environment.[23,24]

The second most common isolate was *S. aureus* (18.75%), again similar to the reports from other studies.[10,23-25] This is in contrast, however, to some other studies, especially from developed countries which report *S. aureus* as the most predominant organism in burn patients.[26] *Staphylococcus* was the predominant cause of burn wound infection in the pre-antibiotic era and remains an important pathogen at present.[25] However, Srinivasan *et al.* stated that the percentage incidence of staphylococci is on the decline from 2002 to 2005.[5]

In our study, CoNS (*S. epidermidis*) were recovered at a frequency of 6.25%. This finding is similar to a study by Mama *et al.* (2014), in which they reported 14.5% CoNS isolated from wounds. CoNS being a normal skin flora and common contaminant of wound most often may be isolated[27] (Mama *et al*., 2014).

The only Gram-positive isolates were *Staphylococcus* and CoNS while Gram-negative bacteria identified were *P. aeruginosa*, *Klebsiella*, *Acinetobacter,* and Enterobacteriaceae (*E. coli*). The findings from the current study are consistent with the studies by Revathi *et al*.[28] (1998), Shahzad *et al.* (2012), Lakshmi *et al*.[20] (2015), Agnihotri *et al*.[19] (2004), Bayram *et al*.,[29] Kaur *et al*.[6] (2006), Nasser *et al*.,[30] and de Macedo and Santos.[8] Regardless of the incidence, in view of the immunocompromised status of the burned patients, it has been consistently stressed that CoNS should be considered a significant pathogen.

K. pneumoniae accounted for 6.25% of all the organisms isolated in our study. Our results were comparable with those of Kaur *et al*.,[6] Ekrami and Kalantar,[21] and Agnihotri *et al*.[18] who also reported a low incidence of this organism.

E. coli accounted for 3.57% of the total isolates. This low incidence of *E. coli* is in agreement with other studies, in which the frequency of the organism does not exceed 5%.[21] Nasser *et al.,* however, reported a higher incidence of *E. coli* (13.6%).[30] Srinivasan *et al.* stated that the prevalence of *E. coli* was on the rise from 2001 to 2004 and it has started to wean off from 2005 and 2006 in the successive years.[5]

The incidence of *Proteus* species is reported at frequencies as high as 11% to no incidence at all.[19] In our study, Proteus isolates were not obtained.

Contrary to the findings in the pre-antibiotic era, the isolation of beta-hemolytic streptococci from burn wounds has now become rare.[24] Our study is consistent with this and we found no isolate.

A. baumannii has also gained importance as an emerging nosocomial pathogen of burn wounds and is a cause for much concern due to rapid increase in resistance to a variety of antimicrobial agents.[31,32] In our study, the prevalence of *Acinetobacter* was found to be 2.68%, which is in correlation with studies conducted by Singh *et al*.[33] and Sengupta *et al*.[34]

Among the patients in whom *S. aureus* was isolated, tests were applied to detect MRSA. The prevalence was found to be 57.14% in patients with *S. aureus* infection and 42.8% in patients with *S. epidermidis*. Overall, the prevalence of MRSA was 51.72%.

According to an Indian study, the prevalence of infections caused by MRSA has increased from 12% in 1992 to 80.03% in 1999. The prevalence of MRSA infection in the study by Naqvi *et al.* was 24.6%. It is less than that reported by Mokaddas *et al.,* 1996, i.e., 74.6% and other studies conducted in Guru Teg Bahadur Hospital in New Delhi from 1997 to 2002 (Singh *et al*., 2003). Muscat, Oman, the prevalence of MRSA was about 95% during 1995–96 (Prasanna and Thomas, 1999). In another study, all isolates of *S. aureus* were resistant to methicillin at Gulhane Military Medical Academy, Istanbul, Turkey (Oncul *et al*., 2009). Authors suggested that many factors may account for increased incidence of MRSA colonization and infection. These included the use of broad-spectrum antibiotics, average length of hospital stay, and poor hospital infection control practices. A similar picture is also reflected in the present study.

The antimicrobial sensitivity testing was done by Kirby–Bauer's disk diffusion method. The drugs most effective against *P. aeruginosa*, the most common isolate, was meropenem (97.62%). *K. pneumoniae* showed 100% sensitivity to meropenem and piperacillin/tazobactam meropenem was similarly being reported by Guggenheim *et al*.[35] (2009). The current study is also consistent with findings by Bayram *et al*.[29] (2013) and Lashkmi *et al*.[20] (2015). Mundhada *et al.* (2015) reported similar findings in their study that Gram negative was susceptible to imipenem (B-lactam antibiotic) and amikacin (an aminoglycoside). Piperacillin/tazobactam (95.24%) was effective against all the isolates. Among the Gram-negative isolates, the most effective drug was meropenem showing 99.40% sensitivity. This is in accordance with a study by Guggenheim *et al.*

The drugs most effective against *P. aeruginosa*, the most common isolate, were meropenem (97.62%) and piperacillin/tazobactam (90.48%) followed by gentamicin (64.29%). The other commonly used drugs that were tested showed moderate sensitivity in the range of 50–60%. The least effective drug was ceftazidime with 30.95% sensitivity.

K. pneumoniae showed 100% sensitivity to meropenem and piperacillin/tazobactam. Ceftazidime and ceftriaxone followed with sensitivity of 57.14% and 28.57%, respectively. The other drugs showed high level of resistance.

Meropenem and piperacillin/tazobactam showed 100% efficacy against the other Gram-negative bacilli isolated as well. Ceftriaxone, ceftazidime, and amikacin also showed good sensitivity against these isolates.

Vancomycin and linezolid remained the most active drug in infections caused by Gram-positive organisms, closely followed by piperacillin/tazobactam with 95.24% sensitivity in *S. aureus* and 85.71% in *S. epidermidis*. The other drugs found to be effective against Gram-positive isolates included clindamycin (73.81%). Penicillin was least effective with a sensitivity rate of 21.43%. Others routinely used antimicrobials such as erythromycin, ciprofloxacin, amikacin, and cotrimoxazole were moderately effective.

Mehta *et al.* saw a significantly high percentage of resistance among Gram-negative bacilli to aminoglycosides, ciprofloxacin, carbenicillin, tobramycin, and ceftriaxone. However, in comparison, imipenem and combination drugs such as cefoperazone/sulbactam were found to be effective.[7]

de Macedo and Santos,[8] Singh *et al*.,[33] and Lari and Alaghehbandan[25] also reported a high degree of resistance to antimicrobial agents.

The Gram-positive isolates showed 100% sensitivity to vancomycin and linezolid followed by 94.29% sensitivity to piperacillin/tazobactam. Only 24.29% of the isolates were sensitive to penicillin.

Similar findings were seen by Lari and Alaghehbandan[25] and Kaushik *et al*.[9]

However, several other studies have observed a higher level of resistant of these organisms to these antimicrobials.

Methicillin resistance was tested using cefoxitin (30 ug) disk and it was found that 57.14% of *S. aureus* isolates and 42.8% of the CoNS isolates were methicillin resistant, but all the MRSA isolates showed 100% sensitivity to vancomycin and linezolid closely followed by piperacillin-tazobactam combination.

This is in accordance with other studies on MRSA in burn patients by Rajput *et al*.[24] and Oncul *et al*.[36] They both reported 40% incidence of MRSA. About 33.3% of the CoNS isolates were methicillin resistant. This finding is similar to that by Altoparlak *et al.* who reported 20.9% isolates of CoNS to be methicillin resistant.

Resistance to antibiotics in burn isolates reported previously has shown a gradual increase in resistance overtime as stated in their study by Agnihotri *et al*.[19] Many studies have shown that most of the organisms causing infection in burn patients are highly resistant to routinely used antibiotics as discussed by Imran *et al*.[26]

High resistance to antibiotic may be due to self-medication, inappropriate antibiotic use as a result of unavailability of guideline regarding drug selection (Mama *et al*., 2014).[27]

From the current study, it may be concluded that some of the patients may have already developed resistance to antibiotics that were administered to them. Subsequently, antibiotics administered to them prior culture may possibly affect bacteria growth and resistance. Paruk *et al.* (2012) in their study in intensive care units in South Africa reported that inappropriate antibiotics administered to patients were associated with poor patient outcome.

The resulting antibiograms give some cause for concern because the predominant bacterial isolates were relatively resistant to the commonly available, more economical antimicrobials. However, this was not entirely unexpected as hospitals are an important breeding ground for the development and spread of antibiotic resistance. This is the consequence of exposing to heavy antibiotic use, a high density of patient population in frequent contact with health-care staff, and patient attendant increase the risk of cross infection.

Relation of isolated organism and patient outcome

Of the seven deaths reported among the culture-positive patients in this study, when correlated with the cultured organism, *Pseudomonas* was found positive in 71.42% where *S. aureus* and *Acinetobacter* were found positive in 14.29%. Infection with microorganisms was responsible for 7 (4.32%) of the total deaths (162).

SUMMARY

1. The overall isolation rate was 75%. Only solitary isolates were studied. Overall, Gram-negative organisms (66.66%) were more common than Gram-positive organisms (33.33%)
2. *P. aeruginosa* (37.5%) was the most common isolate followed by *S. aureus* (18.75%), CoNS (6.25%), *K. pneumoniae* (6.25%), *E. coli* (3.57%), and *Acinetobacter* (2.68%)
3. The prevalence of MRSA was 57.14%, but all the MRSA isolates showed 100% sensitivity to vancomycin and linezolid closely followed by piperacillin-tazobactam combination. The prevalence of methicillin resistance overall among *S. aureus* and *S. epidermidis* was found to be 51.72%
4. On antibiotic sensitivity testing, piperacillin/tazobactam (95.24%) was found to be the most effective drug against all the organisms isolated
5. Meropenem (99.40%) was the most effective drug against the Gram-negative organisms. Least effective drug against Gram-negative organisms was cotrimoxazole
6. Vancomycin (100%) and linezolid (100%) were the most effective drugs for the Gram-positive organisms. Least sensitive drug against Gram-positive organisms was penicillin (21.43%).

CONCLUSIONS

To ensure early and appropriate therapy, routine microbiological surveillance and a regular update of their antimicrobial susceptibility pattern could help in prevention of the development of multidrug resistance. Among other precautions, personal hygiene of the patients and handwashing practice among health-care providers are to be emphasized and practiced routinely.

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Original Article

Comparison of Hemodynamic Response and Vasopressor Requirement Following Spinal Anesthesia between Normotensive and Hypertensive Women Undergoing Elective Cesarean Section

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Abstract

Introduction: Spinal anesthesia (SA) is the technique of choice in cesarean sections, but it is not widely accepted in hypertension due to fear of sudden and extensive sympathetic blockade. Sympathetic blockade induced hypotension may occur in up to 64–100% of pregnant women who have been given spinal anesthesia for cesarean delivery, especially when hyperbaric solutions are used. Severely pre-eclamptic patients were previously believed to be at high risk of severe hypotension, with maternal and fetal consequences because of reduced plasma volume and because of the need to limit i.v. fluids to avoid iatrogenic pulmonary edema.

Methodology: The present study, "comparison of hemodyanamic response and vasopressor requirement following spinal anesthesia between normotensive and hypertensive women undergoing elective cesarean section" 100 women of age 20–35 years, the American Society of Anesthesiologists physical Status I and II carrying a singleton pregnancy and scheduled to have elective cesarean section in Netaji Subhash Chandra Bose Medical College, Jabalpur, were enrolled into two groups. Group A: 50 were normotensive women and Group B: 50 were hypertensive women. All patients received a standard subarachnoid block under all aseptic precautions with 12.5 mg 0.5% hyperbaric bupivacaine.

Results: Based on the data from our study, it could be concluded that after spinal anesthesia in patients undergoing elective cesarean section-hypertensive group of parturients had less fall in mean systolic blood pressure (SBP), diastolic BP, and mean arterial BP in comparison to normal healthy pregnant women which were statistically significant ($P < 0.05$). Hypertensive group of patients required less ephedrine to treat hypotension in comparison to normotensive patients which were statistically significant ($P < 0.05$). The incidence of hypotension was almost 7 times less in hypertensive parturients than healthy parturients (odds ratio = 23.14, relative risk of hypotension in Group A = 7.2, confidence interval = 7.6–70.3).

Conclusion: To summarize, our results showed that hypotension following SA administered for cesarean section was significantly less in hypertensive patient than in healthy pregnant women. In addition, vasopressor requirements were also less in hypertensive parturients and neonatal outcome was comparable between the two groups. Therefore, subarachnoid block is an acceptable technique to perform in hypertensive parturients due to its virtue of simplicity, rapidity, cost-effectiveness, and intensity of block.

Key words: Caesarean, Hypertension, Spinal anaesthesia, Vasopressor

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INTRODUCTION

Spinal anesthesia has been shown to block the stress response to surgery, decrease intraoperative blood loss, lower the incidence of post-operative thromboembolism, and decrease morbidity and mortality in high-risk patients.[1]

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Cardiovascular system may be profoundly affected by spinal anesthesia (SA) due to unavoidable sympathetic blockade.[2] Numerous studies have been conducted to study the cardiovascular effects of spinal blockade. Hypotension is the most frequent side effect of spinal anesthesia, occurring in more than 30% of patients.[3]

SA is the technique of choice in cesarean sections, but it is not widely accepted in hypertension due to fear of sudden and extensive sympathetic blockade.[4]

In a normal pregnancy, there is reduced sensitivity to exogenous vasoconstrictors leading to the increased vasopressor requirement to reverse the hypotensive effect after subarachnoid block (SAB). In preeclampsia, there is an increased sensitivity to vasoconstrictor agents and less vasopressor is required.[5]

Ephedrine is an indirectly acting α and β adrenergic agonist. A recent survey found that it was used as the sole vasopressor by 95% of consultant obstetric anesthetists in the UK.[6]

The purpose of our study was to compare the hemodynamic response and vasopressor requirement following spinal anesthesia between normotensive and hypertensive women undergoing cesarean section.

METHODOLOGY

The study was carried out in the Department of Anaesthesiology and Critical Care, Netaji Subhash Chandra Bose (NSCB) Medical College and Hospital, Jabalpur (Madhya Pradesh).

Selection of Cases

In this study, 100 women of age 20–35 years, the American Society of Anesthesiologists (ASA) physical Status I and II carrying a singleton pregnancy and scheduled to have an elective cesarean section were enrolled into two groups.

- Group A: 50 were normotensive women
- Group B: 50 were hypertensive women.

The patient with severe preeclampsia was treated with antihypertensive and anticonvulsant (labetalol and alpha methyldopa) and prophylactic dose of magnesium sulfate as part of their routine management in the department of obstetrics and gynecology.

A detailed history, thorough physical examination, routine investigations, and any special investigation if required done for the study.

Criteria for Exclusion

- Patients who refuse for spinal anesthesia
- Patients in whom regional anesthesia is contraindicated
- Patients suffering from coagulopathy, blood dyscrasias, and on anticoagulant therapy
- Patients with congenital heart disease
- Patients with increased intracranial pressure
- Patients with skin sepsis and marked spinal deformity
- Patient with fetal distress, eclampsia, and HELLP syndrome
- Patients with a decreased level of consciousness.

Design of Study

This was a prospective cohort study.

Study Protocol

The careful pre-anesthetic examination was performed and informed consent was taken. No premedication was given.

After shifting the patient in the operating room, routine monitoring devices such as electrocardiogram leads, noninvasive blood pressure (BP) cuff, and pulse oximetry probe were setup. Baseline hemodynamic variables (heart rate [HR], systolic BP [SBP], diastolic BP [DBP], and mean arterial pressure [MAP]) were recorded. Baseline BP was measured as the mean of the three readings taken 5 min after arrival in operation theatre and before doing any invasive procedure. An intravenous access (18 G cannula) was inserted. Ringer lactate (15 ml/kg) was infused as preload. All patients received a standard spinal block under all aseptic conditions as following:

The patient was placed on the operating table in the left lateral position with back and thighs curved and flexed. Under all aseptic precautions, SAB was administered using 25 G Quincke needle in the left lateral position at L3-L4 intervertebral space with 12.5 mg hyperbaric 0.5% bupivacaine. All patients were placed in supine position. All patients received supplemental oxygen immediately after administration of spinal anesthesia.

Sensory level was tested by pinprick method, surgery was allowed as soon as upper level of sensory block reached at T4 level. BP and HR of the patient were measured in the 1st min and then every 3 min until fetal delivery and then every 5 min until the end of operation.

We administered 6 mg of ephedrine when SBP falls about 30% of baseline or when it is <100 mmHg. Lowest SBP, DBP, and MAP were noted for each patient and for the HR both lowest and highest value was recorded.

We also evaluated dose of ephedrine requirement and total amount of ephedrine administered.Patients with inadequate SAB were excluded from the study.

Materials Required

1. Spinal trolley with 25 G spinal needle
2. 5 ml disposable syringe
3. Inj. bupivacaine heavy (0.5%)
4. Inj. ephedrine
5. Emergency drugs/intubation kit
6. Resuscitation kit.

OBSERVATION AND RESULTS

In the present study, 100 women of age 20–35 years, ASA physical Status I and II carrying a singleton pregnancy and scheduled to have an elective cesarean section were enrolled into two groups.

- Group A: 50 were normotensive women
- Group B: 50 were hypertensive women

The patient with severe preeclampsia was treated with antihypertensive and anticonvulsant (labetalol and alpha methyldopa) and prophylactic dose of magnesium sulfate as part of their routine management in the department of obstetrics and gynecology

- All patients received a standard subarachnoid block under all aseptic precautions with 12.5 mg 0.5% bupivacaine heavy
- All data pertaining to demographic characteristics, pulse rate, SBP, DBP, mean arterial BP, and ephedrine requirement in the study group were recorded and subjected to statistical analysis. All case report forms were checked for completeness and inappropriate or illogical responses. The databases were validated and all inconsistencies and differences were resolved. Statistical analyses were performed using software IBM SPSS version 20. Alpha error was considered to be 0.05 (5%). Student's *t*-test, Fisher exact test, and Chi-square test were used the difference in various variables as age, weight, height, and other indicators monitored in the study. In all tests, $P < 0.05$ was taken as statistical significance level.

Table 1 shows the mean age, weight, and height of patients in both the study groups. These data are statistically not significant, as $P > 0.05$ [Graphs 1-3].

Table 2 shows the change in pulse rate in patient of two study groups. There was an initial rise in pulse rate after giving spinal anesthesia and positioning and then gradual fall in pulse rate in patients of both groups which was statistically but not clinically significant. Later on, pulse rate was observed to rise back to pre-operative value [Graph 4].

Table 3 shows the change in mean SBP in patient of two study groups. There was a fall in mean SBP from

Table 1: Demographic data (age, weight, and height)

	Group A		Group B		*P*-value
	Mean	±SD	Mean	±SD	
Age (years)	26.7	1.8	23.7	1.01	0.804
Weight (kg)	57.3	2.1	56.6	3.0	0.176
Height (cm)	157.1	2.4	156.8	2.6	0.54

SD: Standard deviation

Table 2: Changes in intraoperative pulse rate

Group	Pre-SBP (mmHg)	1 min SBP	3 min SBP	8 min SBP	13 min SBP	18 min SBP	23 min SBP	28 min SBP	33 min SBP	38 min SBP	43 min SBP	48 min SBP	53 min SBP	58 min SBP
A (50)														
Mean	75.90	79.4	82.9	82.2	80.0	79.2	77.0	76.2	75.4	75.4	75.3	74.5	74.8	75.4
Standard deviation	5.350	4.92	5.04	4.82	4.71	5.60	5.54	4.40	4.30	3.91	3.89	4.46	5.42	5.20
B (50)														
Mean	96.04	98.6	102	96.5	94.2	92.6	90.6	89.3	87.8	88.0	89.0	89.8	90.5	90.5
Standard deviation	4.526	4.53	4.13	3.73	3.85	4.77	4.22	3.56	3.83	4.10	3.89	3.64	3.86	3.41
P-value	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

SBP: Systolic blood pressure

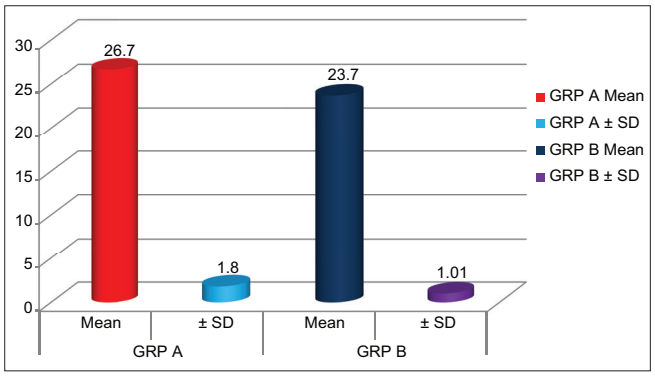
Table 3: Intraoperative SBP

Group	Pre-SBP (mmHg)	1 min SBP	3 min SBP	8 min SBP	13 min SBP	18 min SBP	23 min SBP	28 min SBP	33 min SBP	38 min SBP	43 min SBP	48 min SBP	53 min SBP	58 min SBP
A (50)														
Mean	117.36	111.18	102.90	97.34	101.02	103.88	102.00	105.26	105.48	106.56	107.52	108.38	109.12	109.80
Standard deviation	4.960	4.159	4.908	7.196	5.430	2.946	5.599	2.354	2.950	2.442	1.919	1.772	2.007	1.852
B (50)														
Mean	154.60	148.06	141.44	135.22	132.48	130.78	130.34	131.06	132.56	134.20	135.62	136.82	138.18	140.02
Standard deviation	3.670	4.515	6.247	9.161	5.060	5.582	5.780	5.593	5.496	5.610	5.066	5.074	4.443	4.167
P-value	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

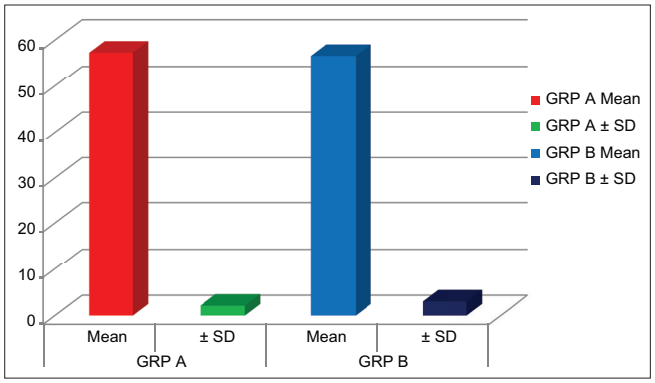
SBP: Systolic blood pressure

pre-operative value in patients of both groups. Later on, the SBP was observed to rise back near to pre-operative values. Fall in mean SBP was more in Group A (117.3 ± 4.9–97.3 ± 7.1) in comparison to Group B (154.6 ± 3.6–130.34 ± 5.7) which was statistically significant ($P < 0.05$) [Graph 5].

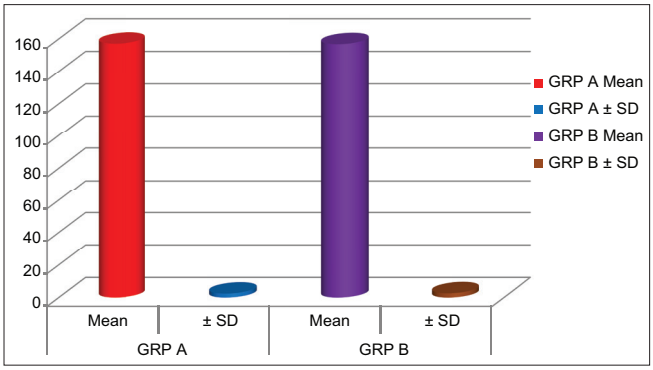
Table 4 shows the change in mean DBP in patient of two study groups. There was a fall in mean DBP from pre-operative value in patients of both groups. Later on, the



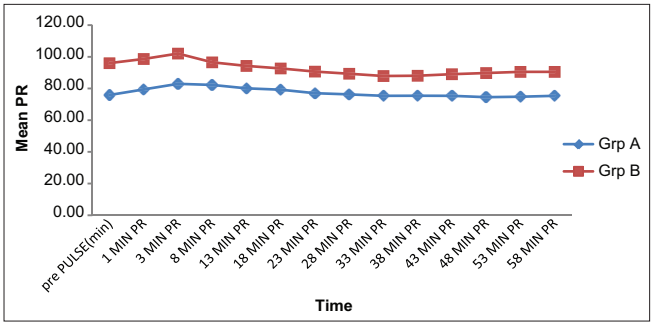
Graph 1: Mean age



Graph 2: Mean weight



Graph 3: Mean height



Graph 4: Changes in intraoperative pulse rate

Table 4: Intraoperative diastolic blood pressure

Group	Pre-SBP (mmHg)	1 min SBP	3 min SBP	8 min SBP	13 min SBP	18 min SBP	23 min SBP	28 min SBP	33 min SBP	38 min SBP	43 min SBP	48 min SBP	53 min SBP	58 min SBP
A (50)														
Mean	76.1	70.4	64.7	60.5	60.0	60.3	59.5	60.4	61.4	62.8	64.2	65.2	66.4	67.3
Standard deviation	5.92	6.49	6.70	6.77	5.21	4.63	4.78	4.46	3.85	3.91	3.56	3.62	3.80	3.42
B (50)														
Mean	100.2	97.0	94.1	90.9	89.6	88.8	89.3	90.1	91.0	91.9	92.5	93.8	94.9	95.4
Standard deviation	3.019	3.80	4.67	7.07	4.69	4.24	4.31	4.51	4.64	4.94	4.25	4.03	3.59	3.32
P-value	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

SBP: Systolic blood pressure

Table 5: Intraoperative mean arterial blood pressure

Group	Pre-SBP (mmHg)	1 min SBP	3 min SBP	8 min SBP	13 min SBP	18 min SBP	23 min SBP	28 min SBP	33 min SBP	38 min SBP	43 min SBP	48 min SBP	53 min SBP	58 min SBP
A (50)														
Mean	89.2	83.6	77.2	72.5	73.4	74.6	73.5	75.1	75.7	77.1	78.4	79.2	80.3	81.1
Standard deviation	5.7	5.4	5.8	6.2	4.2	3.4	4.5	2.7	2.7	2.8	2.4	2.7	2.9	2.5
B (50)														
Mean	117.9	113.8	109.6	105.4	103.6	102.6	102.6	103.3	104.4	105.5	106.6	107.8	109.0	109.9
Standard deviation	2.9	3.7	5.0	7.6	4.5	4.3	4.2	4.3	4.2	4.4	3.9	3.6	3.4	3.0
P-value	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001	<0.001

SBP: Systolic blood pressure

DBP was observed to rise back near to pre-operative values. Fall in mean DBP was more in Group A (76.1 ± 5.9–59.5 ± 4.7) in comparison to Group B (100.2 ± 3.0–88.8 ± 4.2) which was statistically significant ($P < 0.05$) [Graph 6].

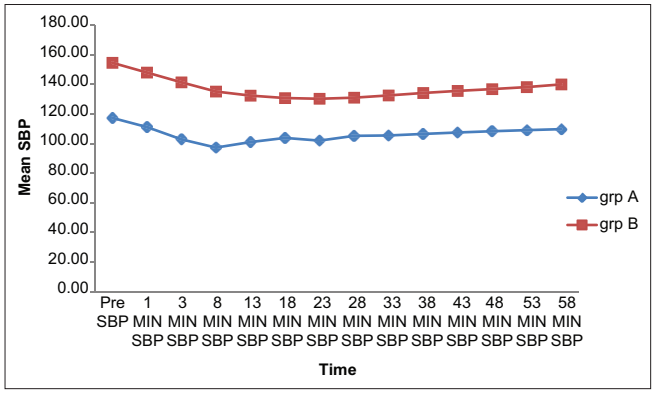
Table 5 shows the change in mean arterial BP in patient of two study groups. There was a fall in mean arterial BP from pre-operative value in patients of both groups. Later on, the arterial BP was observed to rise back near to pre-operative values. Fall in mean arterial BP was more in Group A (89.1 ± 5.6–72.5 ± 6.2) in comparison to Group B (117.9 ± 2.9–102.56 ± 4.2) which was statistically significant ($P < 0.05$) [Graph 7].

Table 6: Intraoperative ephedrine requirement

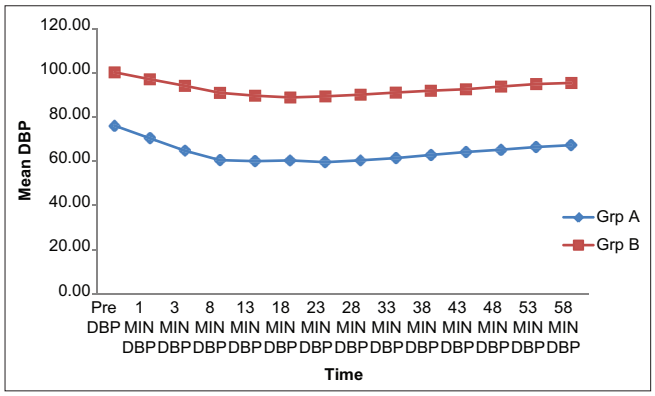
Group	*n*	Mean	Standard deviation
A	36	8.50	3.0
B	5	6.00	0.0
Total	41	8.20	2.9

Table 7: Cases with significant hypotension

Groups	Cases with significant hypotension	Percentage
A	36	72.0
B	5	10.0
Total	41	41.0



Graph 5: Intraoperative systolic blood pressure



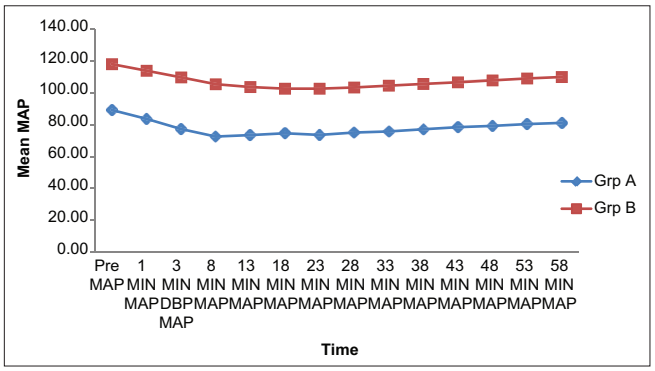
Graph 6: Intraoperative diastolic blood pressure

Table 6 shows the mean ephedrine requirement intraoperatively in both the study groups. Mean ephedrine requirement was less in Group B (5 patients; 6 mg) as compared to Group A (36 patients; 8.5 mg) which was statistically significant [Graph 8].

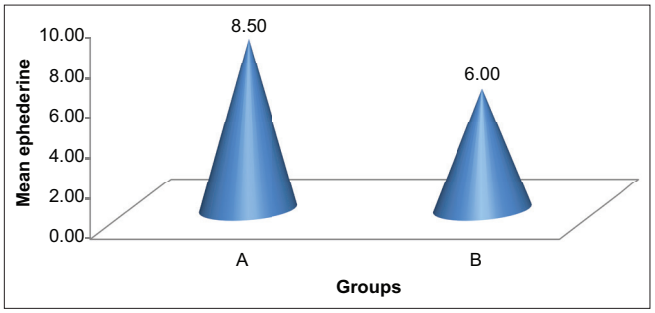
Table 7 shows cases with significant hypotension in both the study groups. In Group A 72% patients experienced significant hypotension requiring ephedrine treatment in comparison to Group B, 10% patients experienced significant hypotension requiring ephedrine treatment which is statistically significant ($P < 0.05$) [Graph 9].

DISCUSSION

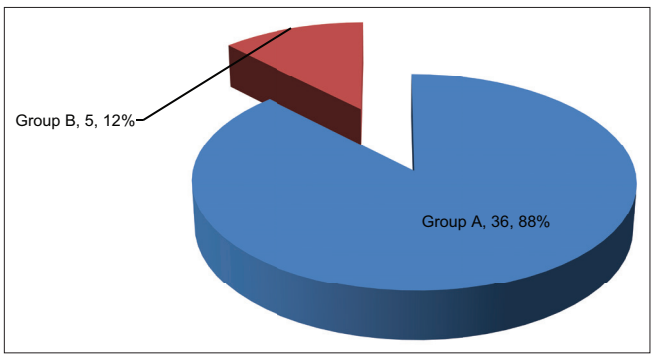
Spinal anesthesia is the most preferred technique because of its simplicity, rapid onset of action, and reliability in



Graph 7: Intraoperative mean arterial blood pressure



Graph 8: Intraoperative ephedrine requirement



Graph 9: Cases with significant hypotension

producing uniform sensory and motor blockade. Spinal anesthesia has been shown to block the stress response to surgery, decrease intraoperative blood loss, lower the incidence of post-operative thromboembolism, and decrease morbidity and mortality in high-risk patients.

Cardiovascular system may be profoundly affected by SA due to unavoidable sympathetic blockade.[2] Numerous studies have been conducted to see the cardiovascular effects of spinal blockade. Hypotension is the most frequent side effect of spinal anesthesia, occurring in more than 30% of patients.[3]

SA is the technique of choice in cesarean sections, but it is not widely accepted in hypertensive patient due to fear of sudden and extensive sympathetic blockade.[4]

Sympathetic blockade induced hypotension may occur in up to 64–100% of pregnant women who have been given spinal anesthesia for cesarean delivery, especially when hyperbaric solutions are used.[7,8] Severely pre-eclamptic patients were previously believed to be at a high risk of severe hypotension, with maternal and fetal consequences[8] because of reduced plasma volume and because of the need to limit i.v. fluids to avoid iatrogenic pulmonary edema.[9,10]

Hypertensive disorders in pregnancy are among the leading causes of maternal mortality, along with thromboembolism, hemorrhage, and nonobstetric injuries.

Although regional anesthesia is used in this group of parturients, current clinical experience demonstrated relative safety of regional technique over general anesthesia. Due to hazards related to the management of the difficult airway and to the hemodynamic consequences of laryngoscopy and tracheal intubation,[11,12] general anesthesia is usually chosen only when regional techniques are contraindicated.

In a normal pregnancy, increased synthesis of endogenous vasodilators such as prostaglandins and nitric oxide produces a vasodilated state, and there appears an increased dependence on sympathetic vasoconstriction for control of vascular tone. This explains the sudden and excessive hypotension after sympathetic blockade produced by SAB in them.[13]

In preeclampsia, vascular endothelial damage occurs, which produces an increased amount of endogenous vasopressors such as thromboxane and endothelin which are responsible in maintaining vessel tone. Sympathetic block following SAB does not alter this vascular response, limiting the excessive fall of BP in pre-eclamptic.[14,15]

In a normal pregnancy, there is reduced sensitivity to exogenous vasoconstrictors leading to the increased vasopressor requirement to reverse the hypotensive effect after SAB. In pre-eclampsia, there is an increased sensitivity to vasoconstrictor agents and less vasopressor is required.[5]

Vascular tone, which modulates BP, is under regulation of two systems: Sympathetic nervous system and vascular endothelium. In pre-eclamptic patients, there are sympathetic over activity and some defects in vascular endothelium which decrease vascular relaxation. Secretion of vasopressor factors in circulation will also be increased. In contrast to sympathetic system, vasopressor factors and endothelial system will not be affected by SA and it may increase the vascular tonicity and reduce the rate of hypotension development. Moreover, due to the presence of high sensitivity of vasculature to vasoconstrictor drugs in pre-eclamptic patients, one can treat hypotension with smaller dose of vasoconstrictors such as ephedrine. All the above mechanisms explain the results of our study that why BP decreases gradually in preeclampsia during cesarean section under SA. On the basis of this theory, BP of these patients will be regulated by a lower amount of ephedrine.

In the present clinical study, "comparison of hemodyanamic response and vasopressor requirement following spinal anesthesia between normotensive and hypertensive women undergoing elective cesarean section."

One hundred women of age 20–35 years, ASA physical Status I and II carrying a singleton pregnancy and scheduled to have an elective cesarean section in NSCB Medical College, Jabalpur, were enrolled into two groups.

- Group A: 50 were normotensive women.
- Group B: 50 were hypertensive women

Patients with severe preeclampsia were treated with antihypertensive and anticonvulsant (labetalol and alpha methyldopa) and prophylactic dose of magnesium sulfate as part of their routine management in the department of obstetrics and gynecology.

- A detailed history, thorough physical examination, routine investigations, and any special investigation as required were done for the study.
- All patients received a standard subarachnoid block under all aseptic precautions with 12.5 mg 0.5% bupivacaine heavy.
- The patients included in this study were comparable regarding demographic characteristics; the mean age of the patients in years in Group A was 26.7 ± 1.8 and in Group B was 23.7 ± 1.0.
- The mean weight of patients in kg in Group A was 57.3 ± 2.1 and in Group B was 56.6 ± 3.0.

- The mean height of patients in cm in Group A was 157.1 ± 2.4 and in Group B was 156.8 ± 2.6.
- Since both the groups were demographically similar ($P > 0.05$ in comparison), it can be presumed that groups were comparable for the purpose of the study. All the patients were preloaded uniformly with Ringer's lactate 10 ml/kg to offset the effect of relative hypovolemia or hypotension.
- The main finding of our study was that in patients undergoing elective cesarean section under hyperbaric bupivacaine spinal anesthesia, hypertensive group of patients experienced less significant fall in BP, and less ephedrine requirement in comparison to normotensive group of patients.

Preoperatively mean pulse rate in Group A was 75.9/min and in Group B was 96.0/min. After giving spinal anesthesia and positioning, there was a initial rise in pulse rate and then gradual fall in both groups of patients. Later on, pulse rate was observed to rise back to pre-operative value. The mean difference between both groups was statistically significant ($P < 0.05$).

Mean SBP in Group A was 117.3 mmHg and in Group B was 154.6 mmHg. There was a fall in mean SBP from pre-operative value in patients of both groups. Later on, the SBP was observed to rise back near to pre-operative values. Fall in mean SBP was more in Group A (117.3 ± 4.9–97.3 ± 7.1) in comparison to Group B (154.6 ± 3.6–130.34 ± 5.7). The mean difference between both groups was statistically significant ($P < 0.05$).

Mean DBP in Group A was 76.1 mmHg and in Group B was 100.2 mmHg. There was a fall in mean DBP from pre-operative value in patients of both groups. Later on, the DBP was observed to rise back near to pre-operative values. Fall in mean DBP was more in Group A (76.1 ± 5.9–59.5 ± 4.7) in comparison to Group B (100.2 ± 3.0–88.8 ± 4.2). The mean difference between both groups was statistically significant ($P < 0.05$).

MAP in Group A was 89.1 mmHg and in Group B was 117.9 mmHg. There was a fall in mean arterial BP from pre-operative value in patients of both groups. Later on, the arterial BP was observed to rise back near to pre-operative values. Fall in mean arterial BP was more in Group A (89.1 ± 5.6–72.5 ± 6.2) in comparison to Group B (117.9 ± 2.9–102.56 ± 4.2). The mean difference between both groups was statistically significant ($P < 0.05$).

Aya *et al.*[14] compared the incidence and severity of SA – associated hypotension in severely pre-eclamptic (*n* - 30) versus healthy (*n* - 30) parturients undergoing cesarean delivery. The severely pre-eclamptic patients comparatively had a less frequent incidence of clinically significant hypotension than the normotensive parturients (16.6% vs. 53.3%).

Aya *et al.*[13] compared the hemodynamic changes between severe pre-eclamptic (*n* - 65) and parturients with pre-term pregnancies (*n* - 71) undergoing SA for cesarean delivery. Hypotension was less frequent in pre-eclamptic patients than in women with pre-term pregnancies (24.6% vs. 40.8%, respectively).

Emmett *et al.*[16] did a hospital-based cohort study comparing the effects of SA between pre-eclamptic patients and normal pregnant women during cesarean section. With their observations, they concluded that the development of hypotension was less in pre-eclamptic women than healthy pregnant women during cesarean section under spinal anesthesia.

Saha *et al.*[17] did a study to compare the hemodynamic response and vasopressor requirement following spinal anesthesia between normotensive and severe pre-eclamptic women undergoing cesarean section. A total of 60 patients included in studies divided into two groups of 30 each (30 healthy patients and 30 severe pre eclamptic patients). The minimum SBP, DBP, and MAP recorded were lower in normotensive, and the difference between two groups was statistically significant.

Our observations in relation to incidence and magnitude of hypotension were congruent to the above-mentioned studies.[13,14,16,17]

We administered 6 mg of ephedrine when SBP falls about 30% of baseline or when it is <100 mmHg. Mean ephedrine requirement was less in Group B (5 patients; 6 mg) in comparison to Group A (36 patients; 8.5 mg). The mean difference between both groups was statistically significant ($P < 0.05$).

In Group A, 72% patients experienced significant hypotension requiring ephedrine treatment in comparison to Group B, 10% patients experienced significant hypotension requiring ephedrine treatment. Risk of hypotension was almost 7 times less in Group B. (odds ratio = 23.14, relative risk of hypotension in Group A = 7.2, confidence interval = 7.6–70.3).

Aya *et al.*[14] observed that severely pre-eclamptic patients had a less frequent incidence of clinically significant hypotension (16.6% vs. 53.3%) which was less severe and required less ephedrine. The risk of hypotension was almost six times less in severely pre-eclamptic patients than that in healthy patients.

Aya *et al*.[13] studied that pre-eclamptic patients (n = 65) required less ephedrine than women in the pre-term group (n = 71) to restore BP to baseline levels (9.8–4.6 mg vs. 15.8–6.2 mg, respectively). The risk of hypotension in the pre-eclamptic group was almost 2 times less than that in the pre-term group.

Valami *et al*.[16] studied that dosage of ephedrine injection in pre-eclamptic patients was less than healthy pregnant women during cesarean section under SA.

Saha *et al*.[17] studied that mean phenylephrine requirement in the normotensive group (151.1 ± 70) was significantly greater (P < 0.0001) than that of pre-eclamptic group (48.3 ± 35). Apgar scores at 1 and 5 min after birth were comparable in both the groups. They used phenylephrine instead of ephedrine.

Our observations in relation to incidence of hypotension and vasopressor requirement were congruent to the above-mentioned studies.[13,14,16,17]

SUMMARY AND CONCLUSION

SA is the technique of choice in cesarean sections, but it is not widely accepted in hypertension due to fear of sudden and extensive sympathetic blockade.[4]

Sympathetic blockade induced hypotension may occur in up to 64–100% of pregnant women who have been given spinal anesthesia for cesarean delivery, especially when hyperbaric solutions are used.[7,8] Severely pre-eclamptic patients were previously believed to be at high risk of severe hypotension, with maternal and fetal consequences[10] because of reduced plasma volume and because of the need to limit i.v. fluids to avoid iatrogenic pulmonary edema.[9,10]

The present study, "comparison of hemodyanamic response and vasopressor requirement following spinal anesthesia between normotensive and hypertensive women undergoing elective cesarean section" 100 women of age 20–35 years, ASA physical Status I and II carrying a singleton pregnancy and scheduled to have and elective cesarean section in NSCB Medical College, Jabalpur, were enrolled into two groups.

- Group A: 50 were normotensive women
- Group B: 50 were hypertensive women.

All patient received a standard subarachnoid block under all aseptic precautions with 12.5 mg 0.5% hyperbaric bupivacaine.

Based on the data from our study, it could be concluded that after spinal anesthesia in patients undergoing elective cesarean section.

Hypertensive group of parturients had less fall in mean SBP, DBP, and mean arterial BP in comparison to normal healthy pregnant women which were statistically significant (P < 0.05).

The hypertensive group of patients required less ephedrine to treat hypotension in comparison to normotensive patients which were statistically significant (P < 0.05).

The incidence of hypotension was almost 7 times less in hypertensive parturients than healthy parturients (odds ratio = 23.14, relative risk of hypotension in Group A = 7.2, confidence interval = 7.6–70.3).

To summarize, our results showed that hypotension following SA administered for cesarean section was significantly less in hypertensive patient than in healthy pregnant women. In addition, vasopressor requirements were also less in hypertensive parturients and neonatal outcome was comparable between the two groups.

Therefore, SAB is an acceptable technique to perform in hypertensive parturients due to its virtue of simplicity, rapidity, cost-effectiveness, and intensity of block.

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Original Article

Impact of Oral Metronomic Therapy on Quality of Life in Advanced/Recurrent Head and Neck Squamous Cell Carcinoma Patients

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Abstract

Introduction: Metronomic chemotherapy (MC) is an emerging therapeutic option in clinical oncology and it may prove useful at least in metastatic head and neck squamous cell carcinoma (HNSCC) patients. To develop rational therapeutic strategies, it is important to identify molecular targets that are linked to the pathogenesis of HNSCC.

Aim: The aim of the study was to assess the effect of oral MC on changes in quality of life (QOL) in advanced/recurrent HNSCC patients.

Materials and Methods: Patients with advanced, metastatic, and recurrent HNSCC patients who are not amenable to local treatment with surgery, radiotherapy, and chemotherapy were included in the study. QOL assessed with the European organization for research and treatment of cancer (EORTC) QLQ-C30 and QLQ-H&N 35 questionnaires.

Results: In this study, 50 patients were included, 37 patients (74%) become pain-free at the end of 6 months. A decreased pain grade was observed in another 13 patients (26%). Mean QLQ-C 30 score at the time of presentation was 68.67, 75.35 at 2 months, 81.26 at 4 months, and 85.38 at the end of 6 months. Mean QLQ-H&N 35 score at the time of presentation was 61.53, 72.16 at 2 months, 76.43 at 4 months, and 81.69 at the end of 6 months. In subgroup analysis, both QLQ-C30 and QLQ-H&N 35 significantly correlated with disease progression.

Conclusion: The use of oral metronomic therapy with methotrexate and celecoxib significantly improves the QOL and improves pain control in patients with advanced/recurrent HNSCC.

Key words: Head neck cancer, Metronomic chemotherapy, Quality of Life

INTRODUCTION

According to the International Agency for Research on Cancer, head and neck squamous cell carcinoma (HNSCC) is the 10th most common cancer worldwide.[1-3] Three percent of all newly diagnosed cancers in humans are HNSCC.[1,3] The incidence of HNSCC is increasing with age.[4] HNSCC is common in Asian countries.[5] HNSCC accounts for 9–10% of the incidence of cancer in India.[6,7] HNSCC is the third commonest cancer in India. Among Indian males, HNSCC forms second leading cancer.[6] Most of the patients with HNSCC present in an advanced stage and they frequently recur after initial therapy.[8,7] Long waiting lists for treatment and poor access to tertiary cancer centers increases the burden of advanced stage HNSCC.[8] Metronomic chemotherapy (MC) is defined as chronic, equally spaced, and low doses of chemotherapeutic drugs without extended rest periods.[8] Metronomic chemotherapies are now called metronomic scheduling of anticancer therapy (MSAT).[5] In this study, we evaluated the impact of oral metronomic therapy on quality of life (QOL), in patients with advanced/recurrent HNSCC, as a palliative treatment.

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Aim

The aim of the study was to assess the effect of oral MC on changes in QOL in advanced/recurrent HNSCC patients.

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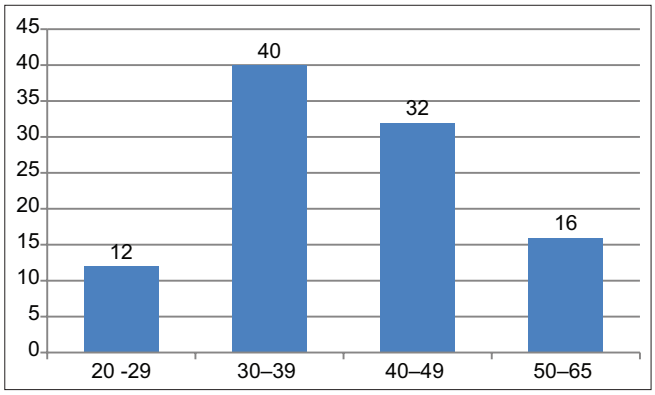

Figure 1: Distribution of age group

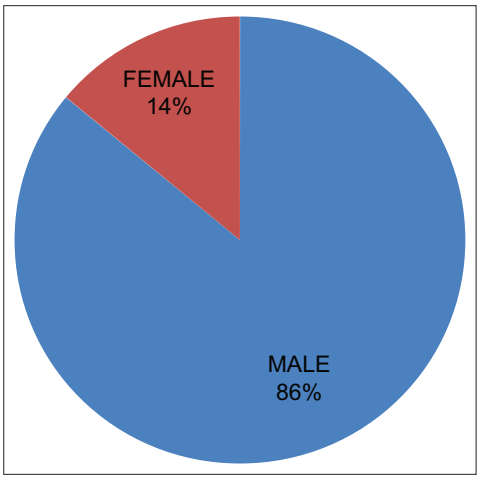

Figure 2: Distribution of gender

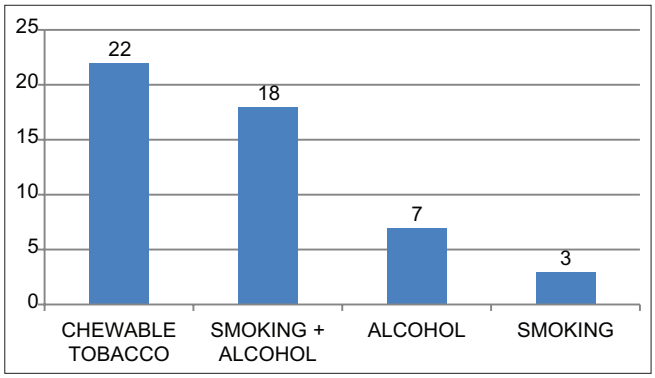

Figure 3: Distribution of risk factors

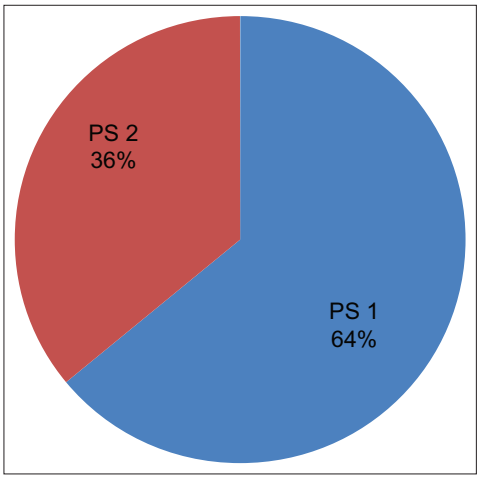

Figure 4: Distribution of performance status (PS) at baseline

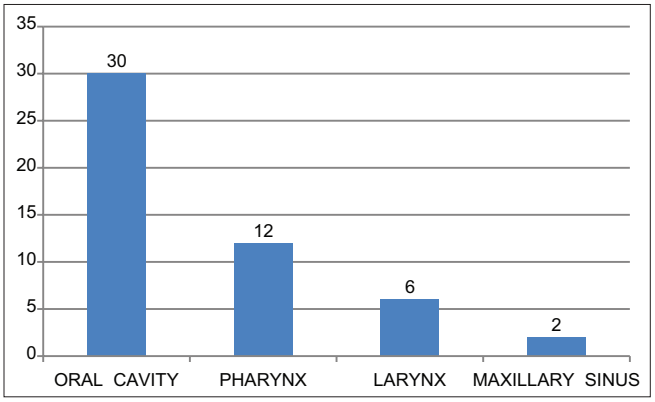

Figure 5: Distribution of sites of HNSCC

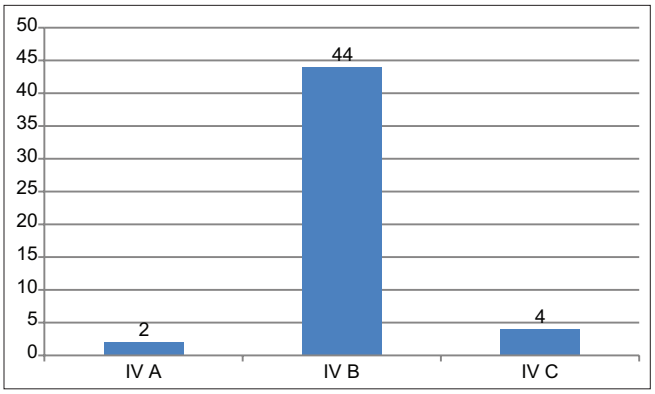

Figure 6: Distribution of AJ CC stage

MATERIALS AND METHODS

This study was designed to assess the QOL in advanced/recurrent HNSCC patients, who progress or recurred after earlier treatment or who have a residual tumor, who are treated with oral metronomic therapy with methotrexate and celecoxib, like the palliative treatment. In this study, we included advanced, metastatic, and recurrent HNSCC patients who are not amenable to local treatment with surgery, radiotherapy (RT), and chemotherapy. Fifty participants, while on oral metronomic therapy, completed two validated questionnaires at baseline and during regular clinical follow-up visits at 2, 4, and 6 months. Informed consent was obtained after explaining the study details, from all patients, before enrollment. The oral metronomic scheduling of anticancer therapy (MSAT) consists of oral methotrexate 15 mg/m^2 once a week and oral

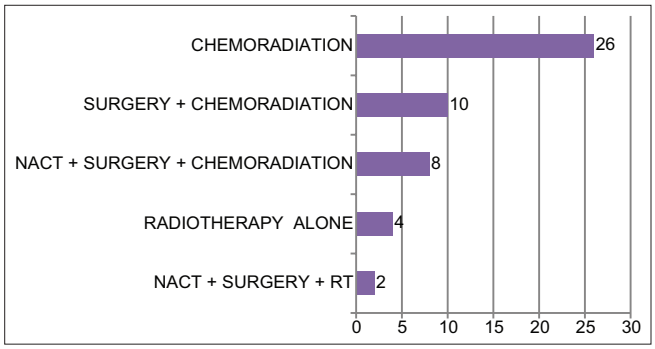

Figure 7: Distribution of prior treatment received

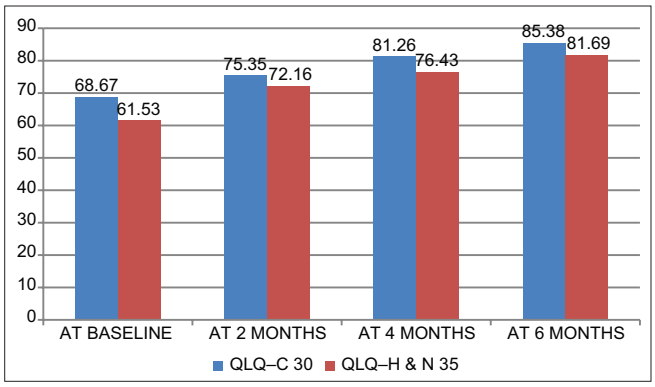

Figure 8: Effect of oral metronomic therapy on quality of life

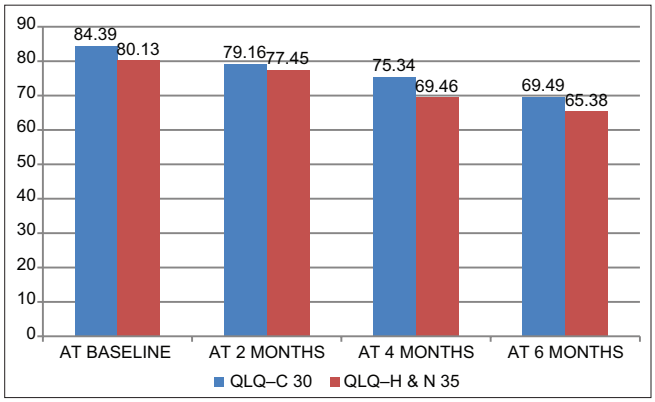

Figure 9: Quality of life in advanced/recurrent HNSCC, in those patients, progressed on oral metronomic therapy

celecoxib 200 mg twice daily. All patients treated on an outpatient basis. Detailed physical examination was done at each clinical visit, including general clinical assessment, specific assessment of tumor response, and toxicities developed if any. Baseline QOL assessment was done before starting oral MC. QOL assessed with the European organization for research and treatment of cancer (EORTC) QLQ-C30 and QLQ-H&N 35 questionnaires. QOL assessment at 2, 4, and 6 months after starting oral metronomic therapy by EORTC: QLQ-C30 and QLQ-H&N 35 questionnaires.

Table 1: Effect of oral metronomic therapy on pain grade

Pain grade	At baseline		At 2 months		At 4 months		At 6 months	
	n	%	*n*	%	*n*	%	*n*	%
<1	0	0	1	2	16	32	37	74
1–2	7	14	26	52	28	56	11	22
2–3	23	46	18	36	4	8	2	4
>3	20	40	5	10	2	4	0	0

Table 2: Treatment-related toxicity

Events	All grades	
	n	%
Mucositis	8	16
Anorexia	12	24
Nausea	9	18
Vomiting	6	12
Fatigue	2	4
Anemia	5	10
Neutropenia	1	2
Thrombocytopenia	1	2
Renal dysfunction	1	2

Statistical analysis was done with SPSS Software (Version 16). One-way analysis of variance was used to establish the significance of disease response on QOL scores, QLQ-C30 and QLQ-H&N 35.

RESULTS

Fifty patients were enrolled in this study, from January 2019 to June 2019. The median age of the patient with advanced/recurrent HNSCC is 45 years, ranging from 20 to 65 years [Figure 1]. The sex distribution was skewed with 43 males (86%) and only seven females (14%) with HNSCC enrolled in this study [Figure 2]. Among risk factors, the chewable form of tobacco tops the list with 44%, followed by combined smoking and alcohol [Figure 3], smoking, and alcohol. The performance status was ECOG PS 1 in 32 patients (64%) and it was PS 2 in 18 patients (36%) [Figure 4]. The most common site of HNSCC is an oral cavity (30 patients; 60%), followed by pharynx, larynx, and maxillary sinus [Figure 5]. Forty-four patients (88%) had locally advanced HNSCC, which is not amenable to any definitive therapy (stage IVB). Four patients (8%) had metastatic disease (stage IVC). Two patients (4%) had a resectable tumor (stage IVA) who was not willing for any form of definitive treatment [Figure 6]. All patients received at least one form of previous treatment. Twenty-six (52%) patients received chemoradiation. Ten patients (20%) treated with surgery followed by chemoradiation. Another eight (16%)

patients treated with NACT followed by surgery and chemoradiation. Four patients (8%) received RT alone as initial treatment. NACT followed by surgery and RT was the initial treatment received in two patients (4%) [Figure 7]. Twenty patients (40%) of patients presented with grade >3 pain; this is reduced to five patients (10%) at the end of 2 months, two patients (4%) at the end of 4 months. None of the patients were in grade >3 pain at the end of 6 months. Thirty-seven patients (74%) become pain-free at the end of 6 months. A decreased pain grade was observed in another 13 patients (26%) [Table 1]. Most common side effect observed in this study was anorexia (24%), followed by nausea, vomiting, mucositis, anemia, fatigue, etc [Table 2]. Mean QLQ-C 30 score at the time of presentation was 68.67. With oral MC, there was a steady increase in QOL score QLQ-C30; 75.35 at 2 months, 81.26 at 4 months, and 85.38 at the end of 6 months. Mean QLQ-H&N 35 score at the time of presentation was 61.53. QLQ-H&N score steadily increases with oral MC; 72.16 at 2 months, 76.43 at 4 months, and 81.69 at the end of 6 months. In subgroup analysis, both QLQ-C30 and QLQ-H&N 35 significantly correlated with disease progression [Figures 8 and 9].

DISCUSSION

HNSCC includes a heterogeneous group of malignant tumors, constitute about 3% of all newly diagnosed cancers in humans.[7,9] Around 90% of head and neck neoplasms are HNSCC.[1] Tobacco and alcohol, the common carcinogens associated with HNSCC.[1]

Surgery and RT are the only curative treatments for head and neck carcinomas.[1] Chemotherapy used alone in HNSCC is not curative, although it enhances the effects of RT and thus is routinely used as part of combined modality treatment in patients with stage III or IV disease.[1,10] In India, the majority of patients (two-thirds) with HNSCC presents in an advanced stage in whom the outcome is poorer even with multimodality therapy which includes surgery, radiation, and chemotherapy.[11] Hanahan *et al.* coined the term MC, in the year 2000.[12] The definition of MC is the administration of chemotherapy drugs at minimal doses with minimal drug-free periods, emerging as a novel form of chemotherapy utilization. In clinical practice, when considering patients with residual toxicity from previous treatment or those who may not be considered fit for maximum tolerated dose (MTD) chemotherapy, such as the elderly and frail, MC become more attractive, as toxicity associated with MSAT is minimal.[13] Lower treatment-related adverse effects observed with the use of MC. The cost of a metronomic regimen may be lower than MTD chemotherapy, as a result of fewer side-effect associated expenditures and the usage of inexpensive oral drugs such as cyclophosphamide and methotrexate.[3] Palan *et al.* evaluated QOL in radically treated head and neck cancers and the problematic domains identified by QLQ-H&N-35 scale were sexual problems, trouble with social contact, symptoms of dry mouth, problem-related to senses, difficulty in mouth opening, and speech problems. About 70.8% of the respondents used painkillers for their pain management.[4] Leung *et al.* evaluated QOL in head and neck cancer survivors after RT and observed that tooth problems, dry mouth, and sticky saliva were prominent worst symptoms.[14] Jyothi *et al.* evaluated QOL in head and neck cancer patients receiving cancer-specific treatments and found a positive correlation between QOL and performance status of the patients.[15]

CONCLUSION

The use of oral metronomic therapy with methotrexate and celecoxib significantly improves the QOL and improves pain control in patients with advanced/recurrent HNSCC.

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Original Article

Prevalence of Middle Mesial Canal Based on Clinical and Radiological Evaluation in Permanent Mandibular First Molar: A Clinical and Cone-beam Computed Tomography Analysis

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Abstract

Background: The success of endodontic therapy depends on the complete debridement of the entire root canal system. Many studies have investigated the morphology of mandibular molar, but the prevalence of the middle mesial canal in the mesial root of the mandibular first molar is still the subject of controversy. Missed canal and consequently inadequate debridement of the root canal system can eventually lead to failure of therapy. Hence, it is imperative to meticulously look for extra canals to ensure successful treatment.

Materials and Methods: In this *in vivo* study, 100 patients who reported for root canal treatment were included in the study. Patients' age and sex were recorded. After access cavity preparation, a standardized technique is performed between the mesiobuccal canal and mesiolingual canal to search for a middle mesial canal using a dental operating microscope and confirmed radiologically by taking cone-beam computed tomographic image and results were analyzed.

Results: In our study, out of 100 patients included that 50 patients were male and 50 patients were female. Based on gender, the prevalence of middle mesial canal in tooth number 36 and 46 is 18% (9 patients) and 19% (10 patients); for females and males, it is 20% (10 patients) and 22% (11 patients). Based on age group, the prevalence of middle mesial canal in tooth number 36 and 46 between the age of 15 and 30 is 23% (13 patients) and 24% (15 patients), between the age of 31 and 60 is 20% (5 patients) and 22% (6 patients), and age above 60 is 14% (1 patient) and 16% (2 patients), respectively.

Conclusion: From this study, we concluded that the prevalence of the middle mesial canal in the permanent mandibular first molar can be as high as 24%, with the prevalence being higher in males than females and the age group between 15 and 30 years had the highest prevalence.

Key words: Cone-beam computed tomography, Extra canals, Mandibular molar, Middle mesial canal

INTRODUCTION

Many studies have investigated the morphology of mandibular first molar, but the prevalence of the middle mesial canal in the mesial root of the mandibular first molar is still the subject of controversy. The success of endodontic therapy depends on the complete debridement of the entire root canal system. Improper cleaning may harbor microorganisms. A strong relationship exists between the existence of an untreated canal space and apical periodontitis.[1] Mandibular first molars are the most frequent tooth to be endodontically treated.[2] Conventionally, mandibular molars are described as two-rooted teeth with 2 canals in the mesial root and 1 or 2 canals in the distal root.[3] Complex anatomy is often seen in the mesial root of the mandibular first molar.[4-6] The presence of independent middle mesial canal was first reported by Vertucci and Williams[4] and Barker *et al.*,[5] in 1974. According to Pomeranz

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et al.,[7] the middle mesial canal can be classified into three categories such as fin, confluent, and independent. Fin is when an instrument can pass freely between the mesiobuccal and mesiolingual canal. Confluent is when the middle mesial canal originates as a separate orifice but apically joins with the mesiobuccal or mesiolingual canal. Independent is when the middle mesial canal originates as a separate orifice and terminates as a separate foramen. Few clinical studies have investigated the incidence of the middle mesial canal in mandibular molar.[6-10]

The complex anatomy of the mesial roots of mandibular molars, if not addressed, may harbor reservoirs of microorganisms.[11] Effective management of a middle mesial canal requires a complete understanding of its complex anatomy and relationship with other root canal space configurations. Hence, the purpose of this study is to evaluate the prevalence of the middle mesial canal in mandibular first molar clinically and radiographically using cone-beam computed tomography (CBCT).

MATERIALS AND METHODS

This prospective study was conducted in dental clinics at Chennai for patients who reported for root canal treatment (RCT) procedure. Inclusion criteria include patients above the age of 15 years with permanent mandibular first molar indicated for RCT either for caries or fractures involving the pulp. Intentional RCT for prosthodontics reasons was also included in the study. Exclusion criteria include teeth with open apices, resorption, endo-perio lesions, calcifications, and developmental anomalies. The patients who met the inclusion criteria were given local anesthesia and rubber dam isolation was done. After achieving the subjective and objective symptoms of local anesthesia, access cavity was prepared. The main canals including mesiobuccal, mesiolingual, and distal were located and pulp was extirpated using size #8, #10 K-file, broaches and biomechanical preparation was done with rotary instruments in sequence, complete irrigation was done with normal saline and then canals are visualized with dental operating microscope to check for the existence of middle mesial canal. CBCT was taken to confirm the presence of the middle mesial canal. The results were statistically analyzed and discussed.

RESULTS

In our study, out of 100 patients included that 50 patients were male and 50 patients were female [Table 1]. Based on gender, the prevalence of middle mesial canal in tooth number 36 and 46 is 18% (9 patients) and 19% (10 patients); for females and males, it is 20% (10 patients) and 22% (11 patients).

Table 1: Cross-tabulation between the gender and prevalence of middle mesial canal

Gender	Number of patients	Prevalence of middle mesial canal	
		Tooth number 36 (%)	Tooth number 46 (%)
Female	50	18	19
Male	50	20	22

Table 2: Cross-tabulation between the age and prevalence of middle mesial canal

Age (years)	Number of patients	Prevalence of middle mesial canal	
		Tooth number 36 (%)	Tooth number 46 (%)
15–30	62	23	24
31–60	27	20	22
Above 60	11	14	16

In our study, out of 100 patients based on age group, the prevalence of middle mesial canal in tooth number 36 and 46 between the age of 15 and 30 is 23% (13 patients) and 24% (15 patients), between the age of 31 and 60 is 20% (5 patients) and 22% (6 patients), and age above 60 is 14 % (1 patient) and 16% (2 patients) [Table 2].

DISCUSSION

Variations in root canal anatomy are so common that many authors now consider it as a normal phenomenon.[12] Earlier studies on root canal anatomy were performed using demineralizing and injecting a dye technique.[6,13-15] However, this technique had the disadvantage of producing irreversible changes to the studied sample.[16] Few studies have used radiographs as a methodology to evaluate root canal morphology.[17-19] Conventional radiographs produce only two-dimensional image of a three-dimensional object and can lead to the superimposition of the root canals (i.e., they tend to lie one behind the other in the buccolingual plane and can easily go undetected).[16] CBCT has the advantage over conventional radiographs in that it three-dimensionally evaluates the root canal morphology and hence was used in this study.

The prevalence of the middle mesial canal in mandibular molar ranges from approximately 0.95%–46.2%.[20,21] Azim *et al*.[21] and Karapinar-Kazandag *et al*.[9] suggested that the use of a dental operating microscope can improve the recognition and negotiation of accessory canals.

In our study, out of 100 patients included that 50 patients were male and 50 patients were female. Based on gender, the prevalence of middle mesial canal in tooth number 36 and 46 is 18% (9 patients) and 19% (10 patients); for females

and males, it is 20% (10 patients) and 22% (11 patients). Thus, the prevalence of the middle mesial canal in the mandibular first molar was higher in males compared to females but statistically insignificant. Tahmasbi *et al.*[22] concluded in their study that there was no statistically significant difference between gender and prevalence of middle mesial canal in a mandibular first molar. Thus, the results of our study correlate with Tahmasbi *et al.*

In our study, out of 100 patients based on age group, the prevalence of middle mesial canal in tooth number 36 and 46 between the age of 15 and 30 is 23% (13 patients) and 24% (15 patients), between the age of 31 and 60 is 20% (5 patients) and 22% (6 patients), and age above 60 is 14% (1 patient) and 16% (2 patients). Thus, the prevalence of the middle mesial canal in mandibular first molar is higher in the age group between 15 and 30 years and decreases as the age increases.

Likewise, Pomeranz *et al.*,[7] 1981; Fabra-Campos,[23] 1989; Azim *et al.*,[21] 2015; Nosrat *et al.*,[24] 2015; Kim *et al.*,[25] 2013; and Goel *et al.*,[26] 1991, supported the view that middle mesial canal can be easily located in patients of a younger age group, but progressively decreased its incidence with age.

CONCLUSION

The presence of an untreated middle mesial canal is a potentially important reason for endodontic treatment failure. The dental operating microscope and CBCT are highly effective in detecting the presence of additional canals. The use of both these aids together results in reliable detection of the middle mesial canal, thus minimizing the risk of the missed canal. With the use of both these aids in this study, we conclude that the prevalence of the middle mesial canal in mandibular first molar can be as high as 24%, with the highest incidence in patients aged 15–30 years and the incidence progressively decreases as the age advances.

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Original Article

Expression of Sirtuin 4 in Oral Squamous Cell Carcinoma and it's Correlation with Clinicopathological Parameters

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Abstract

Introduction: SIRTs (Sirtuins) are class III histone deacetylase enzymes that use NAD+ as a co-substrate for their enzymatic activities. In mammals, there are seven sirtuin proteins (SIRT1–SIRT7) among which SIRT4, SIRT3 and SIRT5 are mitochondrial sirtuins that regulate enzymes and other mitochondrial proteins to coordinate oxidative production of ATP with the availability of energy in the diet. SIRT4 is known to have tumor suppression activity in many human cancers. However, the role of SIRT4 in oral squamous cell carcinoma is not known. It is present at higher levels under nutrient-rich conditions, and inhibits glutamine catabolism through ADP-ribosylation and hence repression of glutamate dehydrogenase (GDH) activity, a rate-limiting enzyme in glutamine catabolism. Due to higher requirement of energy and bio-molecules for proliferation, cancer cell often resort to various metabolic pathways that are otherwise uncommon in normal cells. One of such mechanism is switching to Glutamine metabolism. SIRT4 acts as a tumor suppressor by repressing glutamine utilisation by cells.

Purpose: Study the role of SIRT4 in oral squamous cell carcinoma and evaluate its tumor suppressor role.

Method: Here we studied expression of SIRT4 in oral cancer tissues by immuohistochemistry and compared it with that of normal tissue.

Results: SIRT 4 was seen to significantly down regulated in oral squamous carcinoma.

Conclusion: The present study suggests SIRT4 as a marker of tumor aggressiveness and as a therapeutic target for OSCC.

Key words: Cancer cell metabolism, Sirtuin 4, Tumor suppressor

INTRODUCTION

The global burden of cancer has kept on increasing with each passing year. According to the latest data released by the WHO, an estimated 14.1 million new cancer cases and 8.2 million cancer-related deaths occurred in 2012, compared to 12.7 million and 7.6 million, respectively, in 2008. It has also been predicted that by 2025, new cancer cases per year will increase substantially to 19.3 million, due to growth and aging of the global population.[1]

The incidence of oral cancer along with lip and pharyngeal cancer in 2012 was 529,500 that correspond to 3.8% of all cancer cases and is predicted to rise by 62% to 856,000 by 2035 because of demographic change.[1] It is the sixth leading cancer by incidence worldwide.[2] The figures are alarming and there is a need for local tailored approaches for prevention, screening, and therapeutic interventions that will optimally reduce the burden of the above anatomical areas in future decades. One of the major hindrances in formulation of these tailored approaches of interventions is lesser understanding of metabolic reprogramming that drives oncogenesis. Although numerous studies are done on cancer genomics, the literature is in dearth of studies

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that focus on altered cellular metabolism in cancer cells. The present study highlights one of such genes that are integrally associated with altered metabolism of cancer cells.

Sirtuins (SIRTs) are Class III histone deacetylase enzymes that use NAD+ as a cosubstrate for their enzymatic activities.[3] These proteins have been shown to counter aging in a broad range of organisms, from yeast to mammals.[4] The effect of SIRT activation in mammals is to forestall the progression of diseases of aging, including neurodegeneration, diabetes, cardiovascular diseases, and many types of cancer.[5] SIRT4, SIRT3, and SIRT5 are mitochondrial SIRTs that regulate enzymes and other mitochondrial proteins to coordinate oxidative production of ATP with the availability of energy in the diet.[6] In humans, SIRT4 expression is reduced in several types of cancers, including small-cell lung carcinoma,[7] leukemia,[8] gastric cancer,[9] bladder cancer,[10] and breast cancer.[11] Unlike other SIRTs that are activated under energy-limiting conditions, SIRT4 is present at higher levels under nutrient-rich conditions, and this SIRT inhibits glutamine catabolism through ADP-ribosylation and hence repression of glutamate dehydrogenase (GDH, also known as GLUD) activity, a rate-limiting enzyme in glutamine catabolism.[11-13]

Although the expression of SIRT4 has been studied in few human cancers, no study on oral cancer has yet been reported in English literature. The present study aims to evaluate and compare the expression of SIRT4 in oral squamous cell carcinoma (OSCC) tissue with adjacent non-tumor tissue using immunohistochemistry (IHC). We also intend to correlate SIRT4 expression in tumor tissue with various clinicopathological parameters of the tumor.

MATERIALS AND METHODS

The study was conducted with prior approval of the Institutional Ethical Committee, SCB Medical College and Hospital, Cuttack. After obtaining necessary consent, 45 formalin-fixed paraffin-embedded tissue samples of diagnosed cases of OSCC and their corresponding microscopically healthy tissue margin were obtained from the tissue archive of the Department of Oral Pathology and Microbiology, SCB Dental College and Hospital, Cuttack. The samples included 31 males and 14 females in the age range of 28 years–72 years. All the patients had undergone radical neck dissection surgery for OSCC between January 2016 and August 2017 at the Department of Oral and Maxillofacial Surgery, SCB Dental College, Cuttack. None of the patients received chemotherapy or radiotherapy before surgery. Recurrence cases were excluded from the study. The OSCC tissue samples were divided into three groups according to the histological differentiation. Group 1 contained 30 tissue samples of well-differentiated OSCC (T1-T30), whereas Group 2 and Group 3 had 10 (T31-T40) and 5 samples (T41-T45) of moderately differentiated and poorly differentiates OSCC, respectively. Tumor margins which were microscopically free of tumor cells were taken as control and were numbered C1-C45.

All the samples were stained with hematoxylin and eosin and viewed under a light microscope to confirm the rendered diagnosis. The samples were subjected to immunohistochemical study using primary antibody anti-SIRT4 polyclonal antibody produced in rabbit (Product code – HPA029692, Sigma-Aldrich Corporation, USA)

The IHC stained slides were scored as per the standard protocol of scoring, 10 random high-power fields were selected for each sample (×400; Leica, Germany). The fields were scored for staining area (0 = <5%; 1 = 5–25%; 2 = 25–50%; 3 = 50–75%; and 4 = More than 75%) and staining intensity (0 = No staining; 1 = Weak staining appearing as light yellow; 2 = Moderate staining appearing as yellowish-brown; and 3 = Strong staining appearing as brown). The overall staining score was calculated by multiplying staining area score with staining intensity score. Average scores of 10 fields were considered as the final staining score of the sample. Staining score <4 was considered as low expression and score ≥4 was considered as high expression of SIRT4.

Statistical analysis was performed using the SPSS software package version 22.0 (SPSS, Inc. IBM, USA). Fisher's exact test was used to analyze the final score of the tumor and non-tumor tissues. Paired *t*-test and ANOVA were employed to evaluate the correlation between expression of SIRT4 and various clinicopathological parameters such as age, gender, site of lesion, size of lesion, differentiation, Union for International Cancer Control staging, and involvement of lymph nodes.

RESULTS

SIRT4 was expressed in cell cytoplasm. It was found to be significantly downregulated in tumor tissues in

Table 1: Sirtuin 4 protein expression in oral squamous cell carcinoma and adjacent normal oral mucosa tissues

Tissue type	Sample No.	Sirtuin 4 expression		X^2	*P* value*
		Low (IHC score <4)	High (IHC score ≥4)		
Normal	45	31 (68.88%)	14 (31.12%)	16.58	<0.001
Tumor	45	45 (100%)	-		

*Fisher's exact test applied. IHC: Immunohistochemistry

comparison to adjacent microscopically healthy appearing tissue [Figure 1]. The difference in the staining score was found to be highly significant ($P < 0.001$). About 31.12% of the normal tissues showed high expression of SIRT4 compared to none of the tumor cases [Tables 1 and 2, Graph 1].

Further on evaluating the expression of SIRT4 protein in various stages of the tumor, patients with higher stage (Stage III and Stage IV) showed significantly lower expression of SIRT4 than early-stage (Stages I and II) disease [Table 3]. The mean value of SIRT4 protein expression was found to be 1.39 ± 0.60 in Stages I and II, 0.51 ± 0.20 in Stage III, and 0.26 ± 0.10 in Stage IV cancers. The difference in the expression was found to be statistically significant ($P < 0.001$). When the scores of Stages I and II cancers were compared with that of Stage III cancer, a significant difference in expression was noted ($P = 0.002$). The difference was even more prominent when compared with Stage IV cancer ($P < 0.001$). However, no significant difference was seen between Stage III and Stage IV cancers ($P = 0.331$) [Table 4].

To further evaluate the role of SIRT4 in tumor spread, we compared the expression of the protein in tumor tissues from patient who had at least one lymph node metastasis with non-metastatic cases. The mean of SIRT4 expression

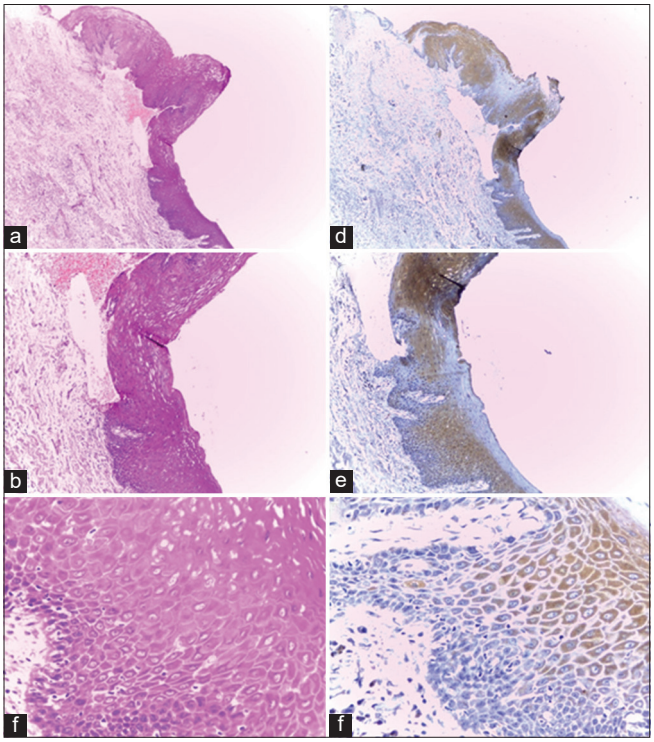
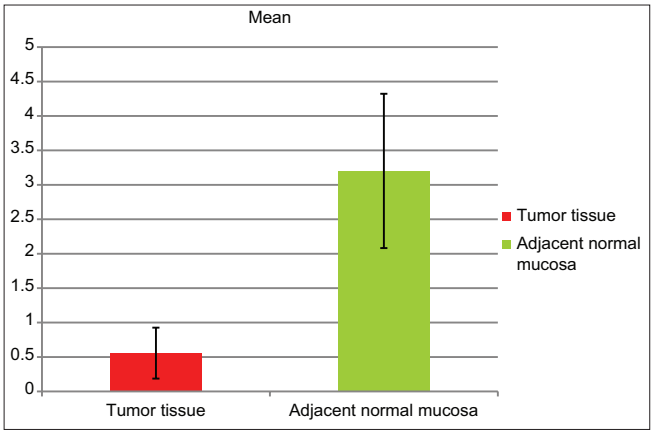


Figure 1: Expression of sirtuin 4 (SIRT4) in microscopically healthy mucosa taken from tumor margins; (a-c) HE stained samples shown at different magnifications ([a] – ×40, [b] –×100, [c] – ×400); (d-f) Samples stained with anti-SIRT4 antibody



Graph 1: Sirtuin 4 protein expression in oral squamous cell carcinomas and adjacent normal oral mucosa tissues

Table 2: Sirtuin 4 protein expression in oral squamous cell carcinoma and adjacent normal oral mucosa tissues

Samples	Mean	Std. deviation	Std. error mean	*t*	Mean difference	*P* value
Tumor tissue	0.55	0.37	0.1000	−13.586	−2.6467	<0.001
Adjacent normal mucosa	3.20	1.12	0.1672			

*Student's *t*-test applied

Table 3: Correlation of sirtuin 4 protein expression in oral squamous cell carcinoma and pathological stage of tumor

Stage	Mean	Std. deviation	Std. error	F	*P* value
1 and 2	1.39	0.60	0.19	11.05	<0.001
3	0.51	0.20	0.22		
4	0.26	0.10	0.09		
Total	0.72	0.53	0.13		

Table 4: Difference in sirtuin 4 protein expression in oral squamous cell carcinoma between pathological stages of tumor

(I) Stage	(J) Stage	Mean difference (I-J)	Std. error	*P* value
1 and 2	3	0.88	0.25	0.002
1 and 2	4	1.13	0.25	0.000
3	4	0.25	0.15	0.331

Table 5: Evaluation of sirtuin 4 protein expression in oral squamous cell carcinoma with respect to lymph node metastasis

Lymph node metastasis	Mean	Std. deviation	Std. error mean	*t*	*P* value
Present	0.19	0.06	0.0526	−3.212	0.003
Absent	0.98	0.46	0.1716		

was found to be 0.98 ± 0.46 in non-metastatic cases and 0.19 ± 0.06 in metastatic lymph node cases. The difference in the expression was statistically significant ($P = 0.003$) [Table 5].

There was no significant difference in expression of SIRT4 across various grades of tumor. The size, site of tumor, gender, and age of patient had no significant effect on expression of SIRT4.

DISCUSSION

Morphological changes in transforming cells are late to appear as they are secondary to the genomic changes that trigger carcinogenesis in the cell. This makes it difficult to diagnose a cell as non-tumorous solely by relying on morphological parameters. Several immunohistochemical markers have been employed to see the changes in a transforming cell at molecular level which is otherwise not appreciated by morphological study under microscope. SIRT4 is one such marker that plays a significant role in deciphering the molecular changes occurring in a cell in the process of carcinogenesis.

Different family members of SIRTs were found to play various roles in carcinogenesis, in a tumor-type dependent manner.[14] For instance, SIRT1 was found to be upregulated in gastric carcinoma,[15] colon cancer,[16] prostate cancer,[17] and skin cancer,[18] whereas the same is downregulated in breast cancer[19] and induced intestine cancer in mouse model.[20] In a similar fashion, an SIRT2 expression is decreased in breast cancer,[21] glioma,[22] and skin cancer[23] but upregulated in acute myeloid leukemia[24] and prostate cancer.[25] Among the mitochondrial SIRTs, the role of SIRT3 in cancer progression has been extensively studied. SIRT3 has been seen to suppress a wide number of caners;[26-34] on the contrary, the same has also been seen to be upregulated in some cancers.[35-39] Unlike SIRT3, limited information are available about SIRT4. The expression of SIRT4 has been evaluated in few cancers, but none of the study was performed on OSCCs.

In the present study, we evaluated the expression of SIRT4 in OSCC and correlated it with various clinical and pathological parameters of OSCC. Expression of SIRT4 was found to be decreased in cancer cells which can be attributed to the activation of mammalian target of rapamycin complex 1 (mTORC1) pathway during carcinogenesis.[13] The tumor cells live in a dynamic environment where the nutrient availability keeps on changing. To survive the nutrient level variation, the anabolism and catabolism need to be regulated. The decision of process between anabolism and catabolism is highly conserved. Atypical serine/threonine kinase mTORC1 which drives nutrient uptake and subsequent proliferation[40] has been seen to be dysregulated in many cancers.[41] mTORC1 get activated by various pathways such as downstream effect of PI3K pathway that is one of the most frequently activated pathways in human malignancies,[42-44] mutation of tumor suppressor gene PTEN which is the second most mutated gene to be involved in carcinogenesis after p53, tumor suppressor LKB1 mutation in the upstream,[45] and Wnt and tumor necrosis factor-alpha pathway.[46,47] PI3K pathway is seen to be frequently mutated in head-and-neck squamous cell carcinoma[48] with a downstream effect on mTORC1 activation. Analyzing the result of the present study, we assume that decreased expression of SIRT4 protein in OSCC is an effect of upstream mutation of PI3K pathway acting through mTORC1.

Further, we found the decreasing expression of SIRT4 with increasing pathological stage of tumor further. As the stage of the tumor is related with its spread, SIRT4 can be assumed to play a significant role in keeping a rein on the spread of tumor by decreasing cellular proliferation. Glutamine is known to be an essential metabolite for proliferation[49-53] and also required for transition from G1 to S phase[54] during cell division. SIRT4 is known to repress mitochondrial glutamine metabolism in response to DNA damage.[11] This phenomenon by SIRT4 might be affecting the cellular proliferation negatively contributing to the tumor suppressor nature.

One more important aspect of tumor spread is lymph node metastasis. Lymph node metastasis cases showed significantly decreased expression than non-metastatic cases. Loss of cell to cell adhesion is an important step associated with tumor invasion and metastases that are frequently accompanied by downregulation of the epithelial molecule E-cadherin.[55] Loss of E-cadherin has been related to cancer development, progression, and poor prognosis.[56] High glucose was found to suppress the mRNA expression of E-cadherin compared to low glucose in pancreatic cancer.[57] The role of glutamine and SIRT4 in cell migration and invasion has started getting attention recently. Wang *et al.*[58] reported that in cell invasion assays, the migratory activity of transformed fibroblasts and cancer cells is highly compromised by glutaminase inhibitor 968, suggesting a role of glutamine metabolism in cancer cell migration. Fu *et al.*[59] indicated that glutamine restriction inhibited attachment, spreading, and migration of melanoma cell lines through the inhibition of specific integrin expression and modulation of actin cytoskeleton remodeling. Miyo *et al.*[60] demonstrated that suppression of glutamine metabolism by SIRT4 resulted in positive regulation of E-cadherin expression. Further, it was

suggested that SIRT4 inhibits EMT through reducing levels of intracellular α-ketoglutarate through the inactivation of GDH. In the present study, decreased expression of SIRT4 in lymph node metastatic cases supports the role of that SIRT4 in suppression of tumor invasion and metastasis.

CONCLUSION

In the present study, the role of SIRT4 as a tumor suppressor in OSCC was established by comparing expression of SIRT4 in various tumor tissues with normal healthy appearing adjacent mucosa. It was observed that tumors with higher stages and with lymph node metastasis showed marked decrease in the expression of the protein; hence, SIRT4 could be considered as a novel prognostic marker of tumor aggressiveness. As SIRT4 plays an important role in suppressing glutamine anaplerosis, it is downregulation in OSCC tissues indicated the dependence of the tumor cells on glutamine for cellular proliferation. This fact can be advantageous and contribute to the development of effective therapeutics for oral cancer. SIRT4 in conjunction with metabolic and cytotoxic chemotherapeutic agents can serve as a promising strategy in the treatment of OSCC. The present study suggests SIRT4 as a marker of tumor aggressiveness and as a therapeutic target for OSCC.

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Original Article

Fracture Clavicle: Is Surgical Fixation a Better Treatment?

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Abstract

Background: Fractures of clavicle represent approximately 3–12% of all fractures treated by orthopedic surgeons. There has been a debate over the years for the best treatment of midshaft clavicle fractures. Our study is intended to find both conceptual and practical guidance for precision treatment with an expectant favorable functional result.

Materials and Methods: Out of 50 patients of clavicle fractures, 25 were treated conservatively and 25 were treated operatively by locking plate fixation. Outcomes were assessed using the disabilities of the arm, shoulder and hand (DASH) score for functional assessment.

Results: Functional and anatomical outcomes were found to be better in patients treated operatively with better DASH scores compared to patients treated with clavicle brace and sling.

Conclusion: Surgical fixation of fracture clavicle gives better functional outcomes and shorter time for union with better anatomical reduction than non-operative treatment. Hence, we recommend surgical fixation with a locking plate is the standard of treatment in these fractures.

Key words: Conservative treatment, Fracture clavicle, Plate fixation

INTRODUCTION

In today's era of metallurgy and fast life, the increasing incidence of clavicle fractures due to road traffic accidents accounting to 94%.[1] More emphasis is being given in the management of these fractures, which brings about the debate of whether clavicle midshaft fractures treated operatively yield better results compared to traditional conservative management. It is one of the most common fractures accounting for 3–12% of all fractures and 45–65% fractures around the shoulder.[2] Midshaft fracture commonly occurs in young adult, whereas lateral and medial end clavicle fracture is more common in the elderly.[3,4] The most commonly used non-operative method is clavicle brace and an arm sling, it has the advantage of being non-invasive and absence of exposure to anesthesia. However, non-operative methods are said to be associated with risk of non-union, residual deformity, and patient dissatisfaction. Most clavicular fractures still are treated closed and heal uneventfully without serious consequences.[5] It is becoming increasingly apparent that clavicular malunion is a distinct clinical entity with radiographic, orthopedic, neurologic, and cosmetic features. Increasing reports of complications associated with non-operative management such as symptomatic malunion, nonunion, shortening, and droopy shoulder, have stirred toward operative management of clavicle fractures. Internal fixation restores the anatomical continuity of the clavicle, early return to functional activity, the shorter period of immobilization, and less complications.[6-11] Therefore, this study was conducted to analyze the outcome of management of non-operative and operative procedures in fracture clavicle and discover whether operative treatment is superior to conservative management. There are various studies conducted in other countries to compare the outcome between surgical and

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conservative management in the treatment of clavicle fractures, but studies in India are less.

MATERIALS AND METHODS

This study is carried out on the patients with fractures of clavicle [collar bone], admitted, and treated in CIMS Medical College and Hospital, Bilaspur, Chhattisgarh from 2016 to 2018. Fifty patients with fractures of clavicle were included in the study, of which 25 cases were treated conservatively and 25 cases were treated operatively. On arrival of patient detailed history, age, sex, mode of injury, days since injury, associated injuries, and underlying medical conditions were noted carefully. The patients were assessed clinically and radiologically. Routine necessary hematological pre-surgical investigations were done and surgery was performed in the operative group after pre-anesthetic fitness.

Inclusion Criteria

Patients above the age of 18 years with fracture of the clavicle were included in the study.

Exclusion Criteria

Pathological fractures, compound fractures, with associated head injury patients, and with medical contraindication for anesthesia and surgery were excluded from the study.

Twenty-five patients of the non-operative group were treated with a commercial clavicle brace and traditional cuff and collar sling. While 25 patients of the operative group were operated by a superior approach to clavicle in beach chair position, the fracture was fixed with pre-contoured S-shaped anatomical locking plate. We excluded terminal, lateral end clavicle fractures where pre-contoured S-shaped anatomical locking plate fixation was not possible.

Pendulum exercises of the affected shoulder started after 10–15 days as and when tolerated, along with elbow range of motion exercises. The patients were asked not to stop their wrist and hand movements soon after the start of treatment. From 6 weeks, onward resistive exercises were encouraged after removal of the brace.

Follow-up

After 3 days postoperatively, with the completion of intravenous antibiotics course, patients were discharged. Later, the follow-up was after 2 weeks, 6, 12, 18, and 24 weeks, respectively (the follow-up protocol was the same for both groups). They were assessed for any wound dehiscence, radiological assessment for fracture healing, range of motion of shoulder joint, DASH score, and any other specific complaints.

All the patients were motivated for physiotherapy and range of motion exercises in every follow-up.

RESULTS

There were 43 males and seven females in our study, the mean age in males was 33.4 years and in females was 32 years. The maximum number of patients was among 21–30 years age group suggestive of more outdoor activities of male patients.

The maximum number of cases was due to road traffic accidents 76%, followed by self-fall 14% and physical assault 10%.

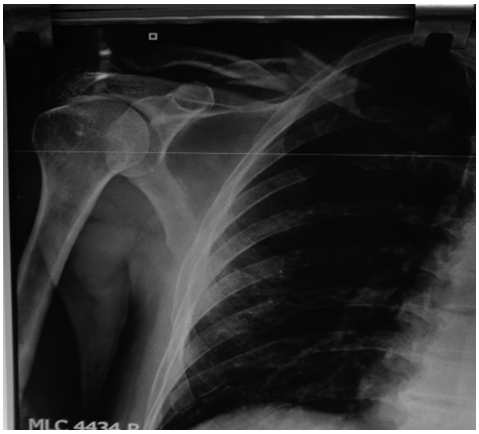
Fracture Healing (Radiological Union)

The mean time of fracture union was shorter in the operative group 15.44 ± 3.24 weeks than non-operative group 21.95 ± 3.26 weeks. There is a significant difference in the time of fracture healing among both groups.

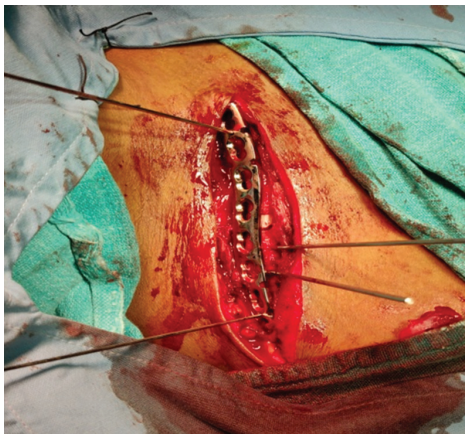
Functional Recovery

Based on the disabilities of the arm, shoulder and hand score (DASH score) operative group of patients had better functional outcomes with the mean score of 14 ± 21.3, suggesting positive results. While in non-operative group, the mean score is 54 ± 18.27.

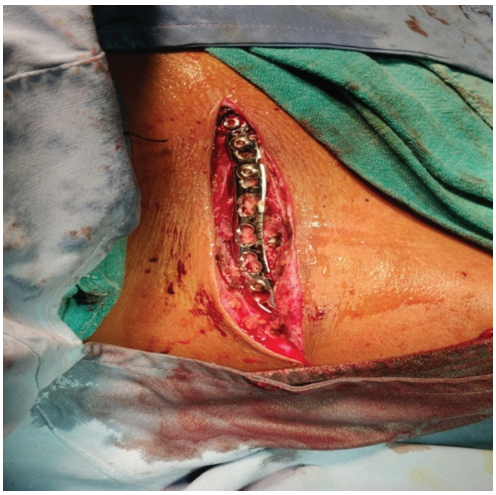
Case No. 1: Comminuted Fracture



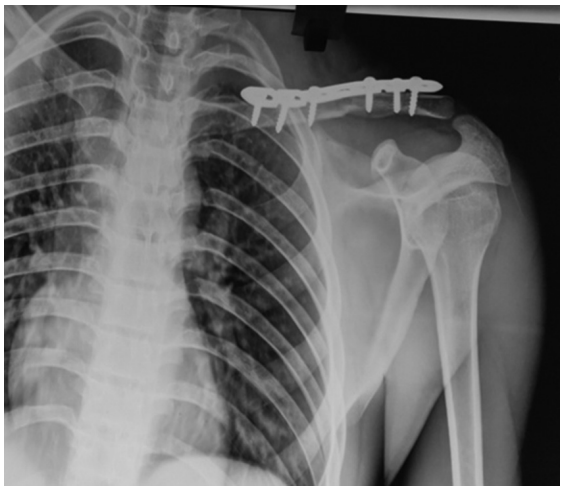
Pre-operative X-ray



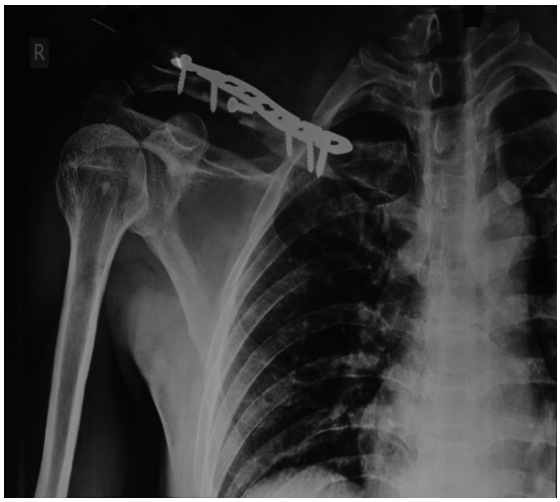
Intra-operative reduction with K-wire



Post operative X-ray

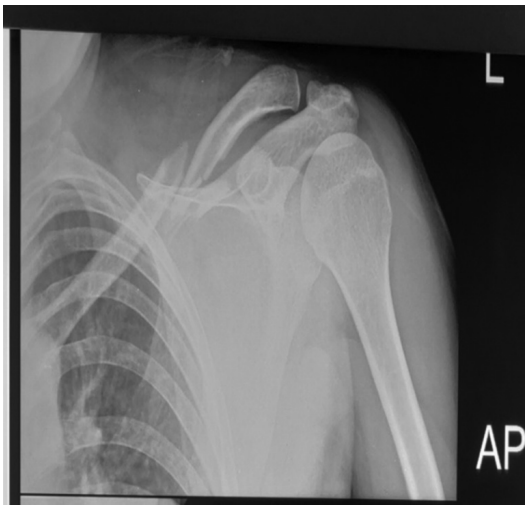


Post-operative X-ray



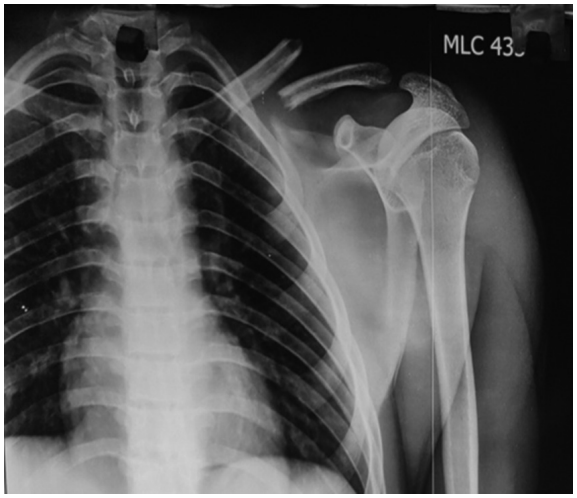
Post-operative X-ray

Case No. 3: Failed Case

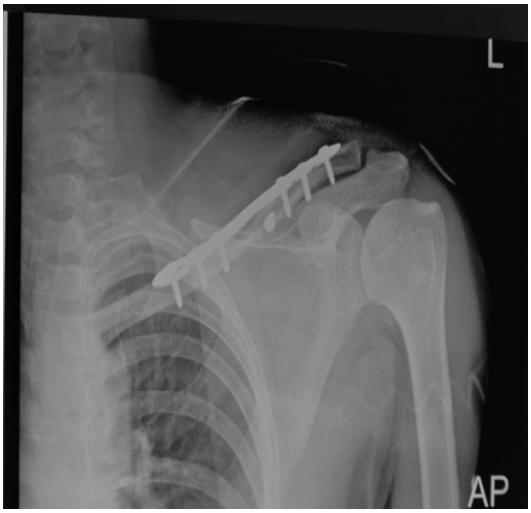


Pre-operative X-ray

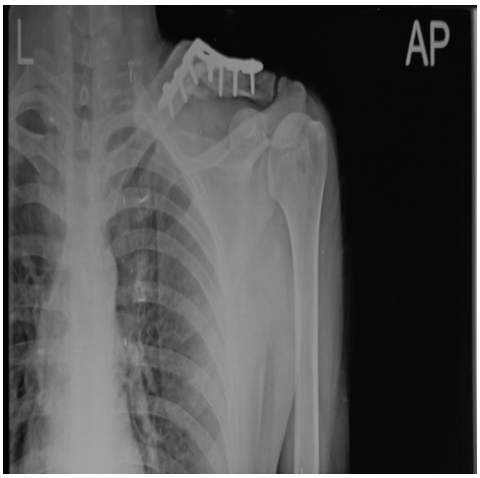
Case No. 2: Transverse Fracture



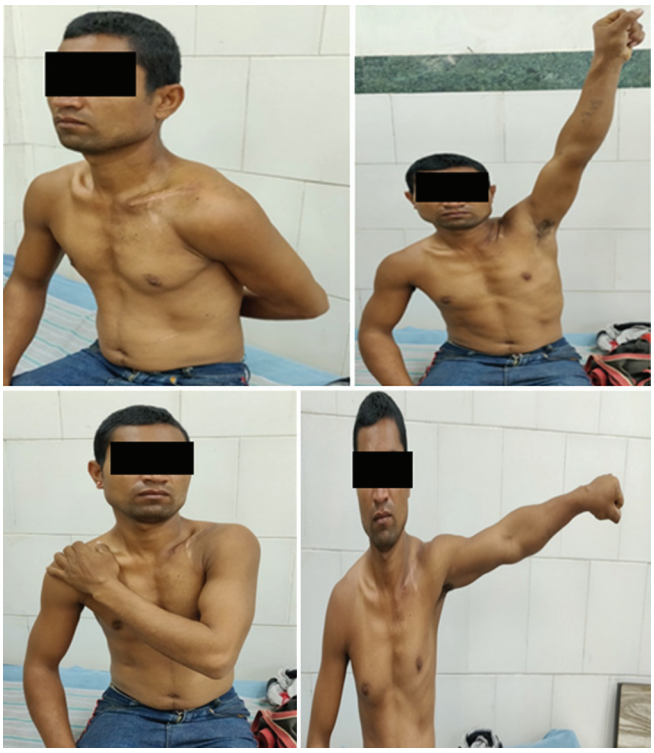
Pre-operative X-ray



Post-operative X-ray



Implant failure after 25 days postoperatively as the patient lifted heavy weight



Post-operative clinical pictures with a full range of shoulder movement

DISCUSSION

Fracture clavicle is the most common fracture of the shoulder. Since centuries clavicle fractures were usually treated conservatively because of the high rate of union, therefore surgical treatment for primary clavicle fractures was avoided. However, with the growing rise of patients' demands with modern fast paced life, the modality of treatment for displaced fracture clavicle is shifting from conservative to operative, resulting into gradual decrease in complications of non-union, malunion, stiffness, and persistent pain around the shoulder due to non-operative management.

In our study, among 50 patients, there were 43 (86%) males and seven (14%) females with the mean age in males was 33.4 ± 11.97 years and in females was 32 ± 10.39 years, which is comparable to Pearson *et al* [Table 1].[12] The youngest patient was 18-year male and the oldest patient was 65-year male. The maximum number of patients was among 21–30 years age group suggestive of more outdoor activities of male patients. Postacchini *et al.* reported male predominance (68%) in their study.[13]

A road traffic accident is the most common mode of injury in our study, constituting 76% of patients, which is comparable to Zlowodzki *et al.* and Mckee *et al.*,[14-16] followed by self fall 14% and physical assault 5% [Table 2]. Among self-fall cases, females were dominant, while males were dominant among RTA's.

The middle one-third clavicle fracture is most common in our study, cumulating 86% patients followed by lateral third 12% and then medial third fracture 2%, which is comparable to the study of Vaithilingam *et al* [Table 3].[17]

In our study, we treated most of the undisplaced to minimally displaced oblique fracture 48% conservatively by clavicle brace and cuff and collar sling, followed by transverse fracture 8% and comminuted fracture 5%. Moreover, we operated most of the comminuted fracture patients 48%, followed by oblique fracture 32% and transverse fracture 5% [Table 4]. We found out that operating comminuted middle third clavicle fracture gives excellent recovery and functional results; also, it reduces the chances of lung injury if treated surgically.

The patient satisfaction in the operative group of patients was higher than the non-operative group as their complaint of pain was less than 50% the next day postoperatively. Their confidence in performing day to day activities was also higher than the non-operative group. They return to normal activity much early than the non-operative group. Based on DASH score operative group of patients had better functional outcomes with the mean score of 14 ± 21.3, suggesting early functional recovery. While in non-operative group, the mean score is 54 ± 18.27.[17,18]

The mean time of radiological fracture union was shorter in operative group 15.44 ± 3.24 weeks than non-operative group 21.95 ± 3.26 weeks, suggestive of significant difference in the time of fracture healing among both groups, which is comparable to Mckee *et al.*, Judd *et al.*, and Vaithilingam *et al.*[15-17]

Table 1: Age and sex distribution

Age in years	Male Number of cases (%)	Female Number of cases (%)	Total Number of cases (%)
<20	3 (6.97)	0	3 (6)
21–30	20 (46.51)	3 (42.85)	23 (46)
31–40	9 (20.93)	4 (57.14)	13 (26)
41–50	5 (11.62)	0	5 (10)
51–60	5 (11.62)	0	5 (10)
>60	1 (2.32)	0	1 (2)
Total	43 (86)	7 (14)	50 (100)
Mean±SD	33.4±11.97	32±10.39	33.26±11.20

Table 2: Mode of trauma (Overall cases)

Mode of trauma	No. of cases (%)
FALL	07 (14)
RTA	38 (76)
Physical assault	5 (10)
Total	50 (100)

Table 3: Fracture type (overall cases)

Middle third	43 (86)
Lateral third	06 (12)
Medial third	01 (2)
Total	50 (100)

Table 4: Pattern of fracture

Pattern of fracture	Management		Total	%
	Conservative (%)	Operative (%)		
Comminuted	5 (20)	12 (48)	17	34
Oblique	12 (48)	8 (32)	20	40
Transverse	8 (32)	5 (20)	13	26
Total	25	25	50	100

Table 5: Complications

Complications	Conservative		Operative	
	Number of cases	%	Number of cases	%
Non-union	4	16	-	
Malunion	16	64	-	
Pressure sore	1	4	-	
Incisional numbness	-		1	4
Implant failure	-		1	4
Implant irritation	-		1	4

The complications were more in non-operative group [Table 5]. Malunion is the most common complication in non-operative group 64% followed by non-union 16%[15,19] and there was one case of pressure sore over the shoulder due to tight bandaging of clavicle brace in non-operative group which was healed after proper padding, local dressing, and a course of antibiotics. Furthermore, the patients complained of visible deformity with shortening of the shoulder and unable to perform the terminal range of shoulder movements in non-operative group. In 24% of cases treated conservatively, we observed that the shoulder abduction was not beyond 90 degrees.

In operative group, there was one case of incisional numbness postoperatively, which was gradually subsided in routine follow-ups and with a course of steroids. There was one case of implant failure, as the patient was non-compliant and alcoholic and lifted heavyweight 25 days after surgery. Moreover, one patient complained of implant irritation 24 weeks after surgery, for which the implant was removed as the fracture was healed completely [Table 5].[17] Rest all the cases achieved a full range of shoulder movements.

We have not observed any case of infection, iatrogenic injury to subclavian vessels, pleural injury, and brachial plexus injury, as these vital structures are around the surgical field.[10,11,20-22]

CONCLUSION

From our study, we concluded, surgical fixation of clavicle fracture provides excellent results with better cosmetic and functional outcome, lesser time of fracture healing, with early return to daily activities and with better patient satisfaction, than by conservative means. We suggest that operative treatment of fracture clavicle has the upper hand over traditional conservative management; also, the treatment must be individualized as per the need and demand of the patient.

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Original Article

Comparison of Diathermy versus Scalpel Skin Incision in Oncological Surgeries

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Abstract

Introduction: Surgical incisions are usually made with scalpel. Usage of scalpel usually results in skin bleeding which obscures the operating field resulting in wastage of operating time. Although diathermy is increasingly used for underlying tissue dissection, cutting, and hemostasis, its use for making skin incisions is not gaining favor.

Aim: The aim of our study was to compare the value outcome of diathermy incisions versus scalpel incisions in abdominal surgeries.

Materials and Methods: This prospective comparative study was conducted to compare the outcome of diathermy incisions versus scalpel incisions in oncological surgeries. Total of 80 patients who divided into Group A (scalpel incision) for 39 patients and Group B (diathermy incision) for 41 patients. Treatment protocol and follow-up protocol were followed and the results were statistically analyzed and discussed.

Results: Out of 80 patients, 39 patients had scalpel incision and 41 patients had diathermy incision. In the scalpel group out of 39 patients, 21 patients were male and 18 patients were female, the mean duration of incision time in the scalpel group is 116 sec, the mean value of incisional blood loss in the scalpel group is 1.9/ml, the mean operating time in the scalpel group is 36.42 min, and the mean value of post-operative pain in day 1 is 6.42, day 2 is 5.18, and day 3 is 3.66. In the diathermy group out of 41 patients, 26 patients were male and 15 patients were female, the mean duration of incision time in the diathermy group is 88.52 sec, the mean value of incisional blood loss in the diathermy group is 1.4/ml, the mean operating time in the diathermy group is 38.75 min, and the mean value of post-operative pain in day 1 is 5.12, day 2 is 3.88, and day is 2.01.

Conclusion: The findings of the present study show that diathermy seems to provide some benefit with respect to post-operative wound pain, less incision time, and less incisional blood loss and has obvious safety advantages to the surgical team compared with scalpel.

Key words: Diathermy, Scalpel, Skin incision

INTRODUCTION

Incision is a "cut or slit" to gain access to the underlying structures. Conventionally, incisions are made with stainless steel scalpel.[1] These incisions are supposed to be more bloody which obscure the surgical field and, in some instances, lead to increased swelling, bruising, and pain.[2]

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To reduce blood loss following surgical incision, many methods have been evolved among which diathermy is the most readily available in operation theater.[3,4] Diathermy is the use of an alternating current through tissue resistance to raise tissue temperature to achieve vaporization or the combination of desiccation and protein coagulation.[5,6] However, diathermy skin incisions are less popular among the surgeons, as it has been hypothesized that the application of extreme heat may result in significant post-operative pain and poor wound healing.[7] Fear of deep burns with diathermy and resultant scarring continues compared with the scalpel, which produces a clean, incised wound with minimal tissue destruction.[8] The use of diathermy in skin incisions reduces bleeding and makes the incision quicker, but there are no differences in wound burst strength.

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Modern electrosurgical units capable of delivering pure sinusoidal currents have evolved a change in this concept. The advantages are rapid hemostasis, faster dissection, and a reduced overall operative blood loss.[8-10] In abdominal surgery, only few studies had compared the surgical outcome of scalpel incision and diathermy. Soballe *et al*.[11] reported that electric coagulation increases the incidence of indurated margins, infections, and weakness of the wound cut in comparison with the knife. Conversely, Groot and Chappell[12] reported that the use of surgical diathermy to create surgical wounds in patients undergoing abdominal or thoracic operations carries a wound infection rate similar to that of scalpel.

Aim

The aim of our study was to compare the outcome of diathermy incisions versus scalpel incisions in abdominal surgeries.

MATERIALS AND METHODS

This prospective comparative study was conducted to compare the outcome of diathermy incisions versus scalpel incisions in oncological surgeries, including breast chest wall tumor laparotomies and musculoskeletal oncology under different study parameters such as sex, incision time, operating time, amount of blood loss, post-operative pain, and wound complication. Inclusion criteria include patients of both sexes and patients in the age group of 8–80 years with clean and clean-contaminated wounds. Exclusion criteria include patients with the presence of untreated coagulopathy, diabetes mellitus, and severely immunocompromised status. All patients undergo elective oncological surgeries such as including breast chest wall tumor laparotomies and musculoskeletal oncology. All emergency oncological surgeries were excluded from the study. The findings of patients' history, examination, laboratory, imaging, operative, and post-operative course were recorded. An informed consent was taken.

The patients were randomized into two groups, such as diathermy (Group A) or scalpel (Group B). In the diathermy group, skin incisions made out by electrosurgical unit. In our institute, we used ARC surgical diathermy D-400 with the setting, cutting – 40–60 was used. In the scalpel group, we used 22 sized blade for all skin incisions. Incision time was calculated from the beginning of skin incision to opening of subcutaneous tissues and it measured in seconds. Incisional blood loss was assessed by weight of gauzes, number of gauzes, and soakage of gauzes. Post-operative pain was assessed by visual analog scale. Treatment protocol and follow-up protocol were followed and the results were statistically analyzed and discussed.

RESULTS

Out of 80 patients, 39 patients had scalpel incision and 41 patients had diathermy incision. In the scalpel group out of 39 patients, 21 patients were male and 18 patients were female, and in the diathermy group out of 41 patients, 26 patients were male and 15 patients were female [Table 1].

Out of 80 patients, 39 patients had scalpel incision and 41 patients had diathermy incision, the mean duration of incision time in the scalpel group is 116 sec and mean duration of incision time in the diathermy group is 88.52 sec [Table 2].

Out of 80 patients, 39 patients had scalpel incision and 41 patients had diathermy incision, the mean value of incisional blood loss in the scalpel group is 1.9/ml and mean value of incisional blood loss in the diathermy group is 1.4/ml [Table 3].

Out of 80 patients, 39 patients had scalpel incision and 41 patients had diathermy incision, the mean operating time in the scalpel group is 36.42 min and mean operating time in the diathermy group is 38.75 min [Table 4].

Out of 80 patients, 39 patients had scalpel incision and 41 patients had diathermy incision. In the scalpel group out of 39 patients, 2 patients had infection, 1 patient had

Table 1: Gender in two groups of patients

Gender	Scalpel group	Diathermy group
Males	21	26
Females	18	15
Total	39	41

Table 2: Incision time in two groups of patients

Incision time, sec	Scalpel group	Diathermy group
Mean	116	88.52
Standard deviation	44.36	48.52

Table 3: Incisional blood loss in two groups of patients

Incisional blood loss/ml	Scalpel group	Diathermy group
Mean	1.9	1.4
Standard deviation	0.1	0.2

Table 4: Operative time in two groups of patients

Operative time (min)	Scalpel group	Diathermy group
Mean	36.42	38.75
Standard deviation	18.49	19.28

wound dehiscence, and 3 patients had hematoma, and in the diathermy group out of 41 patients, 4 patients had infection, 1 patient had wound dehiscence, and 2 patients had hematoma [Table 5].

Out of 80 patients, 39 patients had scalpel incision and 41 patients had diathermy incision. In the scalpel group, the mean value of post-operative pain in day 1 is 6.42, day 2 is 5.18, and day 3 is 3.66. In the diathermy group, the mean value of post-operative pain in day 1 is 5.12, day 2 is 3.88, and day 3 is 2.01 [Table 6].

DISCUSSION

Diathermy is used increasingly for hemostasis and tissue dissection. Despite this, few surgeons use diathermy to incise skin; this reluctance is partly attributable to the belief that electrosurgical instruments increase devitalized tissue within the wound, which consequently leads to increased wound infection, increased scar formation, and delayed wound healing. However, these concerns have not been substantiated by recent studies of skin incision, which have shown faster operating times, reduced blood loss, reduced early post-operative pain, and lower analgesia requirements with diathermy compared with scalpel incision.[8] In an experimental study on rats, fascia incisions with cold scalpel were found to gain tensile strength faster than with harmonic scalpel or diathermy.[13] Another study on rats concluded healing of abdominal wall after dieresis with cold scalpel or electrocautery is equivalent and does not differ.[14] It has been suggested that local tissue heating increases subcutaneous oxygen tension, thus enhancing the resistance of the surgical wounds to infection.[7]

In our study out of 80 patients, 39 patients had scalpel incision and 41 patients had diathermy incision, the mean duration of incision time in the scalpel group is 116 sec and mean duration of incision time in the diathermy group is 88.52 sec. Thus, incision time is shorter in the diathermy group compared to the scalpel group. Other studies also stated that cutting diathermy resulted in a statistically significant shorter incision time than the use of the scalpel.[8,15]

In our study out of 80 patients, 39 patients had scalpel incision and 41 patients had diathermy incision, the mean value of incisional blood loss in the scalpel group is 1.9/ml and mean value of incisional blood loss in the diathermy group is 1.4/ml. Thus, incisional blood loss is less in diathermy compared to scalpel incision. Other studies also stated that cutting diathermy resulted in a statistically significant less incision blood loss than the use of the scalpel.[8,15]

Yilmaz *et al.*[16] compared scalpel and electrocautery and reported that seroma incidence was higher in the electrocautery group than the other groups and there was no difference between groups with respect to hematoma. In our study, infection rate was higher in the diathermy group compared to the scalpel group.

There was a significant difference in post-operative pain scores at the 1st day, 2nd day, and 3rd day between incisions made with cutting diathermy and scalpel. This finding is consistent with the results of two meta-analyses.[17] Our study results suggested a significantly reduced post-operative pain in the diathermy group.

Table 5: Wound complications in two groups of patients

Wound complications	Scalpel group	Diathermy group
Infection	2	4
Wound dehiscence	1	1
Hematoma	3	2

Table 6: Post-operative pain assessment in two groups of patients

Post-operative pain assessment	Scalpel group	Diathermy group
	Mean±SD	Mean±SD
Day 1	6.42±0.8	5.12±0.52
Day 2	5.18±0.9	3.88±0.64
Day 3	3.66±0.54	2.01±0.76

SD: Standard deviation

CONCLUSION

The findings of the present study show that diathermy seems to provide some benefit with respect to post-operative wound pain, less incision time, and less incisional blood loss and has obvious safety advantages to the surgical team compared with scalpel.

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Original Article

Histological Patterns and Management Options in Malignant Tumors of Scalp

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Abstract

Introduction: The scalp is the most frequent site of occurrence of malignant tumors because this area is generally neglected by the patient and not closely monitored during physical examinations, scalp tumors can go unnoticed until they become malignant.

Aim: The aim of our study was to analyze the histological patterns and management options in malignant tumors of the scalp.

Materials and Methods: This prospective study was conducted to analyze the histological pattern and management options in malignant tumors of the scalp. Medical reports of patients diagnosed with the clinical diagnosis of scalp lesions were studied. H&E stained slides of the scalp lesions were retrieved and reviewed. Clinical and histopathological diagnoses were studied for each case to evaluate clinically misdiagnosed cases. Data so obtained were tabulated and were analyzed statistically, and results were discussed.

Results: Out of 25 cases, male patients were 13 (52%) and female patients were 12 (48%), age distribution ranges from 20 to 80 years with <30 years 2 patients (8%), 31–40 years 4 patients (16%), 41–50 years 3 patients (12%), 51–60 years 9 patients (36%), >61 years 7 patients (28%), based on histological pattern squamous cell carcinoma is most common of 10 cases (40%), basal cell carcinoma 8 cases (32%), dermatofibrosarcoma 2 cases (8%), fibroxanthoma 1 case (4%), melanoma 2 cases (8%), and metastatic tumors 2 cases (8%) where the primary site is the lung in both the cases. Sixteen cases (64%) were managed by split skin graft, 7 cases (28%) by rotational/transpositional flap, and 2 cases (8%) by free flap.

Conclusion: Although malignant scalp tumors are not common, when facing a patient with scalp lesions or lumps, physicians should be alert in detecting any suggestive new growth hidden in this hairy area to make an early diagnosis and perhaps to detect primary cancer in case of metastatic scalp tumors.

Key words: Examination, Histological pattern, Malignant tumor, Scalp

INTRODUCTION

The scalp is the most frequent site of occurrence of malignant tumors because this area is generally neglected by the patient and not closely monitored during physical examinations, scalp tumors can go unnoticed until they become malignant. Although the incidence of tumors arising on the scalp is not high compared to those occurring elsewhere on the skin, these neoplasms are mostly benign, while only approximately 1–2% of all scalp tumors are malignant, they comprise up to 13% of all malignant cutaneous neoplasms.[1]

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The knowledge of various patterns and subpatterns in different tumors helps in the diagnosis and delivery of appropriate treatment. The most common histological patterns include non-glandular epithelial, glandular/pseudo glandular, round cell pattern, spindle cell pattern, biphasic pattern, and surface epithelial pattern. However, these histological patterns are not always diagnostic; there may be variations present along with the subpatterns.

The treatment of choice of most malignant neoplasms of the scalp is surgical excision. Low voltage irradiation has been used in selected cases in small superficial basal- and squamous-cell carcinomas. In basal-cell and squamous-

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cell carcinomas, the extirpative technique is developed according to the size, position, and infiltrative characteristics of the neoplasm. If the tumor is under 2 cm in diameter, primary resection and direct approximation of the wound is usually possible. If the tumor is more extensive than 2 cm, the wound will have to be rehabilitated with either a split skin graft or a regional scalp flap or free flap.

Aim

The aim of our study was to analyze the histological patterns and management options in malignant tumors of the scalp.

MATERIALS AND METHODS

This prospective study was conducted to analyze the histological pattern and management options in malignant tumors of the scalp. Medical reports of patients diagnosed with the clinical diagnosis of scalp lesions were studied. H&E stained slides of the scalp lesions were retrieved and reviewed. Special stains were done wherever needed. The data retrieved included demographic data such as age, sex, occupation, relevant positive and negative clinical history, radiologic findings, and histological diagnosis.

A detailed and systematic list of histologic types was designed according to the classification of Lever's Histopathology of the Skin.[2] The histologic categories consisted of a panel of malignant tumors from different tissue origins, including tumors of the epidermis, skin appendages (follicular, sebaceous, eccrine, and apocrine differentiation), fibrous tissue, fatty tissue, neural tissue, muscular tissue, osseous tissue, blood vessels, lymphomas and leukemia, and metastatic tumors.

The types of pathologic entities that appeared in the scalp were tabulated. We counted the number of patients rather than the number of cancers to assess the number of cases. Clinical and histopathological diagnoses were studied for each case to evaluate clinically misdiagnosed cases. Data so obtained were tabulated and were analyzed statistically, and results were discussed.

RESULTS

Out of 25 cases, male patients were 13 (52%) and female patients were 12(48%) [Figure 1].

Out of 25 cases based on age distribution ranges from 20 to 80 years with <30 years 2 patients (8%), 31–40 years 4 patients (16%), 41–50 years 3 patients (12%), 51–60 years 9 patients (36%), and >61 years 7 patients (28%) [Figure 2].

Out of 25 cases based on histological pattern squamous cell carcinoma is most common of 10 cases (40%), basal cell carcinoma 8 cases (32%), dermatofibrosarcoma 2 cases (8%), fibroxanthoma 1 case (4%), melanoma 2 cases (8%), and metastatic tumors 2 cases (8%) [Table 1].

Out of 25 cases metastatic tumors of 2 cases (8%) where the primary site is one primary case from lung cancer and primary case from well differentiated thyroid cancer.

Out of 25 cases, 16 cases (64%) were managed by split skin graft, 7 cases (28%) by rotational/transpositional flap, and 2 cases (8%) by free flap [Table 2 and Figures 3-6].

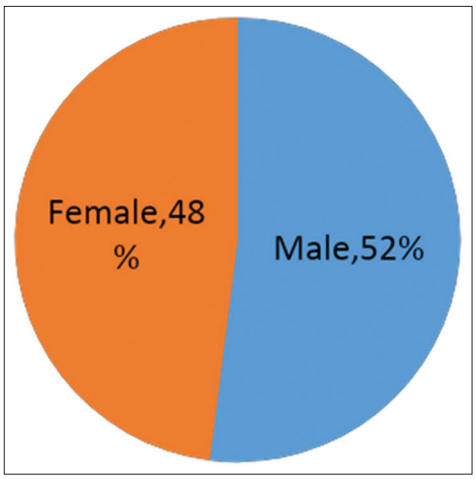

Figure 1: Sex distribution

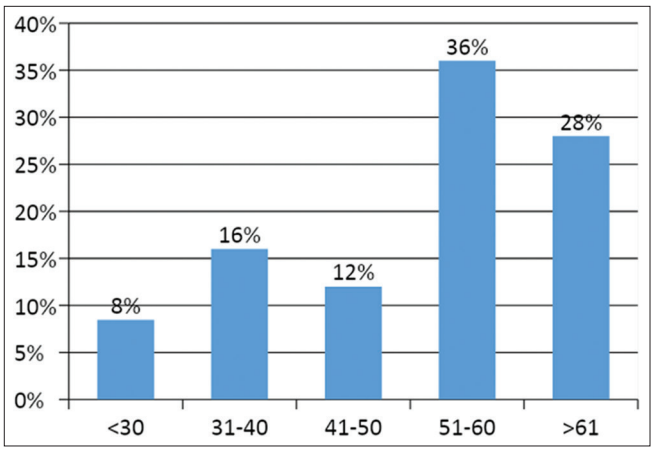

Figure 2: Age distribution

Table 1: Histologic distribution

Histologic distribution	Percentage	Number of cases
Basal cell carcinoma	32	8
Squamous cell carcinoma	40	10
Dermatofibrosarcoma	8	2
Fibroxanthoma	4	1
Melanoma	8	2
Metastatic tumors	8	2

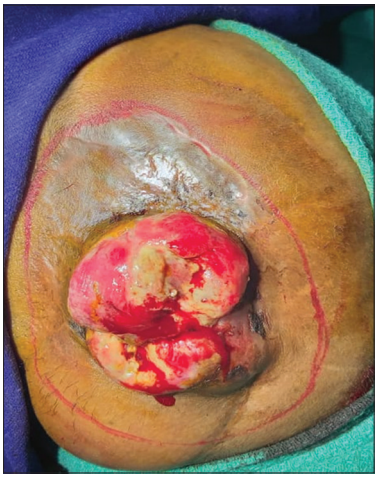

Figure 3: Recurrent dermatofibrosarcoma protuberans scalp

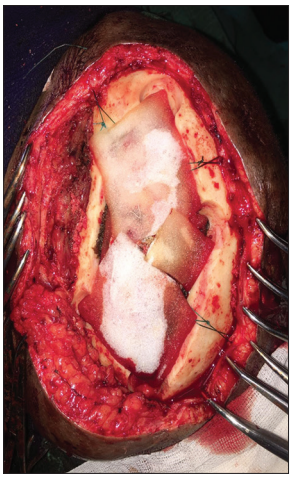

Figure 5: Wide monobloc excision

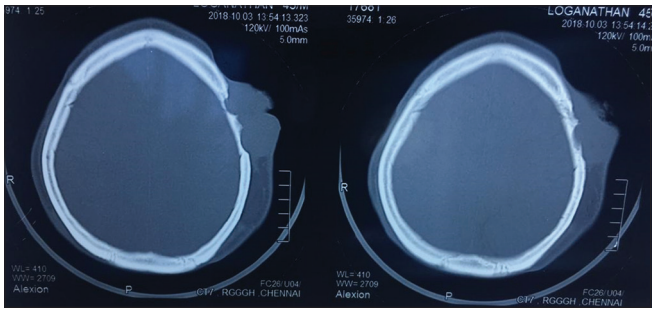

Figure 4: Computed tomography scan – lesion: Recurrent dermatofibrosarcoma protuberance

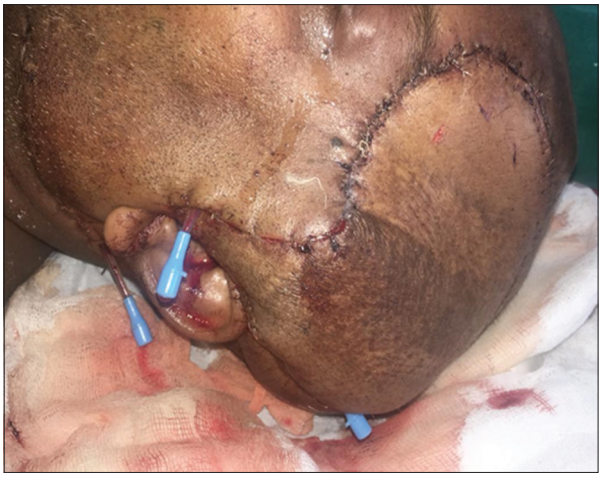

Figure 6: Anterolateral thigh free flap reconstruction

DISCUSSION

Malignant tumors occurring in the scalp are not common.[3] We found that the majority of the malignant scalp tumors occurred in middle-aged and elderly individuals, a finding consistent with previous reports.[3,4] Obtaining histopathologic diagnosis through biopsy is the gold standard to diagnose any suspicious pathologic lesion.[5]

In our study, the patient's age ranged from 20 to 80 years. The mean age being 40 years, which is in discordance with a study conducted by Spitz *et al.*[6] in which the age group ranged from 29 to 91 years, with a mean age of 61 years, the male to female ratio in our study was 1:0.9, whereas 1.1:1 was reported by Carson *et al.*[7] in their study. Spitz *et al.*[6] reported a similar sex distribution of 1.3:1.

In our study, based on histologic distribution, squamous cell carcinoma was the most common malignancy among all malignant tumors of the scalp. The present study result correlated with the studies carried out by Leena *et al.*[8] and Adu *et al.*[9] Another study by Manchanda and Al-Mutairi[10] found that basal cell carcinoma was more common than squamous cell carcinomas and was seen in elderly patients.

Table 2: Management procedure of scalp tumors

Procedure	Number of cases	Percentage
Split skin graft	16	64
Rotational/transportal flap	7	28
Free flap	2	8

Minor and Panje[11] from Illinois mentioned that malignant melanoma was the third most common variety of scalp cancers. In our study, however, malignant melanoma comprised only 2% of all malignant scalp tumors.

Although lung cancer ranks fifth among the major cancers in Taiwan, it ranks first (23.53%) among the primary sites of metastatic scalp tumors. Therefore, the frequencies of metastatic scalp tumors do not correspond well to the frequencies of primary tumors in the Taiwanese population. In our study, metastatic tumors of 2 cases

(8%) where the primary site is one primary case from lung cancer and primary case from well differentiated thyroid cancer. This also indicates lung cancer and thyroid cancer has a much higher tendency to metastasize to the scalp.

Basal and squamous cell carcinomas, angiosarcoma, and dermatofibrosarcoma protuberans can have aggressive and destructive behaviors; invade beyond the periosteum, skull bone, dura, and even brain; and result in profound morbidity and mortality.[12,13] In advanced scalp tumors with deep and extensive invasion, an interdisciplinary approach is required to excise tumors completely, reconstruct massive surgical defects successfully, and improve cure rates significantly, followed by adjuvant therapy were indicated.[14,15]

CONCLUSION

Although malignant scalp tumors are not common, when facing a patient with scalp lesions or lumps, physicians should be alert in detecting any suggestive new growth hidden in this hairy area to make an early diagnosis and perhaps to detect primary cancer in case of metastatic scalp tumors.

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